ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S): NONYLPHENOL AND NONYLPHENOL ETHOXYLATE

IUPAC NAME: NONYLPHENOL[1]
MOLECULAR FORMULA: $(C_6H_4(OH)C_9H_{19})$
EC NUMBER: NOT APPLICABLE
CAS NUMBER: NOT APPLICABLE

IUPAC NAME: NONYLPHENOL ETHOXYLATE [2]
MOLECULAR FORMULA: $(C_2H_4O)_nC_{15}H_{24}O)$
EC NUMBER: NOT APPLICABLE
CAS NUMBER: NOT APPLICABLE

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[1] **Nonylphenol, linear and branched** - covering UVCB substances and well-defined substances including all compounds in which an alkyl chain with carbon number of 9 (branched and / or linear alkyl chain) is "attached" to phenol.

[2] **Nonylphenol, linear and branched, ethoxylated** - covering UVCB substances and well-defined substances including polymers and homologues; an alkyl chain with carbon number of 9 (branched and / or linear alkyl chain) is "attached" to phenol.

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Content

About this report

The restriction proposal in this report targets nonylphenol (NP) and nonylphenol ethoxylate (NPE) in clothing and household textile articles (including their prints) that can be washed in water if they contain nonylphenol or nonylphenol ethoxylat alone or in combination in concentrations equal or higher than 100 mg/kg textile. A transitional period of 5 years after entry into force of the restriction is proposed. The proposal is based on the results of the quantitative risk assessment and the qualitative risk assessment of the endocrine disrupting properties and the conclusion is that there is concern for nonylphenol and nonylphenol ethoxylates in the pelagic aquatic compartment. NP enters the aquatic compartment directly as NP or as breakdown products from NPE. NP and NPE are released to the waste water from a number of sources of which the release from washing of textiles contributes to approximately half of the estimated amount.

NPE is mainly used as a detergent or an emulsifying agent in the manufacturing of textiles. Except from textiles the largest volumes of NP/NPE originate from paints/lacquers, glue and cleaning agents (Månsson et al. 2009).

The use of NP and NPE in concentrations equal or higher than 0,1 % is restricted within the EU since 2005 in chemical products for among others the processing of leather and textiles, industrial and institutional cleaning, metal working (if not used in close systems), domestic cleaning and cosmetics (REACH Annex XVII, Entry 46).

As detergents alcohol ethoxylates (AE) are pointed out as the most used alternative to NPE in the manufacturing of textiles (ToxEcology 2002, HERA 2009, Posner 2012, TEGEWA 2012, Nimkartek 2012). Alternatives to NPE as emulsifier is not as clear choice since different groups are mentioned for this purpose, for example; a mix of alcohole etoxylates or alkanol fatty acid amides, (BREF 2003, Posner 2012, Nimkartek 2012). When it comes to NPE in the printing process also alcohol based substances are mentioned as alternative. The key issue to replace NPE is the need to evaluate the alternatives on a case-by-case basis.

The proposed restriction has been assessed in terms of effectiveness, proportionality and practicality. The proposed restriction would effectively reduce the major part of NP/NPE that are currently estimated to be emitted from textile articles imported to the Union. The restriction will reduce the concern for nonylphenol in the environment, with regards to both the expected combined toxicity of NP and NPE and the endocrine disrupting properties of NP in the environment. The limit value and transitional period to be proposed have been subject to stakeholder consultation and in summary the restriction is found to be technically and economically feasible. However there is expected to be significant costs due to increased compliance control primarily to textile importers and retailers within the Union.

A. Proposal

A.1 Proposed restriction

A.1.1 The identity of the substance(s)

Substance name	Nonylphenol[3]
IUPAC name	Nonylphenol
Molecular formula	$C_6H_4(OH)C_9H_{19}$
EC number	Not applicable
CAS number	Not applicable

Substance name	Nonylphenol[1]ethoxylate
IUPAC name	Nonylphenol ethoxylate
Molecular formula	$(C_2H_4O)_nC_{15}H_{24}O$
EC number	Not applicable
CAS number	Not applicable

A.1.2 Scope and conditions of restriction(s)

Based on the justifications summarised in section A.2 the following restriction is proposed regarding nonylphenol and nonylphenol ethoxylate in textile articles:

Clothing and household textile articles that can be washed in water shall not be placed on the market 60 months after entry into force of the restriction if they contain nonylphenol or nonylphenol ethoxylat alone or in combination in concentrations equal or higher than 100 mg/kg textile. The limit value includes prints on the textile articles covered by the proposed restriction.

The standards adopted by the European Committee for Standardisation (CEN) shall be used as test methods for determining the content of nonylphenol or nonylphenol ethoxylate for demonstrating the conformity of the restriction. There is an ongoing work to develop a new CEN standard for textiles to detect and quantify APEOs adressed “Detection and determination of APEO in textiles by HPLC-MS” (Posner 2012).

A proposal for an addition in REACH Annex XVII, Entry 46 in is compiled in Table 1.

In the RMO and in the Registry of Intention a restriction covering nonylphenol and nonylphenol ethoxylate in textiles and leather articles was announced. Since leather articles are not normally washed in water, the release to the waste water from this source is very limited. Leather articles are therefore not included in the restriction proposal.

[3] The substance name nonylphenols is covering a multitude of compounds in which an alkyl chain with the carbon number of 9 (branched and linear alkyl chain) is “attached” to the phenol.

Nonylphenol (NP) or nonylphenol ethoxylate (NPE) could be unintentionally added to textiles during the manufacture process by using contaminated water in the washing processes, by leakage from lubricants in the process equipment or by contamination by other fabrics during transport or storage. The limit of detection in analytical methods used to determine the content of NPE in textiles is 1 mg/kg. However, in order to balance the need for a reduction of the discharge of NP/NPE to the environment and to ensure a margin between intentionally and unintentionally added NP/NPE to the textile but also to avoid a conflict with the current REACH regulation (Annex VII, Entry 46) which allows the use of 0,1 % NP/NPE in the textile processing, the limit value 100 mg/kg textile is proposed (see section E.2.1.2). Depending on the function of the NPE in the manufacturing of the textile the length of the chain varies. Short-chained (< 10 ethoxylates) NPE are used as detergents in different steps of washing. NPE with chains of medium length (between 10 and 30 ethoxylates) are used as emulsifiers e.g. during the dying process (see section C). The test methods used thus need to have the capacity to analyse chain lengths of NPE up to and including 30. There is an ongoing work to develop a new CEN standard for textiles to detect and quantify APEOs adressed "Detection and determination of APEO in textiles by HPLC-MS" (Posner 2012).

The wording textile is a wide and dispersive term which includes all kind of textile materials. Since the main route of discharge to the environment of NPEs in textile articles is by washing in water, the proposal for restriction is therefore limited to apply only to textile articles that can be washed in water. The proposal will thereby not affect suppliers of textiles not washable in water. Examples of textile articles comprised by the restriction are given in a non exhaustive list in the proposal for an extended scope of REACH Annex XVII, Entry 46. The examples and the specification of the scope applying to clothing and household textile articles are based on a JRC Report [4] where these groups are the most dominant groups of textile articles at the EU27 market.

Technical textiles are included by the proposed restriction if they are submitted to washing in water and hence contribute to the release of NPE to waste water. Technical textiles are however a heterogeneous group of textiles of which primarily Clothing textiles and Sports textiles are assumed to be washed in water (see section B 9.3.4.1 "Technical textiles manufactured in the EU").

A transitional period of 5 years is proposed enabling the market to adjust in terms of possibility to place on the market articles in stock, inform and educate EU-suppliers as well as non EU-suppliers about the regulation and establish a system for control of compliance. The non EU-suppliers will during this period have time to test and implement alternatives also in applications where the replacement of NPE by suitable alternatives not yet is in place (see section E.2).

Since NPE is a non-ionic surfactant, easily dissolved in water, most NPE is likely to be washed out after repeated washing, regardless type of textile (Månsson et al. 2008). In the light of a transition period of 5 years, used textile articles that enter the "second hand market" could be assumed to be washed for a couple of times and thus have a content of NP/NPE below the limit value in the restriction. Taking this into account the proposed restriction is not assumed to imply any

[4] Environmental Improvement Potential of Textiles (Beton et al. 2012),

consequences for the sale of textile articles on the "second hand market". A need for a derogation covering textiles sold on the "second hand market" is therefore not considered as necessary.

In order to facilitate the interpretation and the practical application, the proposed restriction includes a definition of the term "textile articles" as meaning textile articles defined in article article 3.1 a-f of the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products. The regulation includes a procedure for the inclusion of new textile fibre names in the Annex II where requirements regarding applications by manufacturers or other persons acting on their behalf for new textile fibre names can add those.

Table 1 Proposal for an addition in REACH Annex XVII, Entry 46 in

Groups of substances	**Proposed restriction**
Nonylphenol ($C_6H_4(OH)C_9H_{19}$) Nonylphenol ethoxylate ($(C_2H_4O)_nC_{15}H_{24}O$)	1. Clothing and household textile articles, such as: –tops -underwear, nightwear, hosiery -buttoms -jackets -dresses -suits and ensembles -gloves -sportwear -swimwear -scarves, shawls, ties -floor coverings -bed linen -articles of bedding -linen (kitchen and toilet) -blankets and traveling rugs -floor cloths, dusters -table linen that can be washed in water shall not be placed on the market after [insert date 60 months after of entry into force of this Regulation] if they contain these substances alone or in combination in concentrations equal or higher than 100 mg/kg textile. The limit value includes prints on the textile articles mentioned above. 2. For the purpose of this entry 'textile articles" shall mean textile products as defined in: Article 3.1 a-f of the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products. 3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as test methods for demonstrating the conformity of the articles in paragraph 1.

A.2 Targeting

The restriction proposal targets nonylphenol (NP) and nonylphenol ethoxylate (NPE) in clothing and household textile articles that can be washed in water in if the concentration alone or in combination is equal or higher than 100 mg/kg textile based on the endocrine disrupting properties of nonylphenol and the combined toxicity of nonylphenol, nonylphenol ethoxylates and nonylphenol ethoxycarboxylates which typically exist together as mixtures in WWTP effluents and in the environment.. According to the endocrine disrupting properties it is difficult to quantify a safe level for nonylphenol in the environment and therefore also the risks, using traditional risk assessment methods.

NP enters the aquatic compartment directly as NP or as breakdown products from NPE. NP and NPE are released to the waste water from a number of sources of which the release from washing of textiles contributes toapproximately half of the estimated amount.

The use of NP and NPE in concentrations equal or higher than 0,1 % is restricted within the EU since 2005 in products for among others the processing of leather and textiles, industrial and institutional cleaning, metal working (if not used in close systems), domestic cleaning and cosmetics (REACH Annex XVII, Entry 46).

NP and NPE are however still used outside the EU as detergents and auxiliaries in the manufacturing of textile articles. According to EU statistics on the import of textiles the annual NP_{equ} release is estimated to 257 tonnes (see section B.9.3.4.1). After imported to the EU, the textile articles will be washed within the EU and the residues of NP and NPE will be released into the environment via waste water treatment.

Other sources contributing to the release of NP and NPE are cleaning agents, plastic products, paints and adhesives. Based on data from the Swedish Product Register[5] the annual contribution from these sources is estimated to 249 tonnes NP_{equ} on an EU level[6] (see section B.9.3.4.2).

A.3 Summary of the justification

A.3.1 Identified hazard and risk

There is concern for nonylphenol in the aquatic compartment based on the following conclusions (see section B.10):

Overall summary

- The risk characterisation for nonylphenol on its own results in concern (RCR 1.3) for the marine pelagic compartment based on the EU median PEC (of 90-percentile values of

[5] The Products Register is a national registry maintained by the Swedish Chemicals Agency (KemI). Companies intending to start an operation in Sweden involving manufacture or import of chemicals are obliged to report this to the Products Register.
[6] Based on population the factor 53 is used for scaling of statistics for Sweden to an EU level.

individual countries) from a database covering only a limited number of countries (n=4). Furthermore, there is concern for the freshwater pelagic compartment based on country specific 90-percentile values for Belgium and Germany, whereas the EU median PEC from a database covering a large number of countries (n=25 although many countries are represented by only a small number of samples, often less than 6) showed no concern (RCR 0.125).

- An assessment of the combined toxicity of nonylphenol ethoxylates, occurring in textiles, and their degradation products such as nonylphenol and nonylphenol ethoxycarboxylates has been included in this dossier since these substances emanate from textiles and will occur as mixtures in WWTP effluents and in the environment. Assessing the combined toxicity of these compounds, using Toxic Equivalency Factors and the pelagic freshwater monitoring database available, results in a RCR ratio ranging from 0.34-0.54 for the EU median PEC depending on which TEF are being used for NPnEO (n=3-8). However based on country specific 90 percentile values there is concern in 8 to 12 (RCR1.1-27) EU countries out of a total of 24 EU countries and Norway for which freshwater monitoring data is available, which corresponds to identified concern in 30 to 50 % of the countries. When in a similar way assessing the combined toxicity in the marine pelagic compartment concern is identified in three to four countries out of four countries with available monitoring data (median RCR 3.5-5.5). However, the marine RCRs are less robust as compared to the freshwater RCRs since the present database is limited and new additional data on further trophic levels would reduce the AF used when the deriving the PNEC.

- Nonylphenol is considered to be an endocrine disrupting substance and when taking the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular into account it is questionable whether the currently available knowledge and evidence can be considered sufficient to establish safe levels for the environmental compartments assessed. A few issues related to these difficulties are presented below.
    - The Reach Guidance Document on Information Requirements/Chemical Safety Assessment offers a possibility of dealing with the incomplete knowledge and uncertainty of ED by introducing an assessment factor, AF. The present knowledge does not provide sufficient information to derive a more specific AF for endocrine disruption, but possibly set the AF to an arbitrary size of 10. If introducing this factor the RCRs derived in this assessment would increase with a factor of 10. Consequently, the EU generic RCRs for freshwater would range from 1.25 (for NP only) to 3.4-5.4 (for the combined TEF approach), respectively. When using the country specific monitoring data for freshwater the use of this extra AF=10 would result in concern in 12 Member States when assessing the toxicity of nonylphenol only and concern in all 24 Member States and Norway for which freshwater monitoring data is available when also taking the combined toxicity into account. Applying an extra AF of 10 on the marine RCRs would increase the RCR of nonylphenol on its own to 13 and the combined toxicity RCRs to 7-99.

  - In the available database there are several studies of somewhat lower reliability, which therefore cannot be used when deriving the PNECs, but where the results indicate that the present freshwater and marine $PNEC_{water}$ may underestimate the toxicity of NP with one order of magnitude or more. Based on the endpoints studied the effects shown may to be due to the ED-properties of nonylphenol. This introduces further uncertainties regarding the possibilities of deriving safe levels for the endocrine properties of NP.

- It is noted that the pelagic freshwater and marine PECs based on monitoring data may be underestimated since there is a study of seasonal variation indicating that it could be expected that the entire distribution of monitoring data would shift towards higher concentration values if it would have been based on sampling performed during the summer.

Overall assessment: When assessing the toxicity of nonylphenol on its own using a standard risk assessment PEC/PNEC approach there is concern for the marine pelagic compartment at EU level. When the combined toxicity of nonylphenol and nonylphenol ethoxylates and their degradation products are assessed using Toxic Equivalency Factors there is concern in the marine compartment at EU level and in freshwater for 8 to 12 EU countries out of a total of 24 EU countries and Norway, but not for freshwater at the EU median level. If the uncertainties regarding the endocrine properties of NP would be accounted for by introducing an assessment factor arbitrarily set at 10 to the risk characterisation ratios of the combined toxicity assessment, there would be concern at the EU median level for the marine and freshwater compartments (and for marine waters in the four MS having marine monitoring data and in freshwater for all 24 Member States and Norway for which freshwater monitoring data are available).

From the above summary of the quantitative risk characterisation information in this assessment it is appropriate to conclude that there is concern for the aquatic compartment, with the combined toxicity of NP and NPEOs and their degradation products and the uncertainty of the endocrine disruptive properties (as provisionally accounted for by the extra AF) being the most prominent contributing factors.

However, considering the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular it is questionable whether the available knowledge and evidence can be considered sufficient to establish appropriate assessment factors and safe levels for the environmental compartments assessed. Therefore, it is concluded that it is not possible in the quantitative assessment approach to determine which concentration should be regarded as safe for the environment. Thus, the assessment of the endocrine disrupting properties should be viewed in a qualitative manner rather than a quantitative manner..

Furthermore, the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

Finally, when considering the results of the quantitative risk assessment and the qualitative risk assessment of the endocrine disrupting properties, the conclusion is that there is concern for nonylphenol and nonylphenol ethoxylates in the pelagic aquatic compartment.

A.3.2 Justification that action is required on an Union-wide basis

The proposed restriction covers clothing and household textile articles (incuding their prints) that can be washed in water extensively traded and used in all Member States. The use of nonylphenol etoxylates within the textile sector in EU is restricted in contrations equal or higher than 0,1 % (if not used in closed systems) since 2005. The major part of textiles consumed within the EU is however imported from suppliers outside the Union. According to statistics from Eurostat the import of textiles was about 6 million tonnes in 2010.

There are several voluntary actions among actors in the textile sector including limit values on NP and NPE in the finished textile article (see section B 9.1.1). The effect of such current activities is hard to quantify on the EU level which makes it difficult to evaluate the effects of voluntary efforts. An optimistic scenario could be that an increasing share of imported textiles would be covered by the Oeko-Tex standard 100 and/or the EU Ecolabel. Though strictly viewed, this would only imply that NPE concentrations higher than 1000 mg/kg textile and NP concentration higher than 100 mg/kg would be avoided.

A union-wide restriction would remove the potentially distorting effect that national restrictions or corresponding measures may have on the free circulation of goods and also ensure a "level playing field" among EU producers and importers of textile articles. A unoin-wide restriction also gives a clear message on the status of the requirements and is easy to communicate to the suppliers outside the EU.

A.3.3 Justification that the proposed restriction is the most appropriate Union wide measure

Effectiveness

The proposed restriction is expected to prompt substitution of NPE used in textiles destined for the EU market. The limit value of 100mg NPE per kg textile will, according to the stakeholders consulted, be interpreted as a ban on intentional use of NPE in textiles and subsequently there should only remain unintentional contamination of NPE in textiles (if any).

The proposed restriction is expected to reduce the mean concentrations of NP/NPE in textile articles to roughly 29 mg/kg, i.e. about 73% lower in the year 2020 compared to the estimated 107 mg NP/NPE per kg textile in the reference year 2010. Compared to the estimated total emission of NP/NPE to the environment (including all the assessed emission sources) the total annual NP/NPE emission reduction from textiles alone would constitute about 34% (as a result of the proposed restriction) of the total emission in 2010. Taking into account also the expected future trend in WWTP removal efficiency and connection rate and the trend in emissions from EU produced technical textiles and other sources than textiles, the total reduction of NP/NPE emissions to the water environment would be about 63% in the year 2020 compared to the estimated emissions in 2010. In other words the identified risk in the water environment should be radically reduced in the year 2020 compared to 2010, primarily because of the proposed restriction.

There are no indications that the available alternative chemicals in textiles production would cause concern for human health or the environment if used to substitute NPEs.

Proportionality
The restriction is applied to the final article (clothing and household textile articles) and does not consider the manufacturing of textiles itself. The proposed limit value of 100 mg/kg textile would according to comments received in stakeholder consultation not conflict with the current REACH (Regulation No 1907/2006/EC) Annex XVII Entry 46 on NP/NPE that applies to manufacturing in the EU. Textile production in the EU should thus not be significantly affected and the restriction would imply a level playing field for textile manufacturers situated within the Union as well as abroad.

The proposed restriction also specifies that only clothing and household textile articles that can be washed in water (examples given in Table 1 in section A.1) shall be subject to the NP/NPE limit value. As described in section B.9.3.4.1 of the various technical textiles it is primarily *Clothing textiles (Clothtech) and Sports textiles (Sporttech)* that consist of products submitted to washing in water and hence contribute to the NPE released to the waste water. Those textiles will therefore be included by the proposed restriction. The vast majority of technical textiles are however excluded from the scope of the proposed restriction.

The actors that are affected by the restriction are thus primarily EU importers who place clothing and household textile articles on the EU market.

It is expected that the actors in the textile supply chain will comply to the proposed restriction by substituting NPEs with other alternative chemicals with similar properties. The restriction will likely not imply any significant investment in new production techniques or equipment. The assessment of alternatives to NPE indicates that there is already a range of alternatives available in the market and they are widely used in textile production. The most likely replacements for NPEs are various forms of alcohol ethoxylates and glucose based detergents. The alternatives to NPEs are generally shown to be comparable to NPE in terms of effectiveness as surfactants, however the prices for alternatives might be somewhat higher.

The cost of substituting NPEs with alternative surfactants is estimated to be minor in comparison to e.g. the total EU import value for textiles. However the costs of compliance control for EU importers and retailers might be considerable (estimated to roughly €44 to 81 million in the years 2020 to 2030) depending on how the actors in the textile supply chain react to the restriction. Though overall the costs impacts are not significant in relation to consumer's prices for the final textile article. The proposed restriction allows 5 years for compliance in order to minimize any costs impacts and allow smooth adaption for all concerned actors. The need for a transitional period of at least 5 years has been emphasized in stakeholder consultation since it is considered essential for sufficient communication to occur among the range of actors in the textile supply chain.

Practicality

The proposed restriction is formulated so that interpretation is facilitated for actors in the textile supply chain as well as for authorities responsible for enforcement, i.e. the restriction is expected to be enforceable and manageable. The proposed restriction sets a clear limit for the NP/NPE content in clothing and household textile articles, i.e. it is recognized that NP/NPE should not be found in the textile above the limit value. The emphasis is thus clearly on the textile material. A list of examples of clothing and household articles is given in order to clarify the scope of the restriction, and furthermore it is stated that the restriction shall only apply to those textile articles that can be washed in water. The wording of the restriction also makes clear that prints on the textiles articles mentioned are also subject to the limit value for NP/NPE. The restriction clearly defines what is meant by 'textile articles' by referring to the definition in Article 3.1 a-f of the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products. Furthermore the restriction refers to the standards adopted by the European Committee for Standardisation (CEN) to be used as test methods for demonstrating the conformity of the articles in question. This means that authorities will be provided with EU standard test methods that will be readily available in the market for laboratory analysis services before entering into force of the proposed restriction. The groups of substances that are covered by the restriction are defined and is deliberately made so that various possible variations of the molecular structure of the substances (NP and NPE) are covered which will facilitate supervision as there are no exceptions defined. Finally the proposed restriction allows sufficient time for the actors in the supply chain to adapt to the restriction and thus to deplete any stocks of textiles that could contain NPE concentrations above the proposed limit.

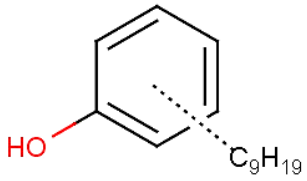
B.1 Identity of the substance(s) and physical and chemical properties

This dossier covers all possible nonylphenol isomers and as such or in a reaction mass and nonyphenol ethoxylates, which degrade to nonylphenol isomers.

Nonylphenol

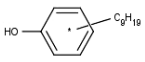
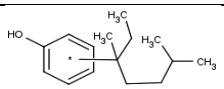
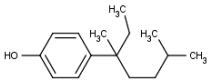
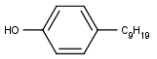
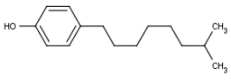
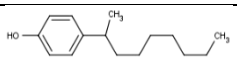
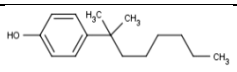
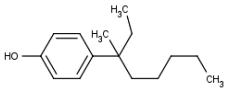
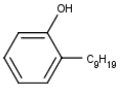
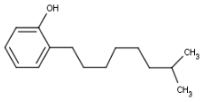
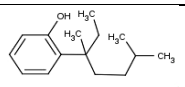
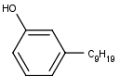
B.1.1 Name and other identifiers of the substance(s)

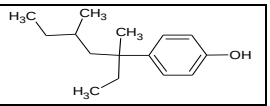
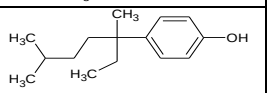
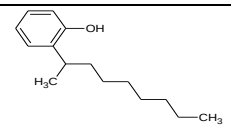
CAS Number: see table below
EC Number: see table below
IUPAC Name: Nonylphenol
Synonym: C9-alkyl-(branched and linear)-phenol(s)
Molecular formula: $C_{15}H_{24}O$
Structural formula (generic):



Nonylphenol, unspecified in position and branching
Molecular weight: 220.34 g/mole
Synonyms: See Table 2 below

Table 2 Nonylphenols

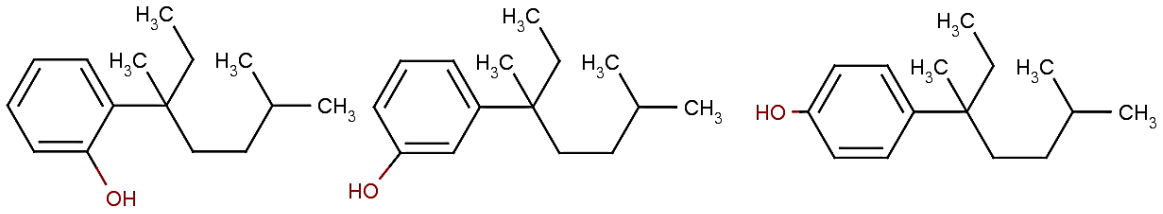
ECnr	CASnr	IUPAC name	Synonyms	Molecular structure
246-672-0	25154-52-3	Nonylphenol	Phenol, nonyl-	
234-284-4	11066-49-2	Isononylphenol	Phenol, isononyl-	
291-844-0	90481-04-2	Phenol, nonyl-, branched	Phenol, nonyl-, branched	 example
284-325-5	84852-15-3	Phenol, 4-nonyl-, branched	Phenol, 4-nonyl-, branched	 example
203-199-4	104-40-5	p-Nonylphenol	4-nonylphenol	
247-770-6	26543-97-5	p-Isononylphenol	4-isononylphenol	
241-427-4	17404-66-9	p-(Nonan-2-yl))phenol	4-(1-methyloctyl)phenol	
250-339-5	30784-30-6	p-(2-Methyloctan-2-yl)phenol	4-(1,1-dimethylheptyl)phenol	
257-907-1	52427-13-1	4-(3-Methyloctan-3-yl)phenol	4-(1-ethyl-1-methylhexyl)phenol	
205-263-7	136-83-4	o-Nonylphenol	2-nonylphenol	
248-741-0	27938-31-4	o-Isononylphenol	2-isononylphenol	
294-048-1	91672-41-2	Phenol, 2-nonyl-, branched	Phenol, 2-nonyl-, branched	 example
205-376-1	139-84-4	m-Nonylphenol	3-nonylphenol	
	1196678-78-0	Neononylphenol-	Phenol, neononyl-	

	186825-36-5	4-(3,5-Dimethylheptan-3-yl)phenol	Phenol, 4-(1-ethyl-1,3-dimethylpentyl)-	
	142731-63-3	4-(3,6-Dimethylheptan-3-yl)phenol	Phenol, 4-(1-ethyl-1,4-dimethylpentyl)-	
	17404-45-4	2-(Nonan-2-yl)phenol	Phenol, 2-(1-methyloctyl)-	
	89585-68-2		Phenol, 2-tert-nonyl-	
	97372-03-7		Phenol, sec-nonyl-	
	58865-77-3		Phenol, 4-tert-nonyl-	
	27214-48-8		Phenol, o-sec-nonyl-	
	27072-91-9		Phenol, p-sec-nonyl-	

The term "nonylphenol" may apply to a large number of substances and/or constituents thereof with the general molecular formula $C_6H_4(OH)C_9H_{19}$. However, the formula $C_6H_4(OH)$ only refers to the phenol unit and C_9H_{19} to a branched or linear alkyl chain.

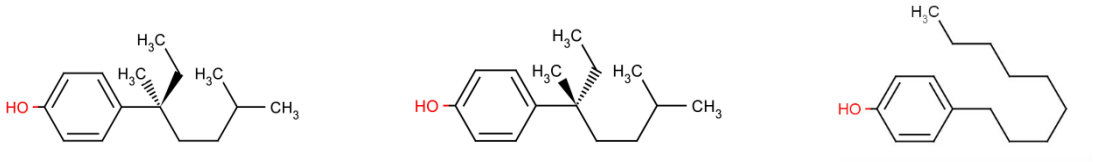
Nonylphenol isomers may vary in two ways:

(1) The substitution position of the nonyl group on the phenol molecule, known as ortho-, meta- and para position;



Ortho-, meta- and para nonylphenol, branched

(2) The degree of branching of the nonyl group. Since the nonyl moiety is formed by oligomerisation of propene to nonene, the carbon skeleton is restratified, giving branched carbon chains. During alkylation of phenol, further restratifications occur, due to the reaction mechanism itself favouring as branched structure as possible. Many of the branched isomers possess chiral C atoms (up to three per isomer), so it is also important to consider optical isomers, which may produce different biological effects. In total, 550 isomers are possible and 80 different isomers were found in technical nonylphenol (Tang 2005). Many of the individual branched isomers have their own CAS numbers. It has been shown that structural features of different alkylphenols affect their estrogenic activity, and the estrogenic effect of an individual nonylphenol isomer is heavily dependent upon the structure of the side chain. It is absolutely necessary to consider NP from an isomer-specific viewpoint.



Stereo isomeric branched nonylphenol and n-nonylphenol

The technical synthesis of NPs starts from phenol, which is alkylated by a mixture of nonene isomers in an acid-catalysed process. The chemical composition of technical nonene leads to a complex mixture of NPs consisting of isomeric compounds with different branched nonyl side chains. Very little, if any, straight chain nonylphenol is produced.

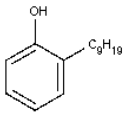
The commercially produced nonylphenols are predominantly 4-nonylphenol with a varied and undefined degree of branching in the alkyl group. This assessment covers commercially produced material (predominantly 4-nonylphenol, branched). This material will also contain smaller amounts of other isomers and impurities, and falls under the EC number 284-325-5 and CAS number 84852-15-3.

In carrying out this assessment data from any of the isomers are assumed to be representative for nonylphenol unless otherwise specified, and nonylphenol (NP) is used as the generic name referring to these substances.

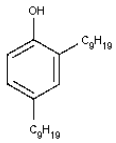
B.1.2 Composition of the substance(s)

In the EU risk assessment (ECB 2002) the purity of commercial nonylphenol is reported as 90% w/w with the following constituents:

- 2-Nonylphenol 5% w/w EC: 294-048-1 CAS nr: 91672-41-2



- 2,4-Dinonylphenol 5% w/w EC: 205-310-1 CAS nr: 137-99-5



There are no reported additives.

B.1.3 Physicochemical properties, nonylphenols

The varied degree of branching in the nonyl group is a factor in the variability of the physical-chemical properties reported. So is the position (o,m,p) of the alkyl group.

B.1.3.1 Physical state (at ntp)

Commercially produced nonylphenol is a clear to pale yellow viscous liquid with a slight phenolic odour.

B.1.3.2 Melting point

A pour point, i.e. the lowest temperature at which movement of the substance is observed, is an appropriate measurement for oily substances of this type. In the EU risk assessment (ECB 2002) a value of circa -8°C (Hüls, 1994), which has been measured according to DIN ISO 3016, was selected. In the CSR (Lead registrant 2010) the melting/freezing point was set to be ≤ 7℃.

B.1.3.3 Boiling point

The actual boiling/decomposition range will depend on the purity and origin of the material. In the EU risk assessment (ECB 2002)a number of studies with boiling ranges around 300℃ were considered representative for the commercial product, which is in agreement with the CSR (Lead registrant 2010) where 302℃ is given.

In the EU risk assessment (ECB 2002) it is written that nonylphenol undergoes thermal decomposition before it reaches its boiling point.

B.1.3.4 Relative density

In the EU risk assessment (ECB 2002)a value of 0.95 at 20℃ was used, which is in agreement the CSR (Lead registrant 2010) (0.9509 at 20℃).

B.1.3.5 Vapour pressure

In the EU risk assessment (ECB 2002)the value 0.3 Pa at 25℃ was used for modelling purposes. This value is the result of an extrapolation of a plot (see Figure 1 below), based on the data by Hüls (1996).

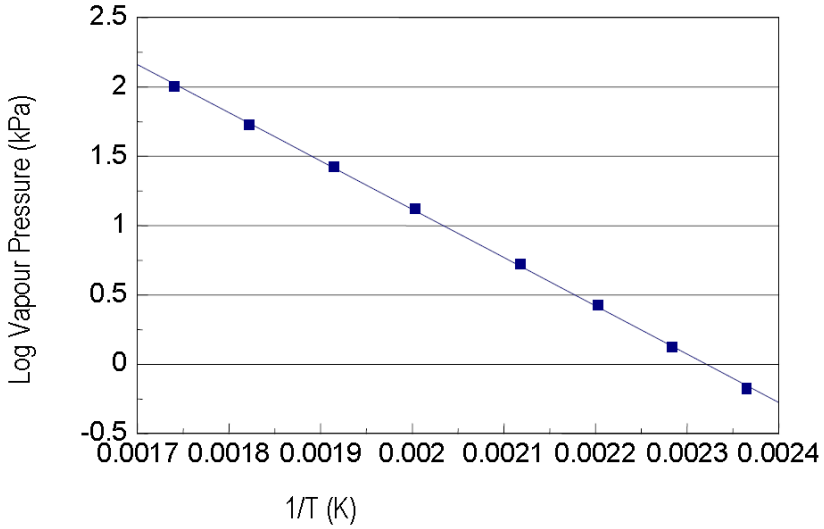


Figure 1 Vapor pressure

In the CSR (Lead registrant, 2010) the value used is 0.01 mbar at 38℃ (corresponding to 1 Pa at 38℃). The study is rated as having reliability 1, it is however impossible, only based on the information included in IUCLID to conclude on which of the two values to use. The EU risk assessment (ECB 2002) value is used for calculating Henry´s constant.

B.1.3.6 Water solubility

In the EU risk assessment (ECB 2002)a value of 6 mg/l at 20℃ was used, which is in agreement the CSR (Lead registrant, 2010) (5.7 mg/l at 20℃). It is therefore decided to use the value of 6 mg/l used in the EU risk assessment (ECB 2002).

In the EU risk assessment (ECB 2002) nonylphenol was considered to be in its neutral form at environmental pH due to a pKa above/around 10.

B.1.3.7 n-Octanol-water partitioning coefficient

In the EU risk assessment (ECB 2002)a log K_{ow} of 4.48 for nonylphenol, originating from the study by Ahel and Giger (1993), was used for the environmental modeling, while in the CSR (Lead registrant, 2010) a log K_{ow} of 5.4 (Sasol, 2009) was used instead. A log K_{ow} value of 5.76 has been reported in the literature (Itokawa et al., 1989), but according to the EU risk assessment (ECB 2002)this value relates to the straight chained 4-(n)-nonyl phenol derivate and not to the 4-nonyl (branched) compound. Considering the method of manufacture of the nonylphenol, very little if any straight chain nonylphenol is produced. That which is produced is only to be present at very low levels in commercial mixtures. The commercially produced nonylphenols are predominantly 4-nonylphenol with a varied and undefined degree of branching in the alkyl group.

The differences observed between the value selected in the EU risk assessment (ECB 2002)and in the CSR (Lead registrant, 2010) may relate to the variability of the commercial 4-nonyl (branched) compound, including its impurities. Since concern was identified in the EU risk assessment (ECB 2002)in both the aquatic and the terrestrial compartment it is decided to use both log K_{ow} values.

This since the lower of the two, i.e. 4.48, is most worst-case for the aquatic compartment and the higher of the two, i.e. 5.4, is most worst-case for the terrestrial compartment.

In the EU risk assessment report, several studies on the n-octanol-water partition coefficient and on water solubility were reviewed. The data show quite some variation (3-11 mg/liter for water solubility and 3.3-5.8 for log K_{ow}), depending on substance tested, testing conditions, and perhaps analytical possibilities. Nonylphenol has been produced with three different methods, probably giving raise to different technical mixtures, e.g., with regard to degree of branching. It is plausible that the varying data partly is explained by the differences in substance composition. Based on an overall assessment of the data for log K_{ow}, a value of 4.48 was chosen for environmental modeling purposes in the EU risk assessment.

In the registration dossier of 4-branched nonylphenol (84852-15-3), a new study is mentioned, giving a log K_{ow} value of 5.4. The study uses the OECD 117 HPLC-method. The value agreed by the EU member states in the EU risk assessment report might still represent the different nonylphenols that may enter EU via imported textiles, but taking into account the present synthetic pathway to nonylphenol both a log K_{ow} of 4.48 and 5.4 should be considered in the modelling.

B.1.3.8 Other physical-chemical properties

In the EU risk assessment (ECB 2002)the Henry´s law constant was calculated from vapour pressure (VP), molecular weight (MW) and water solubility (WS) using the equation:

HENRY = VP x MW/WS

Using a vapour pressure of 0.3 Pa, a molecular weight of 220.34 g/mol and a water solubility of 6 mg/l resulted in a Henry's law constant for nonylphenol of 11.02 Pa m^3/mol.

In the EU risk assessment (ECB 2002)a pKa is considered to be ~10 (or even somewhat higher), and nonylphenol will as a consequence of that remain undissociated at environmental pH-values.

B.1.3.9 Summary of physico-chemical properties

There is in general a good agreement between the phys-chem properties presented in EU risk assessment (ECB 2002) and in the CSR (Lead registrant, 2010). They differ however as regards the n-octanol-water partition coefficient in that the former uses a log K_{ow} value of 4.48 and the latter a value of 5.4.

In the EU risk assessment (ECB 2002) differences in reported n-octanol-water partition coefficient between the two main sources of data, Hüls (1989a) and ICI (1995) were discussed. ICI quoted log K_{ow} at 4.2-4.7, Hüls at 3.28, while data from an additional source (Chemical Manufacturers Association) suggested a log K_{ow} of >3.8 to >4.77. It was in the EU risk assessment (ECB 2002)considered that some of these differences may relate to experimental methods but that there were some evidence that the products made by the two companies have slightly different physico-chemical properties, possibly due to different degrees of branching in the nonyl chain. It was

considered that this may also explain the differences between physico-chemical data for nonylphenol from USA reports.

Since concern was identified in the EU risk assessment (ECB 2002) in both the aquatic and the terrestrial compartment it is decided to use both log K_{ow} values. This since the lower of the two, i.e. 4.48, is most worst-case for the aquatic compartment and the higher of the two, i.e. 5.4, is most worst-case for the terrestrial compartment.

The physical and chemical properties of nonylphenol are summarized in Table 3.

Table 3 Physical and chemical properties of nonylphenol

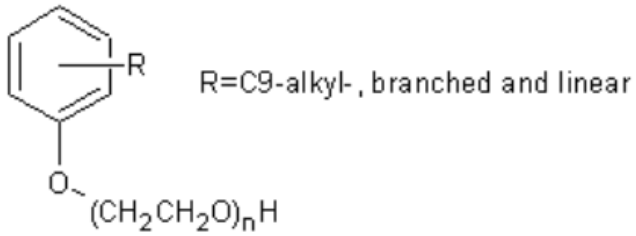
Property	**Value**	**Comments**
Physical state at ntp	Clear to pale	Slight phenolic odour
Molecular weight	220.34 g/mol	
Melting point	ca. -8℃	Approximate only due to nature of the material – may vary according to production process used.
Boiling point	290-300℃ d	Nonylphenol undergoes thermal decomposition at this temperature
Relative density	0.95 at 20℃	ASTM 3505
Vapour pressure	ca. 0.3 Pa at 25℃.	IUCLID CSR
Partition coefficient	Log K_{ow} 4.48 and log K_{ow} 5.4 will be used	See text.
Water solubility	6 mg/l at 20℃	At environmental pH.

Nonylphenol ethoxylates

B.1.1 Name and other identifiers of the substance(s)

CAS Number: Not applicable
EINECS Number: Not applicable
IUPAC Name: Nonylphenol ethoxylates
Molecular formula: $(C_2H_4O)nC_{15}H_{24}O$

Structural formula (generic):



Synonyms: See Table 4 below
Table 4 Groups of nonylphenol, ethoxylated

EC-number	CAS-number	CAS name	Synonyms	Mw
248-291-5	27176-93-8	Ethanol, 2-[2-(nonylphenoxy)ethoxy]-	2-[2-(Nonylphenoxy)-ethoxy]ethanol	308
230-770-5	7311-27-5	Ethanol, 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]-	2-[2-[2-[2-(4-Nonylphenoxy)ethoxy]ethoxy]-ethoxy]ethanol	396
294-139-6	91673-24-4	Ethanol, 2-[2-[2-[2-(4-nonylphenoxy)ethoxy]ethoxy]-, branched	2-[2-[2-[2-(4-Nonylphenoxy)ethoxy]ethoxy]-ethoxy]ethanol, branched	396
248-292-0	27177-03-3	3,6,9,12,15,18-Hexaoxaeicosan-1-ol, 20-(nonylphenoxy)-	Nonylphenol septaethoxylate	529
248-294-1	27177-08-8	3,6,9,12,15,18,21,24,27-Nonaoxaeicosan-1-ol, 29-(nonylphenoxy)-	Nonylphenol nonaethoxylate	660
248-293-6	27177-05-5	3,6,9,12,15,18,21-Heptaoxaeicosan-1-ol, 23-(nonylphenoxy)-	Nonylphenol octaethoxylate	572
248-762-5	27986-36-3	Ethanol, 2-(nonylphenoxy)-	2-(Nonylphenoxy)ethanol	264
284-987-5	85005-55-6	Ethanol, 2-(isononylphenoxy)-	2-(Isononylphenoxy)ethanol	264
243-816-4	20427-84-3	Ethanol, 2-[2-(4-nonylphenoxy)ethoxy]-	2-[2-(4-Nonylphenoxy)-ethoxy]ethanol	308
	39587-22-9	Poly(oxy-1,2-ethanediyl), α-nonylphenyl-ω-hydroxy-	Nonylphenol, branched, ethoxylated	polymer
500-209-1	68412-54-4	Poly(oxy-1,2-ethanediyl), α-nonylphenyl-ω-hydroxy-, branched	Nonylphenol, branched, ethoxylated	NLP

500-024-6	9016-45-9	Poly(oxy-1,2-ethanediyl), α-nonylphenyl-ω-hydroxy-,	Nonylphenol, ethoxylated	NLP
500-315-8	127087-87-0	Poly(oxy-1,2-ethanediyl), α-nonylphenyl-ω-hydroxy-, branched	4-Nonylphenol, branched, ethoxylated	NLP
500-045-0	26027-38-3	Poly(oxy-1,2-ethanediyl), α-4-nonylphenyl-ω -hydroxy-,	4-Nonylphenol, ethoxylated	NLP
	37205-87-1	Poly(oxy-1,2-ethanediyl), α-isononylphenyl-ω-hydroxy-,	Isononylphenol, ethoxylated	polymer
	51938-25-1	Poly(oxy-1,2-ethanediyl), α-(2-nonylphenyl)-ω-hydroxy-,	2-Nonylphenol, ethoxylated	polymer

Reaction of any nonylphenol with oxirane produces an ethylene glycol monoether of nonylphenol. With an excess of oxirane the ethoxylation process proceeds and ultimately produces a polyglycol with a nonylphenyl ether in one end of the chain.

A polymer is defined as a compound built from not less than three monomer units with a molecular weight distribution in which no single molecular weight is present with >50% . This definition generates two groupings of ethoxylates:

1. Compounds with the formula $(C2H4O)nC_{15}H_{24}O$ where 50% or more consists of a compound where n is defined as a discrete number
2. Compounds fulfilling the polymer definition

Substances not matching the definition of a polymer shall be registered as such according to Reach while substances matching the polymer definition are covered by the registration of the monomers and other substances used to generate the polymer.

Although many NPEs are listed in the database of the Chemical Abstract Service (CAS) and in the EC inventory, analyses carried through do not give information on which NPEs the textiles contain. It could therefore be assumed that not only some specific NPEs are used in the production of the textiles but rather abroad variation of different NPEs which could vary from time to time or depending on the production site. In order to avoid a substitution between different NPEs, the molecule formula ($C_2H_4O)_nC_{15}H_{24}O$) is proposed for describing generally all possible NPE substances.

B.1.2 Composition of the substance(s)

No information is available.

B.1.3 Physicochemical properties, nonylphenol, ethoxylated

There is no easily available physicochemical information of the above identified substances except on the NLP nonylphenol, branched, ethoxylated, 1<EO>2.5 (CAS-number 68412-54-4; EC-number 500-209-1, see Table 5) which has been registered.

Table 5 Physical and chemical properties of nonylphenol, branched, ethoxylated

Property	Value	Comments
Physical state at ntp	Clear to pale	Weak or no odour
Molecular weight	308 g/mol	Calc on 2 EO
Melting point	ca. -54,8℃	
Boiling point	354,34℃	
Relative density	0.95 at 20℃	ASTM 3505
Vapour pressure	ca. 0.043 Pa at 20℃.	
Partition coefficient	Log K_{ow} 4.48 and log K_{ow} 5.4 can be used	
Water solubility	<4.55 mg/l at 20℃ 3,26<sol<3,5 mg/l at 20.5℃	Read across value cited in the same source

The other discrete substances are pre-registered and may give better information later on.

B.1.4 Justification for grouping

Nonylphenol (NP) is the substance of concern in this proposal. The term "nonylphenol" however applies to a large number of linear and branched compounds of the general molecular formula $C_6H_4(OH)C_9H_{19}$ in which an alkyl chain with the carbon number of 9 is “attached” to the phenol. The inherent properties are however likely to be similar for all of them.

Nonylphenol (NP) is used as an intermediate in the production of various NP derivatives, mainly nonylphenol ethoxylates (NPEs) which can break down into NP in the environment. NPEs are used in the manufacturing of textiles and will be released from the textile during washing. Although many NPEs are listed in the database of the Chemical Abstract Service and in the EC inventory, analyses carried through do not give information on which individual NPE the textiles contain. It could therefore be assumed that not only some specific NPEs are used in the manufacturing of the textiles but rather a broad variation of different NPEs. The NPEs could vary from time to time or depending on the function of the NPE and the production site (for further information, see section B.1). Based on the lack of data of exactly which NPEs are used in the manufacturing of textiles and the NPEs common ability to break down into NP in the environment, the proposal also covers the NPEs as a group of substances.

The current restriction in REACH Annex XVII, entry 46 covers NP and NPE as groups of substances.

B.2 Manufacture and uses

B.2.1 Manufacture and import of NP/NPE

Nonylphenol (NP) is mainly used as an intermediate in the production of various NP derivatives. The derivatives are used in formulation into mixtures. Nonylphenol ethoxylates (NPEs) are the most common substances based on NP. They are part of the alkylphenol ethoxylate (APE) group, a

family of nonionic surfactants. NPEs are stable against alkali and other ions, they foam relatively little and they are moderately low-priced (OSPAR 2001).

As a surfactant NPE has historically been used as a tenside in household and commercial products (e.g. personal care, laundry products and cleaners) (Kjølholt et al. 2007). Short-chained NPEs are used as detergents and other cleaning products. NPEs with chains of medium length (between 10 and 30 ethoxylates) are used as emulsifiers, i.e. they help to form stable systems of more fat in less water. Long-chained NPEs (with up to 80 ethoxylates) can be used as dispersants; because of their ability to retain small particles in solutions (www.kemi.se/flodessok/floden/kemamne/nonylfenol.htm).

NP is also used as a catalyst in the curing of epoxy resin and as a binder, e.g. in various alkydes (www.kemi.se/flodessok/floden/kemamne/nonylfenol.htm). In Denmark the primary use of NP and NPEs are reported to be as hardeners in epoxy, PUR and concrete materials. An example of the use of NP as hardener is when laying out an epoxy floor where NP is used for accelerating the epoxy hardening process (Kjølholt et al. 2007). Another widely used NP derivate has been as a stabiliser in rubber and plastic by more hydrolytically insensitive substances like tris-(2,4-di-tert-butylphenyl) phosphite. Barium and calcium salts of NP are used as heat stabilisers in plastic. Phosphate esters of nonylphenol can be used as flame retardant (www.kemi.se/flodessok/floden/kemamne/nonylfenol.htm).

Since a couple of years there are restrictions on the use of NP/NPE in several applications of cleaning products as well as for other applications for end use. Data on market volumes and end use applications are available from the end of 1990´s. It is difficult to find up to date information on market volumes, but one could presume that for all restricted applications the volumes are lower today than they were 10-15 years ago.

In the late 1990´s NPEs represented 80 to 90% of the APEs used in the EU (by tonnage) (Postle et al 2003). The corresponding market share for octylphenols (OP) was 10-15%. Most such figures refer to market surveys that are 10-15 years old (Andersson et al. 2010, European Chemicals Bureau, 2002). More recent official data of the current market shares have not been found, neither in EU nor on the world market. Neither did we find any indications that a decrease in use of NP compounds leads to an increase of octylphenols or other similar substances. KemI states that the demand for NP is very much governed by the use of NPE, which at least in Europe can be expected to decrease (www.kemi.se/flodessok/floden/kemamne/nonylfenol.htm).

B.2.2 Manufacture, import and export of a substance

In 1997 four companies within the EU produced NP. A fifth company is reported to have ended the production of NP in 1996 (European Chemicals Bureau 2002). In 2006 only three producers were left producing NP in the EU (Feenstra et al. 2009). During the period 1994-1997 one major producer of nonylphenol stopped manufacture and another smaller producer was identified (European Chemicals Bureau 2002). Akzo Nobel produced NP in Sweden until 1999 (Björklund et

al. 2007). In 2006 following producers were active in Europe 2006 (Feenstra et al. 2009) according to public sources:

- Sasol Germany GmbH, Germany (previously Hüls AG, Condea GmbH)
- Polimeri Europe, Italy (previously Enichem S.P.A.)
- Synteza, Kedzierzyn-Kozle, Poland

In 2011 one can see from the companies' web pages that Synteza is still active. Regarding the two other producers it could not be verified from official sources that they still produce NP in Europe (http://www.pccsynteza.pl).

According to information from the AMEC consulting report (AMEC 2012) the total EU production of nonylphenol was 10 000-50 000 tonnes in 2010. This is based on confidential quantity information hence the data span. In 1997 the production in EU was 73 500 tonnes (European Chemicals Bureau 2002).

The same report stated, based on personal communication with CEPAD (European Council for Alkylphenols and Derivatives), that the production in 2010 of alkylphenol ethoxylates in EU + Norway and Switzerland was approximately 32 000 tonnes of which the majority was nonylphenol ethoxylates.

The trend has been that both the total production volumes as well as the number of producers have decreased in Europe the last 20 years (European Chemicals Bureau 2002, Feenstra et al. 2009). We have not found any documented indications whether this trend will continue in a short or long time perspective.

As import data for NP seems to include derivatives and polymers it is difficult to distinguish between different forms of NP substances. The total amount used for manufacturing (synthesization of other substances, formulation of mixtures and manufacturing of articles) is quite limited according to the registration dossiers. Production volume, exports and imports in EU is listed in Table 6.

Table 6 Production volume, exports and imports in EU (amount in tonnes/year)

	1997[7]	**2008**[8]	**2009**[7]	**2010**[8]	**2010**[9]
Production volume NP	73,500				10 000-50 000
Exports NP from EU	3,500	1 000	1 000	2 000	
Imports NP into EU	8,500	3 500	3 000	6 000	
Tonnage (Use) [10]	78,500				
Exports NPE from EU[11]	2 200 (5 600)				
Imports NPE into EU[11]	18 000 (46 000)				

There are different systems for classification of international trade. In the so called Harmonized System tariff the code 2907.13 is used for both nonylphenols and octylphenols. This code has been used for searching in the Eurostat data base. It is not obvious that there is a clear trend of increase or decrease of the traded volumes of NPs/OPs in/out of EU27.

There are various data available on the export volumes of NPE from 1997. As this is historic data no attempts have been made to investigate the reasons behind.

B.2.3 Uses

The use of NP can be divided into several main areas.
1) Industrial production: as intermediate in the production of other more complex substances
2) Industrial production: in the manufacturing of articles
3) Professional use in industry
4) Professional use in other areas than manufacturing industry
5) Consumer use

There is a certain element of overlap between these categorizations and uses. The amounts reported in manufacturing processes can show up again i.e. in a paint or rubber product (Postle et al 2003). One should thus be careful with adding figures of different areas of use. The total flow is probably lower than the sum of all reported uses. Data can also be expected to vary over time due to the expansion of the number of EU countries. In 1997 there were 15 Member States and today they are 27.

[7] European Chemicals Bureau, 2002, Feenstra et al. 2009, Andersson et al. 2010
[8] European Commission, Eurostat (http://ec.europa.eu/eurostat/); Octylphenol included.
[9] AMEC 2012
[10] Production volume + Imports of NP – Exports of NP
[11] Weights as NP (weights as NPE in brackets). The used relation in weights have been 1 unit weight of NPE = 0.4 unit weights of NP.

In the CSR **Industrial uses** are described as: Formulation of Paints, Formulation of adhesives, manufacture of coating and inks in wet or dry products, Intermediate for production of other substances (TNPP[12], Phenolic oxime, plastic stabilizer and ethoxylates), monomer for production of polymers, emulsion polymerization processes, tackifier in manufacture of tyres and rubber products. Industry is an end user of NP/NPEs in paints (painting and spray coating) and adhesives, coatings or inks. Professional uses are describes as: Adhesives, coatings and inks.
Consumer uses are described as: Adhesives, coatings and paints (CSR 2011).

Uses of NP in industrial production

NP and NP ethoxylates (NPEs) are used in a wide range of industry sectors. Data and nomenclature vary between the references, while the same application can be presented by different names and sorted in different ways, which is not always easy to see through. In
Table 7 the uses as intermediates in the productions of other substances and polymers are presented.

Table 7 The use in EU of NP as an intermediate in industrial production of other substances and in polymer production processes

Industrial production Intermediates	**1997[13]**	**1997 [14]**
Intermediate - NPE nonyl phenol etoxylates	**47 000**[15]	
Intermediate - Phenolic oximes	**2 500**	**2 500**
TNPP Production	4 000	4 000
Plastic Stabilizer Production		1 000
Phenol/formaldehyde resin production	22 500	22 500
Epoxy resin Production	1 500	1 500
Production of other organic basic chemicals	7 000	
Intermediates Plastic, resins and stabilisers Total	**35 000**	**29 000**
Industrial production Materials		
Monomers in Polymers		
Emulsion polymerization	3 600[16]	

The data that is presented in the registration dossiers are widely spread and probably not complete. However it seems like the total production of NP derivatives has decreased substantially the last 10-15 years.

[12] Tris(Nonylphenyl) Phosphite
[13] Andersson et al. 2010
[14] European Chemicals Bureau, 2002
[15] 118 000 tonnes/year as NPE (based on NPE with 8 ethoxy unitis where the NP/NPE ratio is 2:5). 31 000 tonnes was used in EU the rest was exported
[16] 9 000 tonnes as NPE

The original NP as well as the derivatives are used in further manufacturing processes to end use articles and mixtures. Some uses are mentioned in published reports although no production or usage figures were found. One could assume that those applications are of minor importance, but still a source where we can expect to find low levels of NP/NPE or other derivatives. Such applications are:

- Textile and leather auxiliaries (manufactured in EU)
- Additives in concrete
- Additive in plastics, food packaging included
- Additive in photographic chemicals
- Component in laboratory chemicals

There are also several lists available that show the market share on the end use of NP/NPE derivatives in different industrial sectors. Those lists can be found in the referred documents (Månsson et al. 2009, Postle et al. 2003, Andersson et al. 2010, European Chemicals Bureau 2002, Feenstra et al. 2009). One example is that in 1997, 14 000 tonnes NP was used in the manufacturing of Textiles & Leather (Postle et al. 2003). In Table 8 below the use of NP and its derivatives when used for formulation of mixtures is presented.

Table 8 The use in EU of NP/NPE in chemical formulations and articles

***Industrial production Products* - Articles**	**1997**
Formulation of paints, lacquers and varnishes	1 600[17]
Formulation of adhesives	9 000[18]

Compared from figures from 1997and later, the trend is leaning towards that the amount of NP/NPE in chemical formulations and articles has drastically decreased in recent years.

Other end uses than imported textiles used by professionals and consumers

According to a Swedish study from 2008 NP/NPE are still available in a vide variety of products. Except from textiles the largest volumes originate from paints/lacquers, glue and cleaning agents (Månsson et al. 2009). Other studies point out tyres as a source of NP as well as octylphenol (OP) (KemI 2006) and floor coverings due to addition of epoxy resins for accelerating the hardening process (Kjølholt et al. 2007).

The most important source of NP and NP derivatives seems to be:

- Coatings
- Paints
- Inks
- Adhesives and
- Tyres and other rubber products

[17] European Chemicals Bureau 2002
[18] Andersson et al 2002 (22 500 tonnes as NPE)

Many uses of NPs and NPs are already restricted in REACH Annex XVII, Entry 46. See section B.2.4 "Uses advised against by the registrants". There are other areas of use which is not regulated, but where the NP volumes are for other reasons relative low, like in:

- Concrete
- Additives for plastics
- Waxes for fruit and vegetables
- Laboratory chemicals
- Photographic chemicals
- Floor coverings

Products where data on end use were found are presented in Table 9.

Table 9 End uses of products containing NP / NPE

Identified product for end use	**1997**[19]
Paints, coatings and inks	4 000
Adhesives	
Tyres and rubber products	
Cleaning agents for professional use	23 000
Agriculture products	5 000

The trend is a decreasing use in end-use products containing NP/NPE such as cleaning agents for professional use and agricultural products while the use seems to increase regarding paints, coatings and inks.

In section B.9.3.4.2 different uses of nonylphenol, nonylphenol ethoxylates and other derivatives are presented based on information from the Swedish Products Register (2009). This can be viewed in Table 31. For comparable reasons the volumes have been converted to nonylphenol equivalents (NP_{equ})[20]. The main release (36 %) is calculated from the use as emulsifier in the chemical industry whereas cleaning agents contribute to 24 %. The production and end use of plastic products contribute to 18 % and paints and adhesives stand for 14 %. Totally 22 334 tonnes/year NP_{equ} are used in different products (Upscaled from Swedish data). In Annex 3 the use of nonylphenol, ethoxylates and other derivatives in different product groups can be viewed in more detail.

B.2.4 Uses advised against by the registrants

Many uses of NPs and NPEs are already restricted, mostly to a level below 0.1 % by weight, in REACH Annex XVII, Entry 46. The uses of NP/NPE in the restricted products have thus decreased within the EU during the last decade. Restricted uses are:

- Cleaning products
- Manufacturing of textiles and leather
- Teat dips (as emulsifier)
- Metal working

[19] Postle et al 2003
[20] Calculation based on NPE with 8 ethoxy unitis (where the NP/NPE ratio is 2:5)

- Pulp & paper production
- Cosmetic products and other personal care products
- Compounds in Pesticides and biocides

B.3 Classification and labeling

Table 10 Substance

Substance	EC number	CAS number	Name
1	246-672-0	25154-52-3	nonylphenol
2	284-325-5	84852-15-3	4-nonylphenol, branched

Information on harmonized classification of nonylphenol etoxylates was not found in Annex VI.

B.3.1 Classification and labeling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Table 11 Regulation (EC) No 1272/2008 Annex VI Table 3.1

Classification		Labelling	
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)
Acute Tox. 4	H302	H302	
Skin Corr. 1B	H314	H314	
Repr. 2	H361fd	H361fd	
Aquatic Acute 1	H400		
Aquatic Chronic 1	H410	H410	

Table 12 Regulation (EC) No 1272/2008 Annex VI Table 3.2

Classification	Risk phrases	Safety phrases	Indication(s) of danger
Repr. Cat. 3; R62-63	22	1/2	C
Xn; R22	34	26	N
C; R34	62	36/37/39	
N; R50-53	63	45	
	50/53	46	
		60	
		61	

B.3.2 Classification and labeling in classification and labeling inventory/Industry's self classification(s) and labeling

Table 13 Industry self classification

Classification		**Labelling**		**Specific Concentration limits, M-Factors**
Hazard Class and Category Code(s)	Hazard Statement Code(s)	Hazard Statement Code(s)	Supplementary Hazard Statement Code(s)	
Acute Tox. 4	H302	H302		M = 10
Skin Corr. 1B	H314	H314		
Eye Dam. 1	H318			
Repr. 2	H361	H361		
Aquatic Acute 1	H400			
Aquatic Chronic 1	H410	H410		

B.4 Environmental fate properties

The main information sources for this section are the EU risk assessment (ECB 2002) and the CSR (Lead registrant, 2010) and to some extent also Environment Canada (2002).

The probably overall most important mechanism determining the fate of nonylphenolic substances in water, sediment and soil appears to be biological degradation and transformation (Environment Canada 2002).

The most important physicochemical process affecting the fate of nonylphenolic substances is the adsorption to particles, while abiotic degradation is not thought to significantly contribute to the dissipation of the compounds (Environment Canada 2002).

B.4.1 Degradation

Biodegradation consist of a two-step process, primary biodegradation and ultimate biodegradation (or total biodegradation). The primary biodegradation results in an alteration of the chemical structure and loss of characteristic properties, which for the nonylphenol ethoxylates results in loss of its characteristic detergent properties. This often results in the formation of the intermediate biodegradation products mono- (NP1EO) and di-ethoxylates (NP2EO), nonylphenoxy acetic acid (NP1EC), nonylphenoxy acetic acid (NP2EC) and nonylphenol. Aerobic biodegradation favours the formation of NP1EC and NP2EC, while anaerobic biodegradation favours the formation of NP1EO, NP2EO and NP. The second step in the two-step biodegradation process is the ultimate biodegradation, which refers to the complete breakdown of a compound to carbone dioxide, water and inorganic salts.

Nonylphenol released to the atmosphere is likely to be degraded by reactions with hydroxyl radicals, with a half-life of around 0.2 days.[21]

According to the EU risk assessment (ECB 2002) hydrolysis and photolysis are not considered to be removal processes of importance for nonylphenol in the aquatic environment.

Studies by Ekelund *et al.* (1993), Chang and Yuan (2004), Yuan and Chang (2004), Ying and Kookana (2003), Bradely *et al*. (2008) and De Weert *et al.* (2009) in surface water, river bed sediment and marine water sediment, indicate that nonylphenol biodegrades under oxic conditions but is persistent under anoxic conditions and will therefore accumulate in anoxic sediments.
The available biodegradation data indicate that nonylphenol undergoes biodegradation in water, sediment and soil systems, and is considered to be inherently biodegradable.[22]

The study by Ekelund *et al.* (1993) is described as follows in the EU risk assessment (ECB 2002):
Ekelund et al. (1993) studied the biodegradation of 4-nonylphenol in seawater and sediment. In the experiments ^{14}C uniformly ring-labelled nonylphenol (synthesised using nonene containing a mixture of branched isomers) was used. The reaction flasks used contained seawater or seawater plus sieved soft bottom sediment. Formalin was added to four flasks containing seawater and half of the flasks containing seawater and sediment were bubbled with nitrogen gas prior to the start of the experiment. 11 µg ^{14}C ring-labelled nonylphenol was dissolved in acetone and added to small glass plates, the solvent was then evaporated and the glass plates added to the reaction flasks. The flasks were incubated at 11 ± 2 °C in the dark for 16 weeks. In flasks containing formalin no $^{14}CO_2$ was recovered, indicating that any $^{14}CO_2$ must come from the nonylphenol in the presence of living organisms. In the absence of sediment, degradation (as measured by $^{14}CO_2$ production) was very slow at 0.06% per day up to 28 days then 1% per day after 28 days, suggesting a period of adaptation is required. In the presence of sediment the degradation rate was faster at 1.2% per day. In the low oxygen experiments the reaction rate was slow. The increase in degradation rate in the sediment system was attributed to the higher number of microorganisms present. The overall recovery of ^{14}C from these experiments was around 64% (44% in the CO_2 fraction) in the flasks without sediment and 49% (46% in the CO_2 fraction) in the flasks with sediment. Thus around 45% of the ring-label was converted to CO_2 in 8 weeks, giving a mineralisation half-life of slightly longer than 56 days. However, the low overall recovery of ^{14}C-label in the experiments indicates that the actual extent of biodegradation may be higher (with a resulting shorter half-life) than implied by the $^{14}CO_2$ measurements (for example incorporation of the ^{14}C-label into biomass may have occurred).

The study by Chang and Yuan (2004) is described as follows in the CSR (Lead registrant 2010):
In freshwater sediments under anaerobic conditions at 30 °C, Chang et al., 2004, report half-lives for NP (linear isomer) ranging from 46.2 to 69.3 days. The degradation rate for NP was enhanced by increasing temperature and inhibited by the addition of acetate, pyruvate, lactate, manganese

[21] This value is estimated for branched nonylphenol (CAS 84852-15-3) by the AOPWIN v1.92. With a 12-h day, the resulting hydroxyl radical half life is 0.208 days/2.495 h. The value used in the EU risk assessment (ECB 2002) was 0.3 days while in the CSR (Lead registrant, 2010) the value used was 5 h.
[22] This is consistent between the EU risk assessment (ECB 2002) and the CSR (Lead registrant, 2010)

dioxide, ferric chloride, sodium chloride, heavy metals, and phthalic acid esters. Moreover, results show the high-to-low order of degradation rates to be sulfate-reducing conditions > methanogenic conditions > nitrate-reducing conditions.

The study by Yuan and Chang (2004) is described as follows in the CSR (Lead registrant 2010): *Under aerobic sediment conditions, Yuan et al., 2004, report half-lives for NP ranging from 13.6 to 99.0 days. The degradation rate for NP was enhanced by shaking and increasing temperature and inhibited by the addition of Pb, Cd, Cu, Zn, phthalic acid esters (PAEs), and NaCl, as well as by reduced level of ammonium, phosphate, and sulfate.*

The study by Ying and Kookana (2003) is described as follows in the CSR (Lead registrant 2010): *Ying & Kookana (2003) measured the biodegradation of NP in saltwater and marine sediments at 20 °C under aerobic and anaerobic (sediment only) conditions. Aerobic degradation of NP in marine sediments occurred very quickly, with a calculated half-life of 5.8 d, based on first-order reaction kinetics. 98.8% of the test substance has been degraded in seawater under aerobic conditions within one week. No degradation could be observed in marine sediments under anaerobic conditions.*

Bradely *et al*. (2008) studied the potential for 4-n-nonylphenol biodegradation in stream sediments in three hydrologically distinct streams impacted by wastewater treatment plants (WWTPs) in the United States. Microcosms were prepared with sediments from each site and amended with [U-ring-^{14}C] 4-*n*-nonylphenol (4-*n*-NP) as a model test substrate. Microcosms prepared with sediment collected upstream of the WWTP outfalls and incubated under oxic conditions showed rapid and complete mineralization of [U-ring-^{14}C] 4-n-NP to $^{14}CO_2$ in all three systems. In contrast, no mineralization of [U-ring-^{14}C] 4-*n*-NP was observed in these sediments under anoxic conditions. The initial linear rate of [U-ring-^{14}C] 4-*n*-NP mineralization in sediments from upstream and downstream of the respective WWTP outfalls was inversely correlated with the biochemical oxygen demand (BOD) of the streambed sediments. According to the authors the results indicate that the net supply of dissolved oxygen to streambed sediments is a key determinant of the rate and extent of 4-NP biodegradation in stream systems. In the stream systems considered by the present study, dissolved oxygen concentrations in the overlying water column (8–10 mg/L) and in the bed sediment pore water (1–3 mg/L at a depth of 10 cm below the sediment–water interface) were consistent with active in situ 4-NP biodegradation.

De Weert *et al.* (2009) studied aerobic degradation on NP in river sediment. The sediment used for the microcosm experiments was aged polluted with NP. The biodegradation of NP in the sediment occurred within 8 days with a lag phase of 2 days at 30 °C. During the biodegradation, nitro-nonylphenol degradation products were formed, which were further degraded to unknown compounds. The attached nitro-groups originated from the ammonium in the medium. In this NP-degrading culture, the microorganisms possibly involved in the biotransformation of NP to nitro-nonylphenol were related to ammonium-oxidizing bacteria. Besides the degradation of NP via nitro-nonylphenol, bacteria related to phenol-degrading species, which degrade phenol via ring cleavage, were reported to be abundantly present.

B.4.2 Environmental distribution

Most of the nonylphenolic compounds entering the environment are expected to be released to surface water via wastewater treated in WWTPs. The type of nonylphenolic species in the effluent depend on the type of WWTP, but in the WWTP-scenario used in the EU risk assessment (ECB 2002) and in this dossier, the majority of nonylphenolic compounds are NP1EO, NP2EO, NP1EC and NP2EC, some NPnEO(n>3) and small amounts of NP, which are all far less readily degradable as compared to the nonylphenol polyethoxylates. Potential abiotic fate processes for nonylphenolic compounds in the aquatic compartment are photolysis, volatilization and adsorption to suspended particles, where the first two are considered to be of less importance as compared to the third. Studies by Kvestak *et al.* (1994) and Sekela *et al.* (1999) have shown that nonylphenol in water readily adsorb onto suspended particles. NP and NPEO adsorbed to suspended particles may settle out of the water column into the sediments. Kvestak and co-workers (1994) reported that partitioning of nonylphenol polyethoxylates between dissolved and particulate phases can vary slightly among various NPEOs, with NP6EO and NP7EO showing a relatively higher tendency to partition into the particulate phase as compared to other NPEOs. Nonylphenolic compounds dissolved in the water may also directly adsorb to particles on the sediment surface (Environment Canada 2002).

The major route of nonylphenolic compounds entering the terrestrial compartment is via application of sludge. The abiotic fate processes affecting nonylphenol and its ethoxylates in soils are, in decreasing order of importance, particle adsorption, infiltatration to groundwater and volatilization (Environment Canada 2002). Beigel *et al.* (1998) reported that the relative degree of adsorption of NPEO tend to increase with decreasing number of EO-units to a maximum soil affinity at about NP9EO, after which the tendency for adsorption decreased with decreasing number of EO-units. The authors (Beigel *et al*. 1998) suggested that the adsorption of the NPEOs with more than nine EO-units increased with a reduced number of EOs due to the increasing hydrophobicity, but for the NPEOs shorter than NP9EO, which have a lower critical micelle concentration, there may instead be a preference for surfactant-surfactant interactions and micelle formation, rather than surfactant-soil surface interactions.

B.4.2.1 Adsorption/desorption

The EU risk assessment (ECB 2002) recommends the use of a K_{oc} of 5360 L/kg. This value has been calculated using EUSES based on a log K_{ow} of 4.48. Although the K_{oc} value estimated in the EU risk assessment (ECB 2002)is lower than that measured in various soils, there is evidence that the experimental values are overestimated due to adsorption of nonylphenol to the test vessel. As a result the EU risk assessment (ECB 2002) recommends using the estimated value (EUSES), although it is possible that the actual adsorption onto soil and sediment may be higher than the estimated value, possibly due to factors other than organic carbon content being important in the process.

In the CSR (Lead registrant 2010) a K_{oc} of 14390 l/kg was used, which was calculated using the log K_{ow} of 5.4 (according to the Technical Guidance Document, Part III, Chapter 4, p. 26, equation for phenols, benzonitriles).

Since both log Kow-values will be used (see text in section B.1.3.7 above), both Koc-values, i.e. 5360 l/kg and 14390 l/kg, will be used in EUSES.

B.4.2.2 Volatilisation

The volatilisation of nonylphenol from surface water to air may be estimated by the Henry's Law constant. This is calculated as 11.02 $Pa.m^3/mol$ for nonylphenol.[23]

B.4.2.4 Summary and discussion of environmental distribution

Nonylphenol (NP) has a low water solubility (6 mg/L at 20 °C) and available data (including Henry's Law Constant: 11.02 Pa m^3/mol) indicates that volatilization of nonylphenol is unlikely to be a significant removal process for nonylphenol from water systems.

Nonylphenol tends to adsorb strongly onto organic matter. Adsorption is likely to play an important role as a sequestration process in soil, sediment, and sewage sludge. Adsorption to solids such as sediments and sewage sludge is likely an important removal process for nonylphenol.

B 4.3 Bioaccumulation

In the EU risk assessment (ECB 2002) the BCF of 1280, calculated from the log Kow of 4.48 using the TGD equation, was considered to agree well with the measured values of up to 1200-1300 in fish (Ekelund *et al*. 1990) and was therefore used in the risk assessment. However the BCF estimated by Ekelund *et al.* (1990) was based on total ^{14}C measurements, and it was stated that the presence of metabolites therefore may have led to an overestimation of the BCF. In the CSR (Lead registrant, 2010), the measured BCF value of 741 (rounded to 740) for *Pimephales promelas* (Brooke 1993b) was considered more reliable than the calculated approach to BCF derivation and therefore used instead. In this assessment the value used in the EU risk assessment (ECB 2002), i.e. 1280, will be used for both the log K_{OW}-values used in EUSES.

It can from the available data (both the EU risk assessment (ECB 2002) and the CSR (Lead registrant 2010)) be concluded that nonylphenol bioconcentrates in aquatic biota, with experimental BCF in fish exceeding the C&L limit of 500 but being lower than the B criterion of 2000 in a PBT assessment. Substances that bioaccumulate or bioconcentrate may also have the potential to biomagnify. This is however not expected to occur for nonylphenol (ECB 2002).

As no experimental data for the bioaccumulation in terrestrial species is available, the BCF for earthworms is calculated using measured Log K_{OW}.

Depending on which log K_{OW}-value that is used the BCF for earthworm, calculated using the ECHA Equation R.16-76 ($BCF_{earthworm}$= (0.84+0.012xK_{ow}) /$RHO_{earthworm}$; with $RHO_{earthworm}$= 1 (kg wwt/L) by default), becomes 363 when using a log K_{ow} of 4.48, or 3015 when using a log K_{ow} of 5.4. This indicates that nonylphenol has the potential to accumulate in terrestrial organisms,

[23] This value is used in both the EU risk assessment (ECB 2002) and the CSR (Lead registrant, 2010)

although similar BCF cut-off criteria as to fish are not presented in ECHA Guidance.

B.4.4 Secondary poisoning

In the EU risk assessment (ECB 2002) the $PNEC_{oral}$ used is 10 mg/kg food (originating from a NOAEL of 15 mg/kg/day from NTP (1997)) and in the CSR (Lead registrant, 2010) it is 2.36 mg/kg food (based on read across from octylphenol).

The following text is taken from the EU risk assessment (ECB 2002):
"No toxicity data are available on avian species; thus a PNEC is derived from laboratory mammal data. From Section 4, a NOAEL of 15 mg/kg body weight was found for reproductive effects. Using the conversion factor of 20 from Appendix VII of the TGD and a further factor of 3 to allow for the fact that calorific content of a laboratory diet is higher than the diet of fish-eating mammals and birds, this NOAEL is equivalent to a daily dose of 100 mg/kg food. The TGD recommends the use of an assessment factor of 10 on reproductive studies. Therefore the $PNEC_{oral}$ is 10 mg/kg food."

The $PNEC_{oral}$ based on nonylphenol, i.e. $PNEC_{oral}$ = 10 mg NP/kg food, will be used in this assessment.

B.5 Human health hazard assessment

B.5.1 Toxicokinetics: absorption, metabolism, distribution and elimination

B.5.1.1 Animal Data

In a pilot pharmacokinetic study preformed in both male and female Sprague-Dawley (SD) rats (Fennel 2001), the application of branched nonylphenol (NP) given as a single i.v. and gavage was compared. The elimination half lives in plasma of labeled NP after i.v. administration was 9.6 h (males) and 9.3 h (females); after oral administration it was 12.4 h (males) and 8.5 h (females). The C_{max}in blood was tenfold lower by gavage administration than i.v. in female rats and 22 fold lower in male rats. Four radioactive moieties were detected in blood after i.v. application: protein-bound NP, NP glucuronide, NP itself and an unidentified glucuronidated metabolite. The protein-bound radioactivity decreased over time and was detected at all the time points during the 24 h experiment, whereas the free nonylphenol was below the limit of detection within 4 h of dosing (i.v.) in female rats. The plasma protein-bound fraction was not detected after oral administration.

The liver, lung, testis, epididymis, subcutaneous fat, abdominal fat and spleen were collected from male rats at 2, 8, and 24 h following i.v. dosing. The liver contained 11.3% of the dose 2 h after application; the subcutaneous fat and the abdominal fat contained 0.31 and 0.2% of the dose per gram of tissue, respectively. The amount of nonylphenol in the total body fat (~ 9%) indicates that fat is a significant reservoir for NP when administered intravenous. When administration occurs by gavage, the NP levels in the liver were 1.8% of the dose 2 h after dosing and 2.2% after 8 h,

declining to 0.8% by 24 h. The fat tissue contained approximately 0.01% of the dose per g tissue at all time points, indicating that fat is a non-significant reservoir for NP when administered orally, in contrast to i.v. administration. For the gavage administration to male rats, less than 0.02% of the dose was recovered in lung, spleen, testis and epididymis after 24 h. The bioavailability calculated from nonylphenol-derived radioactivity in blood was 0.25 and 0.29 for female and male rats, respectively.

A study by Fennel (2001) focused on the distribution and the metabolic profile of NP in SD rats after single gavage of 0, 5 and 200 mg/kg bw. The majority of the administered dose was excreted within seven days in feces (81-85%) and to lesser extend in urine (12-17%). The total dose recovered in excreta amounted to approximately 90-97%, except for the high dose group (200 mg/kg bw/day), in which approximately 75% of the dose was recovered. A small amount of radioactivity was exhaled as CO_2in male rats in the low dose group (amounting to 0.14% of the applied dose), suggesting a breakdown of NP into volatile metabolites. The rate of excretion of radioactivity in the urine was faster in female rats compared with males. In addition qualitative differences were observed in urinary metabolites between male and female rats. No radioactivity was detectable in the reproductive organs (testes, ovaries, epididymis, and uterus) examined at day 7 after administration. The majority of the radioactivity recovered after 7 days was in the liver (0.14%), the intestinal tissue (small: 0.08%; large: 0.1%) and the contents of the small (0.5%) and large (0.8%) intestines. There was no accumulation in abdominal and subcutaneous fat tissue in accordance with the findings of the pharmacokinetic study (Fennel 2001).

Green (2003) published a toxicokinetic study in SD rats. P-NP was administered by i.v. (10 mg/kg bw) and by oral administration (10 and 100 mg/kg bw) for up to 14 days. 75% of the radioactivity applied by i.v. was being eliminated within 24 h, mainly in the feces. After 7 days, 13% of the dose applied by i.v. was found in the carcass. The concentration of radioactivity in fat increased 4-5 folds over the duration of the study. The absolute amounts in fat, however, were less than 0.06% of the amount found in excreta on day 14 of the study.

Up to 64% of the dose was eliminated in bile following 10 mg/kg oral dose and up to 49% at the higher dose. Similar amounts were excreted in bile after i.v. application. From the proportion of the dose eliminated in bile and urine, an absorption rate of 65% and 80% can be concluded at 10 mg/kg, respectively. The absorption rate was calculated to be ~50% at the 100 mg/kg dose. Following absorption, NP was metabolized in the liver, with the majority of the metabolites excreted in bile, mainly as glucuronide conjugates.

Sex related differences were seen in the blood and plasma, with a maximum concentration in males being 2-3 folds higher than that in females. The ability to clear NP and its metabolites from blood was also different. In males, the half live in plasma was not affected by the increase in dose from 10 to 100 mg/kg (7 vs. 9 h), whereas in females the half-life increased approximately fourfold with the increase in dose (3 vs. 13 h). The capacity of the female rat to metabolize and excrete NP is lower than that of males at high doses. The sex-related differences were also seen in the metabolic profiles in urine, bile and feces. The NP-glucoronide (NPG) represents the only significant metabolite in the bile at the 10 mg/kg dose; following 100 mg/kg significant amounts of NP itself were present in female but not in male bile. Similar, NP was a major component in female urine following a 100 mg/kg, but not a 10 mg/kg dose. Both of these findings suggest that the capacity of the liver to form

glucoronide is saturated at the higher dose in females. NP was more extensively metabolized in male rats, with a number of metabolites present in urine, bile and fecal extracts that were not seen in female rats. NPG, the major metabolite in female rats was not present in male urine, although it was present in bile.

Following repeated dosing, a steady state was reached within 7 days. There was no evidence of significant accumulation into tissue compartments or of a significant change in clearance or metabolite profiles in urine. Enterohepatic circulation of metabolites does not appear to be a major feature in the NP metabolism. Recirculation would be reflected in the blood concentration of radioactivity. An early peak concentration around 6 h after oral dosing may be indicative of a limited amount of enterohepatic circulation, but there is no evidence to suggest that recirculation is sustained for any length of time. Extraction of fecal samples revealed that feces contained mainly NP itself. With regard to the fast absorption this is an unexpected finding suggesting, that excreted NP is deconjugated by biliary and enterobacterial enzymes and being transported through the GI tract bound to diet.

The toxicokinetic effect of linear 4-n-nonylphenol was investigated in a 4 day *in vivo* metabolic balance study in Wistar rats conducted by Zalko (2003). The metabolic profile after oral administration of 10 mg/kg bw/day and 1 µg/kg bw/day was characterized in urine, feces and bile. In addition, metabolism and distribution was tested in pregnant rats up to day 20 of gestation.

4-n-nonylphenol is extensively metabolized and predominantly eliminated in urine (57% in males and 40% in females within 96 h). Ten major metabolites were characterized. Most of them were formed by ω- or β-oxidation of the 9-carbon side chain and conjugation of phenol moieties to sulfate or glucuronic acid. No 5-carbon and 7-carbon side chain metabolites were detected. The main part of urinary radioactivity was associated with 1-3-carbon side chain metabolites, most or which were identified as conjugates.

The bile and feces contain several 4-n-NP metabolites resulting from β-oxidation but the metabolites were only detected in very low amounts. The major metabolite in these samples is hydroxylated NP. Biliary hydroxyl-4-n-NP was excreted as glucuronide which is very likely deconjugated by the intestinal flora into the corresponding aglycone. Sulfo-conjugaties was notably higher in males than in females. The major metabolites are para-hydroxy benzoic acid and the corresponding sulphate. Although female rats excreted more radio activity in feces, biliary excretion was significantly more important in males. Thus, the intestinal re-absorption of 4-n-NP residues and their possible entero-hepatic cycling show gender-related differences. Neither the distribution pattern nor the residual levels of 4-n-nonylphenol were found to be different between the dose groups. Most tissue extractions led to the conclusion that the radioactivity present in tissues was mainly associated with volatile compounds, supporting the hypothesis of a complete breakdown of 4-n-NP.

Experiments carried out in pregnant rats exposed to 1 µg/kg bw/day from day 3 to day 19 of gestation demonstrated similar metabolic pathways. Very limited amounts, if any, of unmetabolized 4-n-nonylphenol did reach the fetuses, suggesting that non-significant amounts of NP cross the placenta barrier. These conclusions are valid only for linear NP. Branched side chains will not undergo a complete breakdown of the alkyl chain.

In addition to the metabolic balance study, metabolism and excretion were determined using an *in vivo* perfused rat liver model (Daidoji 2003). 4-n-nonylphenol and additional short-chain alkylphenols were injected into the portal vein of the liver of Sprague-Dawley rats at concentrations of 0.025 or 0.05 mM. Liver perfusion was carried out in a flow-through mode. Subsequent excretion into bile and vein was monitored. About 800 to 1000 nmol of injected nonylphenol could be conjugated as glucuronide within 1 h. Most of the glucuronide and free nonylphenol remained in the liver. In addition to the perfused liver model absorption, distribution and elimination were investigated in everted intestinal tissue of SD rats (Daidoji 2006). NP is readily absorbed and glucuronidized within intestinal tissue of SD rats. This was confirmed by a simulation of organ specific metabolism using microsomes prepared from intestinal tissue. The intestine microsomes showed strong glucuronidation activity. Nonylphenol was glucuronidated within the intestinal wall but NP and NPG was not excreted from intestinal tissue within 10 h. Orally administered nonylphenol remained for long periods in the gastrointestinal tissue as neither the parent compound nor glucuronide was excreted into the mucosal or serosal side. As though the present study confirmed that intestinal tissue possesses a strong alkylphenol elimination system using UDP glucuronosyltransferase, this system is impaired by the marginal transport of alkylphenol-glucuronide possessing long alkyl chain, such as nonylphenol.

B.5.1.2 Human data

The toxicokinetic behavior of 4-n-nonylphenol was investigated in two human volunteers (i. v.: 14 µg/kg body weight; oral: 66 µg/kg body weight) by Müller et al. (1998). After intravenous and oral application, the elimination half-life of the parent compound from the blood was 2–3 h. The bioavailability after oral application (determined by oral and intravenous AUCs) was about 20%. After a single oral application the blood concentration did not exceed 650 pg/g blood. A distribution volume of 2800 L was calculated, suggesting migration primarily into deeper lipoid compartments after the initial 2-3 h distribution phase. The elimination half-life in blood was found to be 2-3 h. The bioavailability was calculated to be 20% based on the AUC ratio between i.v. and oral application. Less than 1% of the orally applied dose was excreted in the feces as NP or from conjugate cleavage, indicating that the substance was quantitatively absorbed in the gastrointestinal tract. The low bioavailability was therefore probably due to extensive metabolism in the gut wall and during the first passage of the liver. This pharmacokinetics study in human volunteers is restricted by the low number of participants.

Furthermore, levels of NP in non-occupationally exposed persons were investigated by analyzing human autopsy adipose tissue samples from people aged 3 to 100. NP concentrations ranged from 19 to 85 ng/g lipids. These values were both in the range of the analytical background contamination and do not indicate a concern of bioaccumulation by non-occupational exposure.

There was a study on nonylphenol in blood from nursing mothers in Uppsala, Sweden (Glynn et al. 2010). The study showed that the dominated form of NP found in the blood of these women was free NP. Despite the knowledge that NP should rapidly be absorbed and glucuronidized within intestinal tissue, this was not the form of NP found in the blood. This study showed that a relatively high number of young women had low but detectable levels of NP in their bloodstream.

B.5.1.3 Summary and discussion of toxicokinetics

Absorption from the gastrointestinal tract is initially rapid. Nonylphenol is widely distributed throughout the body, with the highest concentration in the fat. The major routes of excretion are via the feces and urine. There are sex related differences in the amount of NP in the blood and plasma and for the ability to clear NP and its metabolites from the blood. The sex related differences were also seen in the metabolic profiles in urine, bile and feces. NP was metabolized in the liver, with the majority of the metabolites excreted in bile, mainly as glucuronide conjugates. However, extraction of fecal samples revealed that feces contained mainly NP itself. There are no data on the toxicokinetics of nonylphenol following inhalation exposure. On the basis of the oral absorption data and high partition coefficient, it would be prudent to assume that significant absorption through inhalation can occur.

B.5.2 Acute Toxicity (animal data)

There is no available human data for acute toxicity.

B.5.2.1 Acute Toxicity: Oral

An acute oral toxicity study was conducted in SD rat using Nonylphenol in liquid paraffin. LD50 vales were reported for males = 1246 mg/kg bw; females = 1648 mg/kg bw and combined = 1412 mg/kg bw (Taupin P J Y 1981). This study was supported by an OECD 401 study conducted in Wister rats with a LD50 of 1900 mg/kg bw. Clinical signs of toxicity included excessive salivation, diarrhea and lethargy.

B.5.2.2 Acute toxicity: Inhalation

Not relevant. Nonylphenol is classified as corrosive.

B.5.2.3 Acute toxicity: Dermal

Not relevant. Nonylphenol is classified as corrosive.

B.5.2.4 Acute toxicity: Other routes

No data related to acute toxicity of Nonylphenol via other routes were found.

B.5.2.5 Summary and discussion of acute toxicity

No human data is available. In animals, nonylphenol is moderately toxic by oral route with reported LD50 values ranging from 1246 mg/kg bw to 1900 mg/kg bw. Nonylphenol is of acute oral toxicity category 4 based on a LD50 (rat) according to Regulation (EC) No 1272/2008, Table 3.1.1, Oral (mg/kg bw): 300<ATE≤2000. Erosion of the stomach mucosa is sometimes seen following the administration of a lethal dose. Nonylphenol has been classified as acute toxic class 4 for oral.

B.5.3 Irritation

B.5.3.1. Skin irritation (animal data)

There is no available human data for skin irritation.

In a primal dermal irritation study (Hüls 0584), three small white Russian rabbits were dermally exposed to 0.5ccm undiluted isononylphenol for 4 hours to 6 sq. cm skin. After 60min of exposure, necrosis was induced. Union Carbide (1992a, b) tested substances named "nonylphenol S" and "nonylphenol RNH" using a method equivalent to OECD test guideline 404. They found severe irritation including full-thickness necrosis and ulceration within 24 h of either 1 or 4 hours application. In a GLP-compliant study sponsored by EniChem (1992), all rabbits showed skin reactions described as erythema grade 2 and edema grade 3 at 24, 48 and 72 hours, progressing to eschar formation grade 4 on day 8. However, Berol Kemi AB (1987) reported less severe skin reactions, graded 2 for erythema and 1-3 for edema at 24, 48 and 72 hours, but with reversible skin reactions within 13 days.
The results of these animal studies suggest that the irritant properties of nonylphenol may vary, depending on the source of the test sample. However, since full thickness destruction or skin necrosis were present in some studies it is reasonable to consider nonylphenol as corrosive on contact with skin.

B.5.3.2 Eye irritation (animal data)

There is no available human data for eye irritation.

There are two well reported studies using methods equivalent to OECD guideline 405 available. In Hüls (1986b) study, ocular lesions indicative of severe irritation were found. Maximum scores for conjunctivael redness were reported for most of the 21-day observational period. Two of the three rabbits tested had grade 3 or 4 corneal opacities at the end of the observational period. The results indicate that nonylphenol is a severe eye irritant. In the other study, nonylphenol from two different sources were tested in groups of three rabbits (ICI 1979). Exposure to nonylphenol caused grade 2 and grade 3 conjuctival redness; conjunctival chemosis grades 1-4, corneal opacity grades 1 or 2, and in two rabbits grade 1 lesions of the iris. At the end of the 7-day observation period eye lesions were still present in two rabbits.

B.5.3.3 Respiratory tract irritation (animal data)

There is no available human data for respiratory tract irritation.

A study from ICI (1995) tested the sensory irritation of nonylphenol by using atmospheres of saturated vapor and one tenth saturated vapor concentration, 3636 mg/m^3 (400 ppm) and 267 mg/m^3 (30 ppm). Groups of five female CD-1 mice were exposed only through the nose to both concentrations. The respiration rates for the mice were monitored by pressure plethysmography. Exposure to 3636 mg/m^3 suppressed the respiratory rate by 25%. However there were no changes to

the respiratory rate at 267 mg/m^3. These results suggest that nonylphenol can cause mild sensory irritation to the respiratory tract at high exposure levels.

B.5.3.4 Summary of irritation

There are no available human data on irritation. The animal data indicate that nonylphenol is corrosive to the skin and can lead to full thickness destruction or skin necrosis. According to Regulation (EC) no 1272/2008 skin corrosive substances shall be considered as leading to serious damage to the eyes as well. This is supported by the studies on eye irritation. Nonylphenol also seems to cause mild sensory irritation to the respiration tract at high exposure levels.

B.5.4 Corrosivity

Not relevant. Nonylphenol is classified as Category 1B.

B.5.5 Sensitization

B.5.5.1 Skin sensitization (animal data)

There is no available human data for skin sensitization.

The skin sensitization potential of nonylphenol has been investigated in several studies. A study (Hüls 1986b) using a method similar to the OECD guideline 404 was preformed on guinea pigs. Concentrations of 0.9 and 50% were used for the intradermal and topical induction phases, respectively. A 10, 30 and 45% concentration was used for challenge. The 50% topical application was slightly irritating. No animals showed skin sensitization reactions.

B.5.5.2 Respiratory system sensitization

There is no available human data for respiratory system sensitization.
There is no available animal data for respiratory system sensitization.

B.5.5.3 Summary of sensitization

There is no human data available. The results from guinea pig maximization tests suggest that nonylphenol does not have significant skin sensitization potential. No information on respiratory tract sensitization is available. However, it can be predicted that from nonylphenol's low chemical reactivity that nonylphenol is unlikely to be a respiratory allergen.

B.5.6 Repeated dose toxicity

B.5.6.1 Repeated dose toxicity: oral route

No available human data

There are two studies that follow OECD guidelines and were in compliance with GLP. Both studies used rats for the duration of 28 and 90 days. In the study (Hüls 1989) with the 28-day duration, the SD rats were divided into groups of five female and five males per dose; 0, 25 100 or 400 mg/kg bw/day. Clinical signs of toxicity, bodyweight and food consumption were recorded for the duration of the study. Towards the end of the study routine hematology, blood clinical chemistry and urinalysis were preformed in addition to changes in relative organ weights of kidney, liver, adrenals and testes. At 400 mg/kg bw/day there was a decrease in bodyweight gain by 26% for males and 13% less for females compared to control rats. For male rats at 400 mg/kg bw/day there were slight differences in comparisons with control rats for certain clinical chemistry parameters; urea and cholesterol levels were increased and glucose levels were reduced. There was also an increase in the group mean relative kidney, liver and testes weights (about 20% compared with control rats). The histopathological examination showed hyaline droplet accumulation in the renal proximal tubules and minor vacuolation in the periportal hepatocytes. There was no treatment related changes in the organs for female rats treated at 400 mg/kg bw. For males and females at 25 and 100 mg/kg bw/day, there were no effects that could be conclusively related to treatment.

In a 90 day feeding study in SD rats Nonylphenol (95.6%) was administered to 15 SD rats/sex/dose at dose levels of 0, 15, 50, 150 mg/kg/d (Cunny 1997). A NOAEL of 50 mg/kg/d was concluded. No treatment-related effects on endocrine organs, estrous cycling, or sperm measurements were seen at any dose. The LOAEL is 150 mg/kg/d based on a small decrease in body weight gain, food consumption, food utilization, together with evidence of morphological changes in the liver and possibly kidneys. Morphological changes in the liver were found in females in the high dose group. Three animals showed slight or moderate individual hepatic cell necrosis. Two of the affected females also had raised serum aspartate aminotransferase (ALT) and alanine aminotransferase (AST). This provides evidence that the liver may be a target organ for nonylphenol toxicity, although this evidence is weak in view of the mild nature of response and small number of animals affected.

A dose-related increase of kidney weight and a decrease in renal hyaline globules/droplets were observed in males. This effect on kidney weight showed complete recovery following the 4-week post dosing recovery period. Due to the small magnitude of the changes (i. e., all weights were within or near laboratory historical control values) and the lack of correlating clinical or histopathological changes, the kidney weight alterations were not considered toxicologically significant. The biological significance of reduced hyaline in the kidneys is uncertain. Renal tubular hyaline is associated with the rat-specific protein, α-2μ-globulin, and, therefore, this finding was not considered toxicologically relevant to humans. Also, a lack of correlation with the findings of the 28- day repeated dose study (Hüls (1989)), in which an actual increase in the incidence of renal hyaline droplets occurred, casts doubt on whether these changes should be considered to be related to treatment. The renal histopathological findings were reviewed by a pathologist (Hard 1998). The predominant renal lesions were described as tubular mineralization at the OSOM/ISOM junction, cystic tubules surrounded by fibrosis, or granular cast formation at the OSOM/ISOM junction. Eleven out of 25 animals from the high dose group were affected, compared with 1 out of 25 control males. Hence, there is evidence of morphological changes in the kidneys.

There are two repeated dose toxicity studies administering Nonylphenol by gavage. In a 28 day study in SD rats Nonylphenol was administered to 10 animals/sex/dose at dose levels of 0, 10, 50, 250 mg/kg/d (Woo 2007). A NOAEL of 10 mg/kg/d was concluded. The LOAEL of 50 mg/kg/d based on some small but significant alteration of glucose and inorganic phosphates levels in females; increase of thyroid weight in males and increase of serum LH in female. At 250 mg/kg/d mortality and clinical signs occur. Three females died or became moribund during the experiment. Hepatic and renal toxicity was evident in both sexes with increase of relative liver and kidney weights as well as histopathological changes, such as centrilobular liver cell hypertrophy and a variety of renal tubular lesions, and alteration of serum biochemical parameters.
Another gavage study was conducted by de Jager (1999) to investigate testicular toxicity in rats. In this study, mortality was observed at 100 (the lowest dose level tested), 250 and 400 mg/kg/d; 3, 15 and 18 out of 20 animals in each group died during a 10-week dosing period. No further information on these mortalities is available. The presence of mortality at such dose levels contrasts with the findings of the dietary administration studies (Hazleton 1989 (28 days); Cunny 1997 (90 days); Chapin, 1999 (multi-generation)). The differences can probably be accounted for by the method of administration; gavage dosing is likely to produce higher peak concentrations of nonylphenol in the blood than dietary administration. This can be explained by toxicokinetic data. Higher peak concentration saturates the metabolic capacity of the liver and GI tract first pass effect resulting in a decreased detoxification and consequently a higher internal dose.

Additional information on repeated dose toxicity can be derived from multi-generation studies. In a 3.5 generation feeding study 0, 200, 650, and 2000 ppm (~0, 15, 50, 160 mg/kg/d) Nonylphenol was administered to 30 SD rats/sex/dose (Chapin 1999; NTP 1997). At 160 mg/kg/d, bodyweight gain was reduced in comparison with controls in adults across all generations. Similar reductions in body weight gain were seen at 50 mg/kg/d in F1 females, F2 males and F3 females. Relative kidney weights were increased at 50 and/or 160 mg/kg/d in adult males of the F0, F1 and F2 generations and also at 160 mg/kg/d in F1 adult females. Histopathological examination revealed an increase in the incidence of renal tubular degeneration and/or dilatation in adult males from all generations and all nonylphenol treated groups; similar findings were reported for adult females at 160 mg/kg/d in the F1, F2 and F3 generations and at 15 and 50 mg/kg/d in the F3 generation. The increased incidence of renal tubular degeneration and/or dilatation was not seen to the same extent in the 90-day study (Cunny, 1997), which was conducted using the same strain of rats. In addition a dose-dependent trend was not apparent in all generations/sexes. The lack of concordance between the studies cannot be explained on the basis of a slightly longer exposure period in the multi-generation study because kidney effects were seen in the F3 generation which was exposed for only 8 weeks, nor on the basis of in utero and neonatal exposure because the effect also occurred in the F0 generation. Giving special emphasis to the fact that the increased incidence occurred consistently across all four generations in the multi-generation study, it is considered that this cannot be dismissed as background variation. The EU risk assessment 2002 concluded a LOAEL for repeated exposure of 15 mg/kg/d, based on histopathological changes in the kidneys.
Nagao (2001) administered Nonylphenol at doses of 0, 10, 50, 250 mg/kg/d by gavage to 25 SD rats/sex/dose. Significant increases in the liver and kidney weights in males, and decreases in thymus weight in males and ovary weight in females were observed in the 50 mg/kg/d group. Histopathologic changes were found in the liver of male and female rats and kidneys of males in the

50 mg/kg group. Hence, a NOAEL of 10 mg/kg/d and a LOAEL of 50 mg/kg/d can be concluded under conditions of this study.

Tyl et al. (2006) conducted a three-generation study administering Nonylphenol to 25 SD rats/sex/dose in two different diets at dose levels of 0, 20, 200, 650, 2000ppm (approx. 0, 1.5, 15, 50, 150 mg/kg/d). The study investigates the reproductive toxicity of NP and compared ambiguous findings of two older studies with regards to specific target organ toxicity (Chapin 1999 and Cunny 1997). The multi-generation study conducted by Chapin et al. (1999) observed kidney toxicity in F0, F1, and F2 males at 200, 650, and 2000 ppm. This contrasts the results of a 90 day study (Cunny, 1997) with the same NP concentrations and route in rats finding kidney toxicity in males only at the highest dietary concentration of 2000 ppm (~150 mg/kg/d) in F0 (2/10), F1 (4/10), and F2 (8/10). In both cases kidney lesions were medullary cysts and mineralization at the corticomedullary junction. Since Chapin et al. observed the kidney effects at the lower doses in the F0 animals (as well as the F1 and F2 males), the only clear difference (other than breeding) between the male treatments in both studies was the diet used. Cunny (1997) used Purina 5002 diet, while Chapin (1999) used NIH-07. In the Tyl (2006) study both diets were compared. Although increased absolute and relative kidney weights were observed in F1 males at 200 ppm NP (Purina 5002), they were not associated with increased incidence of the two microscopic findings (medullary cysts and mineralization at the cortico-medullary junction) and there were no renal effects (organ weights or histopathology) in F0 or F2 males at the lowest concentration (200 ppm) NP. Based on the absence of histopathological findings at this concentration a NOAEL of 200 ppm (15 mg/kg/d) was derived. At higher concentrations this study verified renal toxicity in F0, F1, and F2 adult male (650 and 2000 ppm) resulting in a LOAEL of 650 ppm (approx. 50 mg/kg/d in males).

B.5.6.2 Repeated dose toxicity: dermal route

No available information.

B.5.6.3 Repeated dose toxicity: respiratory route

No available information.

B.5.6.4 Repeated dose toxicity: Other routes

No available information.

B.5.6.5 Summary and discussion of oral repeated dose toxicity

There are differences between the different administration routes; feeding and gavage, in relation to oral repeated dose toxicity. The feeding studies showed that the kidney is a target organ for NP toxicity for males, and the liver for females. The gavage studies showed hepatic and renal toxicity in both sexes at a lower dose than seen in the feeding studies. The mortality rate was much higher at a lower dose for gavage administration of NP.

B.5.7 Mutagenicity

There is no available human data for mutagenicity.

B.5.7.1 Mutagenicity: In vitro data

Three negative Ames tests are available. None were repeated, as required by OECD guidelines in case of a negative result. However, the three studies taken together are considered sufficient to address in vitro gene mutation in bacteria.

B.5.7.2 Mutagenicity: In vivo data

One negative Chromosome Aberration assay was reported by Tayama (2008), together with two additional indicator studies for mutagenicity. A COMET assay generated positive results (weak but statistically significant increase in chromosome breakage at 0.125 and 0.15 mM NP). There is currently no (OECD) guideline for COMET assays and the documentation is insufficient (Klimisch 3). The method was 'mostly in accordance with the protocol for the COMET assay kit'. A significant decrease in viable cells at 0.15 mM NP was recorded; however this cytotoxic effect is not relevant for the mutagenicity endpoint. A positive result was also reported for a Sister Chromatide Exchange (SCE) assay; SCE may be an indicator for repaired DNA damage. The CA test carried out by Tayama is considered a reliable study indicating the absence of cytogenicity in mammalian cells in vitro. Both additional indicator tests reported in the same publication gave positive results. However, in each case there are concerns regarding the reliability of the test method and/or the relevance of the result. The Chromosome Aberration test is considered sufficient to address this endpoint, and over-rules the results of both other indicator studies. This is in accordance with the endpoint specific guidance R.7a (ECHA).

Creutzinger (1990) reported a negative in vitro mammalian cell gene mutation test according to OECD 476.

Three in vivo micronucleus studies are available. Hüls (1999) was conducted according to OECD guideline 474. NMRI mice/sex received a single intraperitoneal dose of 50, 150 or 300 mg/kg bw. The highest dose level was chosen as the maximum tolerated dose, based on the results of a preliminary study. Toxicity was elicited at 150 and 300 mg/kg, seen as clinical signs (sedation, squatting posture, abnormal gait and piloerection). There was no consistent effect on the PCE/NCE ratio. No increases in the frequency of micronucleated PCEs were seen. Thus, the test is considered to be negative. Although the PCE/NCE ratio was not affected, the fact that the study was conducted at the maximum tolerated dose and using the intraperitoneal route of administration, it can be presumed that exposure of the bone marrow was maximized. Accordingly, a high level of confidence can be given to this negative result. In contrast, an earlier micronucleus test (Hüls 1988, limit test) was conducted using the oral route of administration. No increases in the frequency of micronuclei were observed within 72 h. The test was considered to be negative. However, the PCE/NCE ratio was not affected by nonylphenol, which raises concerns about adequacy of exposure of the bone marrow to the test substance. Toxicokinetic data suggests that the bioavailability of Nonylphenol after oral exposure is restricted due to an extensive first pass effect.

Thus, the oral route is considered not appropriate for the assessment of Nonylphenol by means of in vivo micronucleus studies.

In a recent publication by Dobrzynska (2008) the induction of micronuclei in somatic cells of mice exposed to x-rays or nonylphenol and to a combination of both agents was assessed. The author concluded an increase in chromosome aberration in mice caused by i. p. administration of 4-Nonylphenol at doses of 25 and 50 mg/kg bw/day for 8 weeks (5 d/w). After translating the Polish study and checking raw data provided by the author, this conclusion could not be affirmed. The description of the methods is poor (e. g. number of animals not indicated) and the results are not significant. In peripheral blood (reticulocytes) no significant difference to control group in the 25 mg/kg/d group and no significant difference in the 50 mg/kg/d group expect in week 1+3+4 (from 8) was observed. No significant difference to control group were observed in reticulocytes at the terminal assessment of bone marrow. If only polychromatic erythrocytes were considered, a significant difference to control group was evident. According OECD 474 this is the more relevant parameter compared to reticulocytes. However, dependency on dosage could not be established (50 mg/kg < 25 mg/kg). The result of this publication does not challenge the negative results reported in both Hüls studies (1999/1988).

B.5.8 Carcinogenicity

B.5.8.1 Carcinogenicity: oral

No available information.

B.5.8.2 Carcinogenicity: inhalation

No available information.

B.5.8.3 Carcinogenicity: dermal

No available information.

B.5.8.4 Carcinogenicity: other routes

No available information.

B.5.8.5 Summary and discussion of carcinogenicity

No available information.

B.5.9 Toxicity for reproduction

B.5.9.1 Toxicity for reproduction: effects on fertility

In an extended 2-generation study (Chapin 1999) 30 SD rats/sex/dose were exposed to NP at dietary concentrations of 0, 200, 650 or 2000 ppm. General toxicity was evident in adults of all generations, seen as a reduction in bodyweight gain at 650 and 2000 ppm and histopathological changes in the kidneys at all dose levels. Considering the reproduction-related parameters, there were no adverse effects on fertility or mating performance. However, there were slight changes, in the estrous cycle length at 2000 ppm (F1/F2), timing of vaginal opening at 650 and 2000 ppm (F1, F2, F3) and ovarian weight at 650 (F2) and 2000 ppm (F1, F2, F3). Changes in sperm endpoints were seen only in the F2 males; epididymal sperm density was decreased at 650 and 2000 ppm and spermatid count at 2000 ppm. The sperm density in all F2 groups, including controls, was considerably greater (by about 25-40%) than reported for F0 and F1 males. Observation of impaired male reproductive tract development in a gavage study (de Jager 1999) suggests additional evidence of the sperm/spermatid count changes related to NP treatment. In this study a detailed evaluation of the male reproductive organs was conducted. Clinical signs of toxicity were not reported. But mortality was observed in 3, 17 and 18 animals from the 100, 250 and 400 mg/kg/day groups. Tubule and lumen diameter and seminiferous epithelial diameter were lower in all dose groups. In addition testicular and epididymal weights were lower at 250 and 400 mg/kg/day and the sperm count was reduced at 400 mg/kg/day. A LOAEL for testicular toxicity of 100 mg/kg/day can be designated (exposure levels which also cause mortality). The observation of mortality at 100, 250 and 400 mg/kg/day in this gavage study contrasts with the findings of studies involving dietary administration summarized in the Repeated Dose Toxicity section (Hüls 1989; Cunny 1997; Chapin 1999). This can be explained by the toxicokinetic of NP. Higher peak concentration can saturate the metabolic capacity of the liver and GI tract (first pass effect) resulting in a decreased detoxification and consequently a higher internal dose. Supporting evidence for testicular toxicity of NP was also provided by El-Dakdoky (2007). The purpose of this study was to investigate the effects of NP on sperm characteristics, fertility index, histopathological and biochemical changes related to oxidative stress in testes. The conclusion was that the exposure of 10 adult male mice to high dose of NP (1/4 LD50) for 35 days had effects on some reproductive organs weight and sperm characteristics (count and motility), testicular MDA, GSH, and SOD but did not influence the mating behavior, male fertility and the developed fetuses.

In a 2 -generation study (Nagao, 2001) NP was administered to 25 SD rats/sex/dose at 0, 2, 10, and 50 mg/kg/d by gavage. No adverse changes in clinical signs were observed throughout the study. Significant increases in the liver, kidney and pituitary gland weights in males, and decreases in thymus weight in males and ovary weight in females were observed in the 50 mg/kg group. At necropsy, no treatment-related alterations were observed in any organs including the reproductive tissues in any group. Histopathologic changes were observed in the liver of males and females and kidney of males in F0/F1 animals at 50 mg/kg/d. F1- and F2-offspring of this dose group showed a reduced viability on PND 0 to 4; the body weight gain of these animals remained unaffected. No effects on preputial separation were observed in males while vaginal opening was accelerated in the female high dose group. No adverse changes in behavior or learning of the offspring were observed. There were no treatment related changes seen in any reproductive parameter including estrous

cycle, mating, fertility, delivery, and lactation except for significant decreases in the numbers of implantation sites in F1 females and in the numbers of F2 pups born alive and a significant decrease in absolute and relative ovary weight in adult F1 females at the high dose group. No treatment related changes were observed in the sperm characteristics. The present data show that exposure to NP for two generations provided indications of estrogen activity in females of the first (F1) generation (acceleration of vaginal opening) and altered kidney and liver structure in rats of the parental (F0) and F1 generations, and an absence of reproductive changes in rats of the F0 and F1 generations. These results confirmed those reported in the Chapin's study (1999). A NOAEL for reproductive effects of 50 mg/kg/day or greater in parent animals, and 10 mg/kg/day in the next generation can be concluded. The NOAEL for general toxicity is 10 mg/kg/d based on organ weight changes and Histopathologic findings in the liver and kidney.

The most recent multi-generation (3.5 generations) study was conducted by Tyl (2006). NP was administered to 25 SD rats/sex/dose in two different diets at doses of ~ 0, 1.5, 15, 45, 145 mg/kg/d (Purina 5002, F0, F1, F2, F3) and 0; 45 mg/kg/d (NIH-07; F0, F1, F2). In addition, 17ß estradiol was administered at a concentration of 2.5 ppm (0.1-0.2 mg/kg/day) as positive control for any estrogenic effects.

This study evaluated the potential for dietary administration of NP to affect parental fertility and growth and development of three offspring generations in SD rats, including sperm counts across generations. The latter was included to determine the validity of equivocal reductions observed in the F2 generation by Chapin (1999). In addition the study investigated ambiguous findings of two older studies with regards to specific target organ toxicity (Chapin 1999 and Cunny 1997).

With regards to reproductive parameters, there were no treatment-related effects which are in accordance with the conclusions of Chapin (1999) and Nagao (2001). Nagao (2001) reported that NP did not affect sperm parameters or estrous cyclicity at any dose. At 50 mg/kg/day ovarian weights were decreased and a significant decrease in the number of implantation sites and live pups per litter at birth was observed, with reduced survival at this dose on PND 0-4. NP did not affect acquisition of preputial separation in males, but did accelerate acquisition of vaginal patency in females at 50 mg/kg/day. Chapin (1999) found similar effects on vaginal patency but found no effect on implantation sites. Relative paired epididymal weights (but not absolute weight) were significantly increased in high does F2 and F3 males. This can be attributed to a reduction in male body weights. Importantly, andrological assessments were unaffected across all groups and generations, thus showing that the equivocal effects on sperm count at 650 and 2000 ppm in the F2 generation observed by Chapin (1999) were not substantiated.

Ovarian weights were reduced at 2000 ppm (F0), at 650 and 2000 ppm (F1) in Purina, and at 650 ppm (F0) in NIH-07. This is consistent with Nagao (2001) and Chapin (1999). There were no effects on reproduction in Tyl (2006), Chapin (1999), and Nagao (2001) as a result of these ovarian weight changes. The positive control, 17b-estradiol, reduced ovarian weights consistent with effects reported in Beigel (1998). The relationship of these 17b-estradiol-induced ovarian weight changes to the reproductive effects of 17b-estradiol is uncertain. However, the effects observed in the 17b-estradiol control, including reduced fertility, gestational, and pregnancy indices, reduced number of implantation sites per litter, reduced numbers of litters, reduced numbers of total and live pups per

litter at birth, reduced adult male testes and epididymal weights, and reduced epididymal sperm counts, were consistent with those reported in Beigel (1998).

The only treatment-related effect on the offspring observed in Tyl (2006) was a decrease in pup body weight at weaning in the high dose group. The decrease was not present earlier in the lactational period, suggesting that the reduced body weight resulted from direct toxic effect from overexposure to NP that occurs when the pups begin to self-feed on PND 14.

Overall, these studies provided evidence that nonylphenol exposure over several generations can cause perturbations in the reproductive system of offspring, which are compatible with the effects of exogenous estrogenic activity. The NOAEL for reproductive toxicity is at or above 2000 ppm (>~ 150 mg/kg/day) in the diet. The NOAEL for systemic toxicity is 200 ppm (~ 15 mg/kg/day), mainly based on adverse effects in male rat kidneys.

B.5.9.2 Toxicity for reproduction: developmental toxicity

In a study by Kom et al. (1992) 25 female Wistar rats were exposed to 0, 75, 150, 300 mg NP/kg/d by gavage at gestation days 6-15. A further group dosed with 600 mg/k/d was terminated prematurely because of high mortality during the first few days of treatment. Clear indications for maternal toxicity (increased mortality, reduced body weight gain and food intake, macroscopic changes in kidney and spleen) were observed at 300 mg/kg/d. At 150 mg/kg/d 3 of 21 females showed affected kidneys or spleens. No maternal toxicity was observed at 75 mg/kg/d. Post-implantation loss, litter size, fetal weights and incidence of both major and minor fetal abnormalities (visceral and skeletal) were not observed. The study provides no evidence of developmental toxicity in the rat at exposure levels which are toxic to the mother; thus the maternal NOAEL was 75 mg/kg/day and the fetal NOAEL was 300 mg/kg/day.

De Jaeger (1999) investigated testicular toxicity. Ten female SD rats were exposed by gavage at doses of 100, 250 and 400 mg/kg/d from gestation day 7 until weaning of their litter. Offspring was exposed in utero, during lactation and by gavage until sexual maturity. No explicit information was presented on maternal toxicity but it was stated that no females showed any physical or behavioral abnormalities. No offspring were born in the high dose group. It is not clear from the report if this was because of maternal deaths or embryonic/fetal desorption. There were no malformations or still births among the F1 Offspring. F1 body weight gain was significantly reduced at 100 and 250 mg/kg/day. F1 absolute testicular and epididymal weights were reduced at 100 and 250 mg/kg/day. Total cauda epididymal sperm count was reduced at 250 mg/kg/day. Seminiferous tubule diameter was slightly lower in both nonylphenol treated groups. Tubule lumen diameter and seminiferous epithelium thickness were reported to be significantly lower at 100 and 250 mg/kg/d, but no data were presented. However, this effect may be related to lower absolute testicular weight. Histopathology revealed pathological changes in the testes of one F1 male from the 100 mg/kg/day group. However, these histopathological abnormalities were not dose dependent, so the changes outlined above cannot be attributed to nonylphenol treatment. The evidence of a reduction in sperm count at 250 mg/kg/day reported is in contrast to a reliable multi-generation study conducted by Tyl (2006). It is not clear if the changes in the tubular measurements represent specific reproductive toxicity or non-specific secondary consequences of the reduction in bodyweight gain. Ferguson (2000) administered 4-NP to pregnant rats at 0, 25, 500, and 2000 ppm (approx. 0, 1.9, 37.5,

150mg/kg/d) in the diet, starting from gestation day 7 until after weaning. NP had no effects on gestation time, birth weights, litter sizes and sex ratios of pups. Neurobehavioral tests on progenies showed no differences compared to the controls. At 2000 ppm NP body weight gain and food consumption were reduced indicating systemic toxicity.

B.5.9.3 Toxicity for reproduction: human data

B.5.9.4 Toxicity for reproduction: other relevant information

NP shows estrogen-like action in several in vitro assays:

The relative estrogenic potency varied in different test systems and is reported to be a factor of 10^-3 – 10^-6 lower than for estradiol. Routledger & Sumpter (1997) reported NP to be 30.000 times less potent in a yeast assay compared to 17ß-estradiol. Soto et al. (1991) found NP at 10 µM eliciting a proliferative response comparable to 30 mM estradiol in an in vitro assay on MCF-7 cells. On a molar basis the estrogenic potency is 3.3 x 10^5 lower than in estradiol. At concentrations of 1 and 0.1 µM the proliferative response produced by NP was similar to that observed in the negative control. In a similar assay White et al. (1994) reported NP at 10 µM eliciting a proliferative response that was concluded to be 1000 times less potent than 17ß-estradiol. No estrogenic activity was detected at NP concentration up to 100 nM. Laws (2006) characterize the estrogen receptor (ER) –binding affinity of Nonylphenol using a rat uterine cytosolic (RUC) ER-competitive binding assay. The inhibitory concentration (IC 50) of NP was 0.3 µM compared to 0.00052 µM for 17ß-estradiol. Although NP has been shown to have a lower binding affinity to the estrogen receptor than estradiol, NP might be more potent than predicted. Studies in mice (Acevedo et al. 2005; Hernandez et al. 2006) have shown that NP induces Cyp2b to a lager extent than Cyp3a and this is due to the activation of the constitutive androstane receptor (CAR) (Hernandez et al. 2007).

NP shows estrogen-like action in several in vivo assays:

In an uterotrophic assay NP was administered to groups of three immature SD rats by a single intraperitoneal injection at dose levels of 0, 1, 2, or 4 mg/animal (Lee & Lee 1996). A dose-dependent increase in uterine weight was observed at all dose levels, with associated increases in uterine protein and DNA content and uterine peroxidase activity. NP was blocked by co-administration of an estrogen antagonist, providing evidence that the effect of nonylphenol is mediated through the estrogen receptor. The potency of NP was estimated to be 1000 - 2000 times lower compared to 17ß-estradiol.

In another uterotrophic assay (Creven and Moreno 1997) 4-Nonylphenol was administered to 10 female SD rats by oral gavage at dose levels of 0, 30, 100 and 300 mg/kg bw/day for 3 days. Treatment with 100 and 300 mg NP/kg bw resulted in uterine weights that were 1.2 and 1.5-fold increased compared to the control group. The NOAEL was 30 mg/kg/d. In a similar assay daily oral administration of NP produced a significant dose related increase in uterine weight in immature female rats at dose levels of 47.5 mg/kg and above when applied by gavage to 6 immature female Alpk: APfSD (Wistar-derived) rats/dose for three consecutive days. The NOAEL was 9.5 mg/kg/d.

In a subacute toxicity 28 d study p-NP was administered to 10 SD rats/sex/dose by gavage at 0, 10, 50, 250 mg/kg bw/day. A NOAEL of 10 mg/kg bw/day was estimated. The LOAEL was 50 mg/kg bw/day based on alteration of glucose and inorganic phosphates levels in females, increase of thyroid weight in males and increase of serum LH in female. At a dose level of 250 mg/kg bw/day: Hepatic and renal toxicity was evident in both sexes with increase of relative liver and kidney weights as well as histopathological changes, such as centrilobular liver cell hypertrophy and a variety of renal tubular lesions, and alteration of serum biochemical parameters. Three females died or became moribund during the experiment at this dose level. Effects on the endocrine system were evident at the same dose level as a decrease in both absolute and relative weights of seminal vesicles and ventral prostate in males; increase in both absolute and relative adrenal weights in females; irregular estrous cycle and vaginal mucosal hyperplasia in females (Woo 2007). Yamasaki (2003) reported that NP does not show androgen or androgen antagonistic effects in a Herschberger assay.

The ability of p-NP, and its principal mammalian metabolite nonylphenol glucuronide (NPG), to affect human estrogen receptors (ER) or androgen receptors (AR) was investigated *in vitro* by Moffat (2001) using a yeast transcriptional activation system. Glucuronidation of NP was found to eliminate the estrogen-like activity of NP in yeast harboring human ER. It is likely, that the weak estrogen-like activity noted for NP at high doses in rats reflects saturation of glucuronide conjugation. At concentrations present in the environment, this metabolic saturation is unlikely to occur, thus enabling glucuronidation of NP to remove the ability of these chemicals to mimic biological estrogens in humans.

B.5.9.5 Summary and discussion of reproductive toxicity

The studies show that nonylphenol exposure over several generations can cause disruptions in the reproductive system of offspring, which are compatible with the effects of exogenous estrogenic activity. These disruptions are seen as in males as a reduction in: sperm count, testicular and epidymal weights, epididymal sperm density. In females the NP changes the length of the estrous cycle, timing of vaginal opening and ovarian weights. There is no evidence of developmental toxicity of NP. NP shows estrogen-like action in several in vitro and vivo assays.

B.5.10 Other effects

In an in vitro study by Matsunaga (2010) NP was shown to cause an inverse agonistic effect on the binding of bovine serum albumin-congugated progesterone to recombinant human microtublule-associated protein 2C (rhMAP2C) and the dendritic outgrowth in hippocampal neurons.
B.5.11 Derivation of DNEL(s) or other quantitative or qualitative measure for dose response
It is not relevant due to the basis of this proposed nonylphenol restriction is for textile and the foundation of risk has been assessed to be based on the environment, not for human health.

B.6 Human health hazard assessment of physic-chemical properties

The substance nonylphenol is of high viscosity, low vapor pressure and flammability and does not have any explosive potential that would cause for concern either from the substance directly or in

solution in water. There are no specific major hazard regulations associated with material and control on storage.

B.6.1 Explosivity

The substance nonylphenol does not have any explosive potential that would cause for concern either from the substance directly or in solution in water.

B.6.2 Flammability

The structure of the substance shows that the substance does not contain any chemical groups which could lead to a formation of a highly flammable gas in contact with air, vapor or water. Due to the structure of the substance pyrophoric properties could be excluded. The substance does not contain any chemical group which could lead to spontaneous ignition after contact with air at room temperature (20 °C).

B.6.3 Oxidizing potential

The substance nonylphenol does not have any oxidizing properties.

B.7 Environmental hazard assessment

Standardised tests, e.g. according to OECD guidelines, are used as reference when test methodology and test conditions, performance and data/treatment/reporting are evaluated. Non-standardised test results may also be reliable, but require a more thorough check on compliance with reliability criteria before being considered reliable. A detailed description of the methods used in the study, measurements and observations performed should be provided. Test conditions should be suitable for the test organism. Minimum requirements (incl. maximum acceptable control mortality) for endpoints such as mortality, growth, and reproduction need to be fulfilled. Information on dose-response and statistics should also be presented.

In order to be considered relevant the toxicity data study should include ecotoxicological parameters such as effects on survival, growth and/or reproduction. Only an effect resulting from exposure of nonylphenol is considered relevant for the effect assessment, i.e. a study will be rejected in case there exist an indication that impurities or other substances have influenced the observed response.

B 7.1 Aquatic compartment (including sediments)

Results from toxicity studies in the pelagic compartment only containing nominal concentrations may be considered informative and indicative but will not be used as such in the derivation of PNEC.

The lowest reliable and relevant toxicity data in the aquatic compartment (including sediment) are summarised in Table 14 below. The structure of sections B7.1.1.1 (Fish), B7.1.1.2 (Invertebrates), and B7.1.1.3 (Aquatic algae and plants) is as follows: first a short information about which values in the respective sections that were selected in the EU risk assessment (ECB 2002), the CSR (Lead registrant 2010) and the value selected in this assessment. Freshwater toxicity data are presented before marine water toxicity data and acute data are presented before chronic data. In addition to this, the studies are presented in alphabetical order with respect to the scientific name of the study organisms. In general, only studies of intrest for the calculation of PNEC are presented in more detail. Studies may however also be described if they are considered to contain interesting information indicating higher toxicity.

B.7.1.1 Toxicity test results

Below in Table 14 is a summary of the lowest relevant and reliable toxicity values of nonylphenol for aquatic species. In order to be considered reliable the studies need to have measured test concentrations.

Table 14 Summary of the lowest relevant and reliable acute and chronic toxicity values of nonylphenol for aquatic species.

Trophic level	**Species**	**Endpoint**	**Concentration**	**Reference**
Freshwater fish	Fathead minnow (*Pimephales promelas*)	Mortality (96 h LC_{50})	128 µg NP/L	Brooke (1993a)
	Rainbow trout (*Oncorhynchus mykiss*)	Growth (NOEC)	6 µg NP/L	Brooke (1993a)
Marine water fish	Winter flounder (*Pleuronectes americanus*)	Mortality (96 h LC_{50})	17 µg NP/L	Lussier *et al*. (2000)
	-	No marine fish long-term toxicity is available		
Freshwater invertebrates	*Hyalella azteca*	Loss of mobility (96 h EC_{50})	20.7 µg NP/L	Brooke (1993a)
	Daphnia magna	Surviving offspring (NOEC)	24 µg NP/L	Comber *et al.* (1993)
Marine water invertebrates	*Mysidopsis bahia*	Mortality (96 h LC_{50})	43 µg NP/L	Ward and Boeri (1990b)
	Mysidopsis bahia	Growth – length (NOEC)	3.9 µg NP/L	Ward and Boeri (1990b)
Freshwater algae	*Scenedesmus subspicatus*	Growth rate (72 h EC_{50})	323 µg NP/L	Kopf (1997)
		Growth rate (NOEC)	25.1 µg NP/L	
Marine water algae	-	No marine algae short-term toxicity data is available		
	-	No marine algae long-term toxicity data is available		
Freshwater aquatic plants	*Lemna minor*	Frond production (NOEC)	901 µg NP/L	Brooke (1993a)
Freshwater sediment species	*Chironomus riparius*	Emergence rate (EC_{10})	231 mg NP/kg dw	Bettinetti and Provini (2002)
Marine water sediment species	*Leptocheirus plumulosus*	Mortality, reproduction (NOEC)	61.5 mg NP/kg dw.	Zulkosky *et al.* (2002)

B.7.1.1.1. Fish

B.7.1.1.1.1 Short-term toxicity to fish

Similar to the EU risk assessment (ECB 2002), the CSR (Lead registrant, 2010) selected the 96-hour LC_{50} of 128 µg NP/L for the freshwater species fathead minnow (*Pimephales promelas*) from the study by Brooke (1993a) to represent the acute toxicity of NP. This is also the LC_{50} value chosen to represent the acute toxicity for freshwater fish in this assessment.

Lower 96-hour LC_{50}-values of 50 µg NP/L, 80 µg NP/L, and 80 µg NP/L were reported by Dwyer *et al.* (2005) for the atlantic sturgeon (*Acipenser oxyrhynchus*), the spotfin chub (*Hybopsis monacha*) and the shortnose sturgeon (Acipenser brevirostrum), respectively. However, according to the authors concerns related to the chemical carrier solvent on the sensitivity of the atlantic and shortnose sturgeon require the test results for these two species to be interpreted with caution. The study also included toxicity data for thirteen other freshwater species, including fathead minnow having a LC_{50} of 270 µg NP/L. Sensitivity ranking based on the LC_{50}-values by Dwyer *et al.* (2005) ranked fathead minnow as 15th out of 16 fish freshwater species, with atlantic sturgeon ranked as the most sensitive. The tests were performed as static acute toxicity tests ASTM (2003). But since the toxicity values for all tests are based on nominal concentrations and the test chemical purity was only 85%, the reported LC_{50}-values only have supportive use. They however indicate that fathead minnow (*Pimephales promelas*) (LC_{50} 128 µg NP/L Brooke (1993a)) may not be the most sensitive freshwater fish species.

The lowest 96-hour LC_{50} reported for seawater species is 17 µg NP/L for the winter flounder (*Pleuronectes americanus*) (Lussier *et al.* 2000). This study is given a validity marking of 'use with care' in the EU risk assessment (ECB 2002) because only a summary report was available at that time and a 96-hour LC_{50} of 310 µg /L for sheepshead minnow (*Cyprinodon variegatus*) (Ward and Boeri,1990c) was selected instead. However, presently a peer-review article exists where the test methods (biological and analytical) are well described. The testing was performed according to ASTM procedures (1988), the test concentrations were measured, etc. and the results are therefore considered reliable. The LC_{50} value chosen to represent the acute toxicity of NP for seawater fish in this assessment is 17 µg NP/L, which is the same as in the CSR (Lead registrant 2010).

B.7.1.1.1.2 Long-term toxicity to fish

Long-term toxicity studies on fish are summarised in Table 15 below.

The long-term toxicity value selected for PNEC derivation in the EU risk assessment (ECB 2002) for freshwater fish was the 33-day $NOEC_{survival}$ of 7.4 µg NP/L for fathead minnow (*Pimephales promelas)* by Ward and Boeri (1991a). This value was also used in the EU risk assessment (ECB 2002) for saltwater fish since no valid chronic saltwater study was available.

However, this study is not included in the CSR (Lead registrant 2010) and the reason why is not given. Instead in the CSR (Lead registrant, 2010) the 91-day $NOEC_{growth\ rate}$ of 6 µg NP/L for rainbow trout (O*ncorhynchus mykiss)* by Brooke (1993b) was selected as the lowest valid for freshwater fish. This value, i.e. 6 µg NP/L, is also the value selected for this assessment.

Brooke (1993a) exposed Bluegill (*Lepomis machrochirus*) and Fathead minnow (*Pimephales promelas*) to nonylphenol in a 28-day chronic toxicity study under flow-through conditions. The exposure groups used in the study with Bluegill (40 fish/group) were control and the NP-exposed groups with the measured concentrations of 5.6, 12.4, 27.6, 59.5 and 126 µg NP/L. The 28-day NOEC/LOEC for mortality was 38.1/77.5 µg NP/L but there were no significant effects observed on the endpoint growth. The exposure groups used in the study with Fathead minnow (40 fish/group) were control and the NP-exposed groups with the measured concentrations of 9.3, 19.2, 38.1, 77.5 and 193 µg NP/L. The 28-day NOEC/LOEC for growth (wet weight) and mortality were 38.1/77.5 µg NP/L and 77.5/193 µg NP/L, respectively.

Brooke (1993b) exposed fertilized eggs/embryos (100 / concentration) of rainbow trout (*Oncorhynchus mykiss*) to nonylphenol in a 91-day chronic toxicity study under flow-through conditions. The exposure groups used were control, and the measured concentrations of 6.0, 10.3, 23.1, 53.0, 114 µg NP/L. The 91– day NOEC value, based on the most sensitive endpoint which was sublethal effects (growth), was 6.0 µg NP/L with a LOEC of 10.3 µg NP/L. Mean percent hatch of any test concentration was not significantly different from that of the controls. Time to hatch was 39 ± 5 days with swim-up at approximately at day 45.

Schwaiger *et al.* (2002) exposed rainbow trout (*Onchorhynchus mykiss*) under flow-through conditions for technical NP, which consisted of 98% NP- isomers (90% 4-NP, 10% 2-NP) and 2% dinonylphenol. The experiment started in 1996 with the exposure of 3-year old rainbow trout (F_0-generation). Four months prior to spawning (July-October), 16 male and 8 female individuals per group were exposed intermittently (10 days/month) to the measured concentrations of 1 µg NP/L (1.0-1.3 µg NP/L) or 10 µg NP/L (9.3-11.2 µg NP/L). The fish were fed between the exposure periods, but not during them. Control fish were maintained without any treatment under otherwise identical conditions. During the exposure periods, concentrations of NP in the test waters were quantified at least twice a week by GC-MS. Three days after the last exposure interval, which coincided with beginning of spawning, fish were anaesthetized and eggs and sperms were obtained for subsequent reproduction studies. In the same time blood samples for analysis of vitellogenin were taken in 15 males of each treatment group and 12 control individuals. Randomly selected eggs from four females were pooled and artificially fertilized with a sperm pool obtained from four males per group. Fertilized eggs were reared in egg incubator trays until hatching. Mortalities occurring before reaching the eyed-egg stage and before completion of the hatching process were protocolled and resulting hatching rates were determined. After resorption of the yolk sac, the offspring of the control and the exposed fish (F_1-generation) were fed commercial food until the juvenile fish were either subjected to histological investigations or grown to sexual maturity. As regards the latter, at the age of 3 years blood samples were taken at spawning time to determine vitellogenin and sex steroid levels in both the male and female individuals (10 males and 10 females from the group exposed to 10 µg NP/L and 9 males and 9 females from the control group). Exposure of NP was restricted only to the F_0-generation, whereas the F_1-generation was maintained without any exposure of NP. No replicates were used for the F_0- or F_1-generations of the different groups. The viability of eggs from both NP-exposed groups was significantly reduced as compared to the control. Mortality prior to the eyed-egg stage was 1.7% in the control, 10.1% in the 1 µg

NP/L-group and 16.1% in the 10 µg NP/L-group. With regard to mortality occurring later during the embryonal development, no differences between control eggs and eggs from the NP-exposed groups were observed. The hatching rate was only significantly reduced in the 10 µg NP/L-group as compared to the control. Histological examination of the testicular tissue of the NP-exposed groups revealed no morphological differences. The levels of vitellogenin in the offspring, of male individuals were not affected, whereas in females they were significantly higher than in the control progeny. Histological examination revealed no altered sex ratios. In single cases, intersex occurred in both male and female offspring of exposed fish. The analysis of sex steroid levels revealed a two-fold increase of estradiol in plasma of male offspring and an almost 13-fold increase of testosterone in the plasma of female offspring as compared to the offspring control. Even though there was a significant reduction in hatching rate in the highest exposure group (10 µg NP/L) and the concentration below that (i.e. 1 µg NP/L) therefore becomes NOEC, this NOEC can only be considered to be indicative due to the distance between these two concentrations being a factor of ten, a dose-response relationship only consisting of a control and these two concentrations combined with the fact that no replicates were used.

Lahnsteiner *et al.* (2005) exposed rainbow trout (*Onchorhynchus mykiss*) for 4-nonylphenol and studied effects both *in vivo* and *in vitro*. No measurements of the actual concentrations were performed. The nonylphenol was dissolved in DMSO and all reported concentrations are based on calculations based on the flow rate of well water and the injection rate of the nonylphenol stem solution. The estimated DMSO exposure levels for the different exposure groups (concentration µg NP/ µg DMSO) were 0/0.715, 0.130/0.130, 0.280/0.270 and 0.750/0.700. Volume and quality of semen of male +2 years rainbow trout (10 fish/group) exposed in a flow-through system were studied during the spawning period (60 days) using three concentrations (0.130, 0.280 and 0.750 µg NP/L) and a solvent control (DMSO) with sampling performed after 0 days, 30 days and 60 days. The semen volume decreased significantly over time in all groups, except in the solvent control. After 60 days the semen production was completely inhibited in the highest dose, i.e. 0.750 µg NP/L, and was significantly reduced, as compared to the solvent control, also in the other two exposure groups. However, the fact that the semen volume in the lowest exposure group, i.e. 0.130 µg NP/L-group, was significantly lower than the solvent control already in the sample taken at day 0 makes the interpretation of the difference in that group as compared to the solvent control at day 30 and 60 less clear, even though the volume decreased over time. Sperm density, sperm motility and sperm fertility were not affected in any of the groups at any time. Development of embryos and larvae was also studied using the same flow-through system as was used for the male +2 years fish by connecting egg incubators to the outflows of the four respective exposure groups (solvent-control and the nonylphenol exposure groups). At estimated nonylphenol exposure levels of 0.280 µg NP/L and 0.750 µg NP/L the percentage of eyed stage embryos was slightly (2-4 %) but significantly lower than the solvent control. Survival of both hatched larvae and yolk sac stage larvae were significantly lower in the two highest dose groups as compared to the solvent control. In order to reduce the risk of fungus infections the eggs were regularly disinfected with 4% formaldehyde. Sperm motility (sperm motility rate, swimming velocity, swimming pattern and motility duration) studied in *in vitro* did not differ between control (without DMSO) and water containing nonylphenol (0.1, 0.3 and 0.75 µg NP/L). The validity criteria for survival were fulfilled, for hatched larvae the survival was 74.8 % (minimum 66%) and for the yolk sac stage larvae it was 70.9% (minimum 70%). However, due to the reasons listed below the results from this study are

only considered to be of informative and indicative value. This since no measurements were performed on the concentrations and oxygen levels, the temperature used (6 °C) is below what is recommended for rainbow trout in guidelines, no control without solvent was used, the study of fish of the age +2 years was performed without replicates, the statistics used require homogenous variance and normal distribution but no information is available if these requirements where fulfilled and if so which methods that where used to test this. In addition, it is unclear if the formaldehyde treatment that, on a regular basis, was used on the eggs may have influenced the sensitivity of the eggs. However, the study is still considered to indicate that nonylphenol may exhibit toxicity well below 1 µg NP/L.

Yokota *et al.* (2001) studied the chronic effects of 4-nonylphenol on reproductive status of Japanese medaka (*Oryzias latipes*) over two generations of continuous exposure. The exposure study of the parental generation (F_0) begun on embryos within 24 h postfertilisation and continued with monitoring through embryological development, hatching, posthatch survival, growth, sexual differentiation, and reproduction under flow-through exposures to controls (control and solvent control-100 µg ethanol/L) and the mean measured NP-concentrations 4.2, 8.2, 17.7, 51.5, and 183 µg NP/L for up to 104 d. The 60 embryos employed for each treatment were randomly separated into four groups of 15 in each test chamber for testing in quadruplicate. Eggs spawned from F_0 at 102 and 103 d posthatch were also examined for hatchability, survival after hatching, growth, and sexual differentiation until 60 d posthatch.
F_0-generation: Hatchability was significantly decreased in the highest exposure group (183 µg NP/L), as compared to the pooled controls. Post-swim-up mortality was significantly decreased in the three highest exposure groups, resulting in a NOEC/LOEC of 8.2/17.7 µg NP/L. No hatched larvae swam up successfully in the highest exposure group. No significant differences were observed in either mean total length or body weight at 60 d posthatch in any of the treatments. NOEC/LOEC for the induction of testis-ova (both testicular germ cells and oocytes in the gonad) was 8.2/17.7 µg NP/L. The male fish in 17.7 µg NP/L groups with testis-ova all displayed externally male characteristics, while all eight fishes in the highest remaining exposure group, i.e. 51.5 µg NP/L, with testis-ova displayed externally female characteristics. Neither the fecundity nor the fertility of paired medaka during the reproductive phase from 71 to 103 d posthatch was significantly different from the controls; however, the fertility was reduced in the highest remaining exposure group (17.7 µg NP/L). GSI of male medaka at the end of the reproductive phase was reduced in the 17.7 µg NP/L group, but the difference was not significant. GSI of female fish increased with increasing concentration of NP, with significantly higher GSI in the two highest exposure groups (8.2 and 17.7 µg NP/L), as compared to control, resulting in the NOEC/LOEC of 4.2/8.2 µg NP/L.
F1-generation: No embryological abnormalities or hatching failures of fertilised eggs (F_1 embryos) were observed in any of the treatments. The growth of the NP-exposed F_1 juveniles at 60 d postatch was not significantly higher in any of the groups as compared to the control. Induction of testis-ova was observed at lower NP-concentrations in the F_1-generation, as compared to the F_0-generation. In the 8.2- and 17.7-exposure groups, testis-ova were observed in two (10%) and five (25%) among 20 fish examined, respectively. However, all these fish with testis-ova displayed clear male external characteristics. The sex ratio in the highest group (17.7 µg NP/L) was significantly different as compared to the control (9:19 with male:female), based on histological examination

Kang *et al*. (2003) exposed mature Japanese medaka (*Oryzias latipes*) to nonylphenol and measured reproductive effects and estrogenic responses. The exposure groups used were control, solvent control (0.0001% DMSO) and the measured concentrations 24.8, 50.9, 101 and 184 µg NP/L. The experimental design consisted of eight breeding pairs per treatment which were exposed in a flow-through system for three weeks and fecundity and fertility of the maiting pairs were measured daily. The production of eggs was significantly reduced in the two highest exposure groups, resulting in a NOEC/LOEC of 50.9/101 µg NP/L. Fertility was significantly reduced in the highest exposure group resulting in a NOEC/LOEC of 101/184 µg NP/L. Induction of testis-ova was observed in male fish in all NP-exposed groups (13% in 24.8-101 µg NP/L and 33% in 184 µg NP/L), whereas abnormality of spermatogenesis (spermatozoa, spermatocytes, and mature spermatids) was only observed at the highest dose, i.e. 184 µg NP/L. In male medaka the gonadosomatic index (GSI) was significantly reduced in the 184 µg NP/L exposure group, and the hepatosomatic index (HIS) in the 101 and 184 µg NP/L exposure group. Hepatic vitellogenin levels in male medaka showed a dose-dependent increase with increasing levels of NP with levels significantly higher than the pooled control at exposure levels ≥ 50.9 µg NP/L. Additionally, the VTG concentrations in male fish in the 101 and 184 µg NP/L- exposure group were higher than those of females in the control or solvent control group. Significantly increased levels, as compared to the pooled control was also observed in female medaka at exposure levels ≥ 50.9 µg NP/L.

Seki *et al.* (2003) exposed Japanese medaka (*Oryzias latipes*) to nonylphenol from fertilized eggs to 60 d posthatch. The exposure groups used were control, solvent control (DMSO) and the measured concentrations 3.30, 6.08, 11.6, 23.5 and 44.7 µg NP/L. The exposure design consisted of an embryological phase (from < 12 h after fertilization to hatching), larval-juvenile phase (from hatching until 60 d posthatch), 60 d posthatch (measurements of length and weight, observations of external secondary characteristics, sampling of gonads and livers), hepatic vitellogenin concentrations (individual measurements in livers from all test fish, including controls) and culture in clean water (remaining fish from the highest exposure group, i.e. 44.7 µg NP/L, were after measurements and observations performed according to above transferred to clean water for an additional two months; half removed after 30d, the remainder after 60 d; observation were made of external secondary sex characteristics and histological examination of gonads). The hatchability of all treatment groups, solvent controls, and controls was ≥90%. No statistically significant differences in mortality were found between the treatment groups and the pooled controls. Neither abnormal behaviour nor appearance was observed in any treatment group during the exposure period. Total length and body weight were significantly reduced 60 d posthatch at with NOECs of 23.5 µg NP/L and 11.6 µg NP/L, respectively. Based on external sex characteristics 60 d posthatch the sex ratio (male:female) were significantly skewed toward female at 23.5 µg NP/L (11:47) and 44.7 µg NP/L (1:59). Induction of testis-ova composed of both testicular germ cells and oocytes in the gonad was observed at ≥ 11.6 µg NP/L. The testes of medaka treated with nonylphenol at the two lowest doses (3.30 µg NP/L and 6.08 µg NP/L) were histologically identical to those of the control and the solvent control. In both male and female fish exposed to nonylphenol hepatic VTG was induced in a concentration-dependent manner and were significantly higher at 11.6 µg NP/L, as compared to the controls. At the beginning of culture in clean water, only one of 36 fish (2.8%) in the four chambers of 44.7 µg NP/L exposure group displayed male secondary sex characteristics.

After 30 d and 60 d after transfer to clean water, four of 18 fish (22%) showed male secondary sex characteristics. The reversion from the feminized appearance to male secondary sex characteristics was according to the authors in good agreement with the observation in gonadal histology. An observation that can be made from this study is that the induction of testis-ova, effects on gonadal histology and induction of hepatic VTG in medaka occur at lower concentration (NOEC/LOEC: 6.08/11.6 µg NP/L) than the more standard ecotoxicological parameters growth (length, NOEC/LOEC: 23.5/44.7 µg NP/L; and weight, NOEC/LOEC: 11.6/23.5 µg NP/L) and mortality (NOEC > 44.7 µg NP/L). The NOEC selected for PNEC derivation from this study is 11.6 µg NP/L, based on growth.

Balch and Metcalfe (2006) exposed Japanese medaka (*Oryzias latipes*) to nonylphenol from fertilized eggs to 100 d post hatch. The exposure groups used were control, solvent control (acetone), positive control (17β-estradiol) and the measured NP concentrations 0.29, 0.87, 2.9, 8.7 and 29 µg NP/L. The exposure to the fry began within 1 day of hatch and continued for 100 days under static conditions. Each group started with 150 fry to ensure that at least 50 survived to the end of the 100-day exposure period. None of the groups were replicated. The test water in the individual exposure tanks was renewed every 48 h. Renewal was 100%, with the exception of the first two weeks when 15-20% of the test water was left so that the young fish did not need to be physically handled. Gentle aeration was applied to the tank water so that dissolved oxygen was at or near saturation. At the end of the 100-day exposure period fifty randomly chosen fish from each treatment were analysed for expression of secondary sex characteristics, total body length & weight, gonadal tissues (to verify the gonadal intersex of the fish and to monitor for evidence of gonadal intersex). The secondary sex characteristics were assessed using criteria described in Metcalfe *et al*. (1999). In brief, the shape of the urogenital papilla, dorsal and anal fins and the presence or absence of papillary processes on the anal fin is phenotypic expressions of gender in mature fish. Male or female phenotypic expressions are consistent among all secondary sex characteristics within individual fish which have not been exposed to endocrine disruptive compounds (EDCs). Exposure to EDCs can alter this consistency resulting in mixed secondary sex characteristics. Common patterns of mixed secondary sex characteristics include attributes such as a female-specific anal fin together with a male-specific dorsal fin or visa versa, within the same individual. The survival rates at the end of the 100-day exposure period were above 70% for all groups; control (82%), vehicle control (73%), positive control (81%) and NP (0.29 µg NP/L = 74%, 0.87 µg NP/L = 80%, 2.9 µg NP/L = 77%, 8.7 µg NP/L = 75%, 29 µg NP/L = 77%). Average length and weight were similar between the NP-groups (23.2-24.6 mm; 118-135 mg) and the control (24.7 mm; 140 mg) and vehicle control (24.3 mm; 112 mg), but lower in the positive control group (18.6 mm; 66.5 mg). All ratios of phenotypic females to males (as determined by gonadal sex) approximated unity with no statistical differences, except for the positive control. Only one male medaka (out of a total of 49) was observed in the positive control, indicating that most fish with male genotype in this treatment had been completely feminized to the female genotype. Fish that exhibited both feminized and masculinized traits were identified as having “mixed” secondary sex characteristics (MSC). Significantly elevated incidence of MSC, as compared to the vehicle control, were observed in the two highest dose groups, 8.7 µg NP/L (20%) and 29 µg NP/L (42%), respectively, resulting in a NOEC of 2.9 µg NP/L. A low percentage (i.e. 4%) of the fish in the clean control also exhibited MSC, but according to the authors this was considered to reflect a small number of errors in

assessing male and female traits. The corresponding percentage in the positive control was 33%. Papillary processes normally found on the anal fins of male medaka were present on the anal fins of males from all treatments except the highest NP exposure group and the positive control. Induction of testis-ova was significantly increased in the highest exposure group (29 µg NP/L; 18 of 22 male fish) resulting in a NOEC of 8.7 µg NP/L (1 of 22 male fish). The observation of testis-ova in one of the male fish in the NOEC-concentration 8.7 µg NP/L, even though not significantly different from the vehicle control, is also considered a positive response since spontaneous development of testis-ova never has been observed in medaka (Yamamoto 1958; Metcalfe et al. 1999).

Ward and Boeri (1991a) exposed <24h old embryos of Fathead minnow (*Pimephales promelas*) to nonylphenol in a 33-d early-life stage toxicity test under flow-through conditions.The exposure groups used were control, and the measured concentrations of 2.8, 4.5, 7.4, 14 and 23 µg NP/L. Embryos in the control and the three lowest NP-exposure groups (2.8, 4.5, and 7.4 µg NP/L) began to hatch on the third day of exposure, while the two highest NP-exposure groups (14 and 23 µg NP/L) began hatching on day four. Growth (length or weight) did not differ significantly as compared to the control for any of the nonylphenol exposure groups. There were a dose-dependent increase in mortality with increasing concentrations of nonylphenol resulting in a NOEC/LOEC of 7.4/14 µg NP/L.

Schoenfuss and co-workers (2008) examined the ability of NP to alter physiology, morphology and reproductive competence in male fathead minows (*Pimephales promelas*). Two 28-day experiments were conducted in succession using eight aquaria only receiving ground water (as control) and eight aquaria receiving ground water spiked with NP. In both experiments mature male fathead minnows were randomly assigned to control or exposure aquaria at a concentration of 6 fish/aquaria in the first experiment and 5 fish/aquaria in the second experiment. The continuous flow-through exposure lasted 28 days and were followed by a 7-day competitive spawning period (conducted in water without NP) during which exposed males were individually paired with control males to compete for reproductive opportunities (nest site) in an aquarium which also included two mature females. Following the 7-day competitive spawning trials, all male were analysed for plasma VTG concentrations, secondary sexual characteristics, and organosomatic indices. In a second experiment, an additional 20 males/concentration were exposed in separate aquaria and used in time series analysis of plasma VTG concentrations. Subsamples of five fish were collected at 24 h, 4, 7 and 14 days after onset of the exposure. The technical NP standard that was used was a complex isomeric mixture of > 90% 4-NP, with minor amounts of 2-NP, 4-octylphenol and dodecylphenol. The solvent (ethanol) concentration did not exceed 1.8 µg ethanol/L. No separate solvent controls were used in the study. The concentrations (nominal/measured) used in experiment 1 were 0.061/0.15, 0.61/0.25, 6.1/0.63 and 61/3.2 µg NP/L and in experiment 2 1/0.3, 6/5, 12/11 and 24/15 µg NP/L. The reason for the differences between nominal and measured concentrations in experiment 1 was reported to be due to solubility limitations in the stock solution used in experiment 1. As a result the volume of the stock solution and mixing ratios were adjusted in experiment 2 resulting in a better agreement between nominal and measured values. Fish in the first experiment were approximately 8 months old at the onset of the experiment, while fish in the second experiment were approximately 9 months old. Environmental conditions were stable throughout the experiments (DO = 6.4 ± 0.3 mg/L, pH = 7.2 ± 0.1) although the temperature

differed slightly (exp 1: 24 ± 0.4 °C; exp 2: 27 ± 0.6 °C). Survival rates exceeded 90% in most NP treatments in both experiments, but were 58% for 0.15 µg NP/L, 84 % for 3.2 µg NP/L in experiment 1 and 80% for the 0.3 µg NP/L-group. Plasma VTG concentrations in fish did not vary significantly among treatments and control 7 days after the end of exposure (i.e. day 35) in either of the two experiments. The VTG concentration in males in experiment 2 differed significantly between the control and the 15 µg NP/L-group at day 7 and day 14, which was the result of two males in that group expressing high concentrations, while the remaining nine males did not express VTG above the detection limit. The hepatosomatic index did not vary significantly between control and exposed groups in experiment 1, but was significantly increased in the lowest exposure group (0.3 µg NP/L) in experiment 2. The gonadosomatic index did not differ significantly in either of the experiments, nor did the expression of secondary sexual characteristics. The histological analysis did not identify any pathological findings of ovarian tissues in testis, extensive apoptosis or inflammation, or proliferation of connective tissues in either testis or liver during either of the two experiments. Male fish in all of the competitive spawning scenarios behaved in an expected competitive manner and nest holding ability differed significantly between treatments in both experiments. In experiment 1, exposed males from the lowest exposure group (0.15 µg NP/L) out-competed control males for access to nest sites (holding 75% of all nest sites). However, in the three higher exposure groups (0.25, 0.63 and 3.2 µg NP/L), control males out-competed the exposed males (holding 56-58% of all nest sites). A similar trend was also observed in experiment 2 where NP-exposed males at the lower concentrations (0.3 and 5 µg NP/L) out-competed control males (holding approximately 75% of all nest sites), while the opposite was true at the highest concentrations where control males out-competed the NP-exposed males (holding 55-60% of all nest sites). The exposure to NP only resulted in significant effects that may be used for setting a NOEC for the competitive spawning assay; all other endpoints resulted in larger-than values. However, the interpretation of the outcome of the performed assays is rather complex. This since the lowest concentration (0.15 µg NP/L) in experiment 1 and the two lowest (0.3 and 5.0 µg NP/L) resulted in NP-exposed males out-competing control males, while the three highest concentrations (0.25, 0.63 and 3.2 µg NP/L) in experiment 1 and the two highest concentrations (11 and 15 µg NP/L) in experiment 2 results in control males out-competing NP-exposed males. It is not clear if it was the higher temperature in experiment 2 (27 ± 0.6 °C), as compared to experiment 1 (24 ± 0.4 °C), that explains part/all of this difference, or if it is something else. A conclusion that however can be drawn is that NP may influence also aspects of reproduction such as competitive spawning behavior.

Kwak *et al*. (2001) studied the effects of nonylphenol on Swordtails (*Xiphophorus helleri*) in a semi-static short-term study (3 d) and a static long-term study (60 d) using adult male and 30 d-old juvenile fish, respectively. The fish was purchased from a local hatchery and were acclimated for at least two weeks before exposure. All fish were maintained under semistatic conditions in dechlorinated tap water at 27 °C on a 14:10 h light:dark photoperiod and fed three times daily. The stock solution was prepared by dissolving the test chemical in 0.01% ethanol. The nominal concentrations used in the short-term study was 100, 130, 170, 220 and 290 µg NP/L and in the long-term study 0.2, 2 and 20 µg NP/L. Experimental conditions for the LC_{50} determinations were based on OECD 203 from 1981. Following the short-term exposure the LC_{50} (3 d) was determined to 206 µg NP/L, vitellogenin mRNA was expressed, flow cytometric analysis and terminal

deoxynucleotidyl transferase assay on the testes of treated fish indicated reproductive damage. Histopathological analysis found degenerative and necrotic cells in seminiferous tubules following the exposure of 100 µg NP/L. The testes with lesions were also associated with high highly suppressed spermatogenesis. In the long term study twenty fish per concentration were exposed under static conditions during 60 d. Following the long term exposure, all nonylphenol exposure groups significantly decreased the growth of swordtails as compared to the controls. The sword is a secondary sexual character of a male, along with a gonopodium, in swordtails. Female swordtails have been shown to prefer males with longer swords to those with short sword length, and the strength of this preference increases with an increase in sword length (Basolo 1990). In adverse conditions, such as lack of food, males tend to increase their sword length instead of their body (Basolo 1990). It is not clear whether or not it was semistatic or static conditions during the long-term exposure since it in the article is stated that all fish were kept under semistatic conditions and further down in the article it is stated that the fish in the 60-d exposure were exposed under static conditions. Since no concentration was measured and the experimental conditions (dissolved oxygen content, pH, etc.) are not explicitly stated the results can not be used directly in the derivation of PNEC, however, the study is still considered to indicate that the NOEC for nonylphenol is well below 1 µg NP/L.

No long-term data is available for marine fish.

Table 15 Long-term toxicity data for fish

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
Freshwater									
Gobiocypris rarus, paired sexually mature adult	4-nonylphenol	Flow-through, equivalent or similar to OECD 229	M (arith. mean)	21	Adult mortality Fertility Reproduction	>20 >20 >20		Zha *et al.* (2008)	R
Lepomis macrochirus, 10-12 w old	4-nonylphenol	Flow-through, ASTM 1993 Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. E1022-84 USEPA equivalent or similar to OECD Guideline 215 (Fish, Juvenile Growth Test)	M (arith. mean)	28	Mortality	59.5	126	Brooke (1993a)	R
Oncorhynchus mykiss, 30 d old	4-nonylphenol	Flow-through, ASTM	M (arith. mean)	91	Growth	6	10.3	Brooke (1993b)	R
Oncorhynchus mykiss, Fertilised eggs/embryos +2 year male	4-nonylphenol	Flow-through	N	60	Eyed stage embryos Hatched larvae Yolk sac stage larvae Semen volume Sperm density Sperm fertility	0.13 0.13 0.13 0.13 >0.75 >0.75	0.28 0.28 0.28 0.28	Lahnsteiner *et al.* (2005)	NR

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
					Motile spermatozoa Average sperm swimming velocity	>0.75 >0.75			
Oncorhynchus mykiss, F_0-generation: 3 year old males and females From fertilization and onwards were all groups kept in clean water F_1-generation: Some were sampled as juveniles for histological examination, while the remains were kept until sexual maturity. For the latter, at the age of 3 years, blood samples were taken at spawning time and the experiment was terminated.	Technical NP consisting of 98% NP isomers (90% 4-nonylphenol, 10% 2-nonylphenol) and 2% dinonylphenol	Flow-through,	M	Intermittent exposure of 10 d/month from July-October prior to spawning. No further exposure was performed after that.	Hatching rate Histological examination of testicular tisue Vitellogenin in male fish Vitellogenin in males Vitellogenin in female Estradiol in males Testosterone in males Estradiol in females Testosterone in females Sex ratios (based on histological examinatios)	1 <1	10 >10 >10 10 10 >10 >10 10 >10	Schwaiger *et al.* (2002)	R

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
Oncorhynchus tschawytscha, alevins	Nonylphenol	Semi-static, equivalent or similar to OECD Guideline 212 (Fish, Short-term Toxicity Test on Embryo and Sac-Fry Stages)	N	29	Mortality	>10		Afonso *et al.* (2002)	NR
Oryzias latipes, 5-8 d old	4-nonylphenol	Flow-through, equivalent or similar to EPA OPPTS 850.1500 (Fish Life Cycle Toxicity)	M (arith. mean)	28	Mortality Growth	>1.9 >1.9		Nimrod and Benson (1998)	R
Oryzias latipes, paired sexually mature adult	4-nonylphenol	Flow-through, equivalent or similar to OECD 229	M (arith. mean)	21	Fertility (and fecundity)	50.9	101	Kang *et al* (2001)	R
Oryzias latipes, started with fertilized eggs/embryos	4-nonylphenol	Flow-through, equivalent or similar to EPA OPPTS 850.1500 (Fish Life Cycle Toxicity)	M (arith. mean)	104	F0 generation post swim-up mortality GSI in paired female (F0) at the end of the reproductive phase	8.2 4.2	17.7 8.2	Yokota *et al* (2001)	R
Oryzias latipes, started with fertilized eggs/embryos	4-nonylphenol	Flow-through, equivalent or similar to OECD Guideline 234	M (arith. mean)	60	Mortality Growth (length) Growth (body weight) External sex characteristics Induction of testis-ova Induction of VTG	 23.5 11.6 23.5 6.08 6.08	>44.7 44.7 23.5 44.7 11.6 11.6	Seki *et al.* (2003)	R
Oryzias latipes, started with	4-nonylphenol	Semi-static, renewal of test	M (arith. mean)	100	Mixed secondary sex characteristics	2.9	8.7	Balch and Metcalfe	R

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
fertilized eggs/embryos		water every 48 h			Induction of testis-ova Sex ratio/phenotype	8.7 >29	29	(2006)	
Pimephales promelas, 30 d old	4-nonylphenol	Flow-through, ASTM 1993 Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. E1022-84 USEPA equivalent or similar to OECD Guideline 215 (Fish, Juvenile Growth Test)	M (arith. mean)	28	Growth Mortality	38 77.5	77.5 193	Brooke (1993a)	R
Pimephales promelas, embryos < 24hrs old	4-nonylphenol, branched	Flow-through,	M	33	Survival	7.4	14	Ward and Boeri (1991a)	R
Pimephales promelas Experiment 1: 8 months old male	4-nonylphenol	Flow-through,	M	28	Comp. spawn. assay	At 0.15 µg NP/L NP-exposed males out-competed control males, but at 0.25,		Schoenfuss *et al.* (2008)	R

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
						0.63 and 3.2 µg NP/L control-exposed males out-competed NP-exposed males			
					GSI (7 d after cessation of exposure)	>3.2			
					HIS (7 d after cessation of exposure)	>3.2			
					Histology (7 d after cessation of exposure)	>3.2			
					Mortality	42% at 0.15µg NP/L, 16% at 3.2 µg NP/L, 10% for control and 0.25 and 0.63 µg NP/L			
					Sec. sex charact. (7 d after cessation of exposure)	>3.2			
					VTG induction (7 d after cessation of exposure)	>3.2			
Experiment 2: 9 months old male					Comp. spawn. assay	At 0.3 and 5 µg NP/L NP-			

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
						exposed males out-competed control males, but at 11and 15 µg NP/L control-exposed males out-competed NP-exposed males			
					GSI (7 d after cessation of exposure)	>15			
					HIS (7 d after cessation of exposure)	>15 (HSI was sign. increased at 0.3 µg NP/L but not in any other group)			
					Histology (7 d after cessation of exposure)	>15			
					Mortality	20% at 0.3µg NP/L , ≤10% for control and the other groups			
						>15			

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
					Sec. sex charact. (7 d after cessation of exposure) VTG induction (7 d after cessation of exposure)	11 (Increased VTG in males after 7 and 14 d exposure in 15 µg NP/L, but no sign. effect 7 d after cessation of exposure)	15		
Salmo salar, juveniles	4-nonylphenol	Flow-through, equivalent or similar to OECD Guideline 215 (Fish, Juvenile Growth Test)	N	30	Mortality	>20		Moore *et al.* (2003)	NR
Xiphophorus helleri, 30d old juveniles	4-nonylphenol	Static	N	60	Growth of swordtail	<0.2		Kwak *et al.* (2001)	NR

B.7.1.1.2. Aquatic invertebrates

B.7.1.1.2.1. Short-term toxicity to aquatic invertebrates

The lowest valid short-term toxicity value for freshwater invertebrates reported in the EU risk assessment (ECB 2002) was the 96-hour EC_{50} of 20.7 µg NP/L for the amphipod *Hyalella azteca* by Brooke (1993a). The lowest valid acute toxicity value for *Daphnia magna* is a 48-hour EC_{50}(immobilisation) of 85 µg NP/L from the same study by Brooke (1993a). This value was selected in the CSR (Lead registrant 2010) and used for the CSR. The value chosen to represent acute toxicity of NP for freshwater invertebrates in this assessment is the same as in the EU risk assessment (ECB 2002)), i.e. the 96-hour EC_{50} of 20.7 µg NP/L for the amphipod *Hyalella azteca.*

For marine invertebrates the lowest value from a valid short-term toxicity study reported in the EU risk assessment (ECB 2002)was a 96-hour LC_{50} of 43 µg NP/L for the mysid *Mysidopsis bahia* (Ward and Boeri, 1990b). The value selected in the CSR (Lead registrant 2010) was the 48-hour LC_{50} of 51 µg NP/L for *Daphnia magna* in saltwater by Hirano *et al.* (2004), which is based on nominal concentrations. The value chosen to represent acute toxicity for marine invertebrates in this assessment is the same as in the EU risk assessment (ECB 2002), i.e. the 96-hour LC_{50} of 43 µg NP/L for the mysid *Mysidopsis bahia.*

Arslan and Parlak (2007) exposed embryos of sea urchin (*Arbacia lixula*) for seven different nominal concentrations of nonylphenol ranging from 0.937 to 18.74 µg NP/L for 72 hours in a static test design. The parameters evaluated were larval malformations, developmental arrest and embryonic/larval mortality. Low concentrations (from 0.937 µg NP/L) caused skeletal malformations in a proportion significantly different from the controls which increased with increasing doses. At the highest concentration (18.74 µg NP/L) resulted in an almost complete inhibition of growth of the embryos in the early life stages by preventing mitosis. These results indicate that the LC_{50} of 43 µg NP/L for *Mysidopsis bahia* (Ward and Boeri, 1990c) may underestimate the acute toxicity of NP for marine invertebrates.

B.7.1.1.2.2. Long-term toxicity to invertebrates

Long-term toxicity studies on invertebrates are summarised in Table 16 below.

The lowest valid long-term toxicity value for freshwater invertebrates reported in the EU risk assessment (ECB 2002) was the 21-day $NOEC_{surviving\ offspring}$ of 24 µg NP/L for *Daphnia magna* by Comber *et al*. (1993). In the EU risk assessment (ECB 2002) the results by Kopf (1997), i.e. a 21-day $NOEC_{reproduction}$ for *Daphnia magna* of 1 µg NP/L, was only considered to show that the NOEC was between 1 and 10 µg NP/L since the interval between test concentrations was considered to large to allow a NOEC to be defined. In addition, the effect value was based on nominal concentrations. The same value as in the EU risk assessment (ECB 2002)), i.e. 24 µg NP/L was selected in the CSR (Lead registrant 2010) for use in the CSA and this is also the value selected for PNEC derivation in this assessment

Höss *et al.* (2002) exposed the nematode *Caenorhabditis elegans* to NP over a whole life-cycle (72 h) under static exposure conditions according to the method presented by Traunspurger *et al.*

(1997), which later was approved as the standard test method ISO 10872:2010 and is a 96 h test. Survival of the nematode was 100% in the control and all the NP exposure groups (mean measured concentrations 40.2, 65.6, 106.5, 150.8, 189.2, 213.9, and 235.2 µg NP/L). The study was considered by the authors to be a full life-cycle test. Both growth and reproduction were enhanced in the presence of NP and were significantly different from control at 65.6 and 40.2 µg NP/L and above, respectively. Effects on growth and reproduction were dose dependent with dose-response curve levelling off at 65.6 and 106.5 µg NP/L, respectively. While growth only increased slightly (max 1.1-fold), the reproduction almost doubled. The reasons for these stimulating effects are not known.

England (1995) exposed neonates of the cladoceran *Ceriodaphnia dubia* to nonylphenol for seven days in a static renewal test. The result showed a significant reproductive impairment at 202 µg NP/L but not at 88.7 µg NP/L, resulting in a NOEC/LOEC of 88.7/202 µg NP/L. NOEC/LOEC for mortality was determined to 202/377 µg NP/L.

Kahl *et al.* (1997) exposed the midge *Chironomus tentans* to nonylphenol from <24-h old larva through emergence (53 d) as adults. Nominal exposure concentrations ranged from 12.5 to 200 µg/L, but mean measured concentrations used were lower. Neither growth nor reproductive endpoints (sex ratio, emergence pattern, and egg production and viability) were negatively affected at any of the exposure concentrations. There was a significant effect on survival of larvae during the first 20 days of exposure, but no effect after 20 days. Based on survival at 20 days, the mean measured concentrations for the NOEC and LOEC for this study were 42 and 91 µg/L, respectively.

Brooke (1993b) conducted a 21-day chronic toxicity study using on *Daphnia magna* exposed to nonylphenol under static renewal conditions. The daphnids were exposed to control and nonylphenol at average measured concentrations of 44.3, 63.1, 116, 215, and 500 µg NP/L. The resulting NOEC/LOEC for growth (mean length of surviving parent) and reproduction (mean number of young/starting adult) were for both endpoints 116/215 µg NP/L.

Comber *et al.* (1993) performed a 21-day-chronic toxicity study on *Daphnia magna* exposed to nonylphenol under static renewal conditions. The daphnids were exposed to control, solvent control, and nonylphenol at average measured concentrations of 14, 24, 39, 71, 130, and 250 µg NP/L. The 21-day NOEC/LOEC based on reproduction was 24/39 µg NP/L and on growth 39/71 µg NP/L. The sublethal effects included were number of offspring/surviving parent and the length of parent.

For marine invertebrates the lowest value from a validated long-term toxicity study reported in the EU risk assessment (ECB 2002) was a 28-day $NOEC_{length}$ of 3.9 µg NP/L for the mysid *Americamysis bahia* (formely *Mysidopsis bahi)a* by Ward and Boeri (1991b). The data by Ward and Boeri (1991b) is not included in the CSR (Lead registrant 2010) where instead the value selected was the 28-day $NOEC_{reproduction}$ of 9.5 µg NP/L for *Americamysis bahia* by Kuhn *et al.* (2001). The long-term toxicity value for marine invertebrates selected for PNEC derivation in this assessment is the same as in the EC (2002), i.e. the 21-day $NOEC_{length}$ of 3.9 µg NP/L for the mysid *Mysidopsis bahia*.

Ward and Boeri (1991b) performed a 28-day chronic toxicity test with the marine mysid *Americamysis bahia*. The exposure groups used were control and the measured concentrations 3.9, 6.7, 9.1, 21 µg NP/L. Growth (length) was the most sensitive endpoint, with a NOEC/LOEC of 3.9/6.7 µg NP/L. There was no effect on either survival or reproduction at 6.7 µg NP/L, but an 18% reduction in survival and a 53% reduction in reproduction were observed at 9.1 µg NP/L.

There are however results indicating that the no-effect level for at least marine invertebrates is below 1 µg NP/L, such as the studies by Marcial *et al.* (2003) and Nice (2005).

Nice (2005) exposed the Pacific oyster *Crassostrea gigas* to nonylphenol at concentrations of 1 or 100 µg NP/L for a duration of 72 h during the period of gametogenesis. As oysters at the onset of gametogenesis were required a number of juveniles (30 out of a total of 150) were sacrificed in order to confirm their stage of development by histological examination (all were confirmed to be at this stage). Six replicates (volume 2 l) were employed at each concentration of nonylphenol in addition to the seawater and solvent controls (methanol). Five oysters/replicate were exposed for a period of 72 hours. Oysters were fed daily to maintain an algal count of 50000 cells/ml from a mixed algal supply. At the end of the exposure all oysters were rinsed with filtered seawater and placed in a flow-through system where they were grown on to a sexual maturity (a further four months). Temperature (20 ± 2 °C), salinity (35 ppt), dissolved oxygen (95-100%) and pH (7.8-8.1) were monitored throughout the duration of the experiment and there were no detectable differences between controls and the exposed groups. Growth was monitored at regular intervals until sexual maturity when sperm motility was assessed. Sperm motility was assessed in males by placing the gamete samples separately in a drop of seawater on a chambered slide and observing for motility for a ten minute period. The growth rate of *C. gigas* remained unaffected by exposure to nonylphenol during gametogenesis. However, the number of individuals with motile sperm was significantly reduced. Hundred percent of the oysters had motile sperm in both the controls (seawater and seawater/methanol) compared with 30% of the oysters from the 1 µg NP/L treatment and 10% from the 100 µg NP/L treatment ($p<0.001$ for both treatments). Monitoring of sperm motility has been criticized in the published literature in a range of studies of fish. Oyster sperm differs from fish sperm in that it typically remains motile for up to 5 hours upon contact with seawater as compared with 1-4 minutes, which is typical for most fish. Based on this and in order to avoid subjectivity in the interpretation of sperm velocity the authors decided simply to monitor the sperm according to whether or not it was motile or not. The results from this study can not be used to derive NOECs for the assessment since no measurements were made of the concentrations used but they do indicate that the NOEC should be well below 1 µg NP/L.

Marcial and co-authors (2003) studied effects on development and reproductive characters in two successive generations of the marine copepod *Tigriopus japonicus* after exposure to a number of estrogenic compounds including nonylphenol. The experiment consisted of one negative control of seawater, a solvent control containing 0.001% DMSO in seawater, and four concentrations of each compound (0.01, 0.1, 1.0, and 10.0 µg NP/L). Each treatment had three replicates. All concentrations were nominal concentrations. Twenty nauplii (<24 h old) were individually allocated to 24-well plates containing 1 ml of the test solution with *Nanochloropsis oculata* (7×10^6 cells/ml)

and checked daily under a stereo-microscope. Test solutions were renewed (~50% of the working volume) daily, at which *N. oculata* was added and survival and developmental stage were assessed. On day 8, all surviving copepodids in each treatment were transferred to each chamber of six-well plate with 10 ml test solution and N. oculata to initiate copulation. After 2 to 3 d, six mature females (females bearing ovisacs) were randomly selected from the population and transferred individually into new plates. The number of nauplii produced up to the third brood was monitored for each copepod. On day 21, the remaining copepods were fixed in 4% buffered formaldehyde solution for determination of sex of unfertilized females based on their antenna ans swimming appendages. Percentage survival was also calculated. The first brood of nauplii (F1) produced by the parental copepods were cultured in the same culture conditions and the same chemical concentrations. The same parameters as the parentals (days to reach copepodid and sexual maturation, fecundity, sex ratio, and survival) were monitored for 21 d. The first brood of nauplii (F1) produced was monitored further under the same culture and exposure conditions. A significant delay in the completion of naupliar stages in the parental generation was observed in copepods exposed to 1 and 10 µg NP/L. The delay was even more apparent in the F1 generation, in which a significant delay was observed in the 0.1, 1 and 10 µg NP/L dose group. The exposure to nonylphenol also significantly delayed the time it took to mature for both the parental (10 µg NP/L) and the F1 (1 and 10 µg NP/L) generations. The results from this study can not be used to derive NOECs for this assessment since no measurements were made of the concentrations used, the large spacing between the doses used and the scarcity of data on the exposure conditions (as regards dissolved oxygen concentration, pH, temperature, etc.), but they do indicate that the NOEC should be below 0.1 µg NP/L.

Table 16 Long-term toxicity data for invertebrates.

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
Freshwater									
Caenorhabditis elegans, juveniles	Nonylphenol	Static, ISO10872:2010	M (arith. mean)	3	Mortality Growth Reproduction	>235 40.2	 65.6 40.2	Höss *et al.* (2002)	R
Ceriodaphnia dubia, <24 hr	4-nonylphenol	24-25°C, 6.4-7.9 mg O_2/L, 144-172 mg $CaCO_3$/L, pH 8.3-8.6	M	7	Reproduction Mortality	88.7 202	202 377	England (1995)	R
Ceriodaphnia dubia, <24 hr	4-nonylphenol	Semi-static, ISO/CD 20665 procedure (2001)	N	7	Reproduction	1		Isidori *et al.* (2006)	NR
Chironomus tentans, first instair	Nonylphenol	Flow-through, equivalent or similar to OECD 219	M (arith. mean)	20	Mortality	42	91	Kahl *et al.* (2002)	R
Daphnia galeata, <24 hr	p-nonylphenol	Semi-static, equivalent or similar to OECD Guideline 211 (Daphnia magna Reproduction Test)	N	21	Mortality Reproduction	50 50		Tanaka and Nakanishi (2002)	NR
Daphnia magna, <24 hr	Nonylphenol	Semi-static, OECD 202, part II, 1984	M*	21	Reproduction Mortality	>100 >100		Scholz (1992b)	R
Daphnia magna, <24 hr	4-nonylphenol	Semi-static, ASTM 1991. Standard Guide for Conducting Renewal Life-Cycle Toxicity Tests with	M (arith. mean)	21	Mortality Reproduction	116 116	215 215	Brooke (1993b)	R

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
		Daphnia magna							
Daphnia magna, <24 hr	Nonylphenol	Semi-static, OECD 202	M (arith. mean)	21	Reproduction Growth Mortality	24 39 130		Comber *et al.* (1993)	R
Daphnia magna, <24 hr	4-nonylphenol	Semi-static, equivalent or similar to ASTM 1988. Standard Guide for Conducting Renewal Life-Cycle Toxicity Tests with Daphnia magna)	N	21	Reproduction Mortality	50 >100		Baldwin *et al.* (1997)	NR
Daphnia magna, <24 hr	Nonylphenol	Static	N	21	Reproduction	1	10	Kopf (1997)	NR
Daphnia magna, <24 hr	Nonylphenol	Semi-static, equivalent or similar to OECD 211 (Daphnia magna Reproduction Test)	N	21	Reproduction Mortality	13 25	25 50	Sun and Gu (2005)	NR
Daphnia magna, <24 hr	4-nonylphenol	Semi-static, equivalent or similar to ISO 2000 Water Quality-Determination of Long Term Toxicity of Substances to Daphnia Magna Straus(Cladocera, Crustacea)	N	21	Mortality Reproduction	40 60		Brennan *et al.* (2006)	NR

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	NOEC (µg/L)	LOEC (µg/L)	Reference	Reliable & relevant
Saltwater									
Mysidopsis bahia, <24 hr	Nonylphenol	Static	M	28	Length	3.9	6.7	Ward and Boeri (1991b)	R
Americamysis bahia, 24 hr	4-nonylphenol	Flow-through, ASTM 1990. Standard Guide for Conducting Life-cycle Toxicity Tests with Saltwater Mysids. E1191-90	M (arith. mean)	28	Reproduction Mortality	9.5 27.6		Kuhn *et al.* (2001)	R
Crassostrea gigas	Nonylphenol	Static 20 ± 2 °C Dissolved oxygen 95-100% Salinity 35 ppt pH 7.8-8.1	N	3	Growth Mean % of oysters with motile sperm	>100 <1		Nice (2005)	NR
Tigriopus japonicas, <24 hr	4-nonylphenol	Semi-static 25 ± 1 °C Salinity 25 ppt	N	21	Development rate F0 (nauplii stages) F1 (nauplii stages) F0 (sexual maturity) F1 (sexual maturity) Mortality Reproduction Sex ratio	 0.1 0.01 1 0.1 >10 >10 >10	 1 0.1 10 1	Marcial *et al.* (2003)	NR
Tisbe batagliai, <24 hr	4-nonylphenol	Semi-static	M (arith. mean)	53	Mortality	20		Bechmann (2005)	R

*The reported effect value is based on nominal concentrations, but the concentrations were measured and within 80% of the nominal values.

B.7.1.1.3. Aquatic algae and plants

Toxicity tests for primary producers in fresh- and marine water are available in Table 17 below. Only studies of relevance for the derivation of $PNEC_{water}$ are commented in detail below. The freshwater and marine water algae studies are discussed first and after that the study on the aquatic plant *Lemna minor* is presented.

The lowest valid short-term toxicity value for freshwater algae reported in the EU risk assessment (ECB 2002) was a 72-hour $EC_{50\ biomass}$ of 56.3 µg NP/L for the algae *Scenedesmus subspicatus* by Kopf (1997). It is noteworthy that it is stated in the CSR (Lead registrant, 2010) that Kopf (1997) could not be used due to ownership issues. The value selected in the CSR (Lead registrant, 2010) was the 96-hour EC_{50} 410 µg NP/L for the algae *Pseudokirchneriella subcapitata* by Ward and Boeri (1990a). The lowest valid value for short-term toxicity to freshwater algae selected in this assessment is from the same study as was selected in the EU risk assessment (ECB 2002)), i.e. Kopf (1997), but with the endpoint growth rate instead of biomass resulting in a 72-hour EC_{50} of 323 µg NP/L for the algae *Scenedesmus subspicatus.*

The lowest valid long-term toxicity value for freshwater algae reported in the EU risk assessment (ECB 2002) was the 72-hour EC_{10} of 3.3 µg NP/L for the algae *Scenedesmus subspicatus* by Kopf (1997). However, the endpoint resulting in 3.3 µg NP/L is biomass which no longer is considered relevant, while the preferred endpoint now is growth rate (ECHA Guidance on information requirements and chemical safety assessment: Chapter 7.b: Endpoint specific guidance), for which the value in the study by Kopf (1997) instead is 25.1 µg NP/L.

As mentioned above, the CSR (Lead registrant, 2010) could not use the study by Kopf (1997) due to ownership issues. The value selected in the CSR (Lead registrant, 2010)was instead the 72-hour EC_{10} of 500 µg NP/L for the algae *Scenedesmus subspicatus* by Scholz (1989), which is higher than the acute toxicity value of 410 µg NP/L selected in the CSR (Lead registrant, 2010). However, this value is not based on the preferred endpoint growth rate, but instead on cell number. No growth rate is available and it is not possible from the data available in CSR (Lead registrant 2010) to calculate it.

Also in the study by Brooke (1993a) the endpoint given is biomass and not growth rate. It is not from the data available in the CSR (Lead registrant 2010) possible to calculate the growth rate and the result from this study will therefore not be used in this assessment.

The lowest valid long-term toxicity value for freshwater algae selected in this assessment is the 72-hour EC_{10} of 25.1 µg NP/L for the endpoint growth rate for the algae *Scenedesmus subspicatus* from the study by Kopf (1997). It is unfortunately not possible to provide a more thorough description of this study since no more information is available. This study has however been considered to be both relevant and reliable in the EU risk assessment (ECB 2002), and will therefore also be considered the same in this assessment.

In the study by Ward and Boeri (1990a) on the freshwater algae *Selenastrum capricornutum* the endpoint given is cell growth (cell number) and not growth rate. Based on the available information

in the robust study summary a 72 hour EC10 growth rate was estimated (fitted-by-eye) to be about 270 µg NP/L.

The lowest valid short-term toxicity value reported in the EU risk assessment (ECB 2002) for marine water was a 96-hour EC_{50} of 27 µg NP/L for the alga *Skeletonema costatum* by Ward and Boeri (1990b. The same value was selected in the CSR (Lead registrant, 2010) for use in the CSA. The basis for effect, according to the robust study summary in CSR (Lead registrant, 2010), is cell number and not the preferred endpoint growth rate. It is not possible from the data available in the CSR (Lead registrant, 2010) to calculate the growth rate. As a consequence of that the results for *Skeletonema costatum* will not be used in this assessment.

As regards effects on aquatic plants, a reliable study on exposure of the monocot *Lemna minor* (Araceae) to nonylphenol performed under flow-through conditions was reported by Brooke (1993b) with 96-hour test results based on frond production. The measured test concentrations used were <88, 109, 375, 901, and 2080 µg NP/L. The NOEC and LOEC for inhibition of *Lemna minor* frond production was 901 µg NP/L and 2080 µg NP/L, respectively. It is unfortunately not possible to provide a more thorough description of this study since no more information is available. This study has however been considered to be both relevant and reliable in the EU risk assessment (ECB 2002), and will therefore also be considered the same in this assessment.

Table 17 Toxicity tests for primary producers in fresh- and marine water.

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	EC_X (µg/L)	NOEC/LOEC (µg/L)	Reference	Reliable & relevant
Freshwater									
Lemna minor	4-nonylphenol	Flow-through, ASTM 1991. E1415-91 Standard Guide for Conducting Static Toxicity Tests with Lemna gibba	M	4	Frond number		NOEC: 901 LOEC: 2080	Brooke (1993a)	R
Scenedesmus subspicatus (new name: Desmodesmus subspicatus)	Nonylphenol	Static, Algal growth inhibition test according to UBA (Feb. 1984)	N	3	Biomass	EC_{10}: 500 EC_{50}: 1300		Scholz (1989)	NR
Scenedesmus subspicatus (new name: Desmodesmus subspicatus)	Nonylphenol	Static	M	3	Growth rate Biomass	EC_{10}: 25.1 EC_{50}: 323 EC_{10}: 3.3 EC_{50}: 56.3		Kopf (1997)	R
Selenastrum capricornutum (new name: Pseudokirchnerella subcapitata)	4-nonylphenol	Static, TSCA Test Standards 40 CFR 792.1050	M	1 2 3	Cell number Growth rate	EC_{10}: 410 EC_{50}: 530 EC_{10}: 80 EC_{50}: 440 EC_{10}: 120 EC_{50}: 330 EC_{10}: 270*		Ward and Boeri (1990a)	R
Selenastrum capricornutum (new name: Pseudokirchnerella	4-nonylphenol	Static, Stephan et al (1985) Guidelines for	M (arith. mean)	4	Biomass		NOEC: 694 LOEC: 1480	Brooke (1993a)	NR

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	EC_X (µg/L)	NOEC/LOEC (µg/L)	Reference	Reliable & relevant
subcapitata)		deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. EPA PB 85-2270 ASTM (1991b) Standard guide for conductiong static 96-hr toxicity tests with algae. ASTM Annual Book of Standards 11.04:1218-90							
Pseudokirchnerella subcapitata	4-nonylphenol	Static, ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with Scenedesmus subspicatus and Selenastrum capricornutum)	M (arith. mean)	3	Growth rate	EC_{50}: 530		Graff *et al.* (2003)	R
Saltwater									
Skeletonema costatum	4-nonylphenol	Static, equivalent or similar to EPA	M	3	Cell number	EC_{50}: 27		Ward and Boeri (1990b)	R

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	EC_X (µg/L)	NOEC/LOEC (µg/L)	Reference	Reliable & relevant
		OTS 797.1050 (Algal Toxicity, Tiers I and II) Test Standard 40 CFR 797.1930							

*Fitted-by-eye, see text above.

B.7.1.1.4 Other aquatic organisms

Studies on amphibians exposed to nonylphenol have been presented in both the EU risk assessment (ECB 2002) and the CSR (Lead registrant, 2010).

Dwyer *et al.* (2005) performed a number of 96-hour static acute toxicity studies on fish (see above) but also included tests on the boreal toad (*Bufo boreas boreas*). The reported 96-hour LC_{50} for the toad was 120 µg NP/L. However, since the toxicity values for all tests are based on nominal concentrations, the test chemical purity was 85%, the reported LC_{50}-values therefore only have informative value.

Ward and Boeri (1992) studied the toxicity of nonylphenol ontadpoles of the American bullfrog (*Rana catesbiana*) by exposing them to nonylphenol for up to 30 days in a sediment/water system. Nonylphenol was added to the sediment in the test vessels and dilution water added on a flow through basis. Concentrations were measured in the sediment and water throughout the test and were found to be highest in the test water at the beginning of the test, decreasing significantly during the first 10 days of the test and more gradually during the last 20 days of the test. The tadpoles used in the study were all stage VI through IX, as characterised by the presence of hind paddles and respiration by gills. The 30-day LC_{50} was 260 mg/kg dry weight and the 30 day EC_{50} was 220 mg/kg dry weight. At 10, 20 and 30 days the lowest observed effect level (LOEL) was 390 mg/kg dry weight and the no observed effect level (NOEL) was 155 mg/kg dry weight. The authors noted that the levels of nonylphenol in the water were high enough to cause the observed toxicity and it is not possible to attribute the toxic effect to either water or sediment exposure.

B.7.1.1.5 Endocrine properties of nonylphenol

The endocrine properties of NP have previously been described in the EU risk assessment (ECB 2002), the CSR (Lead registrant 2010) and the German SVHC-proposal (BAuA 2012). Much of the text below in this section originates from these sources. In order to increase the transparency all citations made in this specific section has a different font (Arial) in *italic* within citation marks.

Endocrine assessment in the EU risk assessment (ECB 2002)

In the EU risk assessment (ECB 2002) it was stated that "*The oestrogenic effect of nonylphenol on fish and Daphnids has been studied by a number of authors. Generally the work shows that nonylphenol and nonylphenol ethoxylates do exhibit oestrogenic activity. For nonylphenol ethoxylates the activity was found to increase with decreasing chain length, with nonylphenol showing the greatest activity. Most of the tests indicate that oestrogenic effects may start to occur at around 10-20 µg/l…*"

The following studies were described in the section on endocrine disruption in the EU Risk assessment (ECB 2002):

- two *in vitro* studies using hepatocytes from rainbow trout (Jobling and Sumpter 1993, White *et al.* 1994) in which exposure to NP resulted in induction of the yolk protein vitellogenin. The relative potency of NP to oestradiol-17β in the study by Jobling and Sumpter (1993) was determined to be 0.0000090. White *et al.* (1994) found that NP displayed competitive displacement of oestrogen from its receptor sites.
- three *in vivo* studies using rainbow trout (Jobling *et al*. 1996, Harries *et al*. 1995, Ashfield *et al*. 1998).
    - In the study by Jobling *et al.* (1996) exposure to NP in water for three weeks resulted in significantly elevated levels of vitellogenin in the blood as compared to the control with NOEC/LOEC of 5.02/20.3 µg NP/L in two-year old male rainbow trout. In addition, at the highest concentration used (54.3 µg NP/L) a significant reduction of testis size, expressed as gonadosomatic index was also observed.
    - In the study by Harries *et al*. (1995) rainbow trout were exposed to NP for three weeks in concentrations ranging from 0.24 – 54.3 µg NP/L, with significantly increased blood levels of vitellogenin at the two highest doses, 20.3 µg NP/L (a 10-fold increase as compared to the control) and 54.3 µg NP/L (a 1000-fold increase as compared to the control).
    - In the study by Ashfield *et al*. (1998) female juvenile rainbow trout were exposed to NP in a flow-through system from hatch to early sexual maturity (approx. 1 month after hatch). "*Two series of experiments were conducted. In the first series, exposure to nonylphenol (nominal concentrations 1, 10 and 50 µg NP/L) was for 22 days from hatch, and monitoring of the fish was continued for a further 86 days. In the second series, exposure to nonylphenol (nominal concentrations 1, 10 and 30 µg NP/L) was for 35 days from hatch, with monitoring of fish continuing for a further 431 days. At the end of the first series of tests, fish that had been exposed to 1 and 50 µg NP/L showed a statistically significant ($\rho<0.001$ and $\rho<0.01$ at the two concentrations respectively) lower body weight relative to controls (the 10 µg NP/L group was not significantly different from the control group).*" In the second series of experiments, effects on growth (mainly decreased body weight) were observed at the two highest concentrations, at various intervals of the experiment. In addition, the ovosomatic index (OSI = (100×gonad weight/[bodyweight-gonad weight]) was determined, and was found to be significantly ($\rho<0.05$) elevated in the 30 µg NP/L group. The authors concluded that "…*significant effects on growth of the fish had occurred during the test, although the mechanism by which nonylphenol caused these effects was unclear.*"
- one *in vivo* study using Japanese Medaka exposed from 1 or 2 days post hatch to 3 months of age (Gray and Metcalfe 1997). Analysis indicated that the nominal concentrations (10, 50 and 100 µg NP/L) fell over the 48-hour (month 1) or 72-hour (month 2 and 3) renewal periods and "…*the mean measured concentration over the renewal period was around 55% of the nominal for 72-hour renewal and 66% for 48-hour renewal.*" The NP exposure resulted in testis-ova with a NOEC/LOEC of 10/50 µg NP/L "…*At 100 µg NP/L the authors suggested that sex reversal (male to female) may also be occurring as the ratio of males to females was different to that seen in controls or*

the 10 and 50 µg NP/L treatments, however this could also be due to different mortality patterns in the various treatments (i.e. greater mortality in male fish at 100 µg NP/L)."

- three studies using intraperitoneal administrations of NP, one in Channel Catfish (Nimrod and Benson 1996) one in flounders (Christensen *et al*. 1995) and on in Alantic Salmon (Arukwe *et al*. 1997).
    - In the study using Channel Catfish the induction of serum vitellogenin from exposure of NP was much lower than that found from exposure of 17β-estradiol by a factor of around 5,000 (i.e. a 500 times higher dose of nonylphenol resulted in a 10 times lower serum vitellogenin level compared with that seen with 17β-estradiol).
    - In the study with flounders Vitellogenin was detected in plasma of fish dosed with 10 mg NP/kg wet weight. Effects were also seen on plasma lipids (increase), protein (increase) and ninhydrin positive substances (decrease). Toxic effects (cell damage), as indicatedby increased activity of the plasma enzyme GPT was also found.
    - In the study using Atlantic salmon the effects on steroid metabolising enzymes from the liver were studied. The report concluded that nonylphenol might increase the activity of steroid-metabolising enzymes at low concentrations but decrease the activity of these enzymes at high concentrations.

- one *in vivo* studiy using *Daphnia magna* in both acute (48-hour) and long-term (3-week) NP exposure regimes (Baldwin *et al.* 1997). After the exposure periods the daphnids were exposed to ^{14}C testosterone for a further 16 hours to investigate the effects on steroid hormone metabolism. The author concluded from the results in the short-term study that NP "…*is capable of significantly perturbing components of androgen metabolism at concentrations ≤ 25 µg NP/L*." In the long-term study "…*the number of off-spring was reduced on exposure to 50 or 100 µg NP/L, but this reduction was only statistically significant (p=0.05) at 100 µg NP/L. The reproductive chronic value derived from these data was 71 µg/l (geometric mean of the NOEC and LOEC for reproduction) and this concentration was estimated to reduce the elimination of testosterone by approximately 50%. The results indicate that nonylphenol can cause effects on steroid hormone metabolism that may contribute to its reproductive toxicity (Baldwin et al., 1997).''*
- one *in vivo* study using *Daphnia galeata mandotae* to study the effects of NP long-term exposure (30-days) on both the asexual and sexual reproduction (Shurin and Dodson 1997). Exposure to the NP resulted in deformed live offspring/adult in a dose-dependent relationship and no such deformed offspring were seen in the two controls. "*The deformed offspring were of similar size to normal offspring but had forward curled tail spines and lacked, or had severely reduced, terminal setae on their second antennae, which reduced the swimming ability of the organism. This deformity was seen in 11% of live young at the lowest NP concentration used (10 µg NP/L) and only animals that were prenatally exposed to nonylphenol exhibited this deformity.''*

Endocrine assessment in the CSR (Lead registrant 2010)

It was in the CSR (Lead registrant 2010) concluded that "*EURAR 2002 found that reliable data indicate oestrogenic effects of nonylphenol can occur around 10-20 ug/L. Although the subsequent individual test data (Nice 2005, Tabata et al. 2001) presents effects seen at lower concentrations study, however reliability is questionable according to ENVIRON. There are no other reliable data available that confirm such results.*
The calculated $PNEC_{freshwater}$ and $PNEC_{marine}$as presented in this CSR Report are 0.614 ug/L and 0.527 ug/L and therefore, likely protective of oestrogenic effects exerted by nonylphenol.'' The following studies were described as below in the section on endocrine disruption in the CSR (Lead registrant 2010):

- *''Fathead Minnow (Pimephales promelas)"*
    - *"Harries et al. (2000) found that serum vitellogenin (VTG) induction occurred at 8.1 – 57.7 µg/L in a paired-breeding experiment. "*
    - *"Giesy et al. (2000) determined a 42-day NOEC of 3.4 µg/L when measured elevation of plasma E2. "*
    - *"Miles-Richardson et al. (1999) found there was no effect on tubercle or fat pad size or survival at 3.4 µg/L when fish were exposed in flow through test for 42 days. "*
    - *"Schoenfuss et al. (2008) determined a 7-day NOEC of 11 µg/L and LOEC of 15 µg NP/L when measuring VTG induction*."
- *''Rainbow Trout (Oncorhynchus mykiss)"*
    - *"Jobling et al. (1996) measured VTG concentration and spermatogenesis in adult males exposed to 30 µg/L (nominal) NP for three weeks. Results indicate VTG increased 100-1000 times more than the control while spermatogenesis was slightly delayed. The 21-day NOEC for reduced testis weight is reported at 20.3 µg/L. "*
    - *"Pederson et al. (1999) found a significant induction of VTG when exposing Rainbow Trout for 9 days in a flow through system. "*
    - *"Ackerman et al. (2002) exposed Rainbow Trout in a flow though system for one year resulting in VTG induction LOEC of 1.05 µg/L. The NOEC for ZRP expression in the liver was given at 1.05 ug/L."*
    - *"Ashfield et al. (1998) exposed Rainbow Trout in a flow-through system from hatch to early sexual maturity and assessed gonado(ovo) somatic index (OSI) of females. Elevated OSI was significant at the 30 µg/L NP exposure. "*
    - *"Tremblay and Van Der Kraak (1998) found increased VTG in blood plasma at 50 µg/L NP after juvenile fish were exposed for 21 days. "*
    - *"An increased VTG mRNA was found at 14.14 µg/L by Lech et al. (1996) when fish were exposed for 72 hrs."*
    - *"Harris et al. (2001) measured the ovasomatic index for 2 year old fish exposed to NP for 18 weeks. Results indicate the NOEC and LOEC to be 8.3 and 85 µg/L NP, respectively."*
    - *"Tollefsen et al. (2008) determined a 96 hr EC50 of 19.6 mg/L for metabolic inhibition.''*
- *''Other fish species''*

- Flounder
  - *"Allen et al. (1999) exposed adult male Flounder (P. flesus) to NP for three weeks. The 21-day NOEC for reduced testis weight is >24.5 ug/L and reduced liver weight is 7.2 ug/L. "*
- Japanese Medaka
  - *"Japanese Medaka (Orzias latipes) were exposed to NP for 100 days. The NOEC for secondary sex characteristics assessed was 10 ug/L, the NOEC for male papillary processes was 100 ug/L, and the NOEC for testis-ova was 30 ug/L (Balch and Metcalfe, 2003). "*
  - *"Gray and Metcalfe (1997) exposed post-hatch Medaka to NP for 90 days and found 50% of males exposed to 50 ug/L NP with testis-ova. "*
  - *"Yakota et al. (2001) found that secondary male sex characteristics were eliminated when Medaka were exposed to 51.5 ug/L NP, in a life-cycle test, but not at 17.7 ug/L NP. Testis-ova were significantly higher in the parent generation exposed at 17.7 ug/L NP, but not at 8.2 ug/L NP. "*
  - *"Kashiwada et al. (2002) found female-specific protein induction occurred in adult males when exposed to 0.1 – 100 ug/L NP for 5 weeks."*
  - *"The draft Environment Agency report also lists eight additional studies which assessed the oestrogenic effects of NP on Medaka. LOECs ranged from 0.1 ug/L for detection of female-specific proteins (Fsp) (Tabata et al. 2001) to 100 ug/L for abnormal gonad and testis-ova (Balch and Metcalfe 2006). However, it should be noted that Tabata et al. (2001) did not state the levels of Fsp that were detected in the male fish and whether it was significantly different from controls."*
- Carp
  - *"The draft Environment Agency report lists two studies which assessed the oestrogenic effects of NP on Carp (Cyprinus carpio) and one study with Swordtail fish (X. helleri). No oestrogenic effects were found when carp were exposed to 5.36 ug/L NP for 28-31 days (Villeneuve et al., 2002). "*
- Swordtail fish
  - *"VTG was induced at 4-100 ug/L NP in a three day exposure to Swordtail fish (Kwak et al., 2001)."*

- *"Water Flea (Daphnia magna)"*
  - *"Baldwin et al. (1997) investigated the effects of NP on testosterone metabolism and resulting effects on reproduction in a three week test. After 48 hr NP exposure to adults and after 3 week exposure to NP for neonates, daphnids were exposed to ^{14}C-labelled testosterone for additional 16 hours. Results indicate NP concentrations of <25 ug/L NP could significantly affect androgen metabolism, which may contribute to effects to reproduction."*

- *"Other aquatic organisms"*
  - Crab
    - *"The draft Environment Agency report summarizes studies performed using a crab (Carcinus aestuarii) and Pacific oyster (Crassostrea gigas). The NOEC for VTG induction were 50 ug/L NP for the crab (Ricciardi et al., 2008)."*
  - Pacific oyster
    - *"Nice (2005) exposed 3 month old juvenile Pacific oysters (Crassostrea gigas) to 1 and 100 ug/L NP for 72 hours. Oysters were then removed, rinsed and grown to sexual maturity in a flow-through system. At test termination, shell length and body weight was determined not significantly different from controls. However, study author found significant effects to sperm motility at 1 ug/L NP exposure. It should be noted that assessment of sperm motility (i. e., length of time, movement) in fish has been criticized for subjectivity by Kime and Nash (1999). The study author believed the method of assessment used in the study (motile or non-motile only) was adequate, however. No other reliable studies assessing sperm motility for NP exposed organisms were available for comparison. Therefore, study results should be taken cautiously."*
- *"Post-September 2008 Literature review"*
  - Shore crab
    - *"Lye et al. (2008) exposed intermoult male Shore crabs (Carcinus maenas) to measured concentrations of 10 and 100 ug/L NP for 12 weeks in a static-renewal system. Although no significant mortality occurred, significant effects were detected for gonad weight at 10 ug/L NP exposure. Significant increase in the hepatosomatic index was seen in the 10 ug/L exposure and a significant decrease in ecdysone equivalents in the 100 ug/L NP exposure. However, no induction of VTG was seen at either concentration."*
  - Atlantic Salmon
    - *"Kortner et al. (2009) exposed immature Atlantic salmon (salmo salar) to NP for 72 hrs. It was found that VTG mRNA in the liver significantly increased and MRNA levels of Cyp19a, step involved in estrogen production, was significantly decreased when exposed to 50 ug/L NP. This study indicates that oestrogenic effects can be observed on mRNA."*
  - *"Results of these studies are in agreement with studies reported and summarized in the EURAR (2002) and the draft Environment Agency report. Reliable studies investigating oestrogenic effects of NP to terrestrial organisms were not found."*

Endocrine assessment in the German SVHC-proposal (BAuA 2012)

The following text is taken from the German proposal to include NP on the Candidate List as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1997/2006 (REACH).

"Summary of how the substances meet the criteria of Article 57 (f)

4-Nonylphenol, branched and linear: substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, covering also UVCB- and well-defined substances which include any of the individual isomers or a combination thereof (short: 4-Nonylphenols) are proposed to be identified as substances of very high concern in accordance with Article 57 (f) of Regulation (EC) 1907/2006 (REACH) because they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which gives rise to an equivalent level of concern to those of other substances listed in points [(a) to (e)] of article 57 of REACH.

This conclusion is based on the fact that there is strong evidence from high quality studies of endocrine mediated adverse effects in fish species. Results for amphibians provide indication that effects in other taxa may be endocrine mediated i.e. caused by an estrogen-like mode of action, too.

According to the OECD (Organisation for Economic Co-operation and development) guidance document for endocrine disruptors (OECD, 2012) 4-nonylphenols need to be considered as endocrine disruptors based on these results. Moreover, based on the widely accepted IPCS definition for endocrine disruptors (WHO/IPCS, 2002; WHO: World Health Organization/IPCS: INSTITUTE OF PEACE & CONFLICT STUDIES) 4-nonylphenols are considered to be endocrine disruptors.

Based on the above conclusion, evidence that the substances are of an equivalent level of concern includes:

Evidence from several test data show that effects of the 4-nonylphenols on fish fit to those of other estrogen agonists which are considered serious for the environment due to the type of effects.

Effects remain manifest even after exposure has ceased and the fact that exposure during sensitive life stages may change the endocrine feedback system resulting in effects during the entire life:

- *Exposure to nonylphenol resulted in effects in fish on reproduction parameters (fecundity) as well as on sexual development (including changes in sex-ratio) and growth. Results for at least 3 fish species show that exposure to nonylphenol may*

result in a complete sex reversal resulting in all female populations. Effects observed include behavioural effects that may influence the gene pool.

- *Effects observed in several fish species show that transient exposure during sensitive life stages may result in effects that remain during the entire life and even in following generations. Thus exposure in one area might influence population stability in another area and effects persist even after exposure has ceased.*

- *In addition to the severity of effects, some results substantiate the hypothesis that it is difficult to quantify a safe level for 4-nonylphenols with regard to endocrine activity.*

- *Effects on non-traditional endpoints indicate that effects may start at much lower concentrations than those considered in OECD test guidelines.*

- *Exposure to 4-nonylphenols resulted in effects on reproduction and development in different invertebrates at concentrations below 1 µg/L (e.g. LOEC sex-ratio < 1 µg/l in mussels, LOEC development 0.09 µg/L in echinoderm species). Although it is not possible to clearly state that the effects are endocrine mediated, these effects fit to the knowledge that steroids are known to play an important role in invertebrates (Kendall et al., 1998). Owing to the lack of in depth knowledge of their endocrine system and the lack of test systems, it is currently nearly impossible to estimate which species are most sensitive and which concentration should be regarded as safe for the environment.*

Thus in summary, effects observed after exposure to 4-nonylphenols are considered to impair population stability and recruitment. They may occur even after short term exposure and thus may result in adverse effects in regions other than those where exposure occurred. Effects persist even after exposure has ceased and may influence population level on a long term basis e.g. due to transgenerational effects or changes in the gene pool. Effects may influence a wide range of taxa and it is difficult to estimate a safe level. Consequently they are considered to be of an equivalent level of concern.

The concern is substantiated by an analysis of literature of current knowledge on endocrine disruptors which reveals strong evidence that exposure to endocrine disrupting chemicals is linked to reproductive disorder and disfunction in wildlife. Although this is mainly due to exposure to steroidal estrogens, at some sites xenoestrogens may significantly contribute to the effect.''

*"**Analysis of available data for fish species**"*

"Effects on Oryzias latipes"
The studies included were Seki *et al*. (2003), Balch and Metcalfe (2006), Gray and Metcalfe (1997), Nimrod and Benson (1998), Yokota *et al*. (2001), Ishibashi *et al*., 2006), Kang *et al*. (2003) and Shioda and Wakabayashi (2000).

For the evaluation of O. latipes the following tests are available: Four fish sexual development tests (partly with considerable deviations), a full life-cycle test (1.5-generation) and 3 reproduction assays with some deviations. Two of the sexual development tests and two of the reproduction tests are scored as reliable 2 while the other tests are used as supportive information only."

"Summary.
Overall, increased levels of VTG (a widely accepted biomarker for an estrogen mode of action) were determined in all studies analyzing this endpoint. The lowest LOEC was 5.4µg/L for hepatic VTG in males (Ishibashi et al., 2006). In addition, the occurrence of testis-ova, as an indicator of an estrogenic effect according to the OECD guidance document 123 (OECD, 2010), was observed in all sexual development tests if examined and in one full life-cycle study, some testis- ova were observed even after short term exposure of adult males. The most significant effects were determined if the exposure began within 24 h after fertilization which is not surprising as female gonad development starts before hatch. The lowest LOEC value was 11.6µg/L (Seki et al., 2003).

Apical effects observed fit to these indicators of an estrogen mediated effect: The sex-ratio was significantly skewed toward females in all sexual development tests which included exposure during sensitive life stages (before hatch). Based on secondary sex characteristics significant effects started at 51.5 µg/L (Yokota) and 23 µg/L (Seki) with no and only one male developed at 51 and 44 µg/L respectively. The effect concentration decreased to 17.5 µg/L when eggs from exposed parents were used (Yokota).

Results from reproduction assays indicate that, in addition to the sex-ratio, 4-nonylphenols influence reproduction in medaka by an estrogen mode of action after exposure of adults. In both reliable tests vitellogenin was increased at lower or similar concentrations compared to impaired fecundity and fertility, with some indication that the increased VTG level in males might have caused male specific mortality at high concentrations."

"Fathead minnow (Pimephales promelas)"
The studies included were Harries *et al*. (2000), Miles-Richardson *et al*. (1999), Giesy *et al*. (2000), Schoenfuss *et al*. (2008), Ward and Boeri (1991b),

"With regard to Pimephales promelas two reproduction screeening assays, determining endpoints indicative for an endocrine disruption as well as apical endpoints are available (all with reliability Klimisch 2). In addition, one behaviour study with two experiments was

performed (including endpoints indicative for an endocrine mode of action as well as apical endpoints) and a normal early life stage test is available.''

''Summary.
In summary, results of the three reproduction assays are conclusive. They show, that 4-nonylphenols act via an estrogen mode of action in P. promelas:
The indicative endpoint VTG was examined in three assays (Harries 2000 and Giesy 2000 and Schoenfuss 2008). In two cases exposed mature males showed VTG induction at a LOEC of 71 µg/L (Harries, limit test) and 15 µg/L (Schoenfuss et al., 2008) while no effects in males up to 3.4 µg/L were observed in the third study (Giesy et al., 2000). Results from the second – less valid - test by Harries showed that vitellogenin induction might occur at lower concentrations (LOEC 8.1 µg/L).

In addition to this indicator for an estrogen mode of action, reduced male secondary sexual characteristics were observed in one test: Male fish at 71µg/L (limit test) had no tubercles and this result was supported by results from the –less valid - second experiment of this study (Harries, LOEC 57.7 µg/L). No such effects were observed at lower concentrations ((Miles-Richardson et al., 1999) and (Schoenfuss et al., 2008)) indicating that the LOEC is between 15 and 71 µg/L.

Results observed by Harries and Giesy, show that nonylphenol also impairs reproduction: (LOEC fecundity 71 µg/L (Harries, limit test, with some indication that effects may start at 3.4 µg/L (Giesy et al., 2000). Although apical effects started at similar or even lower concentration compared to biomarker responses, it seems very likely that they are estrogen mediated. Effects observed fit the endocrine mode of action and to effects observed in other species.

The endpoints for behavior determined by Schoenfuss during two competitive spawning assays are in line with the values for VTG and support the estrogen mode of action. Exposed males were outcompeted in two experiments with regard to access to nest-sites at 0.25 µg/L and 11µg/L for about 5 – 10%. Similar results with other endocrine disrupting substances support the hypothesis.

Results from the fish early life stage test by Ward and Boeri (1991) (LOEC mortality and time to hatch = 14 µg/L) fit to these findings. It is well known, that estrogens may induce mortality and delays in development.''

''Danio rerio:''
The studies included were Yang *et al*. (2006), Lin and Janz (2006), Weber *et al*. (2003), Hill and Janz (2003).

''With respect to Danio rerio, one modified reproduction screening assay (reliability 3) and two prolonged fish sexual development tests are available (reliability 2 and 3). All Studies include endocrine specific biomarkers as well as apical endpoints.''

‘‘Summary.
Tests available clearly prove an estrogen mode of action. All experiments showed an elevated concentration of VTG in males. The lowest concentration for VTG revealed was at 30µg/L in the fish sexual development test ((Hill and Janz, 2003), by western blot, no statistical analysis). In all other tests elevated VTG was observed at 100µg/L.

Other endpoints indicating the endocrine mode of action are:

- *The impaired gametogenesis described in the two FSDT studies by Lin and Janz (2006) and Weber (2003). In both studies the gametogenesis was shifted to younger stages of cells in males and females at 100µg/L. Weber conducted no statistical evaluation for that endpoint.*
  But Lin and Janz showed that the effect on the oogenesis in females at 100µg/L was significant. In males at 10µg/L initial effects on testicular development were observed; at
  100µg/l only histological females existed. In addition in one study ovo-testes were observed by Hill and Janz: At 30µg/l 1 of 20 fish and at 100µg/l 2 of 20 fish had ovo-testes.
- *The increase of ovarian follicle atresia being significant at 100 µg/L even 180 days after the end of exposure (Weber et al, 2003).*

In addition, the endpoint sex ratio was significantly impaired in two sexual development tests (Hill and Janz, 2003; Lin and Janz, 2006), with significant effects at 10 µg/L in one study (Lin and Janz, 2006) and no or only few males being observed in both studies after exposure to 100 µg/L nonylphenol.

Effects observed on fecundity by (Lin and Janz, 2006; Yang et al., 2006) at 50 and 100 µ/L even after exposure has been ceased, fit to the endocrine mode of action.

In summary, adult exposure as well as exposure during sexual development resulted in clearly endocrine mediated changes on the biomarker and the histological level. Changes in sex-ratio (a clear indicator of an estrogen agonist mode of action) as well as changes in fecundity fit to these changes. Fecundity was lowered (but not significantly) at 50µg/L, while the sex ratio was significantly impaired at 10µg/L. Thus, with regard to D.rerio, exposure to nonylphenol results in clearly endocrine mediated adverse effects, which are considered relevant for the population.’’

‘‘Rainbow trout: Oncorhynchus mykiss’’
The studies included were Ashfield *et al*. (1998), Ackermann *et al*. (2002b), Brooke (1993) (from the report U.S.EPA, 2005b), Jobling *et al*. (1996), Harris *et al*. (2001), Lahnsteiner *et al*. (2005), *Schwaiger et al. (2002),* Ward *et al*. (2006),

‘‘For the evaluation of the effects on O. mykiss several tests are available. Three tests can roughly be classified as short term screening assays (Harris et al., 2001; Jobling et al., 1996; Lahnsteiner et al., 2005; Schwaiger et al., 2002) and two tests are similar to the OECD fish sexual development test (Ackermann et al., 2002b; Ashfield et al., 1998); in addition one extended early life stage test is available (Brooke 1993 from the report (U.S.EPA, 2005b)).’’

‘‘Summary.
The studies revealed effects of 4-nonylphenols on endpoints indicative for an estrogen mode of action as well as on apical endpoints.

An indicative endpoint is the increasing concentration of VTG. This was examined in 4 tests (3 screening or reproduction assays and 1 development test). Vitellogenin induction was observed in all tests with LOEC values in the range from 1 µg/L to 36.81µg/L. Results by Schwaiger et al (Schwaiger et al., 2002) showed that the vitellogenin level is increased even in adult fish if only their parents were exposed (LOEC 10 µg/L). Similarly, this holds true with regard to changes of estradiol and testosterone level observed in that test. A further endpoint substantiating an estrogen mode of action is the effect on spermatogenesis observed in a screening assay by Jobling et al. (Jobling et al., 1996) at 36.8 µg/L and the inhibition of testicular growth (measured as GSI) at 54 µg/L. Thus study results clearly indicate 4-nonylphenols induced endocrine activity in O.mykiss.

No apical endpoints which are clearly endocrine mediated (i.e. effects on sex-ratio) were examined. Results by Ackermann et al. (Ackermann et al., 2002b) which found induced vitellogenin but no effects on gonads and sex-ratio should not be considered as an indicator that estrogen activity does not result in adverse effects as the lack of effects could be due to the fact that fish were not mature enough at the end of the test to detect such effects.

However, apical effects observed by Ashfield et al. (Ashfield et al., 1998) and Brooke et al. 1993 such as reduced growth and impaired development- with an high level of larval abnormalities (LOEC 10 and 53 µg/L respectively) fit to the endocrine mode of action. Reproduction was not assessed in any of these tests. But effects observed by Jobling et al (Jobling et al., 1996) with regard to testicular growth should be considered as strong evidence for an impaired reproduction. Testicular growth during the annual sperm production period (August) was totally inhibited at 54 µg/L indicating, that males did not produce sperms. This is in line with a delayed spermatogenesis observed early in the year by the same author and results by Lahnsteiner and co-workers. (Lahnsteiner et al., 2005) who found a reduction in the total sperm number. Similar holds true for effects observed by Harris and colleagues. (Harris et al., 2001) who found ovaries did not develop at all after exposure to 85.6 µg/L based on GSI during oocyte production (March-July). Again, total inhibition of oocyte germination is considered to be a strong evidence for impaired reproduction. Induction of vitellogenin and estradiol provide some evidence that the effect is endocrine mediated. However, due to high mortality at this concentration it can not be

excluded that reduced ovarian growth was a result of a reduced overall fitness. Results observed by Lahnsteiner and co-workers (Lahnsteiner et al., 2005) provide some indication that effects on reproduction may occur at much lower concentration. The semen volume was significantly reduced after exposure to 0.75 µg/L with the effect that no semen was available for a third stripping. The biological relevance of such effects is unclear. However, as no real reproduction data are available, effects should be considered in the overall assessment.

In summary the observed elevated concentration of VTG is an indicative endpoint, that is unambiguously caused by an endocrine mode of action and the apical endpoints semen production and development of ovaries are relevant for the viability of the population. Effects observed on growth and development are known to be estrogen sensitive (growth and abnormal development). Results by two tests show that adverse effects which are considered endocrine sensitive start at 10 µg/L (LOEC). All in all the results give clear indications for an endocrine mediated mode of action of the 4-nonylphenols and subsequent adverse effects."

"Viviparous fish species"
The studies included were Cardinali *et al*. (2004), Li and Wang (2005), Drèze *et al*. (2000), Kwak *et al*. (2001).

"Tests are available for three viviparous fish of the family Poeciliidae (Poecilia reticulata, Xiphophorus helleri and Gambusia holbrooki):

Two assays for Poecilia reticulata (adult males and a sexual development test with following reproduction period; (Cardinali et al., 2004; Li and Wang, 2005)), one for Gambusia holbrooki (sexual development, (Drèze et al., 2000)) and two for Xiphophorus helleri (juvenile growth test and short term test (Kwak et al., 2001)). Tests include endocrine biomarkers as well as apical endpoints."

"Poecilia reticulata"
"In summary, induction of vitellogenin as well as the sex-ratio skewed to females clearly indicates an estrogen mode of action for P. reticulata. Significant apical population relevant effects fit to this mode of action (sex-ratio, behavior, first appearance of progeny)."

"Gambusia holbrooki"
"In summary, for Gambusia holbrooki indications are available that proves an endocrine mode of action (gonadal histology in males and females) and population relevant effects (skewed phenotypic sex-ratio, only females at 50µg/L)."

"Xiphophorus hellerie (swordtail)"
"In summary, increased vitellogenin level as well as changes in secondary sex characteristics clearly indicates an endocrine mode of action in X. hellerie. Based on available tests, apical effect concentrations are not available."

''Other fish species''
The studies included were Zha *et al*. (2008) and Yang *et al*. (2008).

''The effects of 4-nonylphenols in two different fish species (Chinese rare minnows – Gobiocypris rarus and Silver Carp – Carassius auratus) are described in the following:

For Gobiocypris rarus a reproduction assay and for Carrassius auratus an experiment with adult male fish is available. Both studies are assessed with Klimisch 2. The experiments give indications for an estrogen mode of action.''

''*Summary.*
Tests for both fish species show that exposure to 4-nonylphenols results in in vivo endocrine activity in these species in the low µg/L range. The observed induction of vitellogenin as well as the induction of testis-ova in male Gobiocypris rarus, are clear indicators for an estrogen mode of action. The induction of hypertrophic leydig cells in C. auratus provide evidence for an endocrine mode of action. Due to the lack of information about apical endpoints it is not possible to conclude about adverse effects as a result of this endocrine activity. With regard to Gobiocypris rarus, no change in fertility was observed up to 18 µg/L. However,this does not exclude effects at higher concentrations. Based on experience with other fish species, it seems likely that 4-nonylphenols will impair reproduction in these two species.''

''Overall summary for fishes
Overall indication of estrogen activity was observed in all fish species tested. Estrogen activity started at the concentration of 1µg/L (O.mykiss) with respect to increased vitellogenin and between
11.6µg/L (O.latipes, testis-ova) and 36.8µg/L (O.mykiss, sperm stages) with respect to histological changes.

In three species (O.latipes, P.reticulata, D.rerio) observed effects on apical endpoints are very likely to be estrogen mediated. In one another species (O.mykiss) and the viviparous fish there is strong evidence for endocrine mediated apical endpoints.

In summary results show that 4-nonylphenols act as endocrine disruptors in all fish species tested. Clearly endocrine mediated effects start between 1.05µg/L (O.mykiss) and 15µg/L (P.promelas).''

*''**Amphibians''***

The studies included were Bevan *et al*. (2003), Park *et al*. (2012), van Wyk *et al*. (2003), Kloas *et al*. (1999), Mackenzie *et al*. (2003), Yang *et al*. (2005), Christensen *et al*. (2005), and Feng *et al*. (2011).

“In this chapter information about the potential endocrine mode(s) of action of 4-nonylphenols in amphibians (only anurans) is summarized, as far as available.
While in fishes estrogen-, and/or androgen-mediated effects are the most commonly assessed modes of action, in amphibians impact on the thyroid activity is a known potent endocrine mode of action which is linked to the thyroid-dependent process of amphibian metamorphosis.

According to the OECD guideline (231) for the amphibian metamorphosis assay (OECD, 2009a), the following effects indicate a thyroid mode of action:
- Advanced development (according to development stages or hind limb length)
- Asynchronous development
- Remarkable histological effects

Delay in development may be induced by a thyroid antagonistic mode of action, but could also be influenced by systemic toxicity. Thus, this parameter should be regarded as indicative for an endocrine mode of action only, if no systemic toxicity (reduced growth, mortality) is observable. Similarly, increased body weight is often observed for substances negatively affecting normal development but should not be used alone.

In order to identify whether or not 4-nonylphenols induce also estrogen-like effects in amphibians, the effects observed are compared to effects observed after exposure to 17ß-estradiol (E2).

Although, no specific guidance is available on how to identify estrogen-mediated effects and knowledge of vertebrate steroid hormones and their role in normal development and reproduction in non-mammalians is scarce (OECD, 2008b; U.S.EPA, 2005a) effects of E2 and/or 17 α- ethinylestradiol (EE2) on larval gonadal sex differentiation and sex -ratio of several frog and toad species were shown in a number of studies summarized by (Kortenkamp et al., 2012).’’

‘‘Overall, 8 studies with 5 frog and 2 toad species are available assessing possible endocrine modulated effects on larval (sexual) development and metamorphosis. Results are summarized in Table 32. As age and developmental stages differed among studies and were examined according to different criteria (by (Gosner, 1960; Nieuwkoop and Faber, 1994)) information about duration, development stage and, criteria used for determination are included. None of the summarized studies was performed according to the OECD Guideline for the amphibian metamorphosis assay (assay (OECD, 2009b)) or is reliable without restriction according to (Klimisch et al., 1997).’’

‘‘In summary, although all studies should be used with care, the overall weight of evidence suggests that organism groups other than fish may be adversely affected by exposure to 4-nonylphenols at low concentrations (low µg/L range and below). Comparison with effects observed for 17ßestradiol is suggestive of being estrogene like with respect to X. laevis

and Rana sp. For R. sylvatica and R. pipiens the effects of 4-nonylphenols exerted on gonadal sexual differentiation and changes in sex-ratio for these 3 species fit to an estrogen-like mode of action.

Thus, in summary some information indicates that 4-nonylphenols might be estrogen like endocrine disruptors for additional taxonomic groups other than fishes whereas no definite conclusion can be drawn on direct or indirect effects of 4-nonylphenols of a thyroid mode of action owing to lack of guideline-conforming metamorphosis studies and/ or lack of knowledge on cross-talk feedback of sex-steroid and thyroid axes."

*"**Aquatic invertebrates**"*

The studies included were Hirano *et al.* (2009), Ward and Boeri (1991 (In: USEPA 2005b), Isidori *et al.* (2006), Fliedner (1993), Shurin and Dodson (1997), Sun and Gu (2005), Brennan *et al.* (2006), Comber *et al.* (1993), Zhang *et al.* (2003), LeBlanc *et al.* (2000), Baldwin *et al.* (1997), Tanaka and Nakanishi (2002), England (1995) (In: USEPA 2005b), Hüls (1992), Gibble and Baer (2003), Spehar *et al.* (2010), Arslan and Parlak (2007), Czech *et al.* (2001), Lalah *et al.* (2007), Liu *et al.* (2011), Quinn *et al.* (2006), Lussier *et al.* (2000), Granmo *et al.* (1989), Nice (2005).

"Invertebrate endocrine systems are highly diverse. Although hormones that can be examined in vertebrate species often also occur in invertebrate species the functions of these hormones differ greatly between the phyla since their action depends on which cell and tissue types express receptors for them, and at what time in an organism's development these receptors are expressed. We have only limited knowledge about invertebrate endocrinology with some focused research on special areas like the juvenile and moulting hormones of insects and some of the mollusc and arthropod neurohormones. There is only limited information available about endocrine disrupting effects of 4-nonylphenols on (aquatic) invertebrates. Even though this phylum is very large and diverse the knowledge on how exogenous substances influence invertebrate endocrine systems is up till now scarce (U.S.EPA, 2005a). OECD development of test methods for the detection of adverse effects on development and reproduction for several groups of invertebrates is still underway (Gourmelon and Ahtiainen, 2007). Owing to our lack of knowledge on hormonal systems of most invertebrates, no biochemical endpoints are available. Therefore no specific mode of action can be ascertained and no conclusion can be drawn if a substance is an actual endocrine disruptor on invertebrate species alone."

"In summary, effects on three different phyla (crustaceans, echinoderms and molluscs) were examined.

Within the group of crustaceans two species were tested (Daphnia magna and Americamysis bahia). No effect on reproduction was observed on D. magna at concentrations lower than 3.45 µg/L (Fliedner, 1993). A 7d-guideline study with Ceriodaphnia dubia revealed an EC50 of 8µg/L for reproduction (Isidori et al., 2006). Ceriodaphnia is morphologically very similar to Daphnia but is smaller and has a shorter

generation time (U.S.EPA, 2002). (Baldwin et al., 1997) investigated the effects on the testosterone metabolism of Daphnia magna. It was shown that concentrations < 25 µg /L can significantly affect the androgen metabolism and therefore may contribute to the overall effects on reproduction. (LeBlanc et al., 2000) describe embryotoxic effects which include developmental abnormalities such as curved or unextended shell spines and underdeveloped first antenna as a result of an exposure of gravid females. At 100 µg 4-nonylphenol/L, 23% of the embryos showed these developmental abnormalities with a NOEC of 44 µg/L. Also prenatally exposed animals were under examination in a study by (Shurin and Dodson, 1997) with similar results beginning at 50 µg/L and a NOEC of 10 µg/L. This examination revealed that prenatally exposed Daphnia galeata mandotae showed abnormalities like curled tail spines and lacked or had severely reduced terminal setae on their second antennae, which is characteristic for Daphnia in embryonic stages. Similar neotade deformities were found in Daphnia magna in the study of (Zhang et al., 2003) with a NOEC of 25 µg/L. (Brennan et al., 2006) describes in a guidelineconform study an effect on Daphnia magna that seems to become more sensitive from the first generation to second. This effect applies to the mortality and cumulative number of offspring per female. In the second generation the NOEC (20 µg/L) is one third lower than in the first generation. A similar NOEC value for the mortality of the offspring resulted from the guidelineconforming study conducted by (Comber et al., 1993).

For the mysid A. bahia the NOEC on reproduction was in the same range as for the daphnids (NOEC = 6.7 µg/L) (Ward and Boeri, 1991). In both species the reproduction was reduced starting from 10 µg/L. No developmental effects (moulting) were observed in A. bahia up to 3 µg/L (Hirano et al., 2009). In the treatment groups from 10 µg/L the total number of moults was significantly lower than in the control groups (Hirano et al., 2009). Molting characterizes the crustacean growth and is under the immediate control of moult-promoting steroid hormones, the ecdysteroids (Verslycke et al., 2007). It should be noted that growth effects in mysids are likely to have important implications for development, metamorphosis, and reproductive success since fecundity is related directly to female body size (Winkler and Greve, 2002). As the endpoints assessed did not include indicative parameters for endocrine mediated effects e.g. biomarkers, it cannot be concluded that it is endocrine mediated but it fits to the assumption of an endocrine activity. However, for A. bahia also the effect of 4-nonylphenol on production of 20-hydroxyecdysone (20E) was compared with the control during a moult cycle. In contrast to the normal pattern of ecdysteroid cycling during the moult cycles of A. bahia, in mysids exposed to 30 µg NP /L a significant suppression in 20E levels was observed (Hirano et al., 2009).

Effects on echinoderms were assessed with two sea urchin species. In the two tested species (P.lividus and A. lixula) larval malformation after exposure of sperms and eggs were observed, starting to occur at concentrations of respectively 1.9 and 0.9 µg/L (Arslan and Parlak, 2007; Arslan et al., 2007). Echinoderms are relatively closely related to vertebrates. Therefore, their endocrine systems may have some similarities. Vertebrate sex steroids may play a role in echinoderm reproduction. (OECD Series on Testing and Assessment No.50 (Kropp et al., 2005)) Pentachlorophenol, an anti-estrogen and thyroid

active substance, tested on P.lividus resulted in a similar effect which means an alteration in embryonic development and differentiation (Ozretic and Krajnovic-Ozretic, 1985).

Effects on molluscs are summarized separately for mussels and snails. For mussels there are six tests with four different species available.

Up to the highest concentration tested (100 or 200 µg/L) there is no effect on sex-ratio or fertilization for Crassostrea gigas (Nice, 2005) and Mytilus edulis (Granmo et al., 1989). Other endpoints like energy budget or sperm motility were more sensitive with a NOEC at concentrations of 18 or lower than 1 µg/L for M. edulis (Granmo et al., 1989) or C. gigas (Nice, 2005). Egg production in oysters requires 50% more energy than sperm production. So it is not surprising that the energy budget of the common mussel was a sensitive endpoint and affected in the study conducted by (Granmo et al., 1989). (Nice et al., 2003) describes an increased incidence of hermaphroditism (17%) and sex ratio skewed towards females resulting from an exposure of C. gigas to nonyphenol (<1 and 4 µg/L - real) at a key stage of sexual differentiation. The global incidence of hermaphroditism in oviparous oysters is generally very low in a range between 0 and 1.1% for C. gigas. In this test there was no significant difference between the sex-ratios in the control and expected from historical data deduced sex ratios. Although Crassostrea gigas has the capability to change sex between seasons, usually there is a clear period during which the gonad remains undifferentiated between reproductive seasons; and once gametogenesis has been initiated the oyster loses the ability to change sex for that season (Kennedy et al., 1996). Eggs usually only begin to develop after the sperm have been extruded – usually with a winter (period of sexual undifferentiation) between the two sexual phases. So it is extremely unusual to find evidence of both male and female gametes in the same individual simultaneously. Several studies describe that estrogens are involved in sexual maturation following an undifferentiated phase in older (2 to 3 years) C. gigas (Matsumoto et al., 1997; Mori, 1968a; Mori, 1968b). In studies where E2 was administered to adult (2 to 3 yr) Crassostrea gigas, sex reversal from male to female was induced when administration began at early stages of sexual maturation between reproductive seasons (Mori et al., 1969). However, at a later stage, i.e. once gonad development had begun, the addition of E2 had no effect on sex- ratio (Mori et al., 1969). Exposure to E2 was also found to accelerate sexual maturation in female C. gigas (Mori, 1969). There is evidence to suggest that the reproductive physiology of an oyster can be affected by water-borne pheromones from another oyster (Kennedy, 1983). Therefore, it follows that this system may also be sensitive to other chemicals, hormonal or otherwise, present in the local environment during particular stages of development. Oestrogens are known to be involved in the development of Crassostrea gigas ovaries and gametes (Matsumoto et al. 1997). Another effect of the 4-Nonylphenol described in the test of (Nice et al., 2003) is a transgenerational one. The examination indicates that 4-Nonylphenol had an influence on the quality of the developed gametes so that they are of poor quality resulting in a reduced survival rate of the offspring from parents where at least one had been exposed to 4-Nonylphenol during the larval development.

A test for the snail species Lymnaea stagnalis shows a NOEC for fecundity and F1 hatching success of 100µg/L (Czech et al., 2001). Adults were exposed and reduction effects on egg production and hatching rate after 6-12 weeks of exposure were seen. (Czech et al., 2001) also reported transfer of the endocrine effect, from maternal exposure to the next generation, by analysis of symptoms in F1 generation snails. According to (Segner et al., 2003) the ovulation and egg-laying behavior in L. stagnalis are regulated by a neurosecretory peptide, the egg-laying hormone. Another test with L. stagnalis (Lalah et al., 2007) with a limit concentration of 105 µg/L Nonylphenol caused significant delay in all stages of growth and an increase in embryo mortality. Also the hatching success of embryos was significantly reduced.''

*''**Overall summary of endocrine disrupting effects of 4-nonyphenols in taxonomic groups analysed***

In summary, available information shows that 4-nonylphenols act as endocrine disruptors in fish and there is some evidence for estrogen-like disruption in anuran amphibians. Some data indicate that 4-nonylphenols may be endocrine active in invertebrate species too, but no clear conclusion can be drawn due to the lack of knowledge about the exact endocrine mechanism in invertebrates and the lack of test systems which include endocrine biomarkers diagnostic of endocrine mechanisms.

These concluding aspects are summarized in Table 34.

Table 34: Endocrine disrupting effects of 4-nonylphenols in different taxonomic groups

Taxonomic group	*Number of species*	*Indication of hormonal activity?*	*Apical adverse effects observed?*	*Indication that apical endpoints fit to mode of action*
Fishes	*9*	*Yes,* *in all species observed (increased vitellogenin level in males and females, changes in female gonadal staging, changes in sperm stages in males, testisova, secondary sexcharacteristics, elevated estradiol levels)*	*Yes,* *effects in all species with tested apical endpoints (6 species).* *Most sensitive adverse endpoints:* *Sex-ratio (O.latipes, D.rerio, P,reticulata, G. holbrooki), Fecundity (P.promelas), growth (O.mykiss)* *Most sensitive fully reliable LOEC = 3.4 µg/L (fecundity, P.promelas) with some indication that effects may start at 0.75µg/L (semen volume O.mykiss)*	*Yes, based on studies with nonylphenol clear link for four fishes* *Effects observed in all species substantiate the endocrine mode of action and are known to be estrogen sensitive*
Amphibians	*7*	*Yes,* *in vitro receptor binding for one species.* *Some hints that effects might be endocrine mediated in another species but not conclusive.*	*Yes,* *in 3 species (change in sex – ratio, occurrence of intersex gonads, changes in development)* *Most sensitive LOEC≤ 10 µg/L (sex-ratio in R. sylvatica,and R. pipiens Klimisch 2)*	*Effects observed on sex-ratio in X.laevis in low quality study and changes in sexratio in R. sylvatica and R. pipelines in a Klimisch 2-study point to an estrogen mediated mode of action*
Invertebrates	*2 crustacean species*	*Yes, effects on androgen metabolism in D.magna* *Depression of 20-hydroxyecdysone production during amolt cycle*	*Yes (reproduction,development, moulting)* *Most sensitive fully reliable EC50 = 8 µg/L (reproduction in C. Dubia)*	*Some indication but no clear conclusion possible due to lack of knowledge*
	2 echinoderm species	*Effects observed are similar to those observed for a known anti-estrogen and thyroid active substance (pentachlorphenol)*	*Yes (larval malformations))* *Most sensitive reliable LOEC = 0.9 µg/L (larval malformation in A. Lixula*	*Some indication but no conclusion possible due to lack of knowledge*
	4 mussel species	*Induced hermaphrodism*	*Yes (sex ratio skewed to females in one study,*	*Some indication but no clear*

		Effects fit to those observed for 17ß estradiol and our knowledge about the influence of estrogens on female sexual maturation	*survival ofspring)* *Most sensitive reliable LOEC ≤ 1 µg/L (survival, sex-ratio in C:gigas*	*conclusion possible*
	1 snail species		*Yes (fecundity, hatching success F1 generation, growth)* *Most sensitive reliable LOEC 1 µg/L (embryonic toxicity in H. diversicolor*	*No conclusion possible*

Conclusion on endocrine disruptive properties for nonylphenol

There is no discrepancy between the EU risk assessment (ECB 2002), the CSR (Lead registrant 2010) and the German SVHC-proposal (BAuA 2012) in that all three consider nonylphenol to possess endocrine disruptive properties. However, both the EU risk assessment (ECB 2002) and the CSR (Lead registrant 2010) considered that the $PNEC_{water}$ derived in the respective reports were protective also as regards the endocrine disruptive properties of NP, while it in the German SVHC-proposal (BAuA 2012) was stated that it is difficult to establish a safe exposure level.

We conclude that nonylphenol possess endocrine disruptive properties and support the conclusions derived in the German SVHC-proposal (BAuA 2012) cited below in that:

- "…*available information shows that 4-nonylphenols act as endocrine disruptors in fish and there is some evidence for estrogen-like disruption in anuran amphibians. Some data indicate that 4-nonylphenols may be endocrine active in invertebrate species too, but no clear conclusion can be drawn due to the lack of knowledge about the exact endocrine mechanism in invertebrates and the lack of test systems which include endocrine biomarkers diagnostic of endocrine mechanisms*."

- *''Overall indication of estrogen activity was observed in all fish species tested. Estrogen activity started at the concentration of 1µg/L (O.mykiss) with respect to increased vitellogenin and between 11.6 µg/L (O.latipes, testis-ova) and 36.8 µg/L (O.mykiss, sperm stages) with respect to histological changes.''*

- the uncertainty of no-effect levels is larger for aquatic invertebrates than for fish "*Owing to the lack of in depth knowledge of their endocrine system and the lack of test systems, it is currently nearly impossible to estimate which species are most sensitive and which concentration should be regarded as safe for the environment.''*

B.7.1.1.6. Calculation of $PNEC_{water}$ for freshwater and marine water

In the EU risk assessment (ECB 2002) the $PNEC_{water}$ for freshwater was 0.33 µg NP/L (using an assessment factor of 10 on the lowest NOEC of 3.3 µg NP/L). This toxicity value, i.e. 3.3 µg NP/L for the endpoint biomass for the algae *Scenedesmus subspicatus* by Kopf (1997), was not included in the CSR (Lead registrant 2010) due to ownership reasons. The reason for not using this value in the derivation of the $PNEC_{water}$ for freshwater in this report is that the endpoint algae biomass no longer is considered to be a relevant endpoint, instead the preferred endpoint as regards algae is growth rate (ECHA Guidance on information requirements and chemical safety assessment: Chapter 7.b: Endpoint specific guidance). According to the UK revised draft version of June 2008 (Building Research Establishment, 2008) "a marine assessment was not included in the published report as this did not form part of the TGD at the time. Marine organism toxicity data are included in the assessment, but no values are lower than that used to derive the freshwater PNEC, and no additional taxonomic groups (e.g. echinoderms) from the marine environment were represented. Therefore a marine PNEC has been derived using an assessment factor of 100 on the lowest freshwater value, giving a PNEC of 0.033 µg NP/L.".

In the CSR (Lead registrant 2010) the species sensitivity distribution according to Aldenberg & Jaworska (2000) was used when calculating PNEC for both the pelagic freshwater and saltwater compartment. The resulting $PNEC_{water}$ for freshwater and marine water were 0.614 µg NP/L (using an assessment factor of 5) and 0.527 µg NP/L (using an assessment factor of 5), respectively. It ishowever not clear which specific values that were used to derive the HC5s in the CSR (Lead registrant 2010) and it is decided to estimate a new $PNEC_{water}$ based on the available data considered reliable and relevant in this assessment..

According to guidance (ECHA 2008) there are two different ways of calculating a $PNEC_{water}$, either using standard assessment factors or using statistical extrapolation techniques.

Alternative 1 – calculating $PNEC_{water}$ using standard assessment factor approach

This approach may be used since long-term results are available from at least three species representing three trophic levels.

The lowest of these values for freshwater is the NOECs of 6 µg NP/L for *Onchorhynchus mykiss*, for the endpoint growth from the study by Brooke (1993b). Using an assessment factor of 10 results in a $PNEC_{water}$ for freshwater of 0.6 µg NP/L.

As regards the brackish/marine compartment only one reliable long-term toxicity value is available, i.e. 3.9 µg/L for the mysid *Mysidopsis bahia*. The $PNEC_{water}$ for marine water may be calculated applying the standard assessment method using an assessment factor of 100 on the lowest long-term result from three freshwater or saltwater species representing three trophic levels. The three lowest long-term freshwater values (representing three trophic levels) are 6 µg NP/L, 24 µg NP/L and 25.1 NP µg/L and the lowest long-term saltwater value is 3.9 µg NP/L. Based on that the $PNEC_{water}$ for marine waters becomes 0.039 µg NP/L. It should however be noted that additional toxicity data from additional marine taxonomic groups (e.g. echinoderms, molluscs) would result in a reduced assessment factor (50 or 10) instead of the presently used assessment factor of 100.

Alternative 2 - calculating $PNEC_{water}$ using statistical extrapolation techniques

In order to make the calculation of HC5 transparent the valid toxicity values based on measured test concentrationsavailable for the different species are presented below in Table 18. Only one value per species are used (lowest or geomean). The geometric mean is used when there is more than one value for the same species and end-point and an analysis of the test conditions used cannot explain the difference in observed response. The values selected for each species and the basis for selection can be found in Table 18 below.

Table 18 Values used to calculate an aquatic HC5.

Phylum	Class	Family	Species	Endpoint (NOEC)	Value (µg NP/L)	Value selected for HC5 (µg NP/L)
Chordata	Osteichthyes	Adrianichthyidae	*Oryzias latipes*	F0 generation post swim-up mortality	8.2	8.2
Chordata	Osteichthyes	Adrianichthyidae	*Oryzias latipes*	Fertility & fecundity	50.9	
Chordata	Osteichthyes	Adrianichthyidae	*Oryzias latipes*	Growth	11.6	
Chordata	Osteichthyes	Centrarchidae	*Lepomis machrochirus*	Mortality	59.5	59.5
Chordata	Osteichthyes	Cyprinidae	*Pimephales promelas*	Survival	7.4*	7.4*
Chordata	Osteichthyes	Cyprinidae	*Pimephales promelas*	Growth rate	38	
Chordata	Osteichthyes	Cyprinidae	*Pimephales promelas*	Mortality	77.5*	
Chordata	Osteichthyes	Salmonidae	*Onchorhyncus mykiss*	Growth rate	6	6
Arthropoda	Crustacea	Daphniidae	*Ceriodaphnia dubia*	Reproduction	88.7	88.7
Arthropoda	Crustacea	Daphniidae	*Daphnia magna*	Reproduction	24	53 (geo mean)
Arthropoda	Crustacea	Daphniidae	*Daphnia magna*	Reproduction, growth	116	
Arthropoda	Insecta	Chironomidae	*Chironomus tentans*	Mortality	42	42
Nematoda	Secernentea	Rhabditidae	*Caenorhabditis elegans*	Growth/ reproduction?	40.2	40.2
Chlorophyta	Chlorophyceae	Scenedesmaceae	*Scenedesmus subspicatus (new name: Desmodesmus subspicatus)*	Growth rate	25.1	25.1
Tracheophyta	Liliopsida	Araceae	*Lemna minor*	Frond numbers	901	901

*Included in the EU risk assessment (ECB 2002) but not in the CSR (Lead registrant, 2010)

According to the "Guidance on information requirements and chemical safety assessment; Chapter R.10: Characterisation of dose (concentration)-response for the environment": "…Confidence can be associated with a PNEC derived by statistical extrapolation if the database contains at least 10 NOECs (preferably more than 15) for different species covering at least 8 taxonomic groups. Deviations from these recommendations can be made, on a case-by-case basis, through consideration of sensitive endpoints, sensitive species, mode of toxic action and/or knowledge from structure-activity considerations." The minimum species requirements (and their coverage in this data set) are:

- fish- *Salmonidae*
- a second family in the phylum Chordata (fish, amphibian, etc.) - *Adrianichthyidae, Cyprinidae, Centrarchidae*
- a crustacean – Daphniidae
- a family in a phylum other than Arthropoda or Chordata – *Nematoda*
- a family in any order of insect or any phylum not already represented – *Chironomidae (Arthropoda)*
- algae - *Chlorophyta*
- higher plants - *Tracheophyta*

Based on the data set available (10 values) and the outcome of the normality test included in the ETX 2.0 software (Anderson-Darling test, Kolmogorov-Smirnov test and Cramer von Mises test; normality accepted at all significance levels by all three tests, i.e. 0.01 – 0.1), there is no indications that the assumption of a log-normal distribution is not valid. In addition, using a QQ-plot (see Figure 2) with logarithmic toxicity values for nonylphenol (and eleven additional QQ-plots, with the ten values randomly drawn from a theoretical normal distribution, for comparison) does not give any indication either that the assumption of a normal distribution of the logarithmic toxicity values would be invalid.

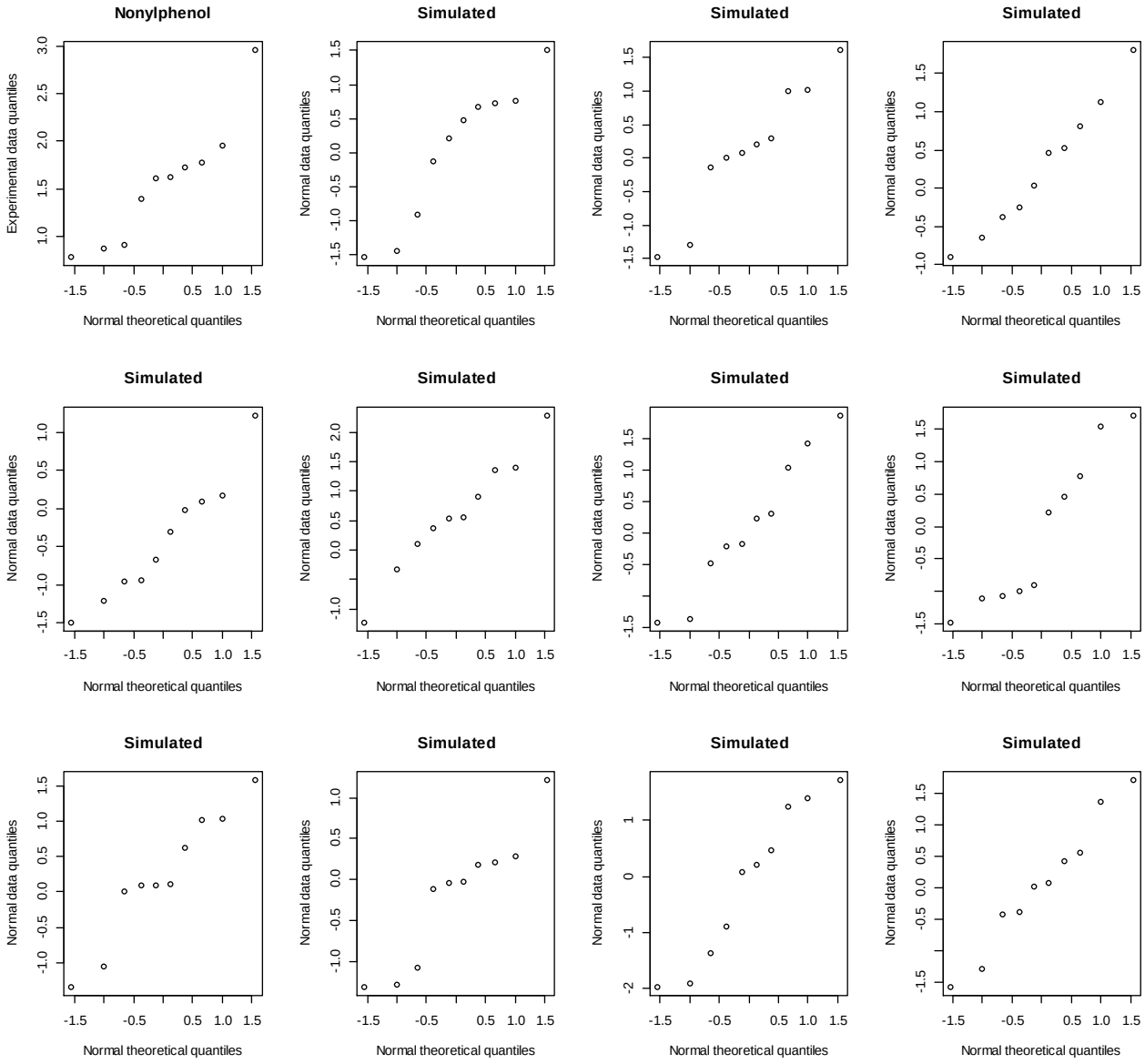


Figure 2 QQ-plot for nonylphenol (upper left), using logarithmic toxicity values and eleven additional QQ-plots, with the ten values randomly drawn from a theoretical normal distribution, for comparison. The plot is constructed using the free software R (http://www.r-project.org/) version 2.12.1

Figure 3 show the SSD graph from the ETX 2.0 software with the names of the individual species inserted.

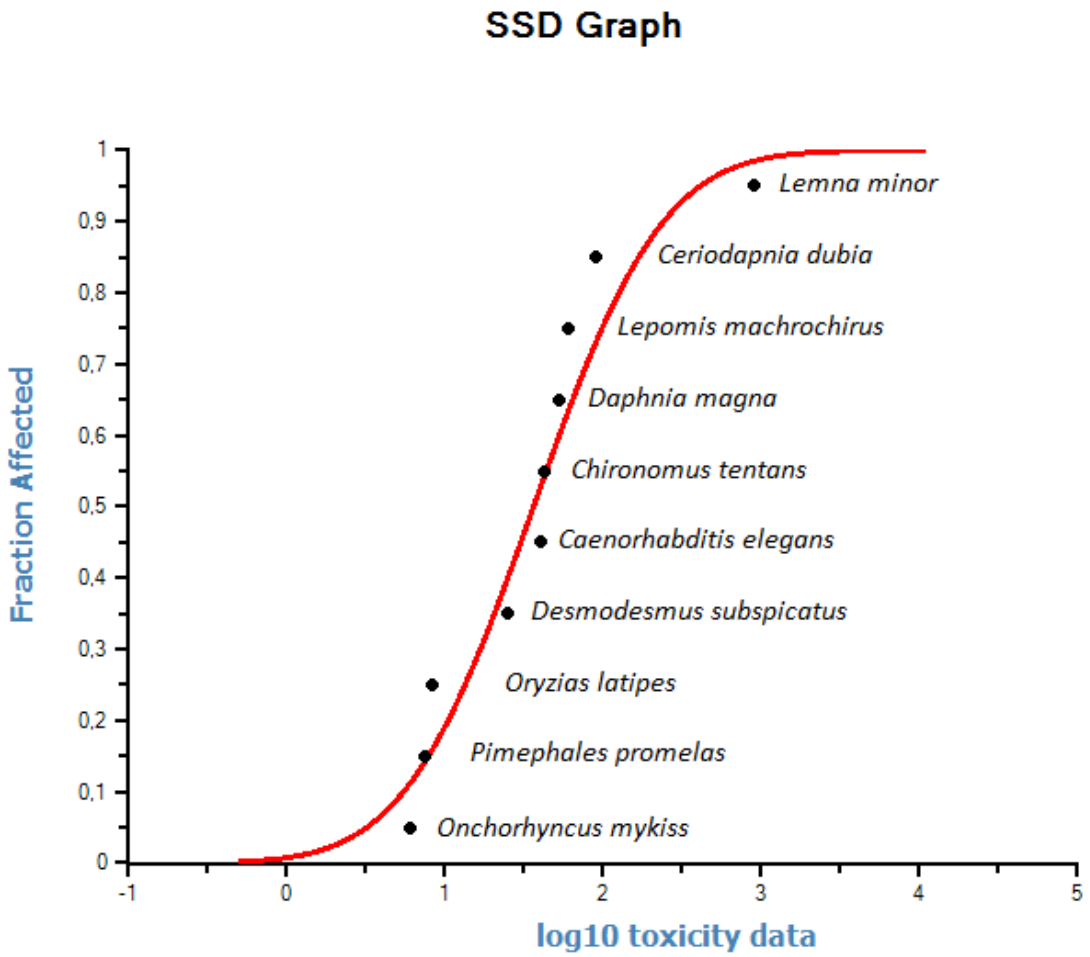


Figure 3 Aquatic species sensitivity distribution for nonylphenol (lognormal distribution) from the ETX 2.0-software with the names of the individual species inserted.

Calculating the HC5 using the available data considered relevant and reliable (see Table Table 18 above) and the RIVM-software ETX 2.0 (which uses a lognormal distribution) results in the value 2.93 µg NP/L, with the 90% confidence interval of 0.49 – 8.1 µg NP/L. In order to derive a $PNEC_{water}$ the HC5 is divided with an AF of the size 5-1. According to R.10 guidance the following five points have to be considered when determining the size of the assessment factor (5-1):

1. The overall quality of the database and the endpoints covered, e.g., if all the data are generated from "true" chronic studies (e.g., covering all sensitive life stages);
    - All data used in the SSD calculation are chronic toxicity data, and cover endpoints such as growth, mortality, reproduction and growth rate. There is no NOEC(s) below the estimated HC5 of 2.93 µg NP/L.

2. The diversity and representavity of the taxonomic groups covered by the database, and the extent to which differences in the life forms, feeding strategies and trophic levels of the organisms are represented;
    - The dataset contain 10 long-term toxicity data, which fulfilles the minimum of 10 NOECs but is at least six below the number "preferably more than 15". The minimum requirement of "at least eight taxonomic groups" is fulfilled.

3. Knowledge of presumed mode of action of the chemical (covering also long-term exposure). Details on justification could be referenced from structurally similar substances with established mode of action;
    - Nonylphenol is considered to be an endocrine disruptor. Exposure to nonylphenol results in effects in fish on reproduction parameters (fecundity) as well as on sexual development (including changes in sex-ratio) and growth. Beside of the endocrine disruptive properties nonylphenol is also capable of exerting toxicity via other mechanisms partly or not at all related to ED.

4. Statistical uncertainties around the 5th percentile estimate, e.g. reflected in the goodness of fit or size of confidence interval around the 5th percentile, and consideration of different levels of confidence (e.g. by a comparison between the 5% of the SSD (50%) with the 5% of the SSD (95%));
    - Neither of the tests included in the ETX 2.0 software for normality (Anderson-Darling, Kolmogorov-Smirnov and Cramer von Mises) rejected the assumption of normality at any of the included significance levels. It is however noteworthy that for the later two of these normality tests it is stated that they may not perform well for sample sizes below 20 and the present dataset only includes 11 values. The QQ-plots in Figure 2 does not give any indication that the assumption of normal distribution of the logarithmic toxicity values would be invalid.

5. Comparisons between field and mesocosm studies, where available, and the 5th percentile and mesocosm/field studies to evaluate the laboratory to field extrapolation.
    - The conclusion for field studies in the EU risk assessment (ECB 2002) was that "*Taken as a whole, the field study provides good supporting data for that generated in the laboratory studies, but cannot on its own be used as the basis for deriving a PNEC to protect the aquatic compartment.*"

There is based on the above no support to reduce the AF from 5. The use of an assessment factor of 5 results in a $PNEC_{water}$ of 0.59 µg NP/L for freshwater.
It is based on the very limited data set available for the pelagic marine compartment (one long-term value) decided to not perform a HC_5 calculation for the marine compartment.

Selection of $PNEC_{water}$ for freshwater
The values of the two PNECs for freshwater derived using the standard assessment approach, i.e. 0.6 µg NP/L, and the SSD approach, i.e. 0.59 µg NP/L, are very similar in size.
Since these two PNECs are almost identical in size the choice of which to choose will not influence the outcome of the risk characterisation as regards the derived risk characterisation ratios.

However, since the concern raised in the risk characterisation is associated with the ED-properties of NP and the PNEC estimated with the standard approach is based on a NOEC for growth in fish this approach have been used in the assessment. It is noted that effects on growth by itself would not lead to a conclusion that a chemical is an ED in fish, but together with available mechanistic

data (in vitro and in vivo) and ED-related adverse effects, in this case, in other fish species (e.g. skewed sex ratio) it is reasonable to assume that the effect is endocrine related.

Discussion about the potential introduction of an extra AF

We share the conclusion made by Germany (BAuA 2012) in that nonylphenol fulfills the 57f-criteria. This needs to be taken into account and will clearly have implications on the further process of the risk assessment of NP.

The ECHA guidance R.10 mentions the following for freshwater: "*...The assessment factors presented in Table R.10-4 should be considered as general factors that under certain circumstances may be changed. In general, justification for changing the assessment factor could include one or more of the following:*

- *...*
- *knowledge of the mode of action including endocrine disupting effects (Some substances, by virtue of their structure, may be known to act in a non-specific manner);*
- *...*"

and for the marine water: "*...When substantiated evidence exists that the substances may be disrupting the endocrine system of mammals, birds, aquatic or other wildlife species, it should be considered whether the assessment factor would be sufficient to protect against effects caused by such a mode of action, or whether an increase of the factor would be appropriate.*"

Thus, as obvious from the above, the guidance opens for the possibility to adjust the assessmet factors under certain circumstances. Such a circumstance is the risk assessment of substances with endocrine disruptive properties and the additional uncertainty that this introduces since the adverse influence on the environment may be expressed in many different ways, some more other less well understood. Even short exposure periods during critical development stages may be sufficient to initiate endocrine mediated effects which adversely affect populations. Sensitive test systems detecting endocrine mediated effects on wildlife are hardly available and are still under development for some taxonomic groups (fish, molluscs and frogs) within the OECD test guideline program, but are still missing for others (e.g. birds and reptiles). Difficulties in assessing ED in traditional risk assessments are among other things caused by ED exerting effects during specific life stages, whereas the consequence may be apparent only later in life.

It is, considering these uncertainties, not certain what would be a safe level. This situation may therefore be handled in one of two ways, either quantitatively using the traditional risk characterisation ratios (RCRs) with an additional assessment factors (AF) or qualitatively not using the RCRs. The potential use of an additional AF is discussed below, and the use of a qualitative approach is discussed in the section on risk characterisation.

If handled by using an additional AF when deriving the $PNEC_{water}$, we consider it most logical to apply this AF on ecotoxicity data directly related to this extra uncertainty. This will for freshwater be the original PNEC of 0.6 µg NP/L, as this value originates from a NOEC of 6 µg NP/L for fish for the endpoint growth, which is associated with the ED-system, as compared to an HC_5 which also uses toxicity data from phyla (plants) not considered relevant for endocrine disruptive toxicity.

It is based on the above not easy to exactely define an appropriate size of an extra AF that would be considered to include/cover the uncertainties described above. Assessment factors used to take into account uncertainties of various kinds are commonly made in steps of 10. It is therefore decided that IF an extra AF would be introduced, in order to take the ED-related adverse effects into account, a size of 10 could be proposed.

If using the extra AF of 10 on the original $PNEC_{water}$ of 0.6 µg NP/L for freshwater, this will result in an adjusted $PNEC_{water}$ of 0.06 µg NP/L.

As regards the marine compartment, a $PNEC_{water}$ of 0.039 µg NP/L is derived above. If an additional AF is considered appropriate to introduce in the limnic compartment then the same should logically also apply for the marine compartment. However, as described in the section above on the endocrine properties of nonylphenol, there are some data that indicate that nonylphenol may act as an ED also in aquatic invertebrates, but any firm conclusion on this can not be drawn due insufficient knowledge about the exact endocrine mechanism in invertebrates and the lack of sufficiently informative test systems. The approach taken here for the marine compartment in this issue will therefore instead be based on the same NOEC that was used to derive the freshwater NOEC, i.e. 6 µg NP/L, which in a first step is used to derive a $PNEC_{water}$ for the marine compartment of 0.06 µg NP/L. This value is then in a second step divided by the extra AF of 10 resulting in an adjusted $PNEC_{water}$ of 0.006 µg NP/L for the marine compartment.

Discussion about a potentially even lower $PNEC_{water}$

There are in the available database studies with ED-related NOECs which indicate that the present freshwater and marine PNECs may underestimate the toxicity of NP. These studies have not been used for the derivation of PNEC since for some of them information on the measured concentrations used is missing, and in some cases also other information. For other studies this information may be included but the resulting NOECs do not represent standard apical endpoints, but instead indications of endocrine mediated effects. Nevertheless, the information they provide is still considered to be of value and is taken into consideration here.

For freshwater the fish study by Lahnsteiner *et al*. (2005) indicate that the present $PNEC_{water}$ may be underestimated. This since a nominal concentration of 0.75 µg NP/L resulted in completely inhibited production of semen in +2 years male rainbow trout. This adverse effect concentration on fish needs to be compared with the lowest NOEC that is used in the derivation of $PNEC_{water}$, which is the fish NOEC (growth) of 6 µg NP/L for rainbow trout. This means that the adverse nominal effect concentration (with complete inhibition of production of semen) is a factor of eight times lower for the same fish species as compared to the lowest NOEC used in the derivation of $PNEC_{water}$.
In addition to this, there exist indications of other ED-related effects on fish occurring at similar or lower levels, from studies where the concentrations used were measured. NOECs for these type of indications have been determined at 6 µg NP/L (testis-ova in *Oryzias latipes* by Seki *et al.*, 2003), and 2.9 µg NP/L (mixed secondary sex characteristics in *Oryzias latipes* by Balch and Metcalfe,

2006). In Schwaiger *et al.* (2002) mortality prior to the eyed-egg stage was significantly increased in fertilized eggs from *Onchorhynchus mykiss* where the F_0-generation had been intermittently exposed (10 d/month in four moths prior to spawning) in both the 1 µg NP/L and 10 µg NP/L exposure groups. This resulted in a significantly decreased hatching rate in the F_1-generation resulting from the higher of these two concentrations, i.e. 10 µg NP/L. In a study by Kwak *et al.* (2001) nominal concentrations of 0.2 µg NP/L resulted in significantly changed external sex characteristics (decreased swordtails) in Swordtails (which may influence mating behaviour and thereby adversely affect the genetic pool of populations).

For marine waters there are two studies on invertebrates (Marcial *et al*., 2003, and Nice, 2005) with ED-related NOECs which indicate that the presently lowest NOEC may underestimate the toxicity of NP. In the study by Marcial *et al.* (2003) nominal concentrations of 1 µg NP/L resulted in a significant delay in the completion of the naupliar stage in the parental generation of the marine copepod *Tigriopus japonicus*. In the F1 generation significant delay was observed already at 0.1 µg NP/L. In the study by Nice (2005) nominal concentrations of 1 µg NP/L resulted in a significantly reduced amount of motile sperms (30% as compared to the controls 100%) in Pacific Oysters. These effect concentrations on invertebrates need to be compared with the lowest NOEC that was used in the derivation of $PNEC_{water}$, which was the marine mysid *Mysidopsis bahia* NOEC (endpoint: reduced growth measured as length) of 3.9 µg NP/L, i.e. the observed effect concentrations are a factor of about four (significantly reduced amount of motile sperms) to almost 40 (significant delay in the completion of naupliar stage) times lower.

To conclude, there are indications that the $PNEC_{water}$ defined above for freshwater and marine water may underestimate the toxicity of nonylphenol.

B.7.1.1.7 Aquatic toxicity of nonylphenol ethoxylates and ethoxycarboxylates

Since nonylphenol, nonylphenol ethoxylates (NPEOs), and nonylphenol ethoxycarboxylates (NPECs) typically exist together as mixtures in WWTP effluents and in the environment their combined toxicity also needs to be assessed.

In general, the toxicity decrease with increasing EO chain length (Environment Canada 2002), e.g. the acute toxicity (LC_{50}) to Japanese medaka (*Oryzias latipes*) was 1.4 mg/L, 3 mg/L, 5.4 mg/L, 12 mg/L and 110 mg/L for NP, NP1EO, NP6.4EO, NP9EO and NP16.6EO, respectively (Yoshimura 1986). NPECs, which are much more water soluble, and are much less toxic than the corresponding NPEOs have acute toxicity similar to NPEOs with 6-9 EO units (Environment Canada 2001). Based on a comprehensive review of available toxicity data Environment Canada (2001) developed Toxic Equivalency Factors (TEFs) for various nonylphenolic compounds. The values were derived based on a broad dataset including both acute and chronic toxicity studies on a range of vertebrate and invertebrate species. Reported toxic concentrations for the various nonylphenolic substances were matched up against similar endpoints for nonylphenol with the same species, and, where possible, from the same laboratory, and based on the outcome of that a relative toxicity ratio was calculated. From the resulting list of relative toxicity values for each group of compounds, a mean relative toxicity value (TEF) was calculated, with more weight given to those studies deemed to be of higher quality. The TEF value for NPEOs containing 3-8 ethoxylate groups were not estimated in

the assessment by Environment Canada because there had been very few tests conducted with these substances and instead an estimate of their toxicity was made. Since the toxicity is known to decrease with increasing number of ethoxylate groups, the relative toxicity of the NP3EO-NP8EO was expected to be between the toxicity of NP2EO (TEF = 0.5) and NPnEO, where n ≥9 (TEF=0.005). As a consequence of that it was recommended that for NPE3EO-NP8EO adopt the conservative estimate of TEF = 0.5, until sufficient toxicity data become available to estimate their relative individual potency, with the caveat that the use of this TEF may overestimate the toxicity of the mixture.

Similar to toxicity, Environment Canada (2001) derived relative estrogenicity (RE) factors based on the data of Jobling and Sumpter (1993), in which induction of vitellogenin in trout hepatocytes was measured. A summary of both the relative toxicity and estrogenicity factors are presented in Table 19 below.

Table 19 Summary of Toxic Equivalency Factors (TEFs) of nonylphenol and related compounds and relative estrogenicity values from Environment Canada (2001).

Chemical	Toxic Equivalency Factors (TEFs) relative to NP	Relative estrogenicity (relative to NP)
NP	1	1
NPnEO (n = 1 – 2)	0.5	0.67
NPnEO (n = 3 - 8)	0.5	
NPnEO (n ≥ 9)	0.005	0
NPnEC (n = 1 - 2)	0.005	0.63
OP	1	4.1
OPnEO (n = 1 – 8)	0.5	
OPnEO (n ≥ 9)	0.005	
OPnEC (n = 1 - 2)	0.005	0.63

Based on the above data both NP1EO & NP2EO and NP1EC & NP2EC are expected to be only slightly less estrogenic than NP. This contrast with the TEFs based on acute/chronic toxicity data, in which NP1C and NP2C are much less toxic than NP.

B.7.1.1.8. Sediment organisms

Toxicity tests for sediment organisms in freshwater and marine water are available in Table 20 below.

In the EU risk assessment (ECB 2002) the equilibrium partitioning method was used to estimate the $PNEC_{sed}$. In using this method it is assumed that sediment-dwelling organisms and water column

organisms are equally sensitive to nonylphenol and that the concentration of nonylphenol in sediment and interstitial water is at thermodynamic equilibrium.

Since the EU risk assessment (ECB 2002), one study presenting sediment toxicity data for freshwater organisms (Bettinetti and Provini 2002) and one study presenting sediment toxicity data for saltwater organisms (Zulkosky *et al.* 2002) have become available. The results from these two studies were used in the CSR (Lead registrant 2010) to derive $PNEC_{sed}$ for freshwater and saltwater, respectively. Both having the reliability code 2 (reliable with restrictions), the first considered to be a key study, the second a supporting study.

Freshwater
In the study by Bettinetti and Provini (2002) the benthic invertebrates *Chironomus riparius* and *Tubifex tubifex* were exposed to nonylphenol in spiked sediments in a 28-day study. 4NP (Sigma-Aldrich, UK), a mixture of ring and chain isomers, was used to spike sediments. 4NP was added directly to the wet sediment, in order to avoid the use of solvents, and HPLC was used to determine the 4NP concentrations in water and sediment. The 4NP concentration of the stock sediment was between 6.0 and 6.6 mg 4NP/g dw; the measured concentrations of the tests obtained from the direct mixing of known quantities of the stock sediment with the reference were generally within 20% of the nominal concentrations. Several subsamples collected randomly before test initiation indicated that 4NP was homogenously distributed in the sediment. At equilibrium, 4NP concentration in the overlying water was within 5 and 20 µg 4NP/L, depending on its concentration in the sediment.

Toxicity to *C. riparius* was assessed according to OECD 218 with minor modifications. One day before the addition of first-instar larvae, 250 ml glass beakers were filled with 70 g of spiked wet sediment (water content about 50%) and 200 ml dechlorinated water; 3.5 ml of a 4 g/L water suspension of fish food, corresponding to 14 mg dw Tetramin, was put in each beaker. The content of the beakers were allowed to settle in the dark at 21 ± 1℃ for 24 h. Five replicated beakers were prepared for each concentration, including the control. At the start of the test, the overlying water of each beaker was gently aerated for 2 h and then the 10 first-instar larvae, chosen at random, were transferred to each beaker. Tests were performed under 16:8 light: dark photoperiod for 28 days. Every 3 days the animals were fed with 3.5 ml Tertramin suspension and the water lost due to evaporation was added. Temperature, pH, and dissolved oxygen were measured in all the beakers before and at the end of the tests, when ammonium was also recorded. The total number of fully emerged male and female midges was recorded daily. The maximum test duration was 28 days and if midges emerged earlier, the test was ended 5 days after the last adult emerged in the control. Egg depositions during the bioassays were noted. Two non-simultaneous tests were performed at concentrations of 270, 290, 320, 410, 480, and 580 mg 4NP/kg dw and 290, 520, 735, 880, 960, and 1100 mg 4NP/kg dw. The average EC_{10} concentration reported for inhibition of *Chironomus riparius* emergence was 231 mg/kg dw.

The toxicity tests with the *T. tubifex* were performed according to Reynoldson *et al.* (1991) with minor modifications, which is equivalent or similar to OECD 225. One day before the addition of worms, 250-ml glass beakers were filled with 70 g of spiked (or control) wet sediment

(approximately 50% water content) and directly mixed with 80 mg of dry powered Tetramin fish food; 150 ml of commercial mineral water was then gently added. The contents of the beakers, covered with a plastic Petri dish with a whole for aeration were allowed to settle in the dark at 21 ± 1℃. Five replicate beakers were prepared for each concentration, including the control. At the start of the test, the overlying water of each beaker was gently aerated for 2 h and then four sexually mature worms at their first reproductive event (approximately 6 weeks) were transferred to each beaker chosen at random. Tests were performed in the dark for 28 days; the overlying water was continually aerated. Every 2 days water was added to beakers, if required, to compensate for evaporation. Temperature, pH, and dissolved oxygen were measured in all beakers at Days 0, 14, and 28, when ammonium was also measured. At the end of the test, the content of each beaker was sieved through 500- and 250-µm mesh. The total number of surviving adults was counted immediately, and cocoons and young worms were preserved in 70% alcohol and counted under a dissecting microscope. The average EC_{10}concentration reported for *Tubifex tubifex* were 360 and 359 mg /kg dw for production of cocoons and production of young worms, respectively.

Marine water
In the study by Zulkosky *et al.* (2002) the marine benthic crustacea *Leptocheirus plumulosus* was exposed to nonylphenol in spiked sediments in a 28-day study. The methods for assessing reproductive toxicity were adapted primarily from Emery *et al.* (1997), but modified to employ smaller, 250 ml experimental chambers with a 50 g of wet sediment and 200 ml of overlying synthetic seawater at a salinity of 20 ‰. Methods for amending the reference sediment (Flax Pond; 40° 37.980´N, 73° 08.216´W) with technical NP (Fluka, Buchs, Switzerland) were adapted from Fay *et al.* (2000). Dosed sediments were extracted for NP analysis by ultrasonication with methanol (four sequential extractions), followed by liquid-liquid extraction from water using dichloromethane. Analysis was performed using GC-MS, and NP quantified relative to surrogate (n-nonylphenol) and internal ($^{13}C_6$-non-nonylphenol) standards. The resulting measured NP concentrations used were 2.1, 4.5, 10.5, 27.2 and 61.5 mg NP/kg dw.

Fifteen juvenile animals (< 2 weeks old) were added to each chamber from populations maintained in laboratory cultures. Five replicates per concentration. The temperature was maintained at 23 ± 1℃. At the end of the 28-d exposure period, the adults and juveniles were differentially sieved from the sediment and the number of young (juveniles + embryos) per surviving female was determined. Adult animals were preserved in ethanol and sexed by the presence of brooding plates or penile papillae.

EC_{10} for survival and reproduction from the 28-d exposure period was reported to be >61.5 mg/kg dw for both endpoints.

The survival, expressed as mean percent ± 95% confidence interval, ranged from 99 ± 3 (control) to 96±5 for the highest exposure group (61.5 mg/kg dw).

As regards the endpoint reproduction, a one-way ANOVA was used to determine differences between the treatments as compared with reference sediment, and a regression analysis was done to correlate the concentration of NP with reproductive output. According to the authors, a significant

negative correlation (P<0.034) was observed between NP sediment concentration and the number of young produced per female, but it explained only 12% of the variance. The reproductive output in animals exposed to 61.5 mg NP/kg dw was reduced by 40% of control values, but this difference was not statistically significant (P=0.299).

However, there are some uncertainties regarding the statistical analysis performed on reproduction.

Firstly, there are a number of assumptions of the one-way ANOVA:

- The data are continuous (not discrete).
- The data follow the normal probability distribution. Each group is normally distributed around the group mean.
- The variances of the populations are equal.
- The groups are independent. There is no relationship among the individuals in one group compared to another.
- Each group is a simple random sample from its population. Each individual in the population has an equal probability of being selected in the sample.

Nothing is mentioned as regards the assumptions of normal distribution or equal variance, or transformations performed in order to fulfill these assumptions. Secondly, given that the ANOVA detects a significant difference among treatment means, the next step then becomes to determine which treatments that are different and in order to do that some kind of multiple comparisons test has to be used (e.g. Dunnett´s test), but none is mentioned. As a consequence of these uncertainties the statistical analysis presented for the reproductive endpoint is not considered reliable.

Based on the figure in the article presenting the result of the reproductive study (mean young (juveniles + embryos) per female vs. NP sediment concentration mg/kg) it can neither be excluded nor concluded if there is a significant response or not in the highest dose group (61.5 mg/kg dw). Measurements performed by hand in the figure results in the approximate values mean young/female (mean ± 95% confidence interval) 17.5 ± 5.25 (control), 14 ± 3.5 (2.1 mg/kg dw), 16.75 ± 5 (4.5 mg/kg dw), 14.75 ± 6.5 (10.5 mg/kg dw), 15.5 ± 5 (27.2 mg/kg dw) and 10.5 ± 3.25 (61.5 mg/kg dw). Performing a step-down approach using the Jonckheere-Terpstra trend analysis, as outlined in the OECD guidance document on statistical analysis of ecotoxicity data (OECD 2006b), on these values (note: only one value/dose) does not reveal any significant trend. Even though it is difficult to come to a really firm conclusion regarding the outcome of this reproduction study, based on the available information $NOEC_{reproduction}$ is determined to be the highest dose tested, i.e. 61.5 mg NP/kg dw.

Table 20 Toxicity tests for sediment living organisms in fresh- and marine water.

Species	Compound	Test conditions	Nominal/ Measured	Exposure period (d)	Endpoint	EC_X (mg NP/kg dw)	NOEC/LOEC (mg/kg dw)	Reference	Reliable & relevant
Freshwater									
Chironomus riparius, first instair	4-nonylphenol	Semi-static, OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)	M	28	Emergence rate	EC_{10}: 203 (Test 1) EC_{10}: 259 (Test 2)		Bettinetti and Provini (2002)	R
Tubifex tubifex, adult	4-nonylphenol	Semi-static, equivalent or similar to OECD 225 or EPA OPPTS 850.6200	N	28	Cocoon production Number of young worms	EC_{10}: 337 (Test 1) EC_{10}: 383 (Test 2) EC_{10}: 335 (Test 1) EC_{10}: 383 (Test 2)		Bettinetti and Provini (2002)	R
Saltwater									
Leptocheirus plumulosus	4-nonylphenol	Static, equivalent or similar to Emery et al. 1997	M (arith. mean)	28	Mortality Reproduction	EC_{10}: >61.5 EC_{10}: >61.5		Zulkosky (2002)	R

B.7.1.1.9. Calculation of $PNEC_{sed}$

The EU risk assessment (ECB 2002) presented a $PNEC_{sed}$ of 0.039 mg NP/kg for freshwater based on the equilibrium partitioning method. As mentioned above a marine assessment was not included in the EU risk assessment (ECB 2002) as it did not form part of the TGD at the time. A marine $PNEC_{sed}$ based on the data available in the EU risk assessment (ECB 2002) would, similarly as the $PNEC_{sed}$ for freshwater, have been based on the equilibrium partitioning method and the lowest pelagic freshwater value resulting in a value of 0.0039 mg NP/kg dw.

In the CSR (Lead registrant, 2010) results from one freshwater study (Bettinetti and Provini, 2002), for two freshwater sediment organisms, and one marine study (Zulkosky et al., 2002), for one marine sediment organism, were used to determine a $PNEC_{freshwatersediment}$ of 4.62 mg NP/kg dw and $PNEC_{marinesediment}$ of 1.23 mg NP/kg dw.

As regards freshwater, long-term toxicity data are available for *Chironomus riparius* and *Tubifex tubifex*. When there are two long-term tests (NOEC or EC_{10}) with species representing different living and feeding conditions an assessment factor of 50 should be used in order to derive a $PNEC_{sed}$. It should however be noted that the assessment factor can be lowered from 50 to 10 in case there are "Three long-term tests (NOEC or EC10) with species representing different living and feeding conditions".

Based on the above, $PNEC_{sed}$ for freshwater becomes 4.62 mg NP/kg dw (= 231 mg/kg dw / 50).

As regards marine water, in addition to the two available freshwater toxicity species tested (see above), a long-term toxicity data is also available for the marine sediment species *Leptocheirus plumulosus*. When there are three long-term tests representing three different living and feeding conditions an assessment factor of 50 should be used in order to derive $PNEC_{sed}$ for marine waters. It should however be noted that the assessment factor can be lowered from 50 to 10 in case there are "Three long-term tests with species representing different living and feeding conditions including a minimum of two tests with marine species".

Based on the above, $PNEC_{sed}$ for marine waters becomes 1.23 mg NP/kg dw (= 61.5 mg/kg dw / 50).

To conclude, the $PNEC_{sed}$ for freshwater and marine water selected for use in the risk characterization are 4.62 mg NP/kg dw and 1.23 mg NP/kg dw, respectively.

B 7.2 Terrestrial compartment

B.7.2.1. Toxicity test results

In the EU risk assessment (ECB 2002) the value driving the $PNEC_{soil}$ (21 d EC_{10} (reproduction) of 3.44 mg NP/kg dw for the earthworm *Apporec-todea calignosa*) originated from a study by Krogh *et al.* (1996). However, according to the UK revised draft version of June 2008 (Building Research

Establishment 2008) the results from that study are no longer consider reliable by the rapporteur of the EC (2002). As a matter of clarification, the UK revised draft version of June 2008 (Building Research Establishment 2008) is an addendum report to the EU risk assessment (ECB 2002) produced by the UK in 2008 and has not been published.

Below in Table 21 is a summary of the lowest reliable and relevant toxicity values of nonylphenol for terrestrial compartment.

Table 21 Summary of the lowest reliable and relevant long-term toxicity data for diferent trophic levels of terrestrial organisms.

Species	**Exposure period (d)**	**Endpoint**	**NOEC/EC_{10}**	**Normalised* NOEC/EC_{10} (mg NP/kg dw)**	**Reference**
Sorghum bicolor *Helianthrus rodeo* *Gycine max*	21	Growth	100	100	Windealt and Tapp (1987)
Enchytraeus crypticus	28	Reproduction	24	12	Domene *et al.* (2009)
Soil microorganisms	40	CO_2-production	100	18.2	Trocmé *et al.* (1988)

*Normalised to standard TGD soil (2% organic carbon or 3.4% organic matter)

B.7.2.1.1. Terrestrial invertebrates

Toxicity data for soil invertebrates are available in Table 22 below.

In the EU risk assessment (ECB 2002) the value driving the terrestrial risk assessment was the 21 day EC_{10} (reproduction) of 3.44 mg/kg for the earthworm *Apporectodeo calignosa* by Krogh et al. (1996). However, according to the UK revised draft version of June 2008 (Building Research Establishment 2008) the rapporteur of the EU risk assessment (ECB 2002)now considers the results from the study by Krogh *et al.* (1996) to be unreliable. This due to uncertainties in the statistical treatment of the *Apporectodeo calignosa* (on which the original $PNEC_{soil}$ was based) data and the low reproduction rate in the control animals.

The study by Holm (undated) results in an EC_{10} (reproduction) of 27 mg/kg for *Folsomia fimentaria*, but no information is available whether this is a wet or dry weight value, or on the organics carbon/matter content. The description of the soil is sandy, indicating a low organic content.

Four new studies of toxicity to invertebrates, as compared to the EU risk assessment (ECB 2002), have been reviewed in the UK revised draft version of June 2008 (Building Research Establishment 2008); Teixeira (2002), Johnson *et al*. (2005), Widarto *et al*. (2004) and Widarto *et al*. (2007).

In the study by Teixeira (2002) the effect of nonylphenol on the earthworm *Eisenia fetida* was studied in an eight-week test. Four soil concentrations were used: 7, 14, 28 and 56 mg NP/kg dw. The soil samples were analysed using both liquid scintillation counting (LSC) on days -2, 8 and 56 and HPLC on days 0, 28 and 56. The LSC analyses resulted in mean measured concentration

between 73-83% of the nominal (resulting in 5.5, 12, 20 and 46 mg NP/kg dw) over the 56 day exposure period. The HPLC analyses resulted in starting concentrations similar to the nominal concentrations but a decrease over time with 18-61% of the initial concentrations after 28 days and 6-30% of the initial after 56 days. The first phase ended after 28 days and the report concludes that there were no significant effects on survival, growth or reproduction in earthworms up to 56 mg NP/kg dw, which was the highest dose used. The reduction in concentrations measured with HPLC makes the results difficult to interpret. The difference in initial concentration at the highest dose measured with HPLC (91 mg NP/kg dw) and LSC (50 mg NP/kg dw) also contributes to the uncertainty. TGD calculates soil concentrations 30 days after application and the geometrical mean calculated over the first 28-day period of 38 mg NP/kg dw for the highest concentration is therefore more comparable than the mean concentration of 46 mg NP/kg dw for the entire 56-day period resulting from the LSC-measurements. The NOEC from this study therefore becomes >38 mg NP/kg dw.

In the study by Johnson et al. (2005) a short-term (14 days) and a long-term (56 day) toxicity test was performed on the earthworm *Eisenia andrei*. The nominal concentrations used in the short-term study were 1.0, 3.2, 10, 32, 100, 320, 1000, 3200 and 10000 mg NP/kg dw. The resulting NOEC and LOEC for mortality reported were 32 mg NP/kg dw and 100 mg NP/kg dw, respectively. A probit analysis performed in the UK revised draft version of June 2008 (Building Research Establishment, 2008) resulted in a LC_{50} of 86 mg NP/kg dw. The nominal concentrations used in the long-term study were 1.0, 3.2, 10, 32 and 100 mg NP/kg dw. No statistical significant effects were seen on the number of hatched cocoons, unhatched cocoons or live worms at any of the exposure levels used. The NOEC therefore becomes >100 mg NP/kg. The reason for the apparent discrepancy between the effects observed after short- and long-term exposures are not known.

In the study by Widarto *et al*. (2004) the effect of exposure of nonylphenol on the earthworm *Dendrobaena octaedra* (Savigny) was studied during a 196 day exposure period. The endpoints studied were survival, growth, time to first reproduction, cocoon production, time between production of cocoons, cocoon incubation time and cocoon viability. The nominal concentrations used were 0, 10, 20, 30, 40 and 50 mg NP/kg dw. The concentrations in the soil were measured several months later (after the soil had been kept frozen in the intervening period) and were considered to be close to the nominal values. It was in the analysis performed in the UK revised draft version of June 2008 (Building Research Establishment, 2008) not considered possible to determine a NOEC from this study, although effect levels around 50 mg NP/kg were indicated.

Widarto and co-workers (2007) studied the effects of noylphenol on reproduction and survival of springtails (*Folsomia candida*) in a 64-day toxicity test. The nominal concentrations 0, 8, 16, 24, 32 and 40 mg NP/kg dw were used. No NOEC was reported in the study, but since the mortality at 32 mg NP/kg dw was zero and it was 100% at the next concentration tested, i.e. 40 mg NP/kg dw, a NOEC of 32 mg NP/kg dw is considered reasonable to assume even though this indicates a very sharp dose-response curve.

There are, in addition to these four studies, also two other studies which are described below.

1) Domene *et al.* (2009) assessed the toxicity of nonylphenol (NP) and a technical mixture of a nonylphenol polyethoxylate containing chain isomers and oligomers with an average of eight ethoxy units (NP8EO) to different taxonomical groups (plants, earthworms, enchytraeids, and collembolans) in two natural soils and the OECD artificial soil. Depending on species and endpoint tested the relative order of the soil with the lowest value varied. However the lowest NP IC10-value resulted from testing in OECD soil and as a consequence of that and the number of species and endpoints tested, only toxicity data resulting from testing in OECD soil will be presented.

   The artificial OECD soil was prepared according to OECD (1984) by mixing Sphagnum peat (10%), kaoline (20%), and quartz sand. Soil pH was adjusted to 6±0.5 with the addition of calcium carbonate.

   Both chemicals were applied to soil dissolved in acetone. Acetone was left to evaporate for 24 h in a fume hood. No difference in the outcomes between controls with and without addition of acetone was found in any of the bioassays described below and the two controls were therefore combined.

   The toxicity of NP and NP8EO for soils was assessed using different bioassays; the effect on germination and biomass production of a monocot plant (*Lolium perenne*) and a dicot (*Brassica rapa*), the effect on survival and reproduction of an earthworm (*Eisenia andrei*), an enchytraeid (*Enchytraeus crypticus*), and a collembolan (*Folsomia candida*). For each bioassay a preliminary assay was carried out in order to find the range of concentrations with effects. The preliminary assay consisted of nominal concentrations of 0, 10, 100, 1000, and 10000 mg of NP or NP8EO /kg. After that, the range of concentrations showing an inhibition between 10% and 90% were selected for the definitive assay. No information is presented about the final concentrations used or the number of concentrations used per assay.

   Earthworm toxicity was assessed according to ISO 11268-2 (ISO 1998). The water content of the soil was adjusted to 60% of its maximum water-holding capacity. Four replicates per concentration were prepared. Ten clitellated individuals of synchronised age (4 weeks difference at most) were placed in each container. Animals were fed with 5 g cooked oat flakes at the start and weekly thereafter. Replicates were maintained in a 16:8 light/dark photoperiod and a constant temperature of 21℃ for 28 days. The moisture loss of each replicate was checked weekly by weight, and restored if necessary with distilled water. After 28 days of exposure, adults were removed from the test substrate, counted and weighed and the replicates were incubated 28 more days in order to allow the juveniles to emerge and grow. This enabled assessment of the survival rates and total earthworm biomass (sum of weights of the survival adults). After this period, each replicate was placed in a water bath at a temperature of 60℃. After 20 min, juveniles appeared at the substrate surface and were collected and counted. In the controls the adult weight of *E. andrei* at the beginning of the test was within the range indicated in the guideline (200 – 650 mg), survival was over 90%, and reproduction was over 30 juveniles with a coefficient of variation below 30%. For NP

the EC_{10} (EC_{50}) for survival, reproduction, and biomass 344 (625) mg/kg, 56 (82) mg/kg, and 88 (309) mg/kg, respectively. For NP8EO the EC_{10} (EC_{50}) for survival, reproduction, and biomass were 436 (1181) mg/kg, 321 (1181) mg/kg, and >3000 (>3000) mg/kg, respectively.

Enchytraeid toxicity was assessed according to ISO 16387 (ISO 2003). The water content of the soil was adjusted to 60% of its maximum water-holding capacity. Five replicates per concentration were prepared. Ten adults (clearly identified by the clitella) were introduced into each flask. The animals were fed 25 mg of ground oats at the start of the assays, and weekly thereafter. Replicates were aerated twice a week and maintained in the dark at 21℃. Some methodological variations were carried out compared to the ISO protocol. Specifically, the adults were maintained in test vessels during all the experimental period (and not removed after 3 weeks). In addition, the test period was also shortedned to 4 weeks compared to the 6 weeks indicated in the protocol. These changes were in accordance to Kuperman *et al.* (2006) and due to the species used, *E. crypticus*, which is more easily damaged and has a shorter generation time than *E. albidus*, the species usually used and for which the protocol was initially designed. At the end of the test period, adults and juveniles were fixed by direct addition of ethanol (80%, v/v) to each flaskafter which a few drops of Bengal red (1% solution in ethanol) were added to colour the individuals. After 2 h, individuals were separated from the more fine soil particles by rinsing with tap water in a sieve (0.2 mm) and were then transferred to a Petri dish for counting. All the individuals counted were assumed to have been alive at the end of the test period given the quick degradation of individuals once dead. In the controls the survival of *E. crypticus* was over 80%, and more than 25 juveniles were produced, with a coefficient of variation below 30%. For NP the EC_{10} (EC_{50}) for survival and reproduction were 663 (907) mg/kg, and 24 (226) mg/kg, respectively. For NP8EO the EC_{10} (EC_{50}) for survival and reproduction were 2059 (3042) mg/kg and 431 (1876) mg/kg, respectively.

Collembolan toxicity was assessed according to ISO 11267 (ISO 1999). The water content of the soil was adjusted to 50% of its maximum water-holding capacity. Five replicates per concentration were prepared. Ten individuals aged 10 to 12 days were added to each replicate, and fed with 3 mg of yeast at the start of the bioassay and after 14 days. After 28 days, the number of surviving adults and juveniles was determined. The procedure for this involved flooding with water followed by the addition of a dark dye to allow the taking of a picture of the individuals floating on the surface of the water surface. Adults and juveniles were differentiated by their size. All the individuals counted were assumed to have been alive at the termination of the study given the quick degradation of individuals once dead. In the controls the survival of *F. candida* was over 80%, and more than 100 juveniles were produced, with a coefficient of variation below 50%. For NP the EC_{10} (EC_{50}) for survival and reproduction were 102 (139) mg/kg, and 63 (93) mg/kg, respectively. For NP8EO the EC_{10} (EC_{50}) for survival and reproduction were 1864 (>3000) mg/kg and 282 (1450) mg/kg, respectively.

The lowest EC_{10} value from this study is the 24 mg NP/mg originating from the enchytraeid *E. crypticus* assay and the endpoint reproduction. It is worth noticing that this value is based on nominal concentrations and maybe therefore underestimate the toxicity.

2) Scott-Fordsmand and Krogh (2004) studied the effect of nonylphenol on the collembolan *Folsomia fimetaria* in soil and sewage sludge using a protocol similar to the ISO 11267. The experiments were performed in microcosms containing 30 g moist soil (27 g dry soil and 3 mL demineralised water). In all experiments the soil used was a sandy loam with a pH of 6.5, humus 3.0%, clay 10.6%, silt 11.8%, and sand 74.6%. Prior to the experiments the soil was dried in an oven at 80℃ overnight, to eliminate undesired soil fauna and to obtain soil nonylphenol concentrations on a dry weight basis. Nonylphenol dissolved in pure acetone was added to dry soil or sludge 24 h prior to the experimental start. The solvent (acetone) was allowed to evaporate within the next 24 h.The water was added on the day of the start of the experiment.

No information of the nonylphenol used, such as purity, is available.

The experiments were run at a constant temperature of 20℃ and with a 12/12 h light/dark regime. The soil was remoistened each 7 days and soil pH measured at the end of the experiment. Three different exposure regimes were used, NP mixed homogenously into soil, NP mixed into sewage sludge which was then mixed into the soils, and NP mixed homogenously into sludge which was then introduced as a pellet into the soils. Only the first of these exposure setups will be described.

NP was mixed homogenously into the soil 24 h prior to start of the experiment. Nominal concentrations used were 0, 20, 40, 60, 80, and 100 mg NP/kg soil dry weight. The animals were fed dried bakers yeast (15 mg dry weight) on Days 0, 7, and 14.

The animals (10 adult female and 10 adult male; age 19-23 days) were added to each replicate microcosm on Day 0 and exposed for 21 days. At the end of the experiments, all surviving animals were extracted in a high gradient Tullgren funnel of the MacFayden type and collected in a cooled (4℃) collecting dish. Adults and juveniles were counted by an automated process and the following measurements were made: individual body area, length, width, slimness, and optical gray intensity by the use of a digital image processing system (DIP). Using the measurements obtained from the DIP it was possible to distinguish among females, males, and juveniles and to calculate the overall reproduction, growth (measured as final body surface area), and survival.

A 10% adult mortality was observed at 55 mg/kg ($P<0.05$), a 10% reduction in adult size was observed at 32 mg/kg ($P<0.05$), a 10% lower reproduction was observed at 23 mg/kg ($P<0.05$), and a 10% reduction in juvenile size was observed at 23 mg/kg ($P<0.05$).

Table 22 Long-term toxicity values for soil invertebrates.

Species	Test substance	Soil type	Endpoint and effect concentration	Reference	Reliable & relevant
Apporectodea calignosa	Nonylphenol	LUFA soil	21 day EC_{10} (Mortality) >40 mg/kg* 21 day EC_{50} (Growth) 23.9 mg/kg* 21 day EC_{10} (Reproduction) 3.44 mg/kg* 21 day EC_{50} (Reproduction) 13.7 mg/kg*	Krogh *et al.* (1996)	NR
Eisenia andrei	Nonylphenol	OECD soil	14 d LC_{50} (Mortality) 86 mg/kg 56 d (Reproduction) >100 mg/kg	Johnson *et al.* (2005)	R
Eisenia fetida	Nonylphenol	Artificial soil	28 d NOEC ( ) >38 mg/kg dw	Teixeira (2002)	R
Dendrobaena octaedra, 1-7d juveniles	Nonylphenol	Sandy loam; 62% sand, 22% silt, 13% clay, 3% humus	196 d NOEC (Survival) >50 mg/kg dw 196 d NOEC (Number of cocoons/day) >50 mg/kg dw 196 d NOEC (Hatching time) >50 mg/kg dw	Widarto *et al.* (2004)	NR
Folsomia candida	Nonylphenol		64 d NOEC (Survival) 32 mg/kg dw	Widarto *et al.* (2007)	R
Enchytraeus crypticus	Nonylphenol	OECD soil	28 d EC_{10} (reproduction) 24 mg/kg dw	Domene *et al.* (2009)	R
Eisenia andrei	Nonylphenol	OECD soil	28 d EC_{10} (Biomass) 88 mg/kg 28 d EC_{50} (Biomass) 309 mg/kg 28 d EC_{10} (Reproduction) 56 mg/kg 28 d EC_{50} (Reproduction) 82 mg/kg 28 d EC_{10} (Survival) 344 mg/kg 28 d EC_{50} (Survival) 625 mg/kg	Domene *et al.* (2009)	R
Folsomia candida	Nonylphenol	OECD soil	28 d EC_{10} (Reproduction) 63 mg/kg 28 d EC_{50} (Reproduction) 93 mg/kg 28 d EC_{10} (Survival) 102 mg/kg 28 d EC_{50} (Survival) 139 mg/kg	Domene *et al.* (2009)	R
Folsomia fimetaria	Nonylphenol	LUFA soil	21 day EC_{10} (Reproduction) 24 mg/kg 21 day EC_{50} (Reproduction) 66 mg/kg 21 day EC_{10} (Mortality) 75 mg/kg 21 day EC_{50} (Mortality) 151 mg/kg	Krogh *et al.* (1996)	R
Folsomia fimetaria	Nonylphenol	Sandy soil	21 day EC_{10} (Reproduction) 27 mg/kg 21 day EC_{50} (Reproduction) 39 mg/kg	Holm (undated)	NR
Folsomia fimetaria	Nonylphenol	4-nonylphenol in sludge	21 day EC_{10} (Reproduction) 48 mg/kg 21 day EC_{50} (Reproduction) 59 mg/kg	Holm (undated)	NR
Folsomia	Nonylphenol	Sandy loam;	21 day EC_{10} (Growth) 32 mg/kg	Scott-Fordsmand	R

fimetaria		72.6% sand, 11.8% silt, 10.6% clay, 3% humus	21 day LC_{10} (Mortality) 55 mg/kg 21 day EC_{10} (Reproduction) 23 mg/kg	and Krogh (2004)	

*Are, according to UK revised draft version of June 2008 (Building Research Establishment, 2008) now considered to be unreliable by the EURAR (2002) rapporteur due to uncertainties in the statistical treatment of the data, and the low reproduction rate observed in control animals.

B.7.2.1.2. Terrestrial plants

The data on terrestrial plants used in the EU risk assessment (ECB 2002) and in UK revised draft version of June 2008 (Building Research Establishment 2008) are presented below in Table 23. However, as regards the later, only the study by Windeatt and Tapp (1986) was listed.

Table 23 Terrestrial plant toxicity data used in the EU risk assessment (ECB 2002).

Species	Test substance	Soil type	Endpoint and effect concentration (wet weight)	Reference
Lettuce (*Lactuca sativa*)	4-nonylphenol	Agricultural loam	7 day EC_{50} (Growth) 559 mg/kg 14 day EC_{50} (Growth) 625 mg/kg	Hulzeboz *et al.* (1993)
Sorghum (*Sorghum bicolour*)	Nonylphenol	Grit/Loam soil	21 day NOEC (Growth) 100 mg/kg 21 day EC_{50} (Growth) 1000 mg/kg	Windeatt and Tapp (1986)
Sunflower (*Helianthrus rodeo*)			21 day NOEC (Growth) 100 mg/kg 21 day EC_{50} (Growth) 1000 mg/kg	
Soya (*Glycine max*)			21 day NOEC (Growth) 100 mg/kg 21 day EC_{50} (Growth) 1000 mg/kg	

In addition to these data an additional study is available and is presented below.

1) Domene *et al.* (2009) assessed the toxicity of nonylphenol (NP) and a technical mixture of a nonylphenol polyethoxylate containing chain isomers and oligomers with an average of eight ethoxy units (NP8EO) to different taxonomical groups (plants, earthworms, enchytraeids, and collembolans) in two natural soils and the OECD artificial soil. Depending on species and endpoint tested the relative order of the soil with the lowest value varied. However the lowest NP IC10-value resulted from testing in OECD soil and as a consequence of that and the number of species and endpoints tested, only toxicity data resulting from testing in OECD soil will be presented.

   The artificial OECD soil was prepared according to OECD (1984) by mixing Sphagnum peat (10%), kaoline (20%), and quartz sand. Soil pH was adjusted to 6±0.5 with the addition of calcium carbonate.

   Both chemicals were applied to soil dissolved in acetone. Acetone was left to evaporate for 24 h in a fume hood. No difference in the outcomes between controls with and without addition of acetone was found in any of the bioassays described below and the two controls were therefore combined.

   The toxicity of NP and NP8EO for soils was assessed using different bioassays; the effect on germination and biomass production of a monocot plant (*Lolium perenne*) and a dicot (*Brassica rapa*), the effect on survival and reproduction of an earthworm (*Eisenia andrei*), an enchytraeid (*Enchytraeus crypticus*), and a collembolan (*Folsomia candida*).

For each bioassay a preliminary assay was carried out in order to find the range of concentrations with effects. The preliminary assay consisted of nominal concentrations of 0, 10, 100, 1000, and 10000 mg of NP or NP8EO /kg. After that, the range of concentrations showing an inhibition between 10% and 90% were selected for the definitive assay. No information is presented about the final concentrations used or the number of concentrations used per assay.

Plant toxicity was assessed according to OECD 208 (OECD 2006a). The water content of soil was adjusted to 60% of its maximum water-holding capacity. Five replicates per concentration were prepared and incubated in a growth chamber at 21℃, 16/8 h (light/dark), and 70% air humidity. Ten seeds per replicate were sown uniformly in each pot (1.5 cm depth in *L. perenne*, 0.5 cm depth in *B. rapa*). When half of the seeds in the control germinated, the germination percentage was determined. Five seedlings per replicate were incubated for another 15 days after which the aerial part of the seedlings was removed and weighed as fresh weight. For the control the germination rates for *B. rapa* and *L. perenne* were over 95%.The fresh weight of their seedlings was 854 ± 119 and 219 ± 22 mg, respectively, with no signs of nutrient deficiency. For NP the EC_{10} (EC_{50}) for germination and fresh weight for were 575 (1449) mg/kg and 696 (8159) mg/kg for *B. rapa* and 739 (4012) mg/kg/1386 (7501) mg/kg for *L. perenne*, respectively. For NP8EO the EC_{10} (EC_{50}) for germination and fresh weight were 211 (>10000) mg/kg and >10000(>10000) mg/kg for *B. rapa* and 303 (>10000) mg/kg/>10000 (>10000) mg/kg for *L. perenne*, respectively.

B.7.2.1.3. Soil micro-organisms

There are no new studies available as compared to the EU risk assessment (ECB 2002), from which the following text originates: "…Trocmé *et al.* (1988) studied the fate of nonylphenol in a simplified soil system and its effect on microbial activity. The authors found that CO_2 production was reduced at 1,000 mg/kg nonylphenol while no effects were observed at 100 mg/kg nonylphenol over a 40 day period. Kirchmann *et al.* (1991) studied the biodegradation of 4-n-nonylphenol in soil. The authors found that upon addition of 500 mg/kg nonylphenol microbial respiration was significantly enhanced, whereas no stimulation was observed upon addition of 10 mg/kg nonylphenol to the soil over a 100 day period. For nitrogen mineralisation they found no effect upon addition of 10 or 500 mg/kg nonylphenol, whereas a temporary reduction in nitrification was observed at 500 mg/kg."

B.7.2.1.4. Other terrestrial organisms

Studies on other terrestrial organisms are not available

B.7.2.1.5 Calculation of $PNEC_{terrestrial}$

The key NOEC values used for the calculation of $PNEC_{Terrestrial}$ are presented in Table 24 below. They have, when possible, been normalised to the standard TGD soil (2% organic carbon or 3.4% organic matter). Using Equation R.10-4
NOEC or $L(E)C_{50(standard)}$ = NOEC or $L(E)C_{50(exp)}$ x $Fom_{soil(standard)}/(Fom_{soil(exp)})$ in the ECHA guidance Chapter R.10 results in the following table.

Table 24 Terrestrial toxicity data used for the calculation of $PNEC_{Terrestrial}$.

Species	**NOEC/EC10 (mg NP/kg dw)**	**OC/OM**	**Normalised NOEC/EC10 (mg/kg dw)**	**Reference**
Collembolan *Folsomia candida*	32 mg/kg	3% OM[b]	36	Widarto *et al.* (2007)
Collembolan *Folsomia fimetaria*	23 mg/kg	3% OM[b]	26	Scott-Fordsmand and Krogh (2004)
Enchytraeid *Enchytraeus crypticus*	24 mg/kg	6.9% OM	12	Domene *et al.* (2009)
Eathworm *Eisenia andrei*	56 mg/kg	6.9% OM	28	Domene *et al.* (2009)
Earthworm *Eisenia fetida*	≥38 mg/kg	8.3% OM[a]	16	Teixeria (2002)
Collembolan *Folsomia fimetaria*	24 mg/kg	0.88% OC	54	Krogh *et al.* (1996)
Plants *Sorghum bicolor* *Helianthrus rodeo* *Gycine max*	100 mg/kg	-	100	Windeatt and Tapp (1987)
Plants *Brassica rapa*	575 mg/kg	6.9% OM /3.45 OC	283/333	Domene *et al.* (2009)
Plants *Lolium perenne*	739 mg/kg	6.9% OM 3.45 OC	364/428	Domene et *al.* (2009)
Soil micro-organisms	100 mg/kg	11% OC	18.2	Trocmé et al. (1987)

Wet/dry wt. – original result on wet or dry basis
OC/OM – organic carbon/organic matter content of the test soil
a – from measurements on artificial soils made in the same way in the same laboratory
b – soil made up with 3% humus, assumed to be 3% organic matter

Having three species of three trophic levels $PNEC_{soil}$ is derived dividing the lowest reliable long-term toxicity value with an assessment factor of 10. Since the lowest value is 12 mg NP/kg dw $PNEC_{soil}$ then becomes 1.2 mg NP/kg dw.

This $PNEC_{soil}$ is a about a factor of 3 larger than the $PNEC_{soil}$ used in the EU RAR (2002). However, according to the UK revised draft version of June 2008 (Building Research Establishment, 2008) the rapporteur for the EU risk assessment (ECB 2002) now considers the

data resulting in the original $PNEC_{soil}$, i.e. the 21-day EC_{10} reproduction of the earthworm *Apporectodea calignosa* of 3.44 mg NP/kg dw by Krogh *et al.* (1996), to be unreliable. This due to reasons of uncertainties in the statistical treatment of the data and the low reproduction rate observed in the control animals.

In the UK revised draft version of June 2008 (Building Research Establishment, 2008), which not included the results by Domene *et al.* (2009), the updated $PNEC_{soil}$ was determined to 1.4-3.2 mg NP/kg wwt (with the minor value in this range originating from a larger-than-value).

In the CSR (Lead registrant, 2010) the $PNEC_{soil}$ is 2.3 mg NP/kg dw, resulting from the use of an assessment factor of 10 on the EC_{10} = 23 mg NP/kg dw with *Folsomia fimetaria* in the study by Scott-Fordsmand (2004). However, when normalising with respect to OM/OC the result by Domene *et al.* (2009) becomes lower (before 24 mg NP/kg dw vs. after 12 mg NP/kg dw) as compared to results by Scott-Fordsmand (2004) (before 23 mg NP/kg dw vs. after 26 mg NP/kg dw).

To conclude, $PNEC_{soil}$ in this assessment is 1.2 mg NP/kg dw.

B 7.4 Microbiological activity in sewage treatment systems

Both the EU risk assessment (ECB 2002) and the CSR (Lead registrant 2010) uses the results from the study by Hüls-Diefenbach (1999) to derive $PNEC_{WWTP}$.[24] The following study description was used in the EU risk assessment (ECB 2002):

"In an inhibition of activated sludge respiration test (OECD Test Guideline 209) an EC_{50} of 950 mg/L was reported for nonylphenol (Hüls 1999a). The sludge used in the test was taken froma sewage treatment plant treating predominantly domestic sewage. The EC_{50} value wasdetermined by linear regression of the available data. The value is higher than the watersolubility of nonylphenol and is probably based on the tendency of nonylphenol to adsorb to the activated sludge used as inoculum."

B.7.2.1.5 Calculation of $PNEC_{WWTP}$

Using the results from the study by Hüls-Diefenbach (1999) with an EC_{50} of 950 mg/L and the assessment factor of 100 results in a $PNEC_{WWTP}$ of 9.5 mg/L. It should however be noted that the assessment factor may be lowered from 100 to 10 or even to 1, depending on the type of new data becoming available.

[24] In the EU risk assessment (ECB 2002) the study is referred to as Hüls 1999a

B.8 PBT and vPvB assessment

B 8.1 Assessment of PBT/vPvB Propertie - Comparison with the Criteria of Annex XIII

The criteria to be used to decide if a substance (or one of its constituents or transformation products in individual amounts ≥ 0.1% (w/w)) must be regarded as a PBT or vPvB substance are set out in Annex XIII of the REACH Regulation.Table 25 below provides an overview of these criteria.

Table 25 PBT and vPvB criteria according to Annex XIII (REACH)

Property	**PBT-criteria**	**vPvB-criteria**
Persistence	- $T_{1/2}$ > 60 days in marine water, or - $T_{1/2}$ > 40 days in freshwater- or estuarine water, or - $T_{1/2}$ > 180 days in marine sediment, or - $T_{1/2}$ > 120 days in freshwater- or estuarine sediment, or -$T_{1/2}$ > 120 days in soil	- $T_{1/2}$ > 60 days in marine, fresh- or estuarine water, or - $T_{1/2}$ > 180 days in marine, freshwater- or estuarine sediment, or -$T_{1/2}$ > 180 days in soil
Bioaccumulation	BCF > 2000 L/kg	BCF > 5000 L/kg
Toxicity	-NOEC (long-term) < 0.01 mg/L for marine or freshwater organisms, or -substance is classified as carcinogenic (category 1A or 1B), mutagenic(category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2), or -there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 3) according to regulation EC No 1272/2008	-

For many substances the available data may not allow a definitive conclusion on the PBT or vPvB properties. In this case so-called screening criteria may be used as surrogate information to decide whether a substance may potentially fulfil the PBT or vPvB criteria. A summary of these screening criteria is provided in Table 26 below.

Table 26 Screening criteria for P, vP, B, vB and T

Type of data	Criterion	Screening assignment
Persistence		
Ready biodegradability test	readily biodegradable	Not P and not vP
Enhanced ready biodegradability test	readily biodegradable	Not P and not vP
Specified tests on inherent biodegradability		
Zahn-Wellens (OECD 302B)	≥70 % mineralisation (DOC removal) within 7 d; log phase no longer than 3d; removal before degradation occurs below 15%; no pre-adapted inoculum	Not P
MITI II test (OECD 302C)	≥70% mineralisation (O2 uptake) within 14 days; log phase no longer than 3d; no pre-adapted inoculum	Not P
Biowin 2 (non-linear model prediction) and Biowin 3 (ultimate biodegradation time) **or** Biowin 6 (MITI non-linear model prediction) and Biowin 3 (ultimate biodegradation time)	Does not biodegrade fast (probability < 0.5)[3] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2) **or** Does not biodegrade fast (probability < 0.5)[1] and ultimate biodegradation timeframe prediction: ≥ months (value < 2.2)	P P
Bioaccumulation		
Convincing evidence that a substance can biomagnify in the food chain (e.g. field data [4])	e.g. BMF > 1	B or vB, definitive assignment possible
Octanol-water partitioning coefficient (experimentally determined or estimated by valid QSAR)	Log Kow ≤ 4.5	Not B and not vB
Toxicity		
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.01 mg/L	T, criterion considered to be definitely fulfilled
Short-term aquatic toxicity (algae, daphnia, fish)	EC50 or LC50 < 0.1 mg/L	T
Avian toxicity (subchronic or chronic toxicity or toxic for reproduction)	NOEC < 30 mg/kg food	T

Persistence Assessment (P)

The available biodegradation data indicate that nonylphenol undergoes biodegradation in water, sediment and soil systems, and is considered to be inherently biodegradable and not persistent in both EU risk assessment (ECB 2002) and CSR (Lead registrant 2010).

Half-life in marine water

- Ekelund *et al.* (1993): seawater, aerobic: $t_{1/2}$ = 58 d (11 °C)
- Ying and Kookana (2003): seawater, aerobic: $t_{1/2}$ = 5 d (20 °C)

→ nonylphenol is not persistent in marine water, since $t_{1/2}$ < 60 d

Half-life in fresh- or estaurine water

- Sundaram and Szeto (1981):
  stream water: $t_{1/2}$ = 16.5 d (16 °C)
  pond water: $t_{1/2}$ = 16.3 d (16 °C)

→ nonylphenol is not persistent in freshwater or estaurine water, since $t_{1/2}$ < 40 d

Half-life in marine sediment

- Ekelund *et al.* (1993): mixed seawater and sediment, aerobic: (11 °C)
  44% degradation in 58 d
- Ying and Kookana (2003): marine sediment, aerobic: $t_{1/2}$ = 5.8 d (20 °C)

→ nonylphenol is not persistent in marine sediment, since $t_{1/2}$ < 180 d

Half-life in fresh- or estaurine sediment

- Chang *et al.* (2004): anaerobic degradation in freshwater sediment:
  $t_{1/2}$ = 46 - 69.3 d (30 °C)
- Yuan and Chang (2004): aerobic degradation in freshwater sediment:
  $t_{1/2}$ = 13.6 - 99.0 d (20 - 50 °C; deceleration of degradation caused by heavy metal application)
- Bradely *et al.* (2008): freshwater sediment (30 °C):
  aerobic conditions: 90% degradation within 32 d or $t_{1/2}$ <32 d
  anaerobic conditions: no biodegradation within 154 d
- De Weert *et al.* (2010): freshwater sediment, aerobic conditions: $t_{1/2}$ = 1.1 – 1.9 d (30 °C)

→ nonylphenol is not persistent in freshwater or estaurine sediment, since $t_{1/2}$ < 120 d

Half-life in soil

- Trocmé *et al.* (1988):
  100 mg/kg; 5 day lag phase, subsequently fast degradation 89% degradation after 40 d
  1000 mg/kg; significant depression of CO_2, 62% degradation after 40 d
- Dettenmaier and Doucette (2007): $t_{1/2}$ = 31 - 51 d
- Topp and Starratt (2000): $t_{1/2}$ = 4.5 – 16.3 d
- Jacobsen *et al.* (2004): $t_{1/2}$ = 37 d
- Mortensen and Kure (2003): 64-99.1% degradation within 30 d

→ nonylphenol is not persistent in soil, since $t_{1/2}$ < 120 d

Bioaccumulation Assessment (B)
Depending on which of the two log K_{OW}-values that is used, 4.48 or 5.4, nonylphenol is either considered not to fulfil or to fulfil the screening criterion of a log K_{OW} of 4.5. However, nonylphenol is not considered to fulfil the B/vB-criteria since measured BCF in fish is below 2000 (B) and 5000 (vB).

It was concluded in the EU risk assessment (ECB 2002) that nonylphenol bioconcentrates to a significant extent in aquatic species, with BCFs (on fresh weight basis) up to 1300 in fish. It was however noted that this value may overestimate the BCF and that more reliable values with a mean of 741 have been measured. Bioconcentration factors of around 2000-3000 have been measured in mussels. The BCF calculated from a logK_{OW} of 4.48, using TGD equation, of 1280 was considered to agree well with measured values and was used in the risk assessment. The BCF of 1280 is also the value selected in this assessment. The measured fish BCF-values are all below the B-criterion of 2000 and nonylphenol is therefore not considered to fulfil the B-criterion.

Toxicity Assessment (T)
Nonylphenol is considered to fulfil the T-criterion since NOEC (long-term) < 0.01 mg NP/L for marine or freshwater organisms are available.

The lowest NOECs for freshwater organisms are the two NOECs of 0.006 mg NP/L for the fish species *Onchorhynchus mykiss*, for the endpoint growth from the study by Brooke (1993b), and for *Oryzias latipes*, for the endpoint testis-ova from the study by Seki *et al.* (2003). The lowest NOEC for marine water organisms is the NOEC of 0.0039 mg NP/L for the mysid *Mysidopsis bahia* for the endpoint growth (length) from the study by Ward and Boeri (1991c). In addition, there are indications that NOEC for fresh- and marine water may be even lower.

PBT Assessment
Based on the above, nonylphenol fulfil the T-criterion, but not the P/vP or B/vB criteria, and is therefore not considered to be PBT or vPvB.

B 8.2 Emission Characterisation

No emission characterisation is required, according to the Guidance on information requirements and chemical safety assessment (May 2008) chapter R.11: PBT Assessment, since nonylphenol not is considered to be a PBT or vPvB.

However, data on exposure, predicted and measured levels in the environment are available in section B.9.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

B.9.1.1 Summary of the existing legal requirements

There are several existing pieces of legislation aiming to reduce the risk arising from NP/NPE. This section has the intention to provide a comprehensive picture as possible of: the legislation (in the EU and national), the conventions, NGO and voluntary measures that cover NP/NPEs in textiles or related compartments. Later on we will try to evaluate how effective these commitments have been to reduce the risk of NP/NPE.

Community regulations

REACH

A risk assessment on EU-level was made under the Existing Substances Regulation (93/793/EEC) since there was evidence that large quantities of nonylphenol (NP) were manufactured and used. Also concern about the substance's toxicity to aquatic organisms and its biodegradability were highlighted. This is the background for the regulation (directive 2003/53/EC) that took place in 2003 under the limitations directive (76/769/EEC). The restriction limits the marketing and use in Europe of products and product formulations that contain more than 0.1% of NP or NPE. This EU directive came into force in January 2005.

In 2006, a new EU chemical safety policy reform was adopted – REACH (Regulation No 1907/2006/EC), where the limitation on NP and NPEO can be found in Annex XVII, Entry 46.

This regulation applies to many industries, including the textile and leather industries, except in the case of closed application systems where no release into waste waters occurs. The presence of NP or NPE in products, for example imported textiles from regions without such restrictions is not controlled by this prohibition (www.eur-lex.europa.eu).

Germany has submited an Annex XV-dossier for nonylphenol identifying it as a substance of very high concern according to Article 57 f in REACH and for inclusion into the Candidate List based on its endocrine disrupting properties.

The water frame work directive (WFD)

The directive 2000/60/EC of the European Parliament and of the Council, also known as the EU Water Framework directive (WFD), establishes a framework for the Community action in the field of water policy. The aim for the WFD is to achieve good water status in all identified water-bodies within the EU by the year 2015. The term water status incorporates chemical as well as ecological parameters. A core principle is that no water status should decline.

The WFD covers several new and existing regulations on water. The European legislation that is relevant to the emissions of NP includes the EU Council regulation 793/93EEC on the evaluation and control of the risks of existing substances and the Directive 76/464EEC on the pollution caused by certain dangerous substances discharged into the aquatic environment of the Community.

The WFD was established to make a frame for the uniform rules on the EU-level to maintain and improve the water quality in lakes, rivers, ground water and coastal water in the community. The directive emphasizes the paths of the water and the natural hydrological borders (e.g. river basins and river basin districts) instead of traditional administrative borders. Each member state was required to adopt targets, action plans and management plans covering all EU water-bodies by the end of 2009. The directive is implemented with a united planning cycle for all Member States. The first step of the cycle was to make a survey and analysis of the waters affected by the directive. Mapping and analysis have provided a basis for setting environmental quality standards (EQS) for water. The EQS are generally set to good ecological status, good chemical status and good groundwater quantitative status, to be attained by the year 2015. However exceptions may be allowed if a member state can show it to be necessary according to certain criteria as defined in the WFD. Such exemptions can be for example phased objectives, extended deadlines or less stringent objectives.

Priority substances

Article 16 in the WFD sets out a strategy against pollution of water, and the first step of the strategy was the creation of a first list of priority substances to become Annex X of the WFD. In 2008 the EU Parliament and the Council decided to replace the aforementioned Annex X with the Annex II of the Directive on Priority Substances (Directive 2008/105/EC). This directive became a so called daughter directive of the WFD. The Annex II of the Directive on Priority Substances includes a list of 33 prioritized substances in the water environment. The list has been developed by experts together with the Commission and the listed substances have been concluded to pose a significant risk to or via the aquatic environment is some way. Both nonyl- and octylphenol are identified on the list. Each substance is considered because of their aquatic toxicity, human toxicity through water, distribution in the environment in time and space, the amount produced, the amount used and the way these substances are used. There is an on going work to expand the list with new substances.

From the list of prioritized substances, 11 “prioritized dangerous substances” have been selected. These substances have been chosen because they have given rise to concern in other relevant community legislation about dangerous substances or in relevant international agreements. The Commission has presented suggestions for regulations on these substances to reach cessation or phasing out of discharges, emissions and losses to the aquatic environment within 20 years. The

phase out obligation is shared between Member States and the European Union. Member States are responsible for taking all the necessary measures to achieve WFD objectives.

Nonlyphenol was identified as a "priority hazardous substance" in 2001. The EQS for NP was set as 0.3µg/l annual average and 2.0µg/l maximum allowable concentration in 2008 (http://ec.europa.eu/environment/water/water-framework/index_en.html).

Directive for Integrated Pollution and Prevention Control (IPPC)

The directive for Integrated Pollution and Prevention Control (IPPC)" (2008/1/EG) was adopted in 1996, addressing pollution from large industrial installations. The legislation is a minimum directive, which means that each Member State is allowed to impose stricter rules in their national legislation.

According to the directive companies requires a permit for industrial activities and agriculture with high pollution potential. Such permission may be granted only if certain environmental requirements are met. Companies must be responsible for the prevention and reduction of pollution they may cause. The companies referred to are those that are producers of energy, or engaged in metal processing, mineral processing, chemical industry, waste management, livestock and other industries for example the textile industry.

BAT

The basic obligation under the IPPC directive is that all appropriate preventive measures should be taken to avoid pollution, in particular by using the best available techniques (BAT).
For a technology to be considered BAT it should be developed on a scale which allows implementation in the relevant industrial sector, under economically and technically viable conditions, taking costs and benefits into consideration.

The European Commission organizes an exchange of information between the Member States and the industries concerning BAT for the areas that is covered by it. The work leads to the "BAT Reference Documents," BREFs. Each document generally gives information on a specific industrial/agricultural sector in the EU, techniques and processes used in this sector, current emission and consumption levels, techniques to consider in the determination of BAT, and emerging techniques. The BREF documents are primarily made for the industries in which the IPPC directive applies. About 35 BREF-documents are available for different sectors, among them a BREF for the textile industry completed in 2003.

The industrial emissions directive

The European Parliament and the Council agreed in 2010 that seven directives on industrial emissions will be one, the industrial emissions directive (IED). The IPPC Directive is one of the directives that will be included in the IED. The new directive, 2010/75/EU, entered into force in January 2011. In 2014, the directive shall also apply to existing plants. The IED involves

tightening the application of BAT and reducing emissions from large combustion plants.

The Commission has stated that having several directives for point sources makes it difficult to enforce at EU level and that it leads to unnecessary administrative burden for authorities and operators (http://ec.europa.eu/environment/air/pollutants/stationary/ippc/index.htm).

The Export/Import Regulation
Through the European Parliament and Council Regulation (689/2008) the Export and import of dangerous chemicals implements the Rotterdam Convention on the Prior Informed Consent procedure for certain hazardous chemicals and pesticides in international trade procedure. NP/NPE is on the list in this regulation.

The reason for this regulation is that many chemicals are banned or heavily regulated in the EU. To reduce damage to human health and the environment in the importing countries there are international rules for trade in hazardous chemicals in the Rotterdam Convention and the Regulation 689/2008. The rules state that all hazardous chemicals may not be exported without the consent of the importing country in advance, PIC (www.eur-lex.europa.eu).

The Detergents Regulation
The detergent regulation (648/2004) entered into force in 2005 and regulates the use of surfactants in detergents for consumers and professional use. According to this regulation, surfactants should be ultimately biodegradable, this therefore disqualify the use of NP/NPE and similar APE since they are not readily biodegradable in standard test methods (www.eur-lex.europa.eu).

Urban waste water directive
The Council Directive (91/271) concerning urban waste-water treatment was adopted in 1991. Its objective is to prevent environmental damage caused by discharges of urban waste water and discharges from certain industrial sectors.

This will include the following demands:

-All urban areas (with respect to size and location) should have a collection system for waste water by the end of: 1998, 2000 or 2005.
-The water that led into the collection system must at least undergo secondary treatment. This usually means biological treatment or some other process that meets the quality standards.
-The waste water that is purified needs to meet the minimum requirements with respect to the water quality.
- In sensitive areas particularly high demands of effective treatment is needed.
(http://ec.europa.eu/environment/water/water-urbanwaste/index_en.html)

Conventions

OSPAR

The OSPAR (The Oslo Paris Convention) is cooperation between fifteen governments of the western coasts of Europe that work together with the European Community to protect the marine environment of the North-East Atlantic. OSPAR's main objective for hazardous substances is to prevent pollution by continuously reducing their releases with the aim of reaching concentrations which are close to zero for man-made substances by the year 2020. There are currently 315 hazardous substances that are important for OSPAR to work on, due to their persistency, liability to bioaccumulate and toxicity or other equivalent concern. Some of these substances have been included on the List of Chemicals for Priority Action. On this list nonylphenol, nonylphenol etoxylates and octylphenol is found (www.ospar.org).

HELCOM

The Helsinki Commission (HELCOM) works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation. HELCOM's objective to hazardous substances is to prevent pollution of the area by continuously reducing discharges, emissions and losses of hazardous substances towards the year 2020, with the ultimate aim of achieving concentrations in the environment close to zero for man-made synthetic substances. The convention has gathered a list of substances of concern from which selected 42 hazardous substances for immediate priority action has been selected. On this list nonylphenol, nonylphenolethoxylate and degradation/transformation products are found (www.helcom.fi).

National initiatives

Sweden

The Swedish paint industry phased out the use of NPEs in water based paints for the building sector by the end of 2001. Most of the companies associated to the Swedish Paint and Printing Ink Manufacturers Association fulfilled the goal set up to reduce the use of alkyl (C8-C10) phenol ethoxylates by approximately 90 % between 1996 – 1999.

When NPEs is used in the binding polymer emulsion of water-based paints for domestic and industrial use, a large part of the substitution and reformulation has been carried out. All newly developed paints do not contain APEs. However, difficulties remain in replacing APEs or NPEs in paints for the metal and wood working sectors.

The aim in Sweden was to achieve use of alternative emulsion polymers products, which do not contain NPEs and APEs, in various industrial sectors such as pulp- and paper, textile, paints, adhesives and plastics. According to the Swedish adhesives industry the use of NPEs in water-based adhesives was reduced by 98 % (between the years 1995-1999) (Begränsningsuppdraget, KemI 10/90, Sveff 1989, OSPAR 2001).

Other countries reducing NPE in the 90´s

The same debate was also ongoing in several other countries in the 90´s. the countries are: Denmark, Italy, Belgium, Schweiz, Spain, Greece, Austria, Netherlands, UK and Germany. This led to general ban on using NPE, particular in consumer products, in some countries also in the industry section. These are results of voluntary agreements (Begränsningsuppdraget, KemI 10/90; RRS Nonylphenol, UK 1999).

U.S.A

The US EPA initiating both voluntary and regulatory actions to manage potential risks from NP and NPEs. In an action plan EPA intends to: support and encourage the ongoing voluntary phase-out of NPEs in industrial laundry detergents. The use of NPEs in industrial laundry detergents would end by 2013 for liquid detergents and 2014 for powder detergents. In addition, EPA intends to encourage development of alternative analysis and the elimination of NPE in other industries that discharge NPEs to water, such as the textile processing sectors, among others, where safer alternatives may be available.

EPA's Design for the Environment (DfE) Program has also developed "The Safer Detergents Stewardship Initiative" (SDSI). The program highlights environmental leaders who voluntarily use safer surfactants in their production. NPE does not meet the definition of a safe surfactant.

The Design for the Environment Program has identified safer alternative surfactants through partnerships with industry and environmental advocates. These safer alternatives are comparable in cost and are readily available. CleanGredients® is a source of safer surfactants and includes mote that 300 surfactants (www.epa.gov.com).

Canada

Canada added in 2001 NP and NPE to the list to the toxic substances under the Canadian Environmental Protection. In 2004 it was implemented in the plan that a 95% reduction of NP and NPE would be done by the year of 2010 (www.Canada.gc.ca)

Norway

From the year 2002 it is in Norway forbidden to produce, import, export, sale and use NP/NPEs and OP/OPE and preparations containing these substances. The regulations do not apply where the use of these substances or preparations is governed by other legislation. The regulations do not apply to solid processed articles. (www.regjeringen.no).

Companies collaborations

Adidas, C&A, H&M, Li Ning, NIKE and PUMA

These companies have in 2011 together written a very ambitious Joint Roadmap and made a commitment towards zero discharge of hazardous chemicals for all products in the supply chain

by 2020. Hazardous chemicals are in this context, substances that shows properties such as: CMR, PBT, vPvB or endocrine disrupting properties. There is a priority group of 11 substances attached to this commitment where APE/NPE are the 10th chemical group on the list. In the year 2012 the platform for the continuing work will take place and also setting the benchmark for the rest of the industry http://www.c-and-a.com/uk/en/corporate/fileadmin/templates/master/img/fashion_updates/International_Press_Releases/111118_JointRoadmap.pdf.

Afirm-group

Afirm-group is an international forum for companies in the textile and footwear industries. The collaboration has a view to reduce use and impact of hazardous chemicals in production. Also to provide a forum to advance the global management of restricted substances in apparel and footwear, communicate information about RSL to the supply chain, discuss concerns, and exchange ideas for improving RSL[25] management, to ultimately elevate consumer satisfaction (www.afrim-group.com).

Blusign®

This is an independent industry textile standard which is a tool for the entire textile production chain. Both the environment, health, safety and working environment is taken into account. The Bluesign criteria limits NPE concentration to 100mg/kg. The cooperation includes many large companies in outdoor products (www.bluesign.com).

Swedish Water Initiative (STWI)

This initiative started in 2010 as a development between textile and leather retail companies in Sweden together with Stockholm International Water Institute. The aim is to produce guidelines for sustainable water management, from thread and leather to product in order to contribute to wiser water management in the supply chain. The STWI companies (which are at present 32) will work with production technique, water treatment, sludge management, and policy engagement, which will serve as platforms for a learning process and the development of guidelines for sustainable water use (www.swedishwaterhouse.se).

Voluntary commitments

Oeko-Tex assocoation

The international Oeko-Tex association was introduced at the beginning of the 1990s as a response to the needs of the general public for textiles which posed no risk to health. The standard 100 certification, which ensures that textile products are tested to be free from harmful levels of more than 300 chemicals believed to be harmful to human health. The association has announced that they will include test for NP/NPE and OP/OPE in its requirement for the Oeko-

[25] Restricted Subtance List

Tex standard 100 certification from the beginning of January 2012. The certificate holders will be expected to comply with these new requirements by April 2013. The limit values for these substances are: NP and OP 100 ppm, NPE and OPE 1000 ppm. The chain lengths to be measured are: nonylphenol, nonylphenol-(1-9) ethoxylates, octylphenol and octylphenol-(1-2) ethoxylates (www.oeko-tex.com).

EU Ecolabel

The European Ecolabel is a voluntary scheme, established in 1992 to encourage businesses to market products and services that are less harmful to the environment. The work is done on behalf of the European Commission. The requirements for the labeling are produced by the responsible bodies in EU member countries. Today the EU Ecolabel covers a wide range of products and services, there among textiles. One of the demands on textile production is that at least 95 % (by weight) of all used detergents shall be sufficiently biodegradable or eliminable in wastewater treatment. There are also demands on chemical substances that are used in the after treatment. The substance that has one or more of the following risk phrases[26]: R40, R45, R46, R49, R50- R53, R60- R63 or R68 should contain less than 0.1% (by weight). Since NP is classified as R62, R63 and R50-53 the substance is covered by the scheme (www.ecolabel.eu).

The Nordic Ecolabel

The Nordic Ecolabel became the official Nordic ecolabel over 20 years ago. The Nordic Council of Ministers stands behind the label but it is administered by each Nordic country. The aim is to provide Nordic consumers an opportunity to choose the best products on the market from an environmental perspective. The requirements of the textile in the Nordic Ecolabel follow the same requirements as the EU Ecolabel (www.nordic-ecolabel.org).

GOTS

Global, Organic, Textile Standards (GOTS) is a worldwide international standard for processing organic fibres, including ecological and social criteria, backed up by independent certification of the entire textile supply chain. The aim of the standard is to define world-wide recognized requirements that ensure organic status of textiles, from harvesting of the raw materials, through environmentally and socially responsible manufacturing up to labeling in order to provide a credible assurance to the end consumer. The list for demands on textiles is long. The regulation that covers NP/NPE is that chemical substance and products may not be used if they have one or more of the following risk phrases: R26, R27, R39, R40, R45, R46, R48, R49, R50- R53, R58-R63 or R68. Chemical substances and products may not be used if they can bioaccumulate and if they are not biodegradable (www.global-standard.org).

[26] Directive 67/548/EEEC

IVN

IVN is the International association of natural textiles industry. From the beginning it was a German standard (Internationaler Verband der naturtextilwirtshaft). The association has one goal, to raise awareness for eco-friendly textiles among consumers, press and the retail trade. The chemical requirement for textiles in this standard is the same as in the GOTS standard. Except that IVN goes a bit further on the use of ecological agriculture (www.naturtextil.com).

EKO sustainable textile

EKO sustainable textile derives from the organization SKAL in Holland and has the same chemical demands as the GOTS standard (www.ekogarderoben.se).

Good environmental choice (Bra miljöval)

This is the Swedish ecolabel from the Swedish Society for Nature Conservation, which collaborates with the Swedish stores. The ecolabel has criteria for many products, among them textiles. The demands that involve NP/NPE are: chemical substances and products that are used are not allowed to have these labeling: R40, R42, R43, R46, R53, R59 and R60-63. There are also limits for the use of persistent chemicals (www.naturskyddsforeningen.se).

Organizations and other relevant actions

Greenpeace

Greenpeace has been working on phasing put NP/NPE for many years and has published several reports on the subject. The work is though mostly focusing on water pollution (www.greenpeace.org)

ChemSec

The International Chemical Secretariat (ChemSec) is a non-profit organisation founded in 2002 by four environmental organisations. The ambition for ChemSec is to work for a toxic free environment by 2020. To achieve this they try to reach broad acceptance in society of the key principles: precaution, substitution, polluter pays and the right to know.
The organisation has developed a list (The SIN List) with substances of very high concern based on the criteria established by the EU chemical regulation, REACH. This list consists of over 378 substances, nonyl- and octylphenol is on this list. The SIN List is meant as a tool for speeding up the REACH legislative process (www.chemsec.org).

The textile importers

The Textile Importers Association in Sweden has facilitated a guide for the Swedish importing companies to comply with the chemical legislation and the recommendations in the fields of textiles, clothes, leather goods and shoes. The guide also applies to import of the mentioned products from for example developing countries to the EU. In addition to referring to existing legislation and regulation concerning NP/NPE, the guide also mentions that occurrence of below

100 mg/kg (for total APE) in products is regarded as unintended residues which are difficult to control. In Norway, Finland and Denmark similar associations are present (www.textileimporters.se).

B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

Concerning other uses of NP/NPE than in textile production, as indicated in section 9.1.1 there were extensive efforts made during the 1990's to phase out the use of NP/NPE. Voluntary bans on NPE in domestic detergents were introduced in several European countries. In addition, the policy measures proposed in the EU Commission's Risk Assessment Report (ECB 2002) and implemented through the former Directive 2003/53/EC (current Reach entry 46 Annex XVII), the use of NP/NPE was further restricted. Furthermore the inclusion of NP on the list of priority substances under the WFD (Directive 2008/105/EC) made NP subject to environmental quality standards that set targets for e.g. large industrial installations and waste water treatment plants covered by the IPPC directive and the later Industrial Emissions Directive in 2010.

The overall effect of the abovementioned policies and the various measures taken by industry has not been studied in detail during the preparation of this restriction proposal. However there are indications that the use of NP/NPE has been reduced substantially during the last two decades (see section B.2.1). It was estimated ex-ante that the EU regulation that came into effect in 2005 would reduce the NP burden by 70% (RPA 1999). Due to confidentiality reasons the current production volume, and hence volumes used according to exposure scenarios, cannot be presented in precise figures. According to AMEC (2012), consultation with industry actors do however indicate a clear decline in both production and use of NP/NPE in Europe since 1997. Thus it appears as if the use of NP/NPE has diminished, which would indicate that emissions to surface water have also have been reduced. The suggested downward trend in emissions is also indicated by the fact that waste water treatment plants in Europe have improved considerably in terms of collection rates and removal efficiency following the requirements set out by the Urban Waste Water Directive (91/271/EEC).

Yet there might be current uses of NP/NPE that are in fact not allowed according to e.g. existing Reach regulation. As discussed in section 9.3.4.2, the assessment of information from the Swedish product register suggests that some 40% of NP_{equ} emissions to waste water in 2010 could possibly originate from uses that are already regulated at the EU-level. The assessment is by no means complete and thorough and there are uncertainties in the data from the product register. Yet this could mean that there remain some efforts by various industry actors in the EU for the current legislation concerning NP/NPE to be fulfilled. The future trend in this regard, and in relation to expected future policy developments are further discussed in section E.1.1.

Regarding the use of NPE in textiles production, AMEC (2012) indicate that NPEs used by EU textile mills in processing has decreased since the introduction of the EU restriction in 2005. The current use in EU textile production is estimated to about 5000 tonnes per year, compared to 8000 tonnes in 1997, but since the REACH regulation does not allow processing with releases to waste water the actual emission to water have probably been reduced much more than the use of NPE. If EU textile producers are assumed to conform to current legislation, the NP/NPE emission to waste water from production facilities would in fact be zero.

As shown in section 9.1.1 there is currently no EU legislation concerning NP/NPE contained in imported textiles. There are several voluntary initiatives by textile importers and retailers, e.g. RSL management and certification, but it is not clear what overall effect such efforts have had during recent years. Judging from the review of studies on NPE in textiles (section B.9.3.4.1 below) there is no clear evidence of a downward trend in NPE concentrations in textile

B.9.2 Manufacturing

B.9.2.1 Occupational exposure

Not relevant since the risk has been assessed to be based on the environment, not on human health.

B.9.2.2 Environmental release

2010 the manufacture volume of nonylphenol in the EU was 10 000-50 000 tonnes/year according to data from the Amec consulting report (see section B.2.1). As also stated, estimations from CEPAD (European Council for Alkylphenols and Derivatives) demonstrate that the production of alkylphenol ethoxylates was for the same year 32 000 tonnes, mainly NPE. However even though this will result in an increase of NP concentrations locally it is not relevant from an EU wide perspective since there are only a few production sites in the Union, as described in section B.2.1.

B.9.3 Uses

Nonylphenol is used to synthetize a considerable number of organic chemicals with a broad society application. It has been observed that some of the derivatives can be degraded back to nonylphenol, during its use, in waste water treatment plants, and in the environment. The ethoxylate group is the most common derivate, but other derivatives can also be assumed to act in the same manner. Nonylphenol is also used as such, in different end-products, which therefore also can be expected to cause diffuse releases. The number of routines these chemicals are connected to involves several life cycle stages, such as industrial use, professional use, private use, service life and waste management.

B.9.3.1 Workers exposure

Not relevant since the risk has been assessed to be based on the environment, not on human health.

B.9.3.2 Consumer exposure

Not relevant since the risk has been assessed to be based on the environment, not on human health.

B.9.3.3 Indirect exposure of humans via the environment

Not relevant since the risk has been assessed to be based on the environment, not on human health.

B.9.3.4 Environmental release

Only wide dispersive uses released to the municipal waste water treatment plants (MWWTPs) are here considered. Large scale industrial production and processing sites are therefore excluded. The nonylphenol and its ethoxylates released to the environment via the MWWTP are of different origins[27]. The environmental release of the quantity nonylphenol originated from imported textiles is in this section compared to that of other sources.

For analogous reasons nonylphenol ethoxylates and other derivatives are converted to NP_{equ}.[28]

B.9.3.4.1 Release from imported textiles to the waste water

Estimations for the contribution of nonylphenol from imported textiles are based on a literary study and import statistics.

Numerous studies have reported levels of NPE (and in some cases also NP) in textiles. After a search for existing material,[29] seven studies from year 2007-2012 were reviewed. An important aspect is that the analysed textiles were selected in a random manner, to give a fair representation of the market. For this reason concerning all studies presented here selection criteria have been backed up by personal contact with people responsible for each study. The total number of textile items analysed in these studies was 251, primaraly clothes. Below are listed a summary of the studies with a short explanation of analysis method used. The results in terms of concentrations are presented as mg NPE/kg textile product.

[27] This environmental exposure assessment is limited to the releases from different wide dispersive uses to the waste water.
[28] Calculations are based on NPE with 8 ethoxy unitis (where the NP/NPE ratio is 2:5).
[29] This was performed in October 2011.

- In an investigation Greenpeace (Greenpeace 2011) analysed 78 articles of sports clothes and shoes from 15 leading brands, all manufactured outside Europe. The selection of the products tested was done on a random basis where the authenticity of the brand items was verified. The ambition was to receive a fair representation of international brands (15 ones) and different markets (18 countries) as well as involving several regions of manufacture (13 countries all outside the EU[30]). In two-thirds of the items, 52, NPE was found over the detection limit. In plain fabrics NPE was detected from just above the detection limit up to 1 100 mg/kg.[31] Seven samples had concentrations above 500 mg/kg. Mean value was 90.3 mg/kg and median value was 5 mg/kg. Analysis method: Samples extracted with an acetonitrile –water mixture (70:30) were analysed with reversed phase HPLC liquid chromatography and mass spectrometry (LC-MS/MS). Limit of detection: 1 mg/kg.

- Eurofins (Hjärtnäs 2009) analysed in 2009 on behalf of Swedish television six pairs of jeans purchased in Swedish stores. They were different common girls' and boys' models in a diverse price range, also available in stores in other EU countries. No information of country of manufacture was included in the study. NPE was found in four of the items in the range of 7-2 200 mg/kg with a mean value of 456 mg/kg and a median value of 59 mg/kg. Analysis method: Samples were analysed with liquid chromatography and mass spectrometry (LC-MS/MS). Limit of detection: 1 mg/kg.

- In 2007 the independent Swedish test and research company Testfakta (Testfakta 2007) analysed 13 children's winter overalls with focus on the overall wind density, tear strength, durability and waterproofness. In the study an analysis for NPE was included. Seven of the overalls were manufactured in China whereas no information was given concerning the others. The result showed a wide range of NPE content, from 2-1 200 mg/kg with a mean value of 421 mg/kg and a median value of 420 mg/kg. Analysis method: Samples were analysed with liquid chromatography and mass spectrometry (LC-MS/MS). Limit of detection: 1 mg/kg.

- In 2007 The Swedish Society for Nature Conservation (Hök 2007) analysed 20 towels for NPE. The towels were bought in stores widespread in Sweden. SSNC ambition was to select companies from which many consumers purchase towels. Products in various price ranges were analysed to see if, based on the small sample size, a pattern in NPE content could be observed. Seven of the towels were manufactured outside EU and no information was given on origin for the rest of the items. In all of the analysed fabrics NPE was detected with a concentration between detection limit up to 10 608 mg/kg. The two highest levels (1 277 and 10 608 mg/kg were textiles from outside EU). The mean value was 685 mg/kg and median

[30] Three products had an unknown origin for whom no NPE was detected
[31] 27 000 mg/kg was found in a pair of sneakers (Converse) with plastisol print design which was manufactured in the Philippines, excluded here when calculating the mean and median value.

value was 9 mg/kg. Analysis method: Samples were analysed with reversed liquid chromatography and mass spectrometry (LC-MS/MS). Limit of detection: 1 mg/kg.

- Further The Swedish Society for Nature Conservation (Prevodnik 2008) tested 17 T-shirts for NPE. Common brands were bought in Sweden with information of manufacturing country for eight of them (five outside EU). The selection criteria were comparable to previous study. The analysis showed NPE content from under the detection limit to 940 mg/kg. The mean value measured was 132 mg/kg and median value was 33 mg/kg. The most NPE found had seven to nine ethoxylate units. For which items it was possible to trace manufacturing country all T-shits that contained more than 100 mg/kg NPE were imported textiles from outside EU. The result demonstrated that T-shirts from China and Turkey had the highest concentrations. Analysis method: Samples extracted with an acetonitrile –water mixture (70:30) were analysed with reversed phase HPLC liquid chromatography and mass spectrometry (LC-MS/MS). Limit of detection: 1 mg/kg.

- In 2011 the Norwegian Pollution Agency, Klif, carried out a chemical study of textiles including NPE and NP (Klif 2011). 31 products were randomly chosen from the categories children's clothing, leisure/sports equipment shoes, and dog toys. NPE and NP was analysed in the clothing items from these categories. This resulted in 22 products of which NPE was found over the detection limit in 8 of them. One item had NPE content <20 mg/kg and for the remaining 13 <10 mg/kg. No NP was detected. Calculated mean value was 43 mg/kg and the median 10 mg/kg. Analysis method: LC /MSD with liquid/liquid extraction in organic solvent in an ultrasonic bath. For detection and quantification LC/MSD was used. Limit of detection: 10 mg/kg[32].

- In 2012 the non-commercial Swedish consumer magazine Råd och Rön published a study analysing men’s and women’s underwear for NPE among other substances (Råd och Rön 2012). When selecting the products for their tests the magazine co-operates internationally, in this case with other EU-countries. Their ambition is to cover 80% of the market. 97 articles with different colours were analysed of which demonstrated concentration under the detection limit for 70 % of the items. The highest value was found in a pair of underwear, 2040 mg/kg textile. A mean value landed on 60 mg/kg, median 10 mg/kg.

Conclusions of reviewed studies and comments from experts on the occurrence of NPE in textiles and release of NPE when washing

In a majority of the reviewed studies country of manufacture is not specified. However in the tests where country of origin is reported several show that imported textiles from outside EU can contain high levels of NPE. It is difficult to draw any conclusion concerning which kind of textiles have the highest concentrations of NPE. The reviewed studies show a wide range of NPE

[32] For one test item the detection limit was 20 mg/kg

content both concerning type of product and type of textile or textile mixture in the product. NPE is detected from just above the detection limit to 10 000 mg/kg, when excluding a pair of sneakers. A summary table of the studies can be viewed in Table 27. A calculation gives a mean value of 107 mg/kg among all the objects in the 7 studies when excluding two extreme values (251 of totally 253 analyses). The median value is 5 mg/kg. The considerably large difference between the median and the mean values indicates a variation concerning NPE content in clothes. In general when dealing with diverging data it is preferable to regard the median rather than the mean value. However this stipulates that the calculations are based on a larger quantity of analyses. 253 items represent only a minor part of the total textiles on the market and therefore the median is not more reliable than the average. Approximately 40 % of the analyses where performed on underwear of which the majority showed concentration under the detection limit. As can be viewed in Annex 1, NPE is found in several analyses at high concentrations.

Table 27 Concentrations of NPE found in textiles. Summary of reviewed studies.

Name of study	**Year of analysis**	**Number of samples**	**Number of samples under detection limit**	**Range (mg NPE/kg textile)**	**Mean value (mg NPE/kg textile)**	**Median value (mg/kg)**
Greenpeace: Dirty Laundry 2. Hung Out to Dry	2011	78	26	**<1- 27 000**	**435**	**6**
Swedish Television	2009	6	2	**<1- 2200**	**456**	**59**
Testfakta/Children's winter overalls	2007	13	0	**2-1200**	**421**	**420**
SSNC: Towels with a dirty past	2007	20	2	**<1- 10 608**	**685 (163)**	**9**
SSNC: T-shirts with a dirty past	2008	17	1	**<1- 940**	**132**	**33**
Klif, Norway	2011	22	14[33]	**<10-360**	**40**	**5**
Råd & Rön (underwear)	2012	97	60	<10-2040	57	5
All 7 studies combined		**Total: 253**	Total: 105	**<1- 27 000**	**Mean value[34]: 107 mg/kg**	**Median: 5 mg/kg**

Eurofins Scientific is an international group of laboratories providing a range of testing. It has on several occasions for the past 5-8 years on behalf of different clients analysed a diversity of textiles for NPE content. Analytical experts (Eurofins 2012) can see a trend which points to three types of results.

In 30-40 % of the tested textiles no or low concentrations (<10 mg/kg) of NPE is present. At these low levels it is not likely there is an intentional use of NPE in the manufacturing process. Possible explanations that analyses despite this indicate NPE content could be contaminated

[33] One <20 mg/kg and the rest <10 mg/kg
[34] When excluding two extreme values.

water in the manufacturing process or contamination by other fabrics during transport or storage. The majority of the tests, 50 %, show concentrations from 10-20 up to 400-500 mg/kg (with an average of 100-150 mg/kg). These levels demonstrate, according to an expert at Eurofins, a use of NPE in the manufacturing process. In about 5 % of analysed samples 500 to 1 000 mg/kg and above are found. An explanation for these high levels could be a use of colour pigment contaminated with a high concentration of NPE during the colouring process of fabrics. According to Eurofins those extreme levels have for the past couple of years been more infrequent.

These comments from experts are consistent with the average value, 107 mg/kg, from the studies above and therefore used for further calculations in this dossier.

The few studies which also analysed for NP in addition to NPE indicate that low levels of NP may be present in textiles. NPEs are used for various purposes in the textile manufacturing process. It is a surfactant used both for dispersion, emulsification, cleaning, etc. NPE degrades to NP in the waste water treatment plants, but it is possible this also takes place somewhere in the manufacturing process and that it is a degradation product found in the textiles. Another possibility may be an impurity in the used NPE.

In a report from the UK Environmental Agency (Cox 2012) NPE imported textiles were analysed. Including those results in the calculations above will however only marginally change the estimated average value.

How much of NPE is released during the washing process differs between different types of textiles and NPE content in the fabric when purchased. No certain conclusion can be drawn on what kind of fabric releases the most NPE when washed which also the few simulated laundry studies performed show. In March 2012 Greenpeace published a report (Greenpeace 2012) following up their Dirty Landry 2 study. Here the items analysed before where subjected to simulated laundry tests which demonstrated that between 9 and 94% of the NPE content was washed out with the one first wash. The study concludes that all NPE will be washed out after frequent washing. Since NPE is a non-ionic surfactant, easily dissolved in water, it is probable that all NPE is washed out after repeated washing, regardless type of textile (Månsson et al. 2008). There might be fabrics not washed as often or maybe ever, but these are a part of an exception. Therefore it is a reasonable to base calculation on the assumption that all NPE in textile will reach the waste water treatment plant.

Trade, production and total consumption of textiles in EU

KemI has identified certain categories[35] of textiles that are likely to be used and washed in such a manner that emissions of NP/NPE are expected. Based on statistics on imports, exports and production (Statistics Sweden 2011 and Eurostat external trade 2011) a rough estimate can be made of consumption as well as import share of total EU consumption of the textiles specified. The statistical data shows that imports (in terms of quantity) of textiles have grown rapidly from about 3.3 million tonnes in 2000 to 6.2 million tonnes in 2008. The growth in import quantity of the specified textiles has stagnated after 2008, likely due to the economic situation in Europe, and the total imported quantity was close to 6.1 million tonnes in 2010. Likewise the value of imported textiles has grown from 2000-2010 but to a lesser extent than quantity, which indicates that unit prices (Euro per tonne) of imported textiles have decreased. The unit price was on average about 20% lower in 2010 compared to 2000.

The import statistics show that China has become an increasingly important source for textiles imported to the EU. China's share of EU imports of the specified textiles has grown from around 21% in 2000 to roughly 50% in 2010. India, Bangladesh and Turkey are also important exporters of textiles to the EU.

The EU production statistics for the same selected categories of textiles as above is not directly comparable in terms of quantity since they are recorded in varying units (e.g. pairs, units, weight etc.). The yearly quantity (in tonnes) of textiles consumed in the EU can thus only be estimated for certain categories of textiles that are reported by weight in the production statistics. However the value in Euros is reported in comparable terms for imports, exports and EU production of textiles. Assuming that consumption is roughly equal to EU production plus imports minus exports, total EU consumption would have been about 95 billions of Euros worth in 2010 for the selected textile categories. The total value of EU consumption appears to show a similar (but weaker) increasing trend as import quantity from 2000 to 2010. The import value constituted about 54% of total computed EU consumption in 2000, and grew to around 75% in 2010. These percentage figures are likely not valid for import shares of consumed quantities, since the average unit price may be considerably lower for imported textiles compared to similar EU produced textiles. The imports share of EU consumption, measured in tonnes, would thus likely be in at least 75% and probably closer to 90%. Assuming that is the case, total EU consumption of the specified textiles would be in the range of 6.7 to 8.1 million tonnes in 2010 (most likely in the lower part of the range).

Import of semi-finished textiles was in 2010 4.1 million tonnes (EU Statistical Database 2012) which will be treated by textile industries within the EU. These textiles can contain NPE and hence pose as a potential source for the NPE release. However, when reviewing these statistic

[35] The categories specified include the CN-codes 6001-6006, 6101-6117, 6201-6217, 6301-6304, 6306-6309, 6404110000, and 9503004100.

categories a majority of them can be excluded. Possible NPE content in the product can either be considered minor or will not be subject to washing. Although some of the categories of the semi-finished textiles in the statistics can be suspected to contribute to the NPE release from washing textiles. This could approximately increase the textile tonnage by up to 10 %, however this is not included in the final release estimates.[36] (ECB 2002).

Estimated total NP/NPE from consumed imported textiles exposed to the waste water
An import to EU in 2010 at 6 037 526 tonnes and an average concentration NPE in textile at 107 mg/kg result in a total of 642 tonnes NPE. Assuming in accordance with argument above this amount will be released to the WWTPs. Calculation based on NPE with 8 ethoxy unitis (where the NP/NPE ratio is 2:5) gives 257 tonnes NP_{equ} annually.

The completed COHIBA project, partially funded by the EU's development fund and the Baltic Sea Region Programme 2007-2013 included NP/NPE (COHIBA 2012). One of the work packages in the project studied substance flow analysis for NP/NPE. The contribution from textiles was based on emissions data calculation from Stockholm (Månsson et al. 2008), which then was extrapolated to EU level. The difference from the Stockholm analysis was the inclusion of a Finnish study of 10 T-shirts, half of which contained nonylphenol. On the basis of this they assumed that half of the imported textiles contain NPE. The estimated amount of NP/NPE emitted to the WWTPs from washing imported textiles were 225-525 tonnes NP_{equ} /year in EU. These approximations are consistent with the quantity NP_{equ} received when using the mean value for the seven studies above.

Technical textiles manufactured in the EU
In a JRC[37] Report, Environmental Improvement Potential of Textiles (Beton et al. 2012), textiles were divided into separate groups; clothing, household (including both household and interior textiles), technical textiles and others. These groups were then differed further for the purpose (among other objectives) to observe the total life cycle and estimate and compare the environmental impacts of textile items consumed in the EU27. According to the report technical textiles represent close to 20 % of the European textile market (in terms of mass). Technical textiles are however not described furher in the report due to the heterogeneous nature of the group.

In an article based on a study of the world market forecast to 2010 of technical textiles and nonwovens[38], technical textiles were defined as quote: *"comprising all those textile-based*

[36] Here should also a default emission factor be taken into the calculations, 85 % goes to the WWTP and 5 % to the air
[37] Joint Research Centre, the European Commission in-house science service
[38] Technical textiles and nonwovens: world market forecasts to 2010. Accomplished by David Rigby Associates, a consultancy specialising in the fibre, textiles and clothing industry. For more information, see its website, www.davidrigbyassociates.com.

products which are used principally for their performance or functional characteristics rather than for their aesthetics, or are used for non-consumer (i.e. industrial) applications." This definition is focused on the merchandise itself rather than the fibre or yarn used. According to the same source technical textiles and nonwovens constitute of over 25 % of the total textile world consumption (in weight terms).

The classifications given by Techtextil, Messe Frankfurt Exhibition GmbH[39], are according to the article above, widely used in Europe, Asia and North America and are described below. The portion of the world-end volume consumption is shown in Figure 4. In the absence of information specific for EU27 this sectioning is assumed to also be applicable for the EU27 market. Further, those figures are based on volume data from year 2000 but it is assumed that the breakdown of the volume consumption is also relevant today.

Protective textiles (Protech) are all textile materials and products dealing with the manufacturing of different kinds of protective clothing to enhance people safety in their workplaces. They are designed to have extra standards in protection (against hazards) rather than fashion. Examples of applications that can be found on the market are: high temperatures (insulating, firefighters); burns (flame, firefighters); bullet impact (security, military); cut resistant (gloves); acid environment (gas, petrochemical, refineries and chemical) and astronaut's suits. In terms of volume this is a small sector (around 1% year 2000) but there is a high unit price. In common consumer clothing those fabrics can at some extent also be used (e.g. breathable waterproofs).

Agro-textiles (Agrotech) represent 8 % of the market and comprise of all activities dealing with crops (growing and harvesting) and animals. The required properties are strength, resistance to toxic environment and resistance to sunlight among others. These properties will facilitate the growth and harvesting of different foodstuffs such as crops. There is an increasing interest in using materials that gradually degrade, known as biodegradables. The fishing area is also an important end user of technical textile products.

Automobile and Aerospace textiles (Mobiltech) is the most important sector when it comes to technical textiles. They speak for 15 % of the volume consumption. Examples of products are airbags applications in cars, lorry covers in the transporting area and performance furnishing materials in public service vehicles. Composite materials in the marine segment are also important applications. Other examples are ship and aircraft constructions and aspects of space travel.

[39] Messe Frankfurt events for Technology & Production, Consumer Goods & Leisure, Textiles & Textile Technologies, Mobility & Infrastructure and Media & Creation are according to their webpage international leaders in their respective fields. http://www.messefrankfurt.com/frankfurt/en.html

Construction Textiles (Buildtech) are often superior to traditionally used materials and stand for 10 % of the consumption in comparison to other technical textiles. There is an increasing content of textile in buildings and constructions where they can occur in different applications; concrete re-enforcement, interior construction, conditioning, noise prevention, insulations, proofing materials, air visual protection and protection against the sun.

Clothing textiles (Clothtech) represent 7 % of the total and is a sector dealing with functional parts of clothing and footwear e.g. sewing tread, interlinings and wadding. Clothtech includes "high performance" apparel fabrics of more sophisticated sort.

Geo-textiles (Geotech) are textile materials (nonwoven, woven and knitted) providing different functions e.g. drainage, support and separation. They are used in application for construction of bridges, buildings, roads etc. The materials in geo-textiles are penetrable fabrics which have the capacity to separate, filter or protect when used with soil. The textiles used must have good thickness and durability. Geo-textiles only stand for 2 % (year 2000) of the market but have a potential for growth.

Domestic Textiles (Hometech) are used in households and includes curtain tapes, carpet backings and wadding for mattresses and furniture. They represented approximately 13 % of the volume consumption in year 2000 and are highly depended on the current economical situation.

Industrial Textiles (Indutech) is a diverse application sector dealing with lightweight nonwoven filters and brushes to heavier coated conveyor belting. It is a large area including chemical and electrical applications as well as fabrics regarding mechanical engineering. Examples are: silk-screen printing, propulsion technology, plasma screen, sound-proofing elements, roller covers and fuel cell. They stand for approximately 13 % of the use consumption.

Medical and hygiene textiles (Medtech) comprise of health and hygiene applications dealing with the consumer as well as the medical market. The area speaks for 9 % of the world market and includes a considerable variety of products with different performance properties. A large portion of these textiles are disposable items or only used once.

Packaging textiles (Packtech) is the largest end use application sector and represent 15 % of the total use. Packing and storage are well established applications for textiles. Packaging, containers, canvas covers, bags and marquee tents are specific examples in this category.

Sports textiles (Sporttech) are sporting materials and correlated goods and equipment. In year 2000 they represented around 6 % of the technical textile sector. Application examples are; shoes, cycling, indoor sports, flying and sailing sports, climbing, angling, winter and summer sports.

A sector not included here but estimated to be a developing area is **Environmentally friendly textiles (Oekotech or Ecotech)**. This sector includes environmental protection, waste disposal as well as recycling. Examples of applications are floor sealing, erosion protection, air and water cleaning, waste treatment/recycling and product extraction.

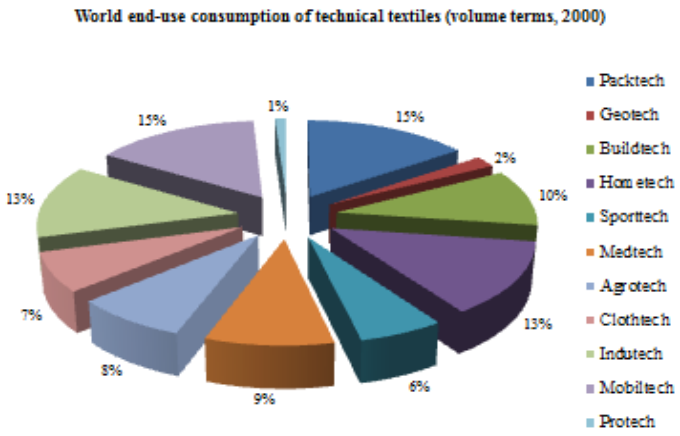


Figure 4 World end-use consumption of technical textiles in volume terms and application area (2000, Source Technical textiles and nonwovens: world market forecasts to 2010, David Rigby Associates)

Primarily *Clothing textiles (Clothtech) and Sports textiles (Sporttech)* consists of products submitted to washing in water and hence contribute to the NPE released to the waste water.[40] Those textiles will therefore be included by the proposed restriction. This is at a worst case scenario approximately 10-15 % of the world end volume consumption. Within the other categories there can also be special products that is washed in water (e.g. among Protective textiles) but the vast majority of the technical textiles are thus handled in such a manner excluding them from the scope of this dossier.

Technical textiles that are not covered by the proposed restriction can however be exposed to e.g. rain with a following leakage of NPE to the environment. According to an AMEC report (AMEC 2012), based on consultation with the industry, 5 000 tonnes NPEs can be used in the EU in the production of technical textiles. The amount NPE used in the textile production is assumed to be 20 kg/tonnes (grounded on an emission scenario from OECD stating a quantity of 20 g surfactant/kg textile (OECD 2004)). An average of 107 mg NPE detected in textiles in EU stores will consequently imply that 0.5 % of the NPE used in the textile production could stay in the textile after the process. 5 000 tonnes result in a quantity of 25 tonnes NPE annually.. Over a

[40] This assumption is based on the descriptions of the different technical textiles categories and after consulting with the industry (see section G.1).

lifetime of ten years[41], 5 % of the NPE still in the textile will each year be emitted to the surface water according to AMEC assumptions. The report then used OECD equation (5) (OECD 2004) to estimate the emission direct to surface water. Applying the same estimations here will result in an annual release to surface water of approximately 10 tonnes NPE and correspondingly 4 tonnes NP_{equ}. This is a small fraction of the NPE released from washing textiles (257 tonnes NP_{equ}).

B.9.3.4.2 Releases from other sources than imported textiles to the waste water

It is apparent, from reviewing the Chemical Safety Report (CSR 2010), that there are several uses sectors for nonylphenol and its ethoxylates. This dossier will be focused on information from the Swedish Products Register (KemI 2012) since it was considered to be a relevant data source for several of these source groups. The Swedish market for chemicals/mixtures has been used to identify potential sources for NP and relevant derivatives in the society. Importers and producers are required to register products covered by chemicals control to the Products Register, when the volume is 100 kg or more annually. Documentation of the use of chemicals on the Swedish chemical downstream market is available here. Sweden is selected as a model for the EU market with the assumption that the consumption pattern is similar throughout the Union. The observed substances cover different product segments, managed with different regulations. This concluded in the following groups:

1: Nonylphenols
2: Nonylphenol ethoxylates
3: Nonylphenol derivatives, other than group 2

Each of these substance groups can be subdivided into releases from chemical mixtures and release from articles.

The definitions of group 1 and 2 follow the nonylphenol restriction in REACH Annex XVII, entry 46. Some of the uses of the substances in the groups 1 and 2 are restricted in concentration $\geq 0.1\%$. Group 3 represents other nonylphenol derivatives found on the Swedish market. Only derivatives that are expected to form nonylphenol, in the same extent as the ethoxylates are considered here. Group 3 is not affected by restrictions.

Another potential source to nonylphenol is impurities, origin from synthesis, when nonylphenol is used as a raw material. The impurity can be expected to be rather high (2-5%) in the cases the synthetized chemical has similar chemical/physical properties as nonylphenol (then it will difficult to purify). This can be expected for some of nonylphenol derivatives in group 3. In this estimation a worst case assumption of 3 % impurities is used for such substances. An analysis of the Swedish product register indicates a number of potential substances. The substances that were identified as relevant sources for nonylphenol and nonylphenol ethoxylates in waste water are

[41] An emission scenario of 5-20 years for tents (OECD 2004)

respectively listed in Table 28 and Table 29.

Table 28 Included Nonylphenols

Nonyl phenol	
4-Nonyl phenol	CAS No. 104-40-5
Nonyl phenol	CAS No. 25154-52-3
4-Nonyl phenol, branched	CAS No. 84852-15-3
Nonyl phenol, branched	CAS No. 90481-04-2

Table 29 Included NPEs

Nonylphenol ethoxylates	
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-	CAS No. 9016-45-9
Poly(oxy-1,2-ethanediyl), .alpha.-(4-nonylphenyl)-.omega.-hydroxy-	CAS No. 26027-38-3
Poly(oxy-1,2-ethanediyl), .alpha.-(isononylphenyl)-.omega.-hydroxy-	CAS No. 37205-87-1
Poly(oxy-1,2-ethanediyl), .alpha.-(nonylphenyl)-.omega.-hydroxy-, branched	CAS No. 68412-54-4
Poly(oxy-1,2-ethanediyl), .alpha.-(4-nonylphenyl)-.omega.-hydroxy-, branched	CAS No. 127087-87-0

Potential nonylphenol releasing derivatives, other than the ethoxylates

At least 14 potential nonylphenol releasing derivatives occur on the Swedish market. They can be categorized into the following six groups:

- Nonylphenyl phosphate esters (six subst.)
- Ethoxylated nonylphenyl phosphate esters (two subst.)
- Nonylphenol blocked diisocyanate polymers (two subst.)
- Nonylphenolphenoxy acetic acid (one subst.)
- Polyethylene glycol nonylphenyl ether sulfate (one subst.)
- Nonylphenol, barium salts (two subst.)

CAS No: 92908-31-1; 84787-78-0; 84787-76-8; 84787-77-9; 35239-35-1; 68412-53-3; 66197-78-2; 119012-32-7; 9014-90-8; 54771-30-1; 103458-32-8; 3115-49-9; 28987-17-9; 68515-89-9.

In this release estimation the transformation rate to nonylphenol is assumed to be the same as for the ethoxylates.The releases from uses of nonylphenols, nonylphenol ethoxylates and other

nonylphenol releasing derivatives have then been aggregated to show the overall release pattern from the Swedish use of mixtures. Release data presented here are to some degree combined to hide confidential information. The estimation on an EU level is scaled from this data, based on population size.

Release rate selection

The predefined Environmental Release Categories (ERCs, Table R.16-22 in REACH 2012) were used for the environmental exposure estimation. Only the release to water before WWTP was used. In this situation several of the default rates were considered to be unrealistic, and therefore modified. Those corrections can be viewed in Table 30 Corrections of ERCsA majority of the default rates were modified for each specific use scenarios and chemical/physical properties of the substances for adequate reasons (see Figure 5).

Table 30 Corrections of ERCs

Influences on the release factor	**Impact on the release factor, (t = times)**
Substance solubility	2-200 t lower when not water soluble
Indoor/Outdoor	2-5 t lower if not indicated
Formulation base	200 t lower if solvent based
Price of end product	0.5 t lower if high
Processing aids, industrial use indoor etc.	20-200 t lower if solvent and cleaning losses

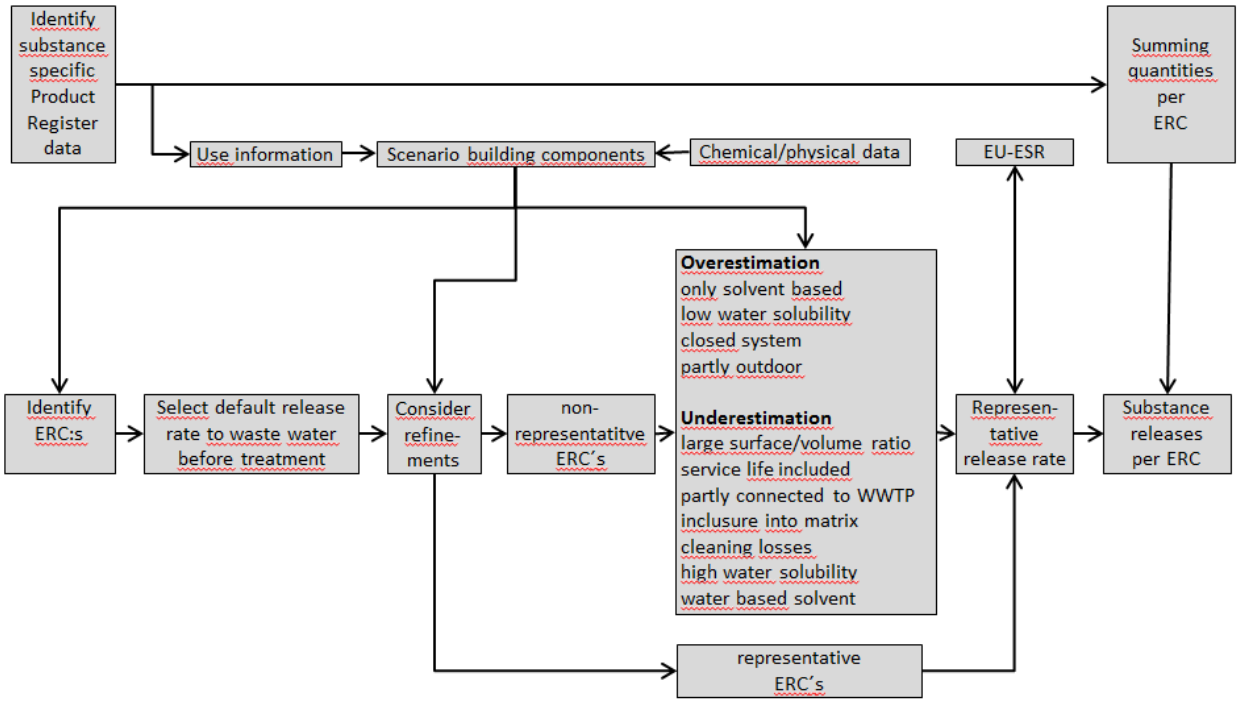


Figure 5 Work flow for the deriving of releases of NP (incl. derivatives) to waste water before treatment from Product Register data.

Uncertainty analysis
There are several uncertainties involved in these release estimations. The following have been identified:

Products register data:

- Underestimation of the releases can occur since not all products on the market are found in the Products register. This takes place when:
    - The product volumes are less than 100 kg/year (the lower limit for registration in the Products Register).
    - The product volumes are larger than 100 kg/year, but the importer/producer does not register because of ignorance of the Products Register regulation.
- A change in a product composition on the market is not followed up by an update of the composition reported to the Products register. This can be expected to cause an overestimation of the releases.
- For the product groups cosmetics and pharmaceuticals there are no requirements for registration of end products. Only the raw materials used in the national production are registered. This will lead to an underestimation if the import of such end-products is higher than the export.

Release rate calculation:

- The used release rates are often more of conservative assumptions, than based on calibrating laboratory studies. This may lead to overestimation of the releases.
- The releases from service life from long life articles assume a steady state of the use on the market. If such use is still increasing, the release will be an underestimation.

Since most of the uncertainties described above are not very well defined it is difficult to quantify the overall uncertainty. The absolute level of exposure represents the highest uncertainty. An inter relationship comparison between the three chemical groups (nonylphenol, nonylphenol ethoxylates and other derivatives) can, however, be expected to have lower uncertainties, since several uncertainties then will be neutralized.

Product groups
When considering various uses as sources for nonylphenol releases, they have been divided into several product group. The releases from the multiple life cycle stages of each product groups have been calculated separately as demonstrated in Table 31. (In Annex 3 the use of nonylphenol, ethoxylates and other derivatives in different product groups can be viewed in more detail.)

The main release (36 %) is calculated from the use as emulsifier in the chemical industry. The data in the Products Register are not detailed enough to identify the end product uses. Only the

life cycle stage formulation and processing (unspecified end product uses) are therefore considered.

Cleaning agents contribute to 24 %, which primary is expected to be released during end product uses. The production and end use of plastic products contributes to 18 %, where the formulation and service life are likely to be the main usage stages. Paints and adhesives stand for 14 %. Releases from the service life stage of the paint dominate.
A combination of the emissions of nonylphenol and nonylphenol ethoxylates from these different uses sectors indicates that close to 40 %[42] is already regulated by REACH. This is a rough estimation generated from a case by case assessment based on the information demonstrated in Annex 3.
The total of release of nonylphenol is 6.4 tonnes/year[43], releases of nonylphenol ethoxylates are 171 tonnes NP_{equ} /year[44] and the annual releases of nonylphenol derivatives are 72 tonnes NP_{equ}.[45] This shows that nonylphenol only represent a small part of the total release (approximately 2.5 %).

Table 31 Releases to WWTP of nonylphenol from use in the EU, based on data in chemical mixtures in Sweden 2009

Product group	**Nonylphenol* in products, 2009** (tonnes) (Upscaled from Swedish data)	**LIFE CYCLE RELEASES TO WWTP**					
		Formulation (tonnes)	**End product use** (tonnes)	**Processing** (tonnes)	**Service life** (tonnes)	**Total** (tonnes)	**Total** (%)
Emulsifier	2544	26.0		63.6		89.6	**36**
Cleaning agent	116.6	0.6	58.8			59.9	**24**
Plastic product	8692	30.2		1.1	13.3	45.1	**18**
Paint	1749	9.0		8.0	9.0	26.0	**10**
Adhesive	530	2.8		3.3	4.6	10.6	**4.3**
Lubricant	265	0.7	0.2	0.00053	5.0	5.8	**2.4**
Pharmaceutical	10.6	0.05	4.8			4.9	**2.0**
Construction material	90.1	0.4		0.7	2.3	3.4	**1.4**
Printing ink	8162	0.8		0.4	0.4	1.6	**0.7**
Other	174.9	1.5		0.6	0.5	2.6	**1.0**
Total (tonnes)	22 334.2	72.1	64.1	77.4	35.5	249	**100**
Total (%)		**29**	**26**	**31**	**14**	**100**	

*presented as nonylphenol equivalents, $NP_{equ.}$
(Swedish Products Register 2009), imported cosmetics and pharmaceuticals are not included

[42] Proportional partition of the releases to WWTP with unclear regulation where the groups with unclear regulation status are proportionally included
[43] "wide dispersive use" from nonylphenol is 53 * 0.121 tpa (scaling factor: Sweden→EU = 53)
[44] "wide dispersive use" from nonylphenol ethoxylates is 53 * 3.22 tpa = 171 tpa (scaling factor: Sweden→EU = 53).
[45] "wide dispersive use" from nonylphenol derivates is 53 * 1.36 tpa = 72 tpa (scaling factor: Sweden→EU = 53).

B.9.3.4.3 Releases from other not quantified sources to the waste water

Several applications for using nonylphenol and nonylphenol ethoxylates are restricted due to REACH Annex XVII, entry 46. When containing above 0.1 % NP or NPE these products can not be placed on the European market. In spite of this it can not be excluded that releases from such sources still might occur and hence contribute to the NP and NPE reaching the WWTPs. Cosmetics and hygienic products are one of the items restricted under REACH. Not all of the Swedish amounts of chemicals in cosmetic and hygiene products can be estimated, due to limitations in the Products Register coverage. The register does, however, contain products used as raw materials. No such products were however found, probably because the main part of the cosmetic products on the Swedish market is imported from another EU country (Jansson 2012). NPE can be used in spermicides which are not covered by current regulations. According to a Swedish study (Andersson and Sörme 2007) close to 10 kg NPE is used in spermicides per year in Sweden. This is however based on old data (from 2004). Four nonylphenol derivatives are generally known to be used on the world wide market as ingredients in cosmetics and hygienic products (mainly as emulsifying agent and/or surfactants, see Annex 4). One of these derivatives is not an ethoxylate, and is therefore not covered by the current restriction (3,6,9,12,15,18,21,24-Octaoxahexacosan-1-ol, 26-(nonylphenoxy)-, dihydrogen phosphate, CAS No. 66197-78-2).

The COHIBA Project (COHIBA 2012) estimated the release of NP and NPE to waste water from the use of cosmetics to an annual EU emission of totally 0.13-3.9 tonnes NP_{equ}. This was based on a study in Stockholm 2004 (Månsson et al 2008) and today with the implementation of the REACH restriction not as applicable and not used for further calculations.

An OECD case study of releases of NP/NPE, using information from the Swedish Products Register among others also pointed out aircraft deicer and electronic components as possible sources for release (OECD 2011). Those are most likely included here in section B.9.3.4.2 as part of cleaning agents.

Cosmetics and other sources for NP/NPE covered by REACH are not considered in further calculations since we assume that current restriction is respected. Due to use under 0.1 % and use that should have ended this might pose as a source of error in our estimations as explained in Section B.9.4.

B.9.4 Environmental exposure

The releases of nonylphenol, nonylphenol ethoxylates and other derivatives from different uses described in section B.9.3.4 will, when connected, reach a municipal waste water treatment plant (MWWTP). In a conventional WWTP the waste water undergoes mechanical, biological and chemical treatment. This is often followed by a filter to catch fine particles.

Initially the raw waste water undergoes mechanical treatment (primary treatment). The primary function is to remove solid impurities which are accomplished by grids, sand (or filters) and pre-sedimentation. The latter generates a homogeneous water mixture when particles of small diameter (e.g. oil, grease and sand) are removed.The primary treatment is the segment of the treatment process that is the most cost effective overall in reducing pollutants in waste water (e.g. nutrients). However further treatment is crucial to obtain current emissions standard.

During the biological treatment (secondary treatment) the waste water is processed with micro organisms, primarily different kind of bacteria. Two major procedures are used; suspended growth (activated sludge) and fixed film (trickling filter). Organic materia is degraded and nitrogen is converted into nitrogen gas and reversed into the air. The waste water is directed into aeration sedimentation basins where sludge descends to the bottom. A large part of the sludge is re-circulated except the surplus which is being removed and treated separately. This so-called activated sludge method is common throughout the EU (Seriki 2008).

In the biological step organic materia is reduced between 90-95 % measured as BOD7[46] (Stockholm Vatten 2012). At some extent suspended materia, phosphorous, nitrogen and inorganic materia such as metals are removed during the treatment. Numerous of reactions occur simultaneously for instance physical/chemical adsorption and absorption along with biochemical reactions and microbial processes. The biological treatment is complicated and sensitive to disturbance and poisoning. Therefore the system needs to be secured against e.g. abnormal flows and sludge loads which can lead to extended retention time (especially when biological nitrogen reduction is conducted).

The chemical treatment consists of chemical precipitation where the chemicals used are salts of primary iron or aluminum. The function of the chemical treatment is to remove impurities in the liquid phase primary phosphorous compounds. Separation of suspended and organic matter also increases during the pre-sedimentation stage. The metal salt converts dissolved phosphorous into a form of poorly soluble metal phosphates.

The tertiary treatment following the secondary implies a variety of processes. For example nutrient removal processes, nitrification/denitrification and phosphorous precipitation are reflected to be tertiary treatment processes. Also because of stricter phosphorous restrictions the usage of filters becomes more and more frequent at MWWTP. Here sludge and particles not already intercepted are separated. The filter can also result in an increasing removal of nitrogen. An anaerobic digestion of sludge is a tertiary treatment stage used to stabilise the surplus of solids. The particles in the sludge are in an anaerobic environment digested and part of the organic materia is degraded to methane gas and carbon dioxide.

[46] Biological Oxygen Demand, 7 days

During conventional waste water treatment (mechanical, chemical, biological treatment and filters) NPE undergoes reactions where metabolites are formed. Several studies have demonstrated the fate of NP, NPE and its metabolites in MWWTPs. In 2008 ScorePP[47] (Seriki 2008) described the behavior of NPE in WWTPs, including a literary survey and fate modeling. Calculations referred to in the report, from a Greek study (Stasinakis et al. 2007), showed that the principal mechanisms involving NPE are degradation and sorption into sludge. Further it was demonstrated that NPEs have low volatilisation potential. The primary and secondary treatments appear to remove a considerable quantity of analysed short-chained NPEs. The ScorePP report concluded based on several studies[48] and three tested models that the removal efficiencies from the water phase in WWTP were in the range of 70-99 % in many cases over 90 %. However when only using mechanical treatment findings indicate that deduction of NP/NPE is less, merely 10-20% are then removed[49].

The EU Risk Assessment report, EU RAR (ECB 2002) considered the fate of nonylphenol ethoxylate during the waste water treatment in terms of the quantity of nonylphenol formed under different conditions. This was based on laboratory biodegradation tests and field studies (see summary and Table 32 cited from the EU RAR below) conducted in the late 1980's and during the 1990's. Even though the concentrations of NP/NPE presented in those old studies are not as relevant today they are still informative regarding the observations of the behaviour of NPE in the WWTP.

Summary of laboratory biodegradation tests and field studies cited from the EU RAR[50]:

"The biodegradation of 14C ring-labelled NPnEO (average n=9) has been studied in a semi continuous activated sludge treatment system. The activated sludge was derived from the mixed liquors from the aeration basin of a wastewater treatment plant. The water used in the test was the primary effluent from the settling basin at the wastewater treatment plant, supplemented with nutrient broth. The background concentration of nonylphenol and NPnEO (range n=1-17) were 43.6 µg/l and 978 µg/l respectively. Before the test was started, the activated sludge was acclimated for 14 days by exposure to the primary effluent. After 14 days 300 ml of the activated sludge was placed into the degradation reactor and primary effluent containing 2 mg/l of the 14C labelled NPnEO was fed into the reactor. A semi-continuous fill and draw procedure was used such that around 200 ml of the liquid in the reactor was drawn off and replaced by the primary effluent containing the 14C-labelled substance every 2.3 days. This gave a sludge retention time

[47] Source Control Options for Reducing Emissions of Priority Pollutants, ScorePP, is a specific targeted research project funded by the European Commission under the Sixth Framework Programme

[48] 69-98 % (Huyard et al. 2006), 23-90 % (Clara et al. 2007), 93 % (Isobe et al. 2001), 92 % (RSDE 2006), 61-75 % (Nakada et al. 2006)

[49] <20 % (Vogelsang et al. 2006), 10 % (Tåstrup WWTP, an appendix in the ScorePP report)

[50] NPEO is in the EU RAR short for nonylphenol ethoxylates. In the effluent there are also degradation products that pose as a potential source for NP, such as carboxylic acid of mono-ethoxylate NPnEC, produced when the terminal hydroxyl group is oxidated (Pettersson and Wahlberg 2010).

and hydraulic retention time of 52 and 3.45 days respectively in the system. The total sampling time was 30 days. Based on radioactivity measurements, 20.8% of the influent radioactivity was removed as CO2, 55.9% was found in effluent as nonylphenol/NPnEO (6.9%), NPnEC (26%) and highly degraded metabolites (23.1%), 6% remained in the test system adsorbed to sludge (3.5% as nonylphenol/NPnEO and 2.5% as biomass), 8.35% remained in the aqueous part of the system (1.03% as nonylphenol/NPnEO, 2.88% as NPnEC, and 3.45% as highly degraded metabolites), 0.72% of the radioactivity was removed from the system in sludge (0.09% as nonylphenol/NPnEO, 0.34% and NPnEC and 0.3% has highly degraded metabolites) and 8.23% of the radioactivity was unaccounted for. Overall, there was a 93% removal of the NPnEO from the influent. Specific analysis for nonylphenol showed that from the total influent concentration of nonylphenol/NPnEO compounds (total 204 μg, of which around 8 μg was nonylphenol), around 4 μg of nonylphenol was discharged in effluent, 5 μg was adsorbed on sludge and 8 μg was retained in the system. Thus there appears to have been a net generation of nonylphenol in the system (i.e. 8 μg was added to the system, 17 μg present in the system - if it is assumed that no degradation of nonylphenol occurred then around 4.6% of the NPnEO was converted to nonylphenol) (Varineau et al., 1996a).”

“Kravetz et al. (1982) looked at the biodegradation of radiolabelled NPnEO (n=9) during wastewater treatment. The radiolabelled compound had 14C-labelling on the ethoxylate chain and 3H-labelling on the phenolic ring. The system used was a closed bench-scale bioreactor that was seeded with mixed liquor from the aeration basin of a domestic activated sludge wastewater treatment plant in Texas. The bioreactor was installed on-site at the wastewater treatment plant and used water from the aeration tank (shown to contain nonylphenol and NPnEO), spiked with labelled or unlabelled NPnEO (concentration 5 mg/l), as continuous influent. Mild mechanical mixing and aeration with CO2-free air was used in the bioreactor, and the hydraulic retention time in the system was around 8 hours. The test was divided into 3 phases: an acclimation period of 14 days, where the reactor was fed unlabelled NPnEO; a 14 day biodegradation test phase with the radiolabelled NPnEO; and finally a 12 day period to monitor the die-away of the radiolabelled components (unlabelled NPnEO was fed into the reactor during this period). During the 14-day acclimation period, >98% removal of NPnEO based on cobalt thiocyanate active substance (CTAS) analysis and >95% removal based on foam height measurements and surface tension data was seen, indicating substantial primary biodegradation of the nonylphenol ethoxylate. When the radiolabelled NPnEO was used, about 40-60% of the 14C was converted to 14CO2 and around 10-40% of the 3H was converted to 3H2O, indicating that some mineralisation of both the ethoxylate chain and phenolic ring was occurring. It was estimated that around 35-50% of the hydrophobe of NPnEO was discharged in the effluent from the system, probably as NPnEO or
NPnEC with low values for n (the EO to hydrophobe ratio in the effluent was estimated to be 2.4).”

"A lab-scale activated sludge system has been used to study the behaviour of several NPnEO (n=8, 10, 14, 16 and 30). Pre-settled sewage was used as the influent to the system. This was found to have a "background" concentration of around 0.5 mg/l of total nonionic surfactants. Activated sludge from a municipal wastewater treatment plant was used as seed for the system and after 1 week of operation, 5 mg/l of NPnEO (n=8) was added to the influent. The other NPnEOs were 212 added to the influent over the next 7-24 days depending on the degradation seen. Degradation of the original NPnEO was determined by monitoring the effluent using methods that detected NPnEO with n>2 and removals of 82-91%, >91%, >90%, 95-96% and 88-93% were determined for NPnEO with n=8, 10, 14, 16 and 30 ethoxylate groups/molecule respectively. In order to establish if removal was due to adsorption or biodegradation to NP2EO, activated sludge and effluent from experiments with NPnEO (n=10 and 14) were analysed by gas chromatography. Neither the original surfactant or NP2EO could be detected (Rudling and Solyom, 1974)."

"Recent measurements of nonylphenol concentrations in sewage sludge from the United States also show a similar increase in the nonylphenol concentration during anaerobic digestion (Williams and Varineau, 1996). Levels of nonylphenol were measured in sludges fed into the anaerobic digester and at the outlet of the anaerobic digester at 4 treatment works. The levels measured in the sludge before anaerobic digestion were 21-64, 3, 180 and 960 mg/kg and the levels measured after digestion were 380, 1,030, 940 and 540 mg/kg at the four plants respectively. In contrast, the levels of nonylphenol measured in aerobic sludges at 5 other treatment plants were in the range 1-175 mg/kg.

Brenner et al. (1987) studied the fluxes of nonylphenol, NP1EO and NP2EO through sewage treatment plants in Switzerland, focusing on the digestion/stabilisation of the sewage sludge at the plants. High levels of nonylphenol (mean 1.27 g/kg dry weight; range 0.64-2.2 g/kg dry weight) were found in samples of anaerobically digested sewage sludge from 24 plants. Significantly lower levels of nonylphenol were found in samples of aerobically stabilised sludge from 5 plants (mean 0.30 g/kg dry weight; range 0.12-0.65 g/kg dry weight). The data showed that nonylphenol accumulated in sewage sludge during anaerobic treatment of sludge. Both NP1EO and NP2EO were present in the sewage treatment works and were thought to be precursors to the formation of nonylphenol. Based on detailed measurements at one plant with anaerobic digestion of sludge it was estimated that 50% on a molar basis or 17% on a weight/weight basis of the NPnEO entering into the plant was converted to nonylphenol in the final sewage sludge.

Ahel et al. (1994b) reported results from surveys of 11 mechanical-biological wastewater treatment plants in the Glatt Valley, Switzerland. The wastewater treatment plants typically consisted of a primary clarifier for mechanical treatment, and aeration tank and secondary clarifier for biological treatment and an anaerobic digester for sewage sludge treatment. Samples were analysed for the presence of nonylphenol, NPnEO (n=1 to 20), NP1EC and

NP2EC. In untreated sewage and primary effluent the main components found were generally NPnEO (n=3-20) which accounted for 82.4% of the total nonylphenol derivatives present, followed by NP1EO + NP2EO (11.5% of the total), nonylphenol (3% of the total) and NP1EC + NP2EC (3.1% of the total). In secondary effluent the composition of the nonylphenol based compounds had changed markedly, with NPnEO (n=3-20) only present in trace amounts. NP1EC and NP2EC were now the most abundant substances found (46.1% of the total), followed by NP1EO + NP2EO (21.8% of the total) and nonylphenol (3.9% of the total). Based on analysis of the various effluents and sludges in the plants, an overall budget for the nonylphenolic compounds (mainly NPnEO) entering the plant was given as:

19% released to the environment as NPnEC
11% released as NP1EO and NP2EO
25% released as nonylphenol (>90% of which is adsorbed onto digested sewage sludge)
8% released as untransformed NPnEO

Thus the overall removal of NPnEO (n>2) is around 92%. The majority of NPnEO, NPnEC, NP1EO and NP2EO released to the environment is via secondary effluents. Most of the nonylphenol is thought to be formed during anaerobic sludge digestion.

In another report of the behaviour of NPnEO in wastewater treatment plants in Switzerland, effluents from the various stages of treatment at 4 plants were studied in detail. When comparing the concentrations of various species seen in primary effluent as compared with secondary effluent it was seen that NPnEO (n=3-20) was eliminated to varying degrees in all plants (approximately 81.3%, 99.4%, 95% and 95.3% at the four plants). The concentrations of NP1EO and NP2EO were only slightly lower in secondary effluent as compared to primary effluent, and at one plant their concentration was higher in secondary effluent. The concentration of nonylphenol was always found to be lowered by activated sludge (secondary treatment), while the concentration of NP1EC and NP2EC increased in the effluent after secondary treatment. Tertiary treatment (anaerobic sludge digestion) was shown to further reduce the concentration of nonylphenol, NP1EO and NP2EO in the effluent, but had little or no effect on the concentration of NP1EC and NP2EC. Sludge samples taken during sludge digestion indicated that accumulation of nonylphenol was occurring (concentration in sludge increased by a factor of 15), while the concentration of NP1EC and NP2EC in sludge reduced slightly (Giger et al., 1987).

Very similar degradative behaviour of NPnEO has been observed in the Glatt River, Switzerland (Ahel et al., 1994c). The main input of nonylphenol based compounds into the river was thought to be from secondary effluents from municipal wastewater treatment plants. The study was undertaken in 1983-1986 using sampling campaigns that simultaneously collected 1-day composite samples from several parts of the river and secondary effluent samples from wastewater treatment plants along the river. This was carried out in such a way that the same

"package" of water was sampled at each point. The most abundant nonylphenol based compounds detected were NP1EC and NP2EC, followed by NP1EO and NP2EO, then nonylphenol and finally NPnEO (n>3), which made up only a very small fraction of the total. The hydraulic residence time of the river was 10-15 hours and it was estimated that 85% of the NPnEO (n>3), 70% of the NP1EO and NP2EO and 62% of the nonylphenol were eliminated in the river (by biodegradation and/or adsorption to sediment), but there was around of 27% increase in NP1EC and NP2EC in the river. Nonylphenol was found to be a major component in sediment.

The behaviour of nonylphenol ethoxylates in sewage treatment plants in the United States has been studied (Naylor, 1992; Naylor et al., 1992)…Removal of the nonylphenol ethoxylate in the plants was generally >92%."

"Di Corcia et al. (1994) studied the behaviour of nonylphenol ethoxylates and nonylphenol in a mechanical-biological wastewater treatment plant in Italy over the period of 1 year. The average removal of nonylphenol ethoxylate by the plant was 94.3%. Based on the concentrations of nonylphenol in influent compared with effluent, the removal of nonylphenol was around 93%, mainly by adsorption onto sludge.

Kubek and Naylor (1990) used a simplified extraction technique to look at the behaviour of NPnEO in a US wastewater treatment plant. They reported that the presence of oxygen in the extraction and work-up procedure could lead to a skewing of the NPnEO oligomer distribution to those with a low value of n and this could, in part, explain the accumulation of these compounds seen in other results. Using the revised technique, influent and effluent NPnEO (n=1-18) concentrations were measured, which indicated a 93-98% removal of NPnEO during treatment. The oligomer distribution in effluent showed on a slight difference (a slight increase in the proportion of low n NPnEO oligomers) when compared with the influent. Nonylphenol was detected in the effluent at concentrations of 0.5-4.0 μg/l, but no influent concentrations were measured so it is not possible to say anything about the possible formation and/or removal during wastewater treatment."

Table 32 Summary of behaviour of nonylphenol ethoxylates during wastewater treatment

Substance tested	Type of test	Results	Reference
NPnEO (n=9)	Coupled Units test	48.6% DOC removal; 97% primary degradation seen in OECD screening test.	(Gerike 1987)
NPnEO (n=9)	Semi-continuous activated sludge test	Overall 93% removal of the NPnEO; 20.8% was mineralised to CO2,, 23.1% converted to highly degraded metabolites, 26% in effluent as NPnEC. Conversion to nonylphenol could be around 4.5% of the NPnEO (by weight), of which around¼ was found in effluent.	(Varineau et al. 1996)
NPnEO (n=8; 10; 14; 16; and 30)	Lab-scale activated sludge system	82-96% removal of the original surfactant was seen. NP2EO was the major degradation product and around 50% of this had itself degraded after 28 days. In contrast to this, when incubated at 15ºC, no further degradation of NP2EO was seen.	(Rudling and Solyom 1974)
NPnEO (n=9)	Lab-scale bioreactors attached to sewage treatment plant, United States	>95% removal of the NPnEO. 35-50% of the hydrophobe was discharged in effluent from the system, probably as NPnEO/NPnEC, with n=0-3.	(Kravetz et al. 1982)
NPnEO	Sewage treatment plants, Switzerland	50% on a molar basis and 17% on a mass basis of the NPnEO entering the plant was estimated to form nonylphenol ethoxylate during anaerobic sludge digestion.	(Brenner et al. 1987)
NPnEO	Sewage treatment plants, Switzerland	Overall removal on NPnEO (n>2) is 92%. Of the total entering the plant: 19% release via effluent as NPnEC 11% release via effluent as NP1EO + NP2EO 25% released as nonylphenol (of which 90% is adsorbed onto digested sludge ⇛ <2.5% released as nonylphenol in effluent)	(Ahel et al. 1994)
NPnEO	Sewage treatment plants in the United States	>92% removal of the original surfactant	(Naylor et al. 1992), (Naylor 1992), (Kubeck and Naylor 1990)

Recited information from the EU Risk Assessment report (ECB 2002)

According to the conclusions drawn in the EU RAR NPEs, when treated, are degraded in the WWTP rather quickly particularly when treated with microorganisms during the biological step. From obtained material the fate of NP and NPE were estimated on a worst case basis. The elimination efficiency from the water phase in MWWTP was calculated. Of the total input of NPE to the plant 2.5 % is released as NP in the effluent. Also 25 % leaves with the effluent as mono-, di-ethoxylates or NPnEC[51] and 8 % as longer chain ethoxylates (NPnE). Further 45 % of the incoming NPEs are degraded in the WWTP and 19.5 % end up in anaerobically digested sludge.

[51] carboxylic acid of mono-ethoxylate produced when the terminal hydroxyl group is oxidated.

The nonylphenol ethoxylates in the effluent waste water will be further degraded. The EU risk assessment report comes to the conclusion based on available information that in addition to the 2.5 % NP leaving the WWTP approximately 2.5 % of the longer chained NPE (NPnEO) in the effluent can end up as NP in the environment. However, the nonylphenol ethoxylates with one or two ethoxylate units (mentioned as NP1EO and NP2EO in the EU RAR) are also a probable source for the nonylphenol found in the environment. According to Ahel et al. (1994) these constitutes of approximately one third of the 25 % NP1EO, NP2EO and NPnEC leaving the WWTP with the effluent as described above. (Adding all nonylphenol ethoxylates (NP1-NPnE) that has a potential to end up as nonylphenol in the environment to the nonylphenol in the effluent will rather result in closer to 3 % of the total input to the WWTP.)

In the UK revised draft version of June 2008 (Building Research Establishment 2008) of the EU risk assessment report it is assumed that 2.5 % of the NPE entering the waste water treatment plant will end up as NP in the water environment. This estimation will also be used in this dossier.

The conclusions from the EU RAR are supported by the result of a more resent study (Loyo-Rosales et al. 2007). Here the fate of NPE was studied in three American waste water treatment plants, two of which involved advanced treatment. The analyses were performed during different seasons. Of a total NPE (by weight) in the influent the release of NPE with the effluent (including NPE-NPE16 and NP1EC-NP2EC) varied between 20-39 %. Average NP0-16E removal (and thus excluding NP1EC-NP2EC) was over 99 % in the summer and close to 94 % in the winter.

As described earlier there are different potential sources for the nonylphenol (NP) measured in the environment (nonylphenol, nonylphenol ethoxylates and other nonylphenol derivatives). For comparable reasons the different sources demonstrated in section B.9.3.4.1 and B.9.3.4.2 have been converted to NPequ. To be able to use the same estimations as described in the EU risk assessment report the NP_{equ} released to the waste water estimated in section B.9.3.4.1 and B.9.3.4.2 is converted to NPE. Although the EU risk assessment report is based on the fate of nonylphenol ethoxylate in the WWTP it is in this dossier, for quantifiable reasons assumed that other potential sources for nonylphenol in the environment submitted to treatment behave in a similar manner.

The part of the population connected to municipal waste water treatment plants (i.e. those attached to sewage treatment of any kind) differs between EU Member States. According to Eurostat (Eurostat 2012) 80 % of the inhabitants in half of the Member States are connected to MWWTP. However there are EU members with less than 50 % connection. Calculations in AMECs consulting report based on Eurostat statistics (AMEC 2012) demonstrate that an average

of approximately 78 % of the population in EU27 as a whole is attached to treatment plants[52]. These statistics are however based on available data with mixed reference years (from the early 2000s to more resent reported data from 2009). A result of stricter waste water treatment demands (see section B.9.1.1) suggests that the percentage might be somewhat higher today.

When reviewing the treatment levels of the waste water plants, obtained data shows that in Belgium, Germany, Greece, Italy, the Netherlands, Austria and Sweden tertiary waste water treatment was most frequent. In some cases over 80 % of the population in those Member States is connected to waste water management of this sort. In contrast, there are Member States with far more modest connection to tertiary treatment. Existing data indicates that less than 1 % of the inhabitants in some EU countries are connected to tertiary waste water treatment. Also here statistics are based on non consistent information.

As stated in the EU risk assessment report 2.5% of the NPnE released to the environment will in time end up as nonylphenol (based on a worst case scenarion). This has been supported by the UK revised draft version mentioned above. This estimation is therefore used in this dossier also when considering the waste water not connected to a MWWTP. The degradation of NPE when released directly to surface water will be prolonged but this is not considered here since this is a steady-state scenario.

Calculations in sections B.9.3.4.1 and B.9.3.4.2 show that the release of NP_{equ} to the waste water is 257 tonnes from washing textiles annually and 249 tonnes from other quantified sources. This corresponds to 642 tonnes NPE and 622 tonnes NPE respectively. On the basis of the estimations above, with 2.5 % eventually ending up in the environment result in a release of approximately 16.1 tonnes NP[53] from textiles and 15.6 tonnes NP[54] from other quantified sources.

Technical textiles

The release of nonylphenol ethoxylates to water from technical textiles as described in B.9.3.4.1 will result in 10 tonnes NPE annually which corresponds to 4 tonnes NP. Only a small fraction of this will eventually end up as nonylphenol in the environment. Using the same estimation from above based on the EU risk assessment report results in 0.25 tonnes NP/year[55].

Table 33 summarizes the nonylphenol released which demonstrates that washing of textiles contribute to approximately 50 % compared to other quantified sources.

[52] Latest available data on MS population connected to MWWT plants (no data for the UK was published but added by compiling information. The data on connection rate per MS was then matched to population data for the particular year plus data queries for 2 (pre-2000) data.
[53] 642 tonnes x 2.5 %
[54] 622 tonnes x 2.5 %
[55] 10 tonnes x 2.5 %

Table 33 Nonylphenol (NP) ending up in the surface water from different sources

Source	**Total tonnes/year**
Textile	**16.1**
Other quantified sources	**15.6**
Technical textiles manufactured in the EU	**0.25**
Total	**32**

B.9.4.1 Comparing calculated and measured waste water concentrations

The wide dispersive use tonnage in Sweden is here chosen as a model when comparing estimated concentrations in the influent and recipient water to measured concentrations. The total volume of waste water going through Swedish municipal waste water treatment plants is estimated to be 1 258 539 000 m^3 (SCB 2008). The influent concentration of nonylphenol ethoxylate (NPE) will then be:

$PEC_{influent, average} = [+ Q_{NPE\ textiles} + Q_{NPE\ other\ quantified\ sourses\ +}\ ] / [V_{waste\ water}] = [(4.85+4.70)/0.4]/\ 1.26 * 10^9 =$

$= 18.95* 10^{-9}$ tonnes/m^3 = 18.95 µg/l.

This is based on calculations in sections B.9.3.4.1 and B.9.3.4.2 which values have been divided by 53 to receive amounts for Sweden. To be able to use the same estimations as described in the EU risk assessment report the NP_{equ} released to the waste water is converted to NPE[56]. As explained earlier in section B.9.4 this is an assumption carried out for quantifiable reasons.

Also, in the calculations above other unquantified sources released to the wastewater are not considered (e.g. cosmetics).

According to a worst case scenario, of the incoming NPE approximately 2.5 % will eventually end up in the environment as NP (ECB 2002). From this the concentration of nonylphenol (NP) in the environment can be calculated which results in 0.47 µg/l ((1-0.975) * 18.95).

EU Member States with the same consumption pattern and waste water volume per inhabitants will obtain the same concentration. A default dilution rate of 10 will give a local PEC_{water} of almost 0.05 µg/l (0.47/10).

The calculated generic concentration of nonylphenol in a WWTP water recipient is 0.05 µg/l. This is in the same magnitude as the monitored concentrations (0.075 µg/l, 90P median, see section B.9.7, Table 34). However, the monitoring data are assumed to be representative and therefore used in the risk characterisation.

[56] where the NP/NPE ratio is 2:5

B.9.4.2 Environmental concentrations for the risk characterisation

A local PEC can also be calculated using the measured concentrations in effluent waste water ($C_{effluent}$). The median measured effluent concentration of NP is 0.67 µg/l (median of the 90P from eight EU countries and Norway). With a default dilution factor of 10 in freshwater the PECwater will be 0.067 µg/l. This compares well with the monitored freshwater concentration of 0.075 µg/l. Based on these comparisons it is decided to use the freshwater monitoring data in the risk characterisation. When using the same approach for marine water with a default dilution factor of 100 the resulting PECwater becomes 0.0067 µg/l, which is lower than the monitored marine water concentration of 0.05 µg/l.

As discussed in section 9.4.1, the median of 90P measured concentration 0.075 µg/l for freshwater and 0.05 µg/l for marine water are used as PEC in the risk characterisation for the freshwater and marine water compartments, respectively. Also in the riskcharacterisation of the freshwater and marine sediment compartments monitoring data are used as PECs.

The median of the 90P measured concentration in municipal WWTP sludge is used in the EUSES calculations of PECs in the soil compartments. A fixed BCF of 1280 (see section B.4.3) is used as input in the EUSES calculations for use in the secondary poisoning scenarios.

As a worst case assumption the 90P monitoring data are used also as PEC regional freshwater and PEC regional marine water, i.e. the same as for PEC local.

Input data:

- Mw: 220.3
- Mp: -8 C°
- Bp: 295 C°
- Vapor pressure: 0.3 Pa (25C°)
- Water solubility: 6 mg/l
- logKow: min. 4.48 - max. 5.40
- BCF–aquatic biota: 1280 (see section B.4.3)
- Sludge concentration: 13 mg/kg dwt (measured, median of 90P, see Table 40)
- Biodegradation: Ready biodegradable, failing 10-d window
- $C_{effluent}$ 0.67 µg/l (measured median of 90P, see Table 39)
- $PECregional_{freshwater}$ 0.075 µg/l (measured median 90P, see Table 34)
- $PEClocal_{freshwater}$ 0.075 µg/l
- $PECregional_{marine\ water}$ 0.05 µg/l (measured median 90P, for calc. of sec. poisoning, see Table 35)
- $PEClocal_{marine\ water}$ 0.05 µg/l
- $PECregional_{agr.soil}$ 20.0 µg/kg dwt (from EUSES, for calc. of sec. poisoning, @ logKow=4.48)
- $PECregional_{agr.soil}$ 70.2 µg/kg dwt (from EUSES, for calc. of sec. poisoning, @ logKow 5.40)

Output data:

The following realistic worst case local concentration was retrieved from the model (two different logKow → min.-max. range):

- $PEC_{soil,\ 30d\ average}$:	20.1 – 70.2	µg/kg dwt
- $PEC_{soil,\ 180d\ average}$:	11.7 – 65.4	µg/kg dwt
- $PEC_{grassland,\ 180d\ average}$:	4.38 – 22.6	µg/kg dwt

Secondary poisoning: prey concentrations (two different logKow → range):

- Fish, freshwater:	0.096	mg/kg wwt
- Fish, marine:	0.064	mg/kg wwt
- Earthworms in agricultural soil:	0.117 – 1.37	mg/kg wwt
- Predator, fish eating - marine:	0.064	mg/kg wwt

B.9.5 Other sources

Due to regulations releases of nonylphenol and nonylphenol ethoxylates to the environment have declined. Emissions are however possible from historical use that are built in the technosphere. This is the case for NPE in concrete which earlier was used primary in specific constructions like bridges and harbour constructions. This application do hower almost no longer occurs in the EU according to consultation with the industry (Sika Sweden 2012). There is no EU regulation regarding the use of NP/NPE in concrete and NPE can appear at small quantities as concrete modifiers (OECD 2011). Emission estimations of NPE from concrete to the urban storm water indicate an annual release of 0.2mg/m^2 (OECD 2011).

Estimations have been made (COHIBA 2011) regarding the atmospheric deposition of NP/NPE where the emission is distributed proportionally to surface water and forest soil. However these estimations are based on few studies all before the REACH restriction came into force and are hence assumed to be of minor importance today.

Nonylphenol in sewage sludge used in agriculture does, as described in section B.4.2.4, adsorb strongly onto organic matter in the soil and will consequently most likely not reach the surface water.

B.9.6 Overall environmental exposure assessment

The majority of the NP/NPE exposed to the environment occurs from releases to waste water via waste water treatment plants. Locally there can be discharges from industrial production sites but from an EU wide perspective releases from different uses pose as the most relevant. Releases from washing textiles are estimated to generate approximately 50 % of the total NP exposed to the surface water as demonstrated in Table 33. In these calculations textiles have been compared to information in the Swedish Products Register. There are however sources not quantified excluded from these calculations as described in section B.9.3.4.3. Of minor importance there are releases from NP/NPE stored in the technoshere which can reach the surface water (see section B.9.5).

The concentrations of nonylphenol in the environment can be estimated via calculations or via available measured data.

Measured concentrations are described in section B.9.7. Comparisons between measured and predicted concentrations are performed in section B.9.4.1.

B.9.7 Measured levels

Only measured data from 2006 and newer are included. For values reported to be below the limit of detection (LOD) alternatively below the limit of quantification (LOQ), half that value will be used instead (EC 2002) when that occurs the value will be marked with *. Values in the tables in Annex 5 that are not included in the derivation of the various RWC-PECs below are not considered relevant. Measurements from urban regions are considered relevant since an important source of NP to the aquatic compartment is the discharge of NP and NPEO from WWTP, which will be of less importance in rural regions.

It should be noted that a number of the available monitoring data constitute of measurements below the limit of detection, for which half that value have been used for the respective data points (EC 2009) . The actual size of the values that are below the limit of detection are unknown, they may be between the detection limit and half detection limit, but they may equally well be below the half detection limit.

Levels in surface waters

Calculation of PEC in freshwater based on monitoring data

A PEC based on measured data is calculated using the median value of 90P of monitoring data from freshwater in 24 EU countries and Norway (see Table 34 below). In case several measurements are available for the same river, lake, etc., for a country the 90P for that water will be used when deriving the PEC.

Table 34 Values used to derive a PEC based on monitoring data for freshwater from 24 EU countries and Norway.

Country	PEC (90P) µg NP/L	Data used (µg NP/L)
Austria	0.331	0.025*, 0.025*, 0.025*, 0.025*, 0.535
Belgium	3.71	3.492, 0.025*, 0.082, 0.782, 0.390, 4.045a, 1.173
Bulgaria	0.265	0.22, 0.270
Cyprus	0.453	0.50, 0.025*
Czeh Republic	0.169	0.025*, 0.230, 0.025*, 0.025*
Denmark	0.025*	All individual values are below the LOD (0.025* is used)
Estonia	0.025*	All individual values are below the LOD (0.025* is used)
Finland	0.025*	All individual values are below the LOD (0.025* is used)
France	0.182	0.088, 0.243, 0.025*, 0.025*, 0.120, 0.025*
Germany	0.9	0.9b
Greece	0.025*	0.025*
Hungary	0.025*	All individual values are below the LOD (0.025* is used)
Ireland	0.075	0.075
Italy	0.182	0.200, 0.005, 0.005, 0.14
Lithuania	0.025*	All individual values are below the LOD (0.025* is used)
Luxembourg	0.025*	All individual values are below the LOD (0.025* is used)
Malta	0.025*	All individual values are below the LOD (0.025* is used)
The Netherlands	0.043	0.025*, 0.025*, 0.050, 0.025*
Norway	0.040	0.025*, 0.025*, 0.0226, 0.0465

Poland	0.025*	All individual values are below the LOD (0.025* is used)
Romania	0.33	0.06, 0.362c
Slovenia	0.183	All individual values are below the LOD (0.025* is used)
Spain	0.475	0.548, 0.025, 0.305, 0.158
Sweden	0.05*	All individual values are below the LOQ (0.05* is used)d
United Kingdom	0.248	0.200, 0.025*, 0.230, 0.025*, 0.230, 0.025*, 0.025*, 0.025*, 0.320
Median	**0.075**	

a) 90P of 0.048 and 4.489
b) German freshwater monitoring data consists of data from two sources, EUR 23568 (2008) with 19 measurements from 2007 and German monitoring data (as a response to the SE request to MS on the restriction proposal) from 2006 (n=42), 2007 (n=117), 2008 (n=93) and 2009 (n=85). The latter source of monitoring data is considered to better reflect the prevailing levels expected to be encountered in Germany. The most recent data of these, i.e. from 2009, are considered the most relevant and will therefore be used. Unfortunately, the individual data points are not available, only (arithmetic?) mean and max values are available. Assuming that the mean value approximately equals the median (=50P) and that the distribution of values are equally spread between the 50P and the 100P (=max value), resulting in a 90P of approximately 0.9.
c) 90P of 0.44, 0.025 and 0.05
d) There are several reports including monitoring data from Swedish freshwater. It is decided to use the most recent (SWECO 2009), which was performed in June 2009.

The basis for the estimated PEC in freshwater, 0.075 µg NP/L, is the monitoring data identified by the rapporteur. Measurements used are from 24 EU countries and Norway, however the number of values per country varies substantially from just a few to over hundred measurements (DE and SE), with the majority of countries having six or fewer measurements (20 out of 25). The absolute majority of measurements used for the different EU countries, except for Germany and Sweden, originate from the report by the Joint Research Center (2008). Germany was the only country providing environmental monitoring data as a response to the Swedish RMO (BAUA 2011).

Detailed information on proximity to point sources for freshwater and brackish/marine waters is only available for the Swedish montoring data (in which the measured values in the most recent study, which was the one that was used, were all below the LOD).

Levels in lakes, rivers and water courses in Europe

The levels of nonylphenol measured in European lakes, rivers and water courses range from below the limit of detection (0.01 - 0.05 µg NP/L) to 4.49 µg NP/L. Values have been reported for 4-NP and/or NP-mix (including iso-forms). The highest values measured are reported for Belgium, where measurements at eight different locations results in a median concentration of 0.59 µg NP/L, a 90 percentile value of 3.71 µg NP/L and a maximum value of 4.49 µg NP/L. The reason(s) for these high values are not known but may be related to textile production since the measurements were made in textile producing regions (former/present?).

Levels of NP measured in European lakes, rivers and water courses are presented in Figure 6 below and
Table 62 in Annex 5.

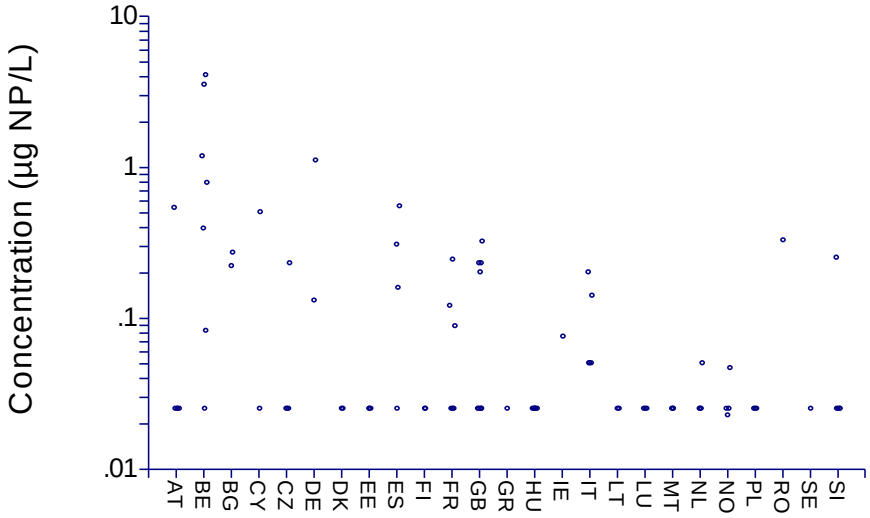


Figure 6 Levels of nonylphenol in European lakes, rivers and water courses. Values reported to below the limit of detection (LOD) are presented at half LOD for the respective studies

The majority of the values presented in Figure 6 above originate from the European monitoring study Joint Research Center (2008) performed during the autumn in 2007 in which 122 individual water samples were taken from over 100 European rivers, streams or similar water bodies from 25 European countries. Sampling appears to have been performed in urban areas (based on the information on sampling locations included in the report). The water samples in that study were analysed for 35 selected compounds ranging from pharmaceuticals, antibiotics, pesticides, perfluorinated compounds PFCs, hormones and alkylphenolics including nonylphenol. Water sampling was performed by the participating Member States laboratories, but all samples were shipped to the facilities of the JRC´IES-Laboratory for analysis by means of SPE-LC-MS. Only the dissolved (liquid) water phase and not the suspended material were investigated. The highest concentrations of NP were detected in Belgium, where five measurements resulted in a median value of 0.59 µg NP/L, a 90 percentile value of 3.71 µg NP/L and a maximum value of 4.49 µg NP/L. Besides Belgium, the highest median concentrations of NP were measured in Cyprus (median = 0.26 µg NP/L, individual values: 0.025 (half LOD) and 0.5 µg NP/L), Bulgaria (median = 0.25 µg NP/L, individual values: 0.22 and 0.27) and Spain (median = 0.23 µg NP/L, max = 0.548 µg NP/L, 90 percentile = 0.475 µg NP/L, n = 4). Nonylphenol was not detected in

Denmark (n = 1), Estonia (n = 3), Finland (n = 2), Greece (n = 1), Hungary (n = 6), Lithuania (n = 4), Luxembourg (n = 3), Malta (n = 3), Norway (n = 1), Poland (n = 3) or Sweden (n = 7).

Loos and co-workers (2007) performed an analysis of the surface and drinking waters around Lake Maggiore in Northern Italy for the presence of a number of polar anthropogenic pollutants, including nonylphenol. Lake Maggiore receives municipal, agricultural and industrial discharges, directly or via its tributary rivers. Water samples were taken from Lake Maggiore and some of its tributary rivers and creeks in the southern part of the lakes between February and April 2006. Nonylphenol was not quantifiable at levels below 0.01 µg NP/L due to high laboratory blanks. Nonylphenol was not detected in either of the samples taken in the lake (n = 8) or in the three tributary mountain rivers considered relatively clean. The concentration detected in the nine tributary rivers considered affected by anthropogenic influence ranged from below detection limit (<0.01 µg NP/L) to 0.14 µg NP/L (only information on the total range for all the nine rivers is available).

German monitoring data, provided as a response to the Swedish "NP NPEO restriction request to MS" (BAUA, 2011), reported mean (max; n) for 2006, 2007, 2008 and 2009 of 0.1 µg NP/L (max = 0.3 µg NP/L, n = 42), 0.21 (max = 0.69 µg NP/L, n = 117), 0.11 µg NP/L (max = 0.36 µg NP/L, n = 93) and 0.13 µg NP/L (max = 1.1 µg NP/L, n = 85), respectively. No individual data points were provided. These data are included in Figure 6 above with the reported mean and max values.

In the COHIBA project measurements of various compounds, including NP, were performed in several countries surrounding the Baltic Sea. In Copenhagen, Denmark, measurements performed in a small river with several upstream urban run-offs and combined sewer overflows resulted in 4-NP (mix) concentration of 0.025 µg NP/L (half LOD) sampled during a period of dry weather and 1.2 µg NP/L sampled during precipitation (COHIBA, 2011a).

The Nordic screening project Tema Nord (Nordic Council of Ministers, 2008) reported the concentrations of 0.0226 µg NP/L (NP-mix) and 0.0465 µg NP/L (NP-mix) in the Norwegian lakes Mjøsa and Vanemfjorden, respectively, with both being reported as WWTP recipient water. Concentrations were also reported for the Swedish background locations Lake Tärnan and Lille Öresjön. The concentrations reported in the former were 0.0683 µg NP/L (NP-mix) and 0.107 µg NP/L (NP-mix), respectively.

Swedish screening data from 2006 from 92 locations, predominantly limnic but also including a few coastal surface waters, are presented in SWECO (2007). Most of the sampling stations were influenced by one or more of the following discharge sources: 1) industrial plants and other point sources, 2) urban runoff and other diffuse sources, 3) landfills, 4) sewage treatment plants. A number of sampling points in unaffected background areas were also used. The interpretation of geographical patterns is complicated by the lower number of sampling points in northern

Sweden. Nonetheless, higher levels of nonylphenol are found in the more populated southern part of Sweden. The reported concentrations (total) range from below the LOD (half detection limit 0.05 µg NP/L is used) to 1.1 µg NP/L, with a median value of 0.31 µg NP/L.

A Swedish screening study (SWECO, 2009a) studied the temporal variation in 15 different sampling locations in Sweden (8 limnic and 7 marine) with different anthropogenic influence using monthly measurements. The temporal concentration variation for the eight limnic locations varied with a factor from about two to 70 (median value 25) with measurements ranging from 0.05 µg NP/L (half limit of quantification = 0.10 µg NP/L /2) to 3.50 µg NP/L. The corresponding figures for the marine locations are a temporal concentration variation with a factor from about three to 30 (median value 6) with measurements ranging from 0.05 µg NP/L (half limit of quantification = 0.10 µg NP/L /2) to 1.50 µg NP/L. The measured concentrations were higher during the summer months both at limnic and marine locations,. The temporal variation may depend on a number of factors such as temporal variability in load, physicochemical conditions (e.g. water temperature), microorganism activity, water flow, etc. The implication for sampling is that the period during the year selected for sampling clearly influence the levels measured and that sampling therefore preferably should be performed during the period of May – August.

A Swedish screening involved sampling at 50 limnic sampling points representing different types of environments all over the Northern Baltic River Basin District (SWECO 2009b). The sampling points were situated both in relatively unaffected areas, and in the vicinity of urban areas and industries. Sampling was done in June following a pre-defined detailed sampling and sample procedure. Nonylphenol was not detected in any of the samples (LOQ = 0.10 µg NP/L). The reason for this may be due to a temporal variation of the concentration of nonylphenol, which was observed in SWECO (2008:7). The sampling period in this study, June, was however selected based on the findings in that report. The authors in SWECO (2009b) does not consider that difficulties in analysing nonylphenol is the reason that nonylphenol was not detected. Another possible reason is decreased emissions of nonylphenol.

Calculation of PEC in brackish and marine water based on monitoring data

A PEC based on monitoring data is calculated using the median value of 90P of monitoring data from combined brackish and marine waters in 3 EU countries and Norway (see Table 35 below). In case several measurements are available for the same sea for a country, the 90P for that water will be used when deriving the realistic worst case PEC.

Table 35 Values used to derive a PEC based on monitoring data for marine water from 3 EU countries and Norway.

Country	PEC (90P) µg NP/L	Data used (µg NP/L)
Denmark	0.051	0.005, 0.0179a, 0.0188, 0.0075, 0.0421, 0.0222, 0.05, 0.0475b
Finland	0.089	0.04515c, 0.0936
Norway	0.01*	All individual values are below the LOD (0.01* is used)
Sweden	0.05*	All individual values are below the LOD (0.05* is used)d
Median	**0.05**e	

a) Inclusion or exclusion of this value will not change the resulting 90P value for Denmark as it in either case still will be 0.051 µg NP/L.
b) 90P of 0.05 and 0.025. A value of 4.199 from the Faroe Island was excluded since it was considered to represent a local hot spot (in addition, the value was an estimate since it was outside of the calibration range). Inclusion of that value would increase the resulting Danish 90P value with a factor of about 30.
c) 90P of 0.0204 and 0.0479.
d) There are several reports including monitoring data from Swedish marine waters. It is decided to use the most recent (SWECO 2009:5), which was performed in June 2009.
e) Inclusion of the excluded value from the Faroe Island would instead result in a median value of 0.069.

Levels of NP measured in brackish and marine waters are presented in Figure 7 below and Table 62 in Annex 5.

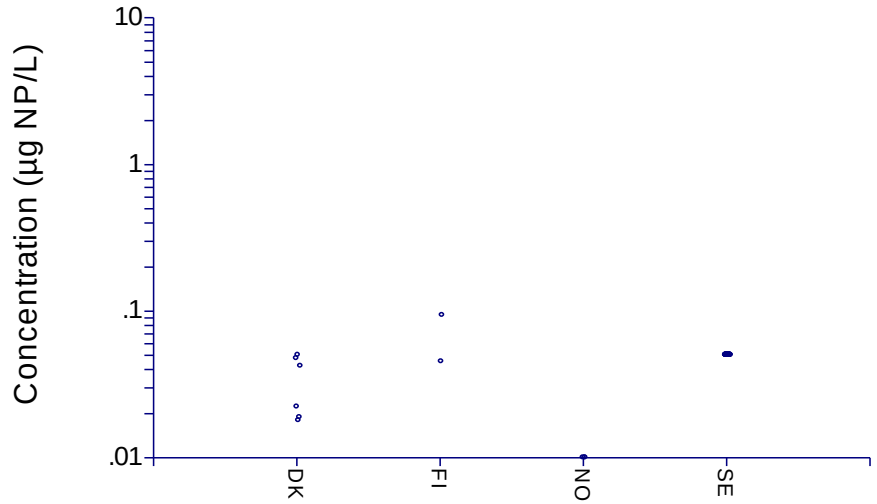


Figure 7 Levels of nonylphenol in European brackish and marine waters. Values reported to below the limit of detection (LOD) are presented at half LOD for the respective studies**.**

The Nordic screening project Tema Nord (Nordic Councils of Ministers, 2008) reported concentrations of nonylphenol measured in the brackish and marine waters. In Denmark, samples were taken in relation to two WWTPs in October 2006. One from Lynetten in Copenhagen (the largest WWTP in Denmark) with samples from the recipient Øresund and one from Bjergmarken,

which is a smaller WWTP in Roskilde (smaller town with about 50 000 inhabitants) with samples from the recipient Roskilde Fjord. Due to its physical form, hydrodynamics (long narrow fjord with limited water exchange) and being a recipient for several smaller towns the brackish Roskilde Fjord was considered to be a hot spot environment by the authors. A recipient sample was also taken from the brackish Limfjorden in November 2006, which may be considered a background area but at the same time Limfjorden also serves as a recipient environment for a number of small towns along its coast. Samples were also taken from two Danish marine background sites in Kattegat in September-October 2006. Measurements resulted in concentrations below the LOD for the NP-mix (<0.010 µg NP/L) in Limfjorden, 0.0179 µg NP/L in the Rosklide Fjord and in 0.0188 µg NP/L in Øresund. Measurements performed on the Faroe Islands in January 2007 in waters defined as being WWTP recipient resulted in a concentrations below the LOD (<0.010 µg NP/L) at Klaksvik and 4.2 µg NP/L at Torshavn (BPA used for estimating recovery). Measurements in September and October 2006 in two Danish background locations in Kattegat resulted in the concentrations 0.0421 µg NP/L and 0.0222 µg NP/L, respectively. In Finland, samples were taken in October 2006 in the coastal bay area outside of Espoo and in the city bay of Helsinki, where the discharge from the WWTPs were let out. The authors considered the Helsinki city bay area near the port to represent a hot spot, and the Espo coastal sea area, to represent a background site (however, note that the outlet pipe for effluent waters from the Espo city WWTP was located near the sampling area). The measurements performed outside of Espoo (near pipeline outlet at 1 and 16 m depth) and Helsinki (near the shipping port) resulted in 0.0204 µg NP/L, 0.0479 µg NP/L, and 0.0936 µg NP/L, respectively. In Norway, sampling were performed in October 2006 in the inner Oslo Fjord, which by the authors were considered to be a hot spot, in November 2006 in the outer of Oslo Fjord, and in August 2006 from northern Norway from Tromsø and in September 2006 from the Varanger fjord, with the later three considered to be background sites. All Norwegian measurements were below the LOD (<0.020 µg NP/L).

Measurements performed in the COHIBA project in Danish reference sites in August 2009 in the Baltic Sea and in November 2009 and June 2010 in the Sound resulted in measurements below LOD (<0.10 µg NP/L and <0.05 µg NP/L)(COHIBA, 2011a).

A Swedish screening involved sampling at 40 marine sampling points representing different types of environments all over the Northern Baltic River Basin District (SWECO 2009c). The sampling points were situated in both relatively unaffected areas, and in the vicinity of urban areas and industries. Sampling was done in June following a pre-defined detailed sampling and sample procedure. Nonylphenol was not detected in any of the samples (<0.10 µg NP/L). The reason for this may be due to a temporal variation of the concentration of nonylphenol, which was observed in SWECO (2009a). The sampling period in this study, June 2009, was however selected based on the findings in that report. The authors in SWECO (2009c) does not consider that difficulties in analysing nonylphenol is the reason that nonylphenol was not detected. Another possible reason is decreased emissions of nonylphenol.

Levels in surface run-offs

Levels of NP measured in surface run-offs are presented in Figure 8 below and Table 62 in Annex 5.

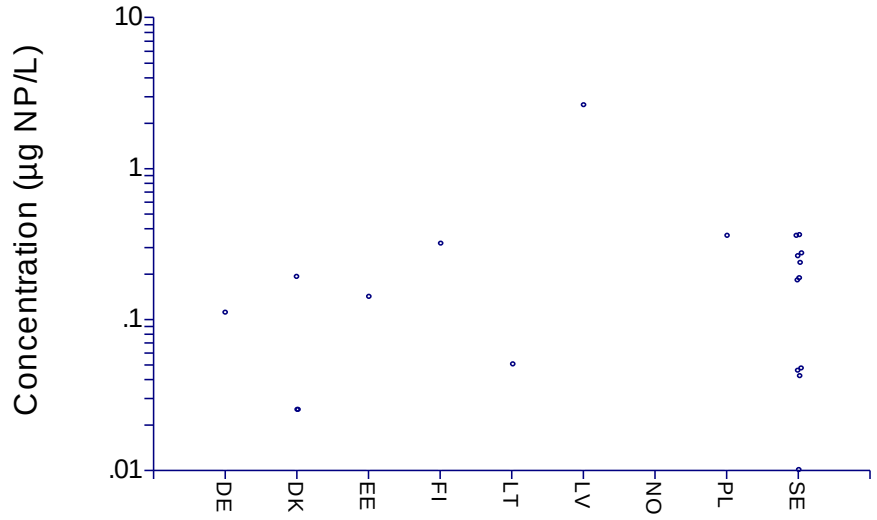


Figure 8 Levels of nonylphenol in European surface run-offs. Values reported to below the limit of detection (LOD) are presented at half LOD for the respective studies.

Measurements of surface run-offs have been performed in the COHIBA project and include measurements in Denmark (COHIBA 2011a) (shredder plant: <0.05 NP-mix/L, <0.05 NP-mix/L; Copenhagen, roads and parking lots: 0.19 NP-mix/L, 0.19 NP-mix/L, <0.05 NP-mix/L; Copenhagen, paved areas in industrial area: <0.05 NP-mix/L), Estonia (COHIBA 2011b) (storm water 20 m from the shoreline: 0.23 NP-mix/L, <0.10 NP-mix/L), Finland (COHIBA, 2011c) (Porolahti creek: 0.38 NP-mix/L, 0.25 NP-mix/L), Germany (COHIBA 2011d) (Wismar: 0.17 NP-mix/L, <0.10 NP-mix/L), Latvia (COHIBA 2011e) (Riga, urban area: 2.6 NP-mix/L), Lithuania (COHIBA 2011f) (Klaipėda: 0.19 NP-mix/L, <0.10 NP-mix/L), Poland (COHIBA 2011g) (five different sampling points pooled together: 0.42 NP-mix/L, 0.29 NP-mix/L) and Sweden (COHIBA 2011h) (Stockholm, traffic related area: 0.42 NP-mix/L, 0.29 µg NP-mix/L). In case of more than one value/sampling location, the median value was used in Figure 8.

Measurements of surface run-offs are also available in the Nordic screening project Tema Nord (Nordic Councils of Ministers, 2008). All Norwegian measurements performed at Lier were below the LOD (NP-mix < 0.015 µg NP-mix/L). Swedish measurements included four locations in Stockholm defined as storm water point source (0.272 µg NP-mix/L, 0.235 µg NP-mix/L,

0.359 µg NP-mix/L, 0.186 µg NP-mix/L), two locations defined as storm water diffuse source (<0.020 µg NP-mix/L, 0.0418 µg NP-mix/L), two locations defined as surface point source (<0.015 µg NP-mix/L, <0.015 µg NP-mix/L) and one location defined as surface diffuse source (0.0454 µg NP-mix/L). In case of more than one value/sampling location, the median value was used in Figure 8. Only NP-mix values were used in Figure 8.

Levels in sediment

Calculation of PEC in freshwater sediment based on monitoring data

A PEC based on measured data is calculated using the median value of 90P of monitoring data from combined brackish and marine waters in 2 EU countries and Norway (see Table 36 below). In case several measurements are available for the same location for a country, the 90P for that location will be used when deriving the PEC.

Table 36 Values used to derive a PEC based on monitoring data for freshwater sediments from 2 EU countries and Norway.

Country	PEC (90P) mg NP/kg dw	Data used (mg NP/kg dw)
Denmark	0.30*	0.30*
Norway	0.0412	0.0434, 0.0214
Sweden	0.259	0.0543, 0.249, 0.064, 0.005*, 0.005*, 0.005*, 0.005*, 0.06, 0.036, 0.35
Median	**0.259**	

Levels of NP measured in freshwater sediments are presented in Figure 9 below and Table 63 in Annex 5.

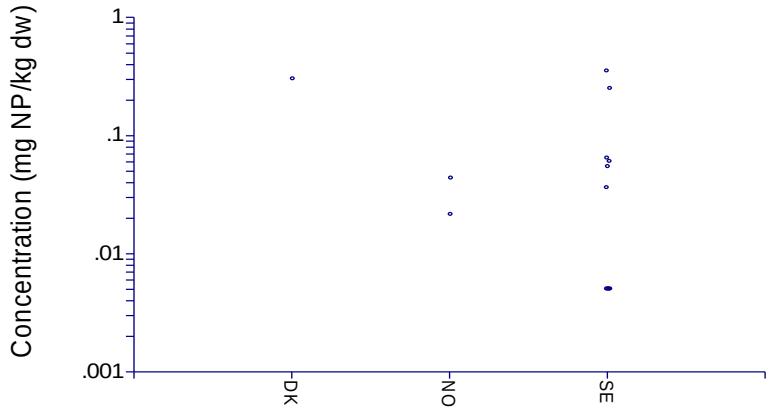


Figure 9 Levels of nonylphenol in European freshwater sediments. Values reported to be below the limit of detection (LOD) are presented at half LOD for the respective studies.

In the COHIBA project (COHIBA 2011a) Danish measurements of NP in sediments in a small river in Copenhagen with several upstream urban run-offs and combined sewer overflows resulted in one measurement, which was below the limit of detection (<0.60 mg NP-mix/kg dw).

The Nordic screening project TemaNord (Nordic Councils of Ministers, 2008) presented measurements of NP in freshwater sediments in Mjøsa (0.0434 mg NP-mix/kg dw) and Vanemfjord (0.0214 mg NP-mix/kg dw) in Norway and Övre Skärsjön (0.0543 mg NP-mix/kg dw) and Krageholmssjön (0.249 mg NP-mix/kg dw) in Sweden.

A Swedish screening study (SWECO 2009a) studied the temporal variation in 15 different sampling locations in Sweden (8 limnic and 7 marine) with different anthropogenic influence using monthly measurements. In addition to the water measurements performed, one sediment sample was also taken at each of the 15 locations. The concentrations measured in limnic locations ranged from below the detection limit (0.01 mg NP/kg dw) to 0.35 mg NP/kg dw measured in Göta Älv (defined as urban background).

Calculation of a realistic worst case PEC in brackish and marine water sediment based on monitoring data

A PEC is calculated using the median value of 90P of monitoring data from combined brackish and marine waters in 3 EU countries and Norway (see Table 37 below). In case several measurements are available for the same location for a country, the 90P for that location will be used when deriving the PEC.

Table 37 Values used to derive a PEC based on monitoring data for marine water sediments from 3 EU countries and Norway.

Country	**PEC (90P) mg NP/kg dw**	**Data used (mg NP/kg dw)**
Denmark	0,436	0.0092, 0.00175*, 0.0856, 0.0015, 0.00136, 0.34, 0.3*, 0.66a
Finland	0.435	0.44, 0.39
Norway	0.017	0.0237, 0.00175*, 0.00175*, 0.00175
Sweden	0.291	0.4742b, 0.005*, 0.005*, 0.012, 0.017
Median	**0.363**	

a) 90P of 0.3* and 0.7 mg NP/kg dw
b) 90P of 0.449, 0.390, 0.485 and 0.257 mg NP/kg dw

Levels of NP measured in brackish and marine water sediments are presented in Figure 10 below and Table 63 located in Annex 5.

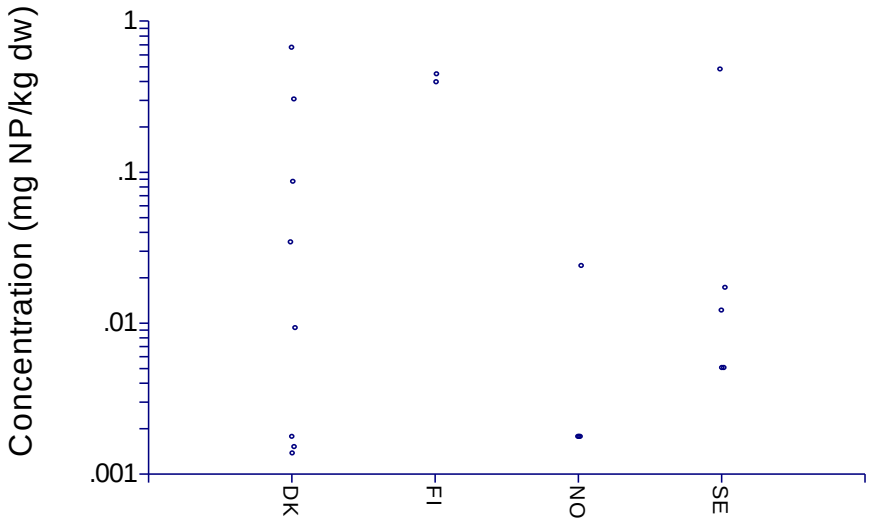


Figure 10 Levels of nonylphenol in European brackish and marine water sediments. Values reported to be below the limit of detection (LOD) are presented at half LOD for the respective studies.

Measurements of nonylphenol in marine water sediments performed in the TemaNord (Nordic Councils of Ministers 2008) project are available for background and recipient backgrounds environments from Denmark, the Faroe Islands and Norway. In Denmark sediment samples were taken from the recipient environments Kattegat (0.0092 mg NP-mix/kg dw), Øresund (< 0.0035 mg NP-mix/kg ww) and Roskilde Fjord (0.0856 mg NP-mix/kg dw). In the Faroe Islands sediment samples were taken from recipient environments Klaksvik (0.0015 mg NP-mix/kg dw), Götuvik (0.00136 mg NP-mix/kg dw) and the harbour of Torshavn (0.340 mg NP-mix/kg dw). Measurements is also reported in brackish water sediments from Finland in what was defined as recipient environments in Espo, coastal sea (0.440 mg NP-mix/kg dw) and Helsinki, city bay (0.390 mg NP-mix/kg dw) in Finland and for four locations in Stockholm, Sweden, Stora Essingen (0.449 mg NP-mix/kg dw), Årstaviken (0.390 mg NP-mix/kg dw), Hammarby Sjöstad (0.485 mg NP-mix/kg dw) and Riddarfjärden (0.257 mg NP-mix/kg dw). Measurements performed in Norway were taken from one recipient environment, inner Oslo Fjord (< 0.0035 mg NP-mix/kg ww), and three background environments, Oslo Fjord (0.0.0237 mg NP-mix/kg dw), Tromsø (< 0.0035 mg NP-mix/kg ww) and Varangerfjorde (< 0.0035 mg NP-mix/kg ww).

In the COHIBA project (COHIBA, 2011a) Danish measurements of NP in marine sediments in the Copenhagen harbour was one sample below the LOD (middle; < 0.60 mg/kg dw) and one slightly above (south; 0.70 mg/ kg dw). A Danish reference sample taken in the Sound was below the LOD (< 0.60 mg/kg dw).

A Swedish screening study (SWECO, 2009a) studied the temporal variation in 15 different sampling locations in Sweden (8 limnic and 7 marine) with different anthropogenic influence using monthly measurements. In addition to the water measurements performed one sediment sample was also taken at each of the 15 locations. The concentrations measured in brackish/marine locations ranged from below the detection limit (0.01 mg NP/kg dw) to 0.017 mg NP/kg dw measured at Hasslö (defined as urban background).

Levels in WWTP

Levels of NP measured in WWTP influents, effluents and sludge are presented in Figure 11, Figure 12 and Figure 13, respectively, below and in Table 64 located in Annex 5.

Influents

Calculation of a concentration in WWTP-influents based on monitoring data

A concentration in influents is calculated using the median value of 90P of monitoring data from WWTP influents in 2 EU countries and Norway (see Table 38 below). In case several measurements are available for the same location for a country, the 90P for that location will be used when deriving the concentration in influents.

Table 38 Values used to derive a concentration in WWTP influents from 2 EU countries and Norway.

Country	**PEC (90P) µg NP/L**	**Data used (µg NP/L)**
Denmark	6.82	3.55, 0.923, 0.969, 2.7, 9
Finland	5.43	3.146, 5.688
Norway	1.02	0.266, 1.108
Median	**5.43**	

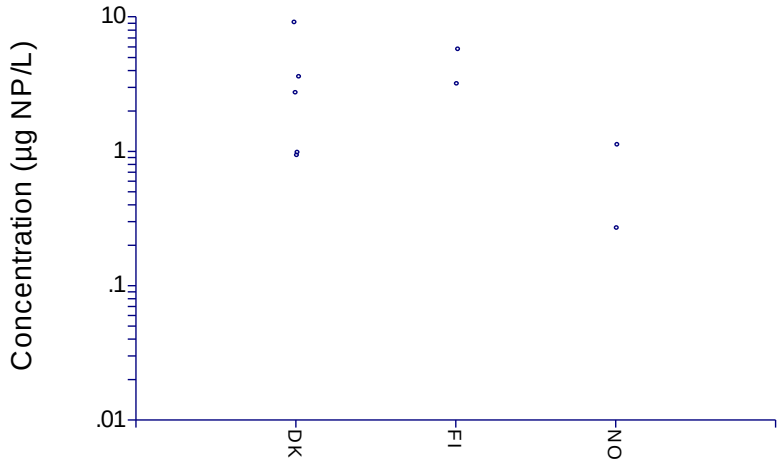


Figure 11 Levels of nonylphenol in WWTP influents. Values reported to be below the limit of detection (LOD) are presented at half LOD for the respective studies

Concentration in WWTP-effluents based on monitoring data

A concentration in effluents is calculated using the median value of 90P of monitoring data from WWTP effluents in 8 EU countries and Norway (see Table 39). In case several measurements are available for the same location for a country, the 90P for that location will be used when deriving the concentration in effluents.

Table 39 Values used to derive a concentration for WWTP effluents from 8 EU countries and Norway.

Country	**PEC (90P) µg NP/L**	**Data used (µg NP/L)**
Denmark	0.271	0.116, 0.0075, 0.0513, 0.169, 0.242a, 0.3b
Estonia	1.572	0.48c, 0.405d, 2.185e, 0.356f, 0.652g
Finland	0.713	0.189, 0.374, 0.065, 0.82h, 0.605i, 0.5j
Germany	1.223	0.755k, 1.275l
Latvia	0.61	0.63m, 0.428n
Lithuania	0.636	0.67o, 0.33p
Norway	0.181	0.189, 0.105
Poland	1.609	0.445q, 0.745r, 1.15s
Sweden	0.095	0.061t, 0.105u, 0.056v, 0.0705w
Median	**0.674**	

a) 90P of 0.05, 0.05 and 0.29.
b) 90P of 0.22, 0.05 and 0.32.
c) 90P of 0.05, 0.3, 0.54, 0.42, 0.05 and 0.25
d) 90P of 0.52, 0.2, 0.29, 0.23, 0.24 and 0.25
e) 90P of 0.75, 0.47, 1.75, 2.62, 0.64 and 1.12
f) 90P of 0.22, 0.26 and 0.38
g) 90P of 0.73, 0.15 and 0.34
h) 90P of 0.29, 0.17, 0.22, 1.19, 0.28 and 0.45
i) 90P of 0.05, 0.15, 0.58, 0.63, 0.28 and 0.32

j) 90P of 0.05, 0.35, 0.46, 0.54, 0.39 and 0.36
k) 90P of 1.14, 0.25, 0.13, 0.21, 0.22 and 0.37
l) 90P of 2.24, 0.15, 0.12, 0.31, 0.15 and 0.25
m) 90P of 0.36 and 0.66
n) 90P of 0.43 and 0.41
o) 90P of 0.18, 0.19, 0.75, 0.59, 0.24 and 0.16
p) 90P of 0.05, 0.17, 0.2, 0.46, 0.1 and 0.16
q) 90P of 0.39, 0.44, 0.21, 0.13, 0.44 and 0.45
r) 90P of 0.76, 0.61, 0.26, 0.27, 0.73 and 0.2
s) 90P of 0.97, 0.37, 0.3, 0.12, 0.6 and 1.33
t) 90P of 0.025, 0.025, 0.025, 0.025, 0.097 and 0.025
u) 90P of 0.025, 0.025, 0.094, 0.1, 0.11 and 0.025
v) 90P of 0.025, 0.025, 0.025, 0.025, 0.087 and 0.025
w) 90P of 0.025, 0.025, 0.064, 0.055, 0.051 and 0.077

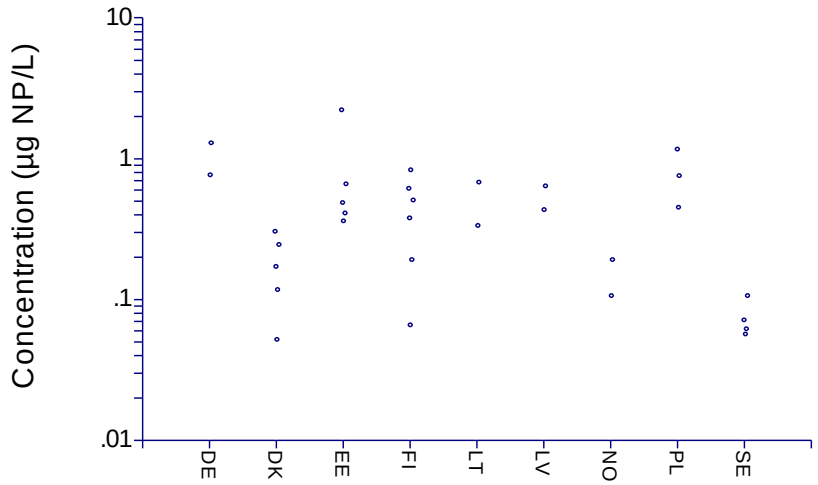


Figure 12 Levels of nonylphenol in WWTP effluents. Values reported to be below the limit of detection (LOD) are presented at half LOD for the respective studies.

Concentrations on NP measured in WWTP influents/effluents in several Denmark, Finland and Norway are reported in TemaNord (Nordic Councils of Ministers, 2008). In Denmark concentrations of NP in influents/effluents has been measured in Copenhagen (3.55 µg NP-mix/L/0.116 µg NP-mix/L) and Roskilde (- /<0.015 & 0.0513 µg NP-mix/L). In the Faroe Islands measurements of influents/effluents are available from two locations in Torshavn, Hospitalet (0.923 µg NP-mix/L/2.173 µg NP-mix/L) and WWTP Sersjantvikin (0.969 µg NP-mix/L/0.169 µg NP-mix/L). In Finland measurements were performed in Espoo (3.146 µg NP-mix/L/0.189 µg NP-mix/L) and Helsinki (5.688 µg NP-mix/L/0.374 µg NP-mix/L). In Norway, measurements of influents/effluents are available for two locations in Oslo, Bekkelaget (0.266 µg NP-mix/L/0.189 µg NP-mix/L) and VEAS (1.108 µg NP-mix/L/0.105 µg NP-mix/L).

In the COHIBA project (2011) measurements of NP in WWTP influents/effluents were performed in Denmark (COHIBA, 2011a), Estonia (COHIBA, 2011b), Finland (COHIBA, 2011c), Germany (COHIBA, 2011d), Latvia (COHIBA, 2011e), Lithuania (COHIBA, 2011f), Poland (COHIBA, 2011g) and Sweden (COHIBA, 2011h). In Denmark values are available for two municipal WWTP (0.22 – 9 µg NP-mix/L / <0.10 – 0.32 µg NP-mix/L), four industrial WWTP (- / <0.05 – 0.23 µg NP-mix/L) and combined sewer overflows (0.39 µg NP-mix/L / <0.10 – 0.51 µg NP-mix/L). In Estonia measurements are available from five municipal WWTP (2.7 µg NP-mix/L / <0.10 – 2.62 µg NP-mix/L). In Finland measurements are available from three municipal WWTP (- / <0.10 – 1.19 µg NP-mix/L) and one industrial WWTP (- / <0.10 – 0.70 µg NP-mix/L). In Germany measurements are available from two municipal WWTP (- / 0.13 – 2.24 µg NP-mix/L) and two industrial WWTP (- / <0.10 – 2.11 µg NP-mix/L). In Latvia values are available from two municipal WWTP (- / 0.36 – 0.66 µg NP-mix/L) and two industrial WWTP (- / 0.12 – 0.32 µg NP-mix/L). In Lithuania measurements of NP in influents/effluents are available from two municipal WWTP (- / <0.10 – 0.75 µg NP-mix/L) and from two industrial WWTP (- / <0.10 – 0.50 µg NP-mix/L). In Poland measurements were performed in three municipal WWTP (- / 0.12 – 1.33 µg NP-mix/L) and one industrial WWTP (- / <0.35 – 0.93 µg NP-mix/L). In Sweden measurements were performed in four municipal WWTP (- / <0.05 – 0.11 µg NP-mix/L).

Calculation of a concentration in WWTP-sludge based on monitoring data

A concentration in sludge is calculated using the median value of 90P of monitoring data from WWTP sludge in 8 EU countries and Norway (see Table 40 below). In case several measurements are available for the same location for a country, the 90P for that location will be used when deriving the concentration in WWTP-sludge.

Table 40 Values used to derive a concentration in sludge for WWTP sludge from 8 EU countries and Norway.

Country	**PEC (90P) mg NP/kg dw**	**Data used (mg NP/kg dw)**
Denmark	6.47	8.35a, 2.25b, 3.658, 1.46, 2.288
Estonia	20.17	3.88, 21.98c
Finland	25.6	28.36, 14.583, 8.932
Germany	3.00	2.653d, 3.04
Latvia	13.21	14.57e, 0.944f
Lithuania	3.95	4.28, 0.95
Norway	3.97	4.078, 3.005
Poland	34.68	15.9, 36.77
Sweden	17	14.328, 6, 14, 20, 15, 11, 9.38g
Median	**13.2**	

a) 90P of 8.6 and 6.1
b) 90P of 2.3 and 1.8
c) 90P of 24.2 and 2.01

d) 90P of 2.7 and 2.23
e) 90P of 10.52 and 15.02
f) 90P of 0.89 and 0.95
g) 90P of 6.5 and 9.7

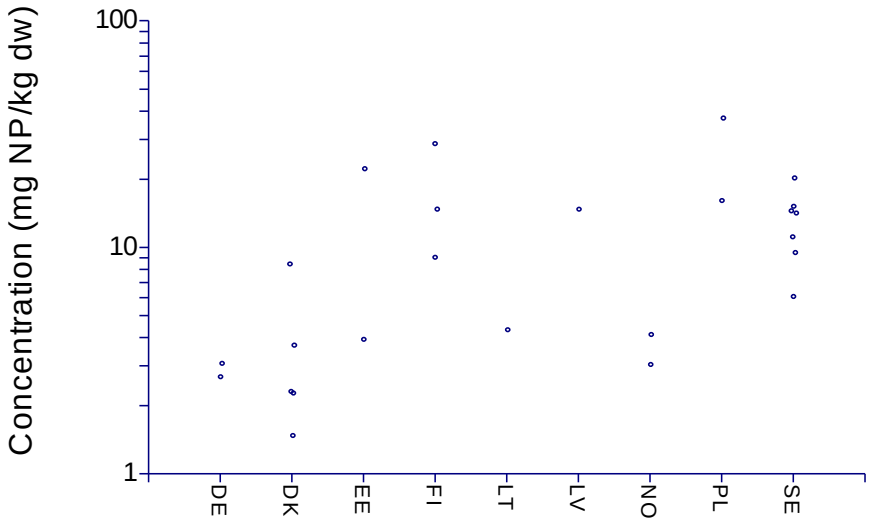


Figure 13 Levels of nonylphenol in WWTP sludge. Values reported to be below the limit of detection (LOD) are presented at half LOD for the respective studies.

Concentrations on NP measured in WWTP sludge in Denmark, Finland, Norway and Sweden are reported in TemaNord (Nordic Councils of Ministers, 2008). In Denmark concentrations of NP in WWTP sludge have been measured in Copenhagen (4.878 mg NP-mix mg/kg dw) and Roskilde (3.658 mg NP-mix mg/kg dw). In the Faroe Islands measurements of influents/effluents are available from two locations in Torshavn, Hospitalet (1.46 mg NP-mix mg/kg dw) and WWTP Sersjantvikin (2.388 mg NP-mix mg/kg dw). In Finland measurements were performed in Espoo (8.932 mg NP-mix mg/kg dw), Helsinki (14.583 mg NP-mix mg/kg dw) and Pornainen (8.932 mg NP-mix mg/kg dw).. In Norway, measurements of influents/effluents are available for two locations in Oslo, Bekkelaget (3.556 - 4.078 mg NP-mix mg/kg dw) and VEAS (1.46 – 3.005 mg NP-mix mg/kg dw). In Sweden measurements were performed in two WWTP located in Stockholm, Henriksdal (7.570 mg NP-mix mg/kg dw) and Hammarby Sjöstad (14.328 mg NP-mix mg/kg dw).

In the COHIBA project (2011) measurements of NP in WWTP sludge were performed in Denmark (COHIBA, 2011a), Estonia (COHIBA 2011b), Finland (COHIBA 2011c), Germany (COHIBA 2011d), Latvia (COHIBA 2011e), Lithuania (COHIBA 2011f), Poland (COHIBA 2011g) and Sweden (COHIBA 2011h). In Denmark values are available for two municipal WWTP; WWTP 1 (6.1 – 8.6 mg NP-mix mg/kg dw) and WWTP 2 (1.8 – 2.3 mg NP-mix mg/kg

dw); and one industrial WWTP, Industrial WWTP 1 (Waste Incineration Plant; <0.60 mg NP-mix / kg dw). In Estonia measurements are available from two municipal WWTP, WWTP 1 (3.88 mg NP-mix mg/kg dw) and WWTP 3 (2.01 – 24.2 mg NP-mix mg/kg dw). In Germany measurements are available from two municipal WWTP, WWTP 1 (- / 0.13 – 1.14 µg NP-mix/L) and WWTP 2 (- / 0.15 – 2.24 µg NP-mix/L). In Latvia values are available from two municipal WWTP, WWTP 1 (10.52 - 15.02 mg NP-mix mg/kg dw) and WWTP 2 (0.89 – 0.95 mg NP-mix mg/kg dw). In Lithuania measurements of NP in influents/effluents are available from one municipal WWTP, WWTP 1 (0.95 - 4.28 mg NP-mix mg/kg dw). In Poland measurements was measurements performed in one municipal WWTP, WWTP 2 (15.9 – 36.77 mg/kg dw). In Sweden was measurements performed in one municipal WWTP, WWTP 1 (6.5 – 9.7 mg/kg dw).

Time trends

The concentrations of NP measured in sludge from Swedish WWTP have decreased since the beginning of 1990 until 2010 (see Figure 14 and Figure 15 below). The decrease appears to start to level out during the last years.

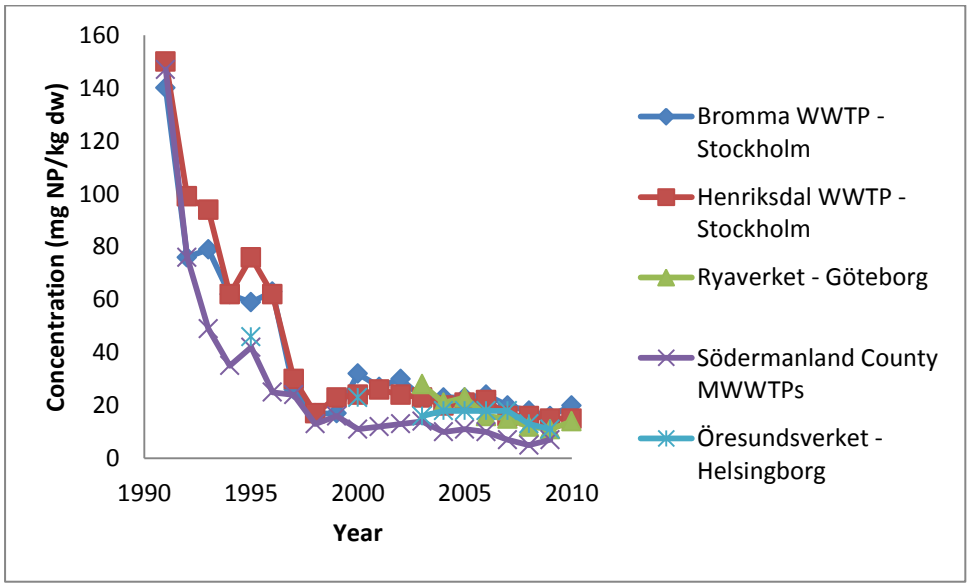


Figure 14 Concentration (mean/median values) of nonylphenol in WWTP sludge in municipal WWTPs in Swedish MWWTPs from year 1991-2010.

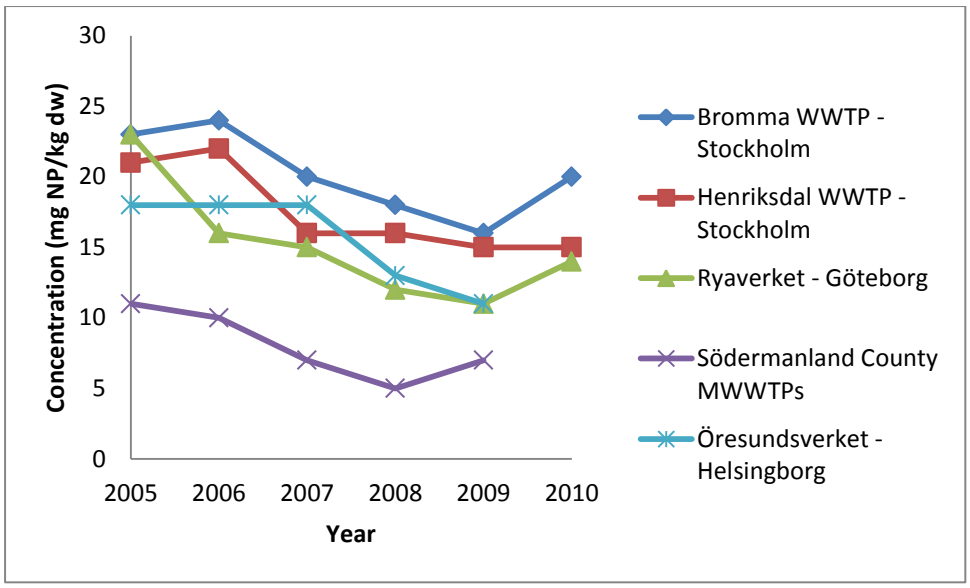
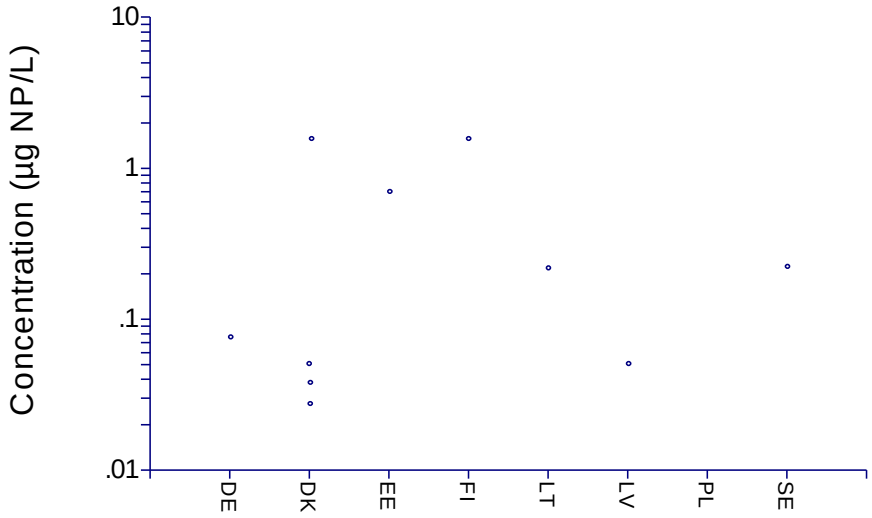


Figure 15 Concentration (mean/median values) of nonylphenol in WWTP sludge in municipal WWTPs in Swedish MWWTPs from year 2005-2010.

Levels in landfills

Levels of NP measured in landfill effluents and soil are presented in Figure 16 below and in Table 65 in Annex 5.



Effluents

Figure 16 Levels of nonylphenol in landfill effluents. Values reported to be below the limit of detection (LOD) are presented at half LOD for the respective studies.

Concentrations on NP measured in landfill effluents in Denmark (Faroe Islands), Finland and Norway are reported in TemaNord (Nordic Councils of Ministers 2008). In the Faroe Islands measurements of effluents are available from one landfill in Torshavn, Husahagi (0.0272 µg NP-mix/L). In Finland measurements were performed in Espoo, Ämmässuo (16.997 µg NP-mix/L).

In the COHIBA project (2011) measurements of NP in landfill effluents were performed in Denmark (COHIBA 2011a), Estonia (COHIBA, 2011b), Finland (COHIBA, 2011c), Germany (COHIBA 2011d), Latvia (COHIBA 2011e), Lithuania (COHIBA 2011f), Poland (COHIBA 2011g) and Sweden (COHIBA 2011h). In Denmark values are available for one landfill (1.39 - 1.7 µg NP-mix/L) and two waste deposits (0.025* - 0.33 µg NP-mix/L). In Finland measurements were performed at two landfills (1.7 – 17 µg NP-mix/L). In Estonia (0.39 - 0.99 µg NP-mix/L), Germany (0.05*-0.10 µg NP-mix/L), Latvia (0.05* µg NP-mix/L), Lithuania (0.20 – 0,23 µg NP-mix/L), Poland (15 µg NP-mix/L) and Sweden (0.20-0.24 µg NP-mix/L) measurements were performed at one landfill each.

Soil

Concentrations on NP measured in landfill soil in Denmark (Faroe Islands) are reported in TemaNord (Nordic Councils of Ministers 2008). Measurements were performed in soil from two landfills on the Faroe Islands, Húsahagi and Havnadalur. The concentration in the former was 0.047 mg NP-mix/mg dw and in the latter below the LOD (0.0035 mg NP-mix/kg dw).

In the COHIBA (2011a) project soil from a Danish waste deposit with public and industrial waste was analysed, but the concentration was below the LOD (<0.60 mg NP-mix/kg dw).

B.9.8 Predicted concentrations of nonylphenol ethoxylates and nonylphenol ethoxycarboxylates

NP, NPEO and NPEC will co-exist in the environment. The exact proportions of these species in freshwater and marine water will vary, but a tentative approach here is to use the proportions described below. It is however acknowledged that the true environmental proportions may differ from the one here hypothised.

By using the proportions of the NP, NPnEOs and NPnEC specified in section "B.9.4 Environmental exposure" above, the proportions of NP1EO/NP2EO vs. NP1EC/NP2EC presented in Ahel *et al.* (1994) and the PEC derived for freshwater in section "B.9.7 Measured levels" above concentrations for NPnEOs and NPnEC is estimated.

In the EU risk assessment (ECB 2002) the assumptions on the fate of NPnEO passing an anaerobic WWTP (based on weight %) is presented as follows:

Mineralised/highly degraded	45%
Released as NP1EO/NP2EO/NPnEC in effluent	25%
Released as NPnEO (n>3)	8 %
Released as nonylphenol in effluent	2.5%
Nonylphenol in anaerobically digested sludge	19.5%

The proportion of NP1EO/NP2EO vs. NP1EC/NP2EC was in the study by Ahel *et al.* (1994) approximately 1:2. It is, as a worst case assumption, assumed that all 8% of NPnEO (n>3) corresponds to the interval n = 3-8. This results in the following proportions of the various species in the effluents:

NP1EO/NP2EO	8.3 %
NP1EC/NP2EC	16.7 %
NPnEO (n = 3 - 8)	8 %
NP	2.5%

If instead expressing this in relation to NP this results in the following proportions:

NP:NP1EO/NP2EO	1:3.3
NP: NP1EC/NP2EC	1:6.7
NP:NPnEO (n = 3 - 8)	1:3.2

It was stated in the derivation of TEFs made by Environment Canada (2001) that the use of

By using these approximate relationships, tentative concentrations for these NP-species can be estimated using the freshwater PEC 0.075 µg NP/L for NP (see Table 41 below):

Table 41 Predicted concentrations of nonylphenol ethoxylates and nonylphenol ethocarboxylates in freshwater.

Species	**Proportion relative to NP**	**Concentration (µg/L) in freshwater**	**Concentration (µg/L) in marine water**
NP	1	0.075	0.05
NP1EO/NP2EO	3.3	0.25	0.165
NP1EC/NP2EC	6.7	0.5	0.335
NPnEO (n = 3 – 8)	3.2	0.24	0.16

B.9.8 Combined human exposure assessment

Not relevant since the risk has been assessed to be based on the environment, not on human health.

B.9.9 Selected environmental concentrations of risk characterisation

The selected values for the respective compartment are listed below.

Atmospheric compartment
Not relevant.

Aquatic compartment (pelagic)

Freshwater
0.075 µg NP/L

Marine water
0.05 µg NP/L

Sediment

Freshwater
0.259 mg NP/kg dw

Marine water
0.363 mg NP/kg dw

Soil compartment

PECsoil, 30d average:	20.1 – 70.2 µg NP/kg dwt
PECsoil, 180d average:	11.7 – 65.4 µg NP/kg dwt
PECgrassland, 180d average:	4.38 – 22.6 µg NP/kg dwt

Secondary poisoning

Fish, freshwater:	0.096	mg NP/kg wwt
Earthworms in agricultural soil:	0.117 - 1.37	mg NP/kg
Fish, marine:	0.064	mg NP/kg wwt
Predator, fish eating - marine:	0.064	mg NP/kg wwt

B.10 Risk characterisation

B.10.1.1 Human health

A risk characterisation for human health is not accounted for in this targeted risk assessment since the risk has been assessed based on the environmental concerns, not for human health. However, potential concerns for human health from exposure to textiles containing NP/NPEO would most probably be removed by the risk reduction measures proposed on the basis of the environmental risk assessment.

B.10.1.2 Environment

B.10.1.2.1 Aquatic compartment (including sediment and secondary poisoning)
The risk characterisation section for nonylphenol will compare the results of the exposure and effects assessments using a standard quantitative risk assessment approach based on the available information on nonylphenol. In addition, information on the contribution to the risks posed by exposure to nonylphenol ethoxylates (NPEOs) relevant for occurrence in textiles and in WWTP effluents and in the environment together with degradation products such as nonylphenol and nonylphenol ethoxycarboxylates (NPECs) will be considered. This mixture toxicity will be assessed using a quantitative risk assessment approach based on toxic equivalency factors (TEFs) for these NPEOs and NPECs in relation to the toxicity of nonylphenol. Furthermore, the uncertainties in the current exposure and effects data and the potential influence on the resulting risk characterisation ratios will be discussed and considered. This discussion will include the difficulties in deriving safe environmental levels for endocrine disruptors based on the current advancement of the science in general and on the available data base for nonylphenol in particular. Finally, an approach using a combination of information from the quantitative assessment with a qualitative assessment will be introduced when summarising the conclusions of the environmental risk assessment.

PECs for NP in the freshwater (pelagic and benthic) and marine water (pelagic and benthic) compartments have been derived using the median value of the 90P of the measured values for the individual EU countries and Norway. It is assumed that the monitoring data is representative for recipients affected by point sources (WWTP). This assumption is based on the available information on sampling sites and that the PEC calculated from measured effluent concentrations from municipal WWTP compares well with the monitoring data. PECs for the secondary poisoning assessments have been calculated using a BCF of 1280.

$PNEC_{water}$ for NP in freshwater was estimated using the standard procedure of dividing the lowest of three long-term NOECs (6 µg NP/L for the endpoint growth for the rainbow trout *Onchorrynchus mykiss*) with an assessment factor of 10, which results in a $PNEC_{water}$ of 0.6 µg NP/L.

$PNEC_{water}$ for NP in marine water was predicted using the freshwater data set and data for marine species and dividing the lowest NOEC of 3.9 µg NP/L (the marine mysid *Mysidopsis bahia*) with an assessment factor of 100 , resulting in a $PNEC_{water}$ for marine water of 0.039 µg NP/L It is, however, noteworthy that if additional relevant and reliable toxicity data from additional marine taxonomic groups (e.g. echinoderms, molluscs) would become available this would result in a reduced assessment factor (50 or 10) instead of the presently used assessment factor of 100.

The PEC derived for pelagic freshwater is considered to be relatively robust and is not expected to change by more than a factor of 2-3 with the inclusion of a limited number of extra measurements.This is largely caused by the way the PEC is calculated as the median of the 90-percentile values from the data from each of the countries. Due to the much larger number of countries with included data for freshwater (n=25) as compared to marine water (n=4), the latter is expected to be less robust as compared to the former with regard to inclusion of additional new data from new and/or already included countries.

The $PNEC_{water}$ for pelagic marine waters is also considered to be less robust than the corresponding $PNEC_{water}$ for freshwater. This is since two additional ecotoxicity data for additional species representing marine taxonomic groups (for example echinoderms or molluscs) would reduce the assessment factor used to derive the $PNEC_{water}$ from 100 to 10, while the assessment factor 10 already is used when deriving $PNEC_{water}$ for freshwater.

$PNEC_{sediment}$ for the freshwater sediment compartment was calculated using an assessment factor of 50 on the lower of two long-term toxicity data for freshwater sediment organisms. $PNEC_{sediment}$ for the marine compartment was calculated using the data for the two freshwater sediment organisms and a marine sediment organism and an assessment factor of 50. $PNEC_{oral}$ for secondary poisoning is the same as was used in the EU risk assessment (ECB 2002) and originates from a mammalian NOAEL of 15 mg/kg body weight found for reproductive effects which using appropriate conversion and assessment factors (as recommended in REACH guidance) results in a $PNEC_{oral}$ of 10 mg NP/kg food.

The PECs, PNECs and resulting PEC/PNEC ratios for the aquatic compartments are listed in Table 42.

Table 42 PECs, PNECs and PEC/PNEC ratios for nonylphenol (NP) in the aquatic compartment.

Compartment	PEC	PNEC	PEC/PNEC
Freshwater	0.075 µg NP/L	0.60 µg NP/L	0.125
Marine water	0.05 µg NP/L	0.039 µg NP/L	**1.3**
Freshwater sediment	0.259 mg NP/kg dw	4.62 mg NP/kg dw	0.056
Marine water sediment	0.363 mg NP/kg dw	1.23 mg NP/kg dw	0.30
Secondary poisoning		10 mg NP/kg food	
Fish, freshwater	0.096 mg NP/kg wwt		0.01
Fish, marine	0.064 mg NP/kg wwt		0.006
Predator, fish-eating - marine	0.064 mg NP/kg wwt		0.006

Using the available monitoring data and PNECs for nonylphenol there is concern for the pelagic marine compartment. For other compartments the calculated PEC/PNEC ratios for nonylphenol are below 1.

However, in the following subsections consideration will be given to further factors influencing the risk assessment, such as information on the contribution to the risks posed by the combined exposure to the nonylphenol ethoxylates (NPEOs) relevant for occurrence in textiles, and their degradation products such as nonylphenol and nonylphenol ethoxycarboxylates (NPECs) consequently occurring in mixture with nonylphenol in WWTP effluents and the environment. Furthermore, the potential influence of the uncertainties listed below will also be considered:

- indications that the present $PNEC_{water}$ for nonylphenol may be too high,
- the endocrine properties of nonylphenol and the uncertainty of a safe level,
- the combined exposure of additional estrogenic compounds,
- PECs, for which there exist indications that they may be too low.

Combined exposure of nonylphenol and nonylphenol ethoxylates and nonylphenol ethoxycarboxylates

Since nonylphenol, nonylphenol ethoxylates (NPEOs), and nonylphenol ethoxycarboxylates (NPECs) will occur as mixtures in WWTP effluents and in the environment due to their occurrence in textiles and/or as degradation products their combined toxicity needs to be assessed. We believe this is an important factor to consider in this assessment because the combined exposure to these multiple substances acting in a similar way and the resulting cumulative risk emanating from their occurrence in textiles would otherwise not be accounted for. Thus, the issue whether the individual doses also are causing effect on their own is less important.

Dose (concentration) addition is considered to be applicable to mixtures composed of chemicals with a similar mode of action (Kortenkamp *et al*., 2009) and is therefore selected as the most relevant method to assess the combined toxicity from NP, NPnEOs and NPnCs.

Using the concept of dose-addition when performing a combined exposure assessment for freshwater, a combined RCR can be calculated using 1) the concentrations estimated in Table 41 and 2) the TEFs based on apical endpoints derived by Environment Canada (2002).

Based on a comprehensive review of available toxicity data Environment Canada (2001) developed Toxic Equivalency Factors (TEFs) for various nonylphenolic compounds. The values were derived based on a broad dataset including both acute and chronic toxicity studies on a range of vertebrate and invertebrate species. Reported toxic concentrations for the various nonylphenolic substances were matched up against similar endpoints for nonylphenol with the same species, and, where possible, from the same laboratory, and based on the outcome of that a relative toxicity ratio was calculated. From the resulting list of relative toxicity values for each group of compounds, a mean relative toxicity value (TEF) was calculated, with more weight given to those studies deemed to be of higher quality. The toxicity was generally expected to decrease with increasing EO chain length.

In the report by Environment Canada (2001) it was stated that the TEF of 0.5 set for NPnEO (n = 3-8) (for which sufficient data to conclude on relative toxicity is not available) may overestimate the toxicity because it was based on a conservative estimate that the toxicity for this group is the same as for NP2EO, i.e. with the shorter ethoxylate chain.

If instead assuming that the toxicity is equal to NPnEO (n>9), i.e. with the longer ethoxylate chain, the TEF would be 0.005. Thus, depending on the assumptions made regarding the toxicity of the NPnEO (n = 3-8)-fraction, the calculated RCR may be underestimating or overestimating the contribution of NPnEO (n = 3-8) to the cumulative risk. In the current dossier by using both these two TEFs for NPnEO (n = 3-8), i.e. 0.005 and 0.5, an interval for the combined RCR can be estimated. By using this approach the resulting interval is assumed to cover the toxicity of NPnEO (n = 3-8).

There is also an assumption related to the predicted concentration of this fraction made in section B.9.8 that all NPnEO(n>3) released in the WWTP effluent is present as NPnEO(n = 3 - 8), which may overestimate the concentration this fraction, which is about three times that of nonylphenol and about the same as the concentration of NP1EO/NP2EO. The assumption made is that all NPnEO (n>3) corresponds to NPnEO (n=3-8). However, when in the lower end of the estimated RCR using the lower TEF of 0.005, the PEC/PNEC-contribution from this fraction will be so insignificant that further adjustments of reducing the concentration of this fraction will not influence the size of the combined RCR. At the higher end of the estimated RCR for this fraction the assumption is, as mentioned above, that all NPnEO (n>3) corresponds to NPnEO (n=3-8).

The resulting combined RCR for NP, NPEOs and NPECs ranges from 0.34 to 0.54 (see Table 43below), which means that the combined risk is a factor of 2.7 – 4.3 larger as compared to when the risk characterisation is based on NP alone.

Table 43 Combined RCRs of NP, NPnEO (n = 1 – 2), NPnEO (n = 3 – 8) and NPnEC (n = 1 – 2) in freshwater.

Chemical	PEC (µg/L)	Toxic Equivalency Factors relative NP	PNEC (µg/L)	PEC/PNEC	Combined RCR
NP	0.075	1	0.6	0.125	0.34 - 0.54
NPnEO (n = 1 – 2)	0.25	0.5	1.2	0.21	
NPnEO (n = 3 - 8)	0.24	0.005-0.5	1.2-120	0.002-0.2	
NPnEC (n = 1 - 2)	0.5	0.005	120	0.004	

In order to calculate the combined RCR for each country a table similar to Table 43 above could be derived for all individual countries. Instead another approach is used here where the country specific combined RCR is based on the ratio between the country specific 90P-PEC value and $PNEC_{water}$ for NP multiplied with a scale factor derived from the relation between the RCR for the combined toxicity of NP, NPnEO and NPnEC and the RCR for NP alone in Table 43 (2.72 = 0.34/0.125 or 4.32 = 0.54/0.125). The resulting country specific combined exposure RCRs are presented in Table 44.

When assessing the combined toxicity of NP, NPnEO and NPnEC using the available freshwater monitoring data presented in Table 34, concern is identified in eight (Austria, Belgium, Bulgaria, Cyprus, Germany, Romania, Spain and in the United Kingdom) to twelve EU Member States (including in addition to the first eight MS also the Czech Republic, France, Italy, and Slovenia), see Table 44 below.

Table 44 Combined RCRs of NP, NPnEO (n = 1 – 2), NPnEO (n = 3 – 8) and NPnEC (n = 1 – 2) in twelve EU-countries based on monitoring data in freshwater. RCRs above one are indicated in bold style.

Country	90P-PEC (µg NP/L)	$PNEC_{water}$ (µg NP/L)	NP-RCR	Combined toxicity scale factor	Combined RCR
Austria	0.331	0.6	0.55	2.72 - 4.32	**1.5 - 2.4**
Belgium	3.71		**6.18**		**17 - 27**
Bulgaria	0.265		0.44		**1.2 - 1.9**
Cyprus	0.453		0.76		**2.1 - 3.3**
Czeh Republic	0.169		0.28		0.77 - **1.2**
France	0.182		0.30		0.83 - **1.3**
Germany	0.9		1.5		**4.1 - 6.5**
Italy	0.182		0.30		0.83 - **1.3**
Romania	0.33		0.55		**1.5 - 2.4**
Slovenia	0.183		0.31		0.83 - **1.3**
Spain	0.475		0.79		**2.2 - 3.4**
United Kingdom	0.248		0.41		**1.1 - 1.8**

Similarly, the RCR for marine water increases when also considering the combined exposure from NPEOs and NPECs and result in a combined RCR of 3.5 - 5.5 (see Table 45 below).

Table 45 Combined RCRs of NP, NPnEO (n = 1 – 2), NPnEO (n = 3 – 8) and NPnEC (n = 1 – 2) in marine water.

Chemical	**PEC (µg/L)**	**Toxic Equivalency Factors relative NP**	**PNEC (µg/L)**	**PEC/PNEC**	**Combined RCR**
NP	0.05	1	0.039	1.28	3.5 - 5.5
NPnEO (n = 1 – 2)	0.165	0.5	0.078	2.11	
NPnEO (n = 3 - 8)	0.16	0.005 - 0.5	0.078 – 7.8	0.02 - 2.05	
NPnEC (n = 1 - 2)	0.335	0.005	7.8	0.04	

The country specific combined toxicity RCRs for marine waters can be calculated in a similar way resulting in concern in three (Denmark, Finland and Sweden) or four (also Norway) out o a total of four countries with marine monitoring data (see Table 46 below).

Table 46 Combined RCRs of NP, NPnEO (n = 1 – 2), NPnEO (n = 3 – 8) and NPnEC (n = 1 – 2) in three EU-countries and Norway based on monitoring data in marine water. RCRs above one are indicated in bold style.

Country	**90P-PEC (µg NP/L)**	**$PNEC_{water}$ (µg NP/L)**	**NP-RCR**	**Combined toxicity scale factor**	**Combined RCR**
Denmark	0.051	0.039	**1.3**	2.7- 4.3	**3.5 – 5.6**
Finland	0.089		**2.3**		**6.2 – 9.9**
Norway	0.01		0.26		0.7 – **1.1**
Sweden	0.05		**1.3**		**3.5 – 5.6**

However, the RCRs for the marine pelagic compartment are less robust as compared to the freshwater RCRs as previously described above.

In addition, there are in the available database several studies of somewhat lower reliability (e.g. the study by Lahnsteiener *et al.* (2005) where a nominal concentration of 0.75 µg NP/L resulted in completely inhibited production of semen in +2 years male rainbow trout and the study by Marcial *et al.* (2003) where a nominal concentrations of 1 µg NP/L resulted in a significant delay in the completion of the naupliar stage in the parental generation of the marine copepod *Tigriopus japonicas* and where a significant delay in the F1 generation was observed already at 0.1 µg NP/L) which therefore cannot be used when deriving the PNECs but still indicate that the present freshwater and marine $PNEC_{water}$ may underestimate the toxicity of NP with one order of magnitude or more (see "B.7.1.1.6. Calculation of PNECwater for freshwater and marine water" above for more details). These efects may be due to the ED-properties of nonylphenol and its precursors.

Nonylphenol and endocrine disruption

Nonylphenol is considered to be an endocrine disruptor (see section on endocrine properties of nonylphenol above for more details). It is generally assumed to result in an inherently larger uncertainty to describe the long-term risk of a substance considered to be an ED since the adverse influence on the environment may be expressed in many different ways, some more other less well understood. Even short exposure periods during critical development stages may be sufficient to initiate endocrine mediated effects which adversely affect populations (note the temporal variability of nonylphenol mentioned above with the highest concentrations measured during the summer). Sensitive test systems detecting endocrine mediated effects on wildlife are hardly available and are still under development for some taxonomic groups (fish, molluscs and frogs) within the OECD test guideline program, but are still missing for others (e.g. birds and reptiles). Difficulties in assessing ED in traditional risk assessments are among other things caused by ED exerting effects during specific life stages, whereas the consequence may be apparent only later in life. It is thus necessary to develop risk assessment/management strategies for dealing with the incomplete knowledge of environmental concerns associated with ED. At the present state of knowledge with the difficulty to establish a safe exposure level, we therefore suggest to handle nonylphenol as a substance for which there exists no safe level.

If dealing with the incomplete knowledge and uncertainty of ED as opened for in the guidance (see section B.7.1.1.6 above), by introducing an extra AF and setting it to the size of 10, the RCRs derived above would increase with a factor of 10 and result in an EU generic RCR of 1.5 based on freshwater monitoring data when only assessing the toxicity of nonylphenol. When also taking the combined toxicity into account the resulting EU generic combined RCRs in table 2 would increase to 3.4-5.4 and the range of country specific combined RCRs in table 3 would increase to 7.7-270.

The use of an extra AF of 10 would in fact result in concern for all twelve EU Member States in table 3 above, when only assessing the toxicity of nonylphenol, and would result in concern in all 24 EU Member States and Norway in table 35 when also taking the combined toxicity into account. Applying an extra AF of 10 on the marine RCRs would increase the already derived concern in table 4 and table XX to 35-55 and 7-99, respectively.

It is however not considered appropriate in case of an ED to introduce an extra AF since it is considered difficult to determine which concentration that should be regarded as safe for the environment and a qualitative risk assessment is therefore performed instead.

Combined exposure of additional ED-substances acting via the estrogen receptor

In addition to the combined toxicity described above a combined exposure is also expected with other estrogenic substances well known to occur in municipal WWTP effluents such as natural and synthetic estrogens as well as other industrial chemical substances like octylphenol. However, the issue of combined exposure of additional substances acting via the estrogen receptor will not be taken further in this assessment since it is focused on the concerns related to nonylphenol ethoxylates and nonylphenol in textiles.

Uncertainty of predicted environmental exposure concentrations (PECs)
There are indications available that the PECs based on the available environmental measurements may be underestimated. A Swedish monitoring study using monthly measurements from December 2007 - November 2008 found large temporal variation over the year with the highest concentrations measured during the summer. The temporal concentrations for the limnic locations varied with a factor from about two to 70 (median value 25) and for the marine locations with a factor from about three to 30 (median value 6). It is therefore, based on these results, assumed that the entire distribution of monitoring data would shift towards higher concentration values if it would have been based on sampling performed during the summer.

A number of the available monitoring data constitute of measurements below the limit of detection, for which half detection limit has been used according to a generally applied approach for such data sets. It is of course uncertain whether the true concentrations of these samples were above or below that chosen default value and what errors this may have introduced in the present PECs. However, if all samples below the limit of detection would be left out of the database from which the country specific 90-percentile values where derived then that would lead to an increase of the overall EU median PEC value.

Overall summary

- The risk characterisation for nonylphenol on its own results in concern (RCR 1.3) for the marine pelagic compartment based on the EU median PEC (of 90-percentile values of individual countries) from a database covering only a limited number of countries (n=4). Furthermore, there is concern for the freshwater pelagic compartment based on country specific 90-percentile values for Belgium and Germany, whereas the EU median PEC from a database covering a large number of countries (n=25 although many countries are represented by only a small number of samples, often less than 6) showed no concern (RCR 0.125).

- An assessment of the combined toxicity of nonylphenol ethoxylates, occurring in textiles, and their degradation products such as nonylphenol and nonylphenol ethoxycarboxylates has been included in this dossier since these substances emanate from textiles and will

occur as mixtures in WWTP effluents and in the environment. Assessing the combined toxicity of these compounds, using Toxic Equivalency Factors and the pelagic freshwater monitoring database available, results in a RCR ratio ranging from 0.34-0.54 for the EU median PEC depending on which TEF are being used for NPnEO (n=3-8). However based on country specific 90 percentile values there is concern in 8 to 12 (RCR1.1-27) EU countries out of a total of 24 EU countries and Norway for which freshwater monitoring data is available, which corresponds to identified concern in 30 to 50 % of the countries. When in a similar way assessing the combined toxicity in the marine pelagic compartment concern is identified in three to four countries out of four countries with available monitoring data (median RCR 3.5-5.5). However, the marine RCRs are less robust as compared to the freshwater RCRs since the present database is limited and new additional data on further trophic levels would reduce the AF used when the deriving the PNEC.

- Nonylphenol is considered to be an endocrine disrupting substance and when taking the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular into account it is questionable whether the currently available knowledge and evidence can be considered sufficient to establish safe levels for the environmental compartments assessed. A few issues related to these difficulties are presented below.
    - The Reach Guidance Document on Information Requirements/Chemical Safety Assessment offers a possibility of dealing with the incomplete knowledge and uncertainty of ED by introducing an assessment factor, AF. The present knowledge does not provide sufficient information to derive a more specific AF for endocrine disruption, but possibly set the AF to an arbitrary size of 10. If introducing this factor the RCRs derived in this assessment would increase with a factor of 10. Consequently, the EU generic RCRs for freshwater would range from 1.25 (for NP only) to 3.4-5.4 (for the combined TEF approach), respectively. When using the country specific monitoring data for freshwater the use of this extra AF=10 would result in concern in 12 Member States when assessing the toxicity of nonylphenol only and concern in all 24 Member States and Norway for which freshwater monitoring data is available when also taking the combined toxicity into account. Applying an extra AF of 10 on the marine RCRs would increase the RCR of nonylphenol on its own to 13 and the combined toxicity RCRs to 7-99.
    - In the available database there are several studies of somewhat lower reliability, which therefore cannot be used when deriving the PNECs, but where the results indicate that the present freshwater and marine $PNEC_{water}$ may underestimate the toxicity of NP with one order of magnitude or more. Based on the endpoints studied the effects shown may to be due to the ED-properties of nonylphenol. This

introduces further uncertainties regarding the possibilities of deriving safe levels for the endocrine properties of NP.

- It is noted that the pelagic freshwater and marine PECs based on monitoring data may be underestimated since there is a study of seasonal variation indicating that it could be expected that the entire distribution of monitoring data would shift towards higher concentration values if it would have been based on sampling performed during the summer.

Overall assessment: When assessing the toxicity of nonylphenol on its own using a standard risk assessment PEC/PNEC approach there is concern for the marine pelagic compartment at EU level. When the combined toxicity of nonylphenol and nonylphenol ethoxylates and their degradation products are assessed using Toxic Equivalency Factors there is concern in the marine compartment at EU level and in freshwater for 8 to 12 EU countries out of a total of 24 EU countries and Norway, but not for freshwater at the EU median level. If the uncertainties regarding the endocrine properties of NP would be accounted for by introducing an assessment factor arbitrarily set at 10 to the risk characterisation ratios of the combined toxicity assessment, there would be concern at the EU median level for the marine and freshwater compartments (and for marine waters in the four MS having marine monitoring data and in freshwater for all 24 Member States and Norway for which freshwater monitoring data are available).

From the above summary of the quantitative risk characterisation information in this assessment it is appropriate to conclude that there is concern for the aquatic compartment, with the combined toxicity of NP and NPEOs and their degradation products and the uncertainty of the endocrine disruptive properties (as provisionally accounted for by the extra AF) being the most prominent contributing factors.

However, considering the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular it is questionable whether the available knowledge and evidence can be considered sufficient to establish appropriate assessment factors and safe levels for the environmental compartments assessed. Therefore, it is concluded that it is not possible in the quantitative assessment approach to determine which concentration should be regarded as safe for the environment. Thus, the assessment of the endocrine disrupting properties should be viewed in a qualitative manner rather than a quantitative manner..

Furthermore, the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

Finally, when considering the results of the quantitative risk assessment and the qualitative risk assessment of the endocrine disrupting properties, the conclusion is that there is concern for nonylphenol and nonylphenol ethoxylates in the pelagic aquatic compartment.

B.10.1.2.2 Terrestrial compartment (including secondary poisoning)

PECs for the terrestrial compartments have been estimated using the median value of the 90P of the measured values in sludge for the individual EU countries and Norway. PECs for the secondary poisoning assessments have been calculated using an equation for BCF calculated for the two different log K_{OW}, 4.48, which was used in the EU risk assessment (ECB 2002), and 5.4, which was used in the CSR (Lead registrant, 2011).

$PNEC_{soil}$ was calculated using an assessment factor of 10 on the lowest NOEC (converted to standard TGD soil) from three trophic levels. PEC_{oral} for secondary poisoning is the same as was used in the EU risk assessment (ECB 2002) and was described in the aquatic compartment above.

The resulting PECs, PNECs and resulting PEC/PNEC ratios for the terrestrial compartment are listed in Table 47below.

Table 47 PECs, PNECs and PEC/PNEC ratios for the terrestrial compartment. The ranges for the PEC:s in secondary poisoning are due to the two log K_{OW}-values used (4.48 and 5.4).

Compartment	PEC	PNEC	PEC/PNEC
Soil		1.2 mg NP/kg dw	
30 d average	0.020 – 0.070 mg NP/kg dw		0.017 – 0.058
180 d average	0.012-0.065mg NP/kg dw		0.01 – 0.054
Grassland	0.004-0.023 mg NP/kg dw		0.003 – 0.02
Secondary poisoning		10 mg NP/kg food	
Earthworm in agricultural soil	0.117 – 1.37 mg NP/kg wwt		0.001-0.14

With a standard approach, using soil concentrations derived on the basis of monitored concentrations in sludge, no concern is identified for the terrestrial compartment, including secondary poisoning.

B.10.1.2.4 Microbiological activity in sewage treatment systems

PEC for the sewage treatment systems was estimated using the median value of the 90P of the measured values in WWTP influents for the individual EU countries and Norway.

$PNEC_{WWTP}$ is the same as was used in the EU risk assessment (ECB 2002) and originate from an EC_{50} derived for respiration for common sewage activated sludge microorganisms and an assessment factor of 100.

The resulting PEC, PNEC and resulting PEC/PNEC ratios for the sewage treatment systems are listed in Table 48.

Table 48 PEC, PNEC and PEC/PNEC ratios for sewage treatment systems.

Compartment	PEC	PNEC	PEC/PNEC
Sewage treatment plant	5.43 µg NP/L	9500 µg NP/L	0.0006

With a standard approach, using a PEC derived on the basis of monitored WWTP influent concentrations, no concern is identified for the sewage treatment systems.

B.11 Summary on hazard and risk

The restriction proposal targets nonylphenol (NP) and nonylphenol ethoxylate (NPE) in textile articles or articles containing textiles. The term "nonylphenol" however applies to a large number of linear and branched compounds of the general molecular formula $C_6H_4(OH)C_9H_{19}$ in which an alkyl chain with the carbon number of 9 is “attached” to the phenol. Nonylphenol is used as an intermediate in the production of various NP derivatives, mainly nonylphenol ethoxylates which can break down into NP in the environment.

Overall summary

- The risk characterisation for nonylphenol on its own results in concern (RCR 1.3) for the marine pelagic compartment based on the EU median PEC (of 90-percentile values of individual countries) from a database covering only a limited number of countries (n=4). Furthermore, there is concern for the freshwater pelagic compartment based on country specific 90-percentile values for Belgium and Germany, whereas the EU median PEC from a database covering a large number of countries (n=25 although many countries are represented by only a small number of samples, often less than 6) showed no concern (RCR 0.125).

- An assessment of the combined toxicity of nonylphenol ethoxylates, occurring in textiles, and their degradation products such as nonylphenol and nonylphenol ethoxycarboxylates has been included in this dossier since these substances emanate from textiles and will occur as mixtures in WWTP effluents and in the environment. Assessing the combined toxicity of these compounds, using Toxic Equivalency Factors and the pelagic freshwater monitoring database available, results in a RCR ratio ranging from 0.34-0.54 for the EU median PEC depending on which TEF are being used for NPnEO (n=3-8). However based on country specific 90 percentile values there is concern in 8 to 12 (RCR1.1-27) EU countries out of a total of 24 EU countries and Norway for which freshwater

monitoring data is available, which corresponds to identified concern in 30 to 50 % of the countries. When in a similar way assessing the combined toxicity in the marine pelagic compartment concern is identified in three to four countries out of four countries with available monitoring data (median RCR 3.5-5.5). However, the marine RCRs are less robust as compared to the freshwater RCRs since the present database is limited and new additional data on further trophic levels would reduce the AF used when the deriving the PNEC.

- Nonylphenol is considered to be an endocrine disrupting substance and when taking the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular into account it is questionable whether the currently available knowledge and evidence can be considered sufficient to establish safe levels for the environmental compartments assessed. A few issues related to these difficulties are presented below.
    - The Reach Guidance Document on Information Requirements/Chemical Safety Assessment offers a possibility of dealing with the incomplete knowledge and uncertainty of ED by introducing an assessment factor, AF. The present knowledge does not provide sufficient information to derive a more specific AF for endocrine disruption, but possibly set the AF to an arbitrary size of 10. If introducing this factor the RCRs derived in this assessment would increase with a factor of 10. Consequently, the EU generic RCRs for freshwater would range from 1.25 (for NP only) to 3.4-5.4 (for the combined TEF approach), respectively. When using the country specific monitoring data for freshwater the use of this extra AF=10 would result in concern in 12 Member States when assessing the toxicity of nonylphenol only and concern in all 24 Member States and Norway for which freshwater monitoring data is available when also taking the combined toxicity into account. Applying an extra AF of 10 on the marine RCRs would increase the RCR of nonylphenol on its own to 13 and the combined toxicity RCRs to 7-99.
    - In the available database there are several studies of somewhat lower reliability, which therefore cannot be used when deriving the PNECs, but where the results indicate that the present freshwater and marine $PNEC_{water}$ may underestimate the toxicity of NP with one order of magnitude or more. Based on the endpoints studied the effects shown may to be due to the ED-properties of nonylphenol. This introduces further uncertainties regarding the possibilities of deriving safe levels for the endocrine properties of NP.

- It is noted that the pelagic freshwater and marine PECs based on monitoring data may be underestimated since there is a study of seasonal variation indicating that it could be expected that the entire distribution of monitoring data would shift towards higher

concentration values if it would have been based on sampling performed during the summer.

Overall assessment: When assessing the toxicity of nonylphenol on its own using a standard risk assessment PEC/PNEC approach there is concern for the marine pelagic compartment at EU level. When the combined toxicity of nonylphenol and nonylphenol ethoxylates and their degradation products are assessed using Toxic Equivalency Factors there is concern in the marine compartment at EU level and in freshwater for 8 to 12 EU countries out of a total of 24 EU countries and Norway, but not for freshwater at the EU median level. If the uncertainties regarding the endocrine properties of NP would be accounted for by introducing an assessment factor arbitrarily set at 10 to the risk characterisation ratios of the combined toxicity assessment, there would be concern at the EU median level for the marine and freshwater compartments (and for marine waters in the four MS having marine monitoring data and in freshwater for all 24 Member States and Norway for which freshwater monitoring data are available).

From the above summary of the quantitative risk characterisation information in this assessment it is appropriate to conclude that there is concern for the aquatic compartment, with the combined toxicity of NP and NPEOs and their degradation products and the uncertainty of the endocrine disruptive properties (as provisionally accounted for by the extra AF) being the most prominent contributing factors.

However, considering the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular it is questionable whether the available knowledge and evidence can be considered sufficient to establish appropriate assessment factors and safe levels for the environmental compartments assessed. Therefore, it is concluded that it is not possible in the quantitative assessment approach to determine which concentration should be regarded as safe for the environment. Thus, the assessment of the endocrine disrupting properties should be viewed in a qualitative manner rather than a quantitative manner..

Furthermore, the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

Finally, when considering the results of the quantitative risk assessment and the qualitative risk assessment of the endocrine disrupting properties, the conclusion is that there is concern for nonylphenol and nonylphenol ethoxylates in the pelagic aquatic compartment.

C. Available information on alternatives

Surfactants (surface-active-agents) are substances that at low concentrations greatly reduce the surface tension of liquids. They are organic compounds and contain at least one hydrophilic group and one hydrophobic group in the molecule.

One of the most important properties that characterize surfactants is their ability to form micelles. The micelles are aggregates of several surfactant molecules. The physical-chemical behavior of a surfactant solution changes drastically if the concentration is increased and the surfactant changes from being free ions or molecules to building micelles. When micelles are built in a water phase, the hydrophobic part of every molecule in the surfactant is turned inside against the water phase. The building of micelles has a great importance to the cleaning process for example of textiles. The conversion to micelles occurs rapidly and at a very precise concentration, which is determined from many factors such as; type of surfactant, electrolyte content, temperature and the length of the carbon chain (Nyström 1996).

The appearance and the chemical composition of surfactants can vary. All surfactants have in common that they increase surface activity and reduce the surface tension of water, allowing easier spreading, wetting and better mixing of liquids. The hydrophilic part of the molecules of a surfactant may carry a negative or positive charge, both positive and negative charges or no charge at all. Surfactants are generally categorized based upon their electric charge in water, due to the charge they can be divided into four categories: anionic (negative charge), cationic (positive charge), amphoteric (both positive and negative charged) and nonionic (no charge), (DfE 2011). The following is a description of the different groups:

Anionic surfactants

Anionic surfactants are historically the earliest and the most common surfactants. These surfactants are in general the easiest to produce, therefore also the cheapest (Nyström 1996). They stand for about 50% of the world production of surfactants (Salager 2002). The hydrophilic part of the molecule is always negatively charged and consists often of carboxyl, sulfate or sulfonate groups. The hydrophobic part is often made of a hydrocarbon chain or an alkyl phenol chain. The positive charged counter ion may consist of an alkali metal, ammonium or amines for example. The most commonly used anionic surfactants are: alkyl sulphates and alkyl ethoxylate sulphates and soaps[57] (Nyström 1997).

[57] Soaps refer to a sodium or potassium salt of a fatty acid.

Anionic surfactants are particularly effective at oily soil cleaning and oil/clay soil suspension. They are often used as surfactant for laundering, dishwashing liquids and shampoos due to their excellent cleaning properties and high foaming potential (www.scienceinthebox.com).
The main disadvantage of anionic surfactants is that they are electrolytes. Since the textile process contains salt, anionic surfactants are not optimal in this environment. The surfactant also interacts with the fibers and with various polar compounds in a non successful manner. The anionic surfactants are therefore not an appropriate alternative to replace NPE in this context (Posner 2012).

Cationic surfactants
Cationic surfactants stand for only about 5-6% of the total surfactant production. Though, in some specific uses they are extremely useful (Salager 2002). These surfactants are often based on ammonium salts. The hydrophilic part of the molecule is always positively charged. The hydrophobic part is often based on a long hydrocarbon chains. The negative loaded counter ion is often a halogen. The cationic surfactant reacts with anionic surfactants and form insoluble complex and should therefore not be used together (Nyström 1996). Cationic surfactants can be used as a softening agent to smoothen out the charges in the material, but they are almost exclusively used as a finishing agent in industrial dyeing. Many cationic surfactants are used as bactericides (Salager 2002). As detergents are cationic surfactants not a suitable alternative to NPE (Posner 2012).

Amphoteric/ zwitterion surfactants
This molecule can occur both as an anionic and cationic surfactant, which depends on the pH-level of the ambient solution. When the pH is high, they occur as an anion surfactant and at low pH-levels as a cationic surfactant. Usually correspond a nitrogen atom of the positive charge, the negative charge occur, for example by a carboxyl or sulfonate group (Nyström, 1996). They are often used in pharmaceuticals and cosmetics (Salager 2002). The amphoteric surfactants are doubtful to use considering its charge that might lead to "error" in a preparation process and unwanted precipitation may occur. This group of surfactant is not an appropriate alternative (Posner 2012).

Nonionic surfactants
Nonionic surfactants are a big family of surfactants. About 40% of the overall industrial production is nonionic surfactants and the production has been increasing the last 35 years (Salager 2002). NPE is included in the group of nonionic surfactants and there are several different derivatives of NPE in use. NPE belongs to the sub group of alkyl phenol ethoxylates (APE), which is described further down in this section.

This group of surfactants has no charge and do therefore not produce ions in aquatic solutions. They are much less sensitive to electrolytes than ionic surfactants and can be used in high salinity or hard water. They are also excellent candidates to be used in complex mixtures (Salager 2002).

The molecule is divided into a hydrophobic and a hydrophilic part which gives the surface activity. The hydrophobic part consists mainly of straight or branched hydrocarbon chains. The hydrophilic part consists often of polymerized ethylene oxide groups, which may vary in number to give different surfactant properties. The hydrophilic properties are obtained by taking up protons from the surrounding water (Nyström 1996). Nonionic surfactants work well as detergents, wetting agents and emulsifiers. Some of them have also good foaming properties. This group of surfactants is the most reasonable alternative to NPE.

The textile manufacturing process

The manufacturing of textiles is a complex process involving several different steps where NPE among many other chemicals are used for different purposes. Textile manufacturing includes both a dry and a wet process where NPEs primary are used in the latter as a detergent in different steps involving washing. In the initial dry step fibres and yarn are manufactured which is followed by spinning, twisting, weaving and sizing. During the yarn manufacturing (spinning) NPE can function as an emulsifier when dealing with a lubricant that is not water soluble (BREF 2003).

The pre-treatment

The purpose of the pre-treatment is to prepare the textile and to receive a better result from the following dyeing process. The steps involving chemicals are for example washing and bleaching. This is to remove all impurities found on fiber (e.g. dirt and spinning-oil), to give the materials an amount of white and make them more absorbent to dyestuff. Here NPEs function as a surfactant, or cleaning agent during the washing steps. This includes the scoring process where the purpose of using NPE is to eliminate fibre by-products (Massey et al. 2008). Also during the carbonizing process NPE is used with the task to remove vegetable contaminations (Posner 2012).

Dyeing/Printing

When colouring a textile, dye is applied uniformly to the textile, there are a variety of technics for printing on textiles. They have all in common that dyes or pigments are transferred via a carrier or other technique onto the surface of the fabric, where the print is then fixed.
During the process a large volume of different chemicals are used with the purpose to facilitate when attaching colour to the fibre. During the printing process, like dyeing, colour is applied to the material. The difference is that in the printing process this is performed only at certain areas of the textile to receive a desired pattern. The functions of NPE are here primary as detergent in washing as well as emulsifiers or dispersing agents in several sub-processes (Table 49). Emulsifiers are substances that are soluble in both fat and water and enable fat to be uniformly dispersed in water as an emulsion. Dispersant is a liquid (or gas) added to a mixture to promote dispersion or to maintain dispersed particles in suspension. NPE can function as both depending on whether the chemical composition is in a particular or in a liquid phase.

Finishing

The textile material is exposed to the finishing process to obtain improvements and preferred properties like waterproofing and non-flammability. This may include different treatment both chemical and mechanical/physical (BREF 2003). During the finishing step NPE can function as detergent if the textile material is subjected to washing.

Table 49 Functions and effects of the different use of NPE in the textile manufacturing process.

Process	**Function**	**Effect**
Dry process		
Spinning	Emulsifying agent	Promote lubricants to solve in water
Washing	Detergent	Remove impurities
Wet process		
Pre-treatment		
Washing	Detergent	Remove impurities
Scoring	Detergent	Remove natural wax, fats and non-fibrous impurities
Carbonizing	Detergent	Remove vegetable by-products using acid/acid salt.
Dyeing/Printing		
Dyestuff[58] dissolving	Emulsifying agent	Enable dyestuff in water to dissolve or to form and stabilise.
Exhaust dyeing (in padding process)	Wetting/Deaeration agent	Enhance wetting effect of dye liquors or dye absorption.
Exhaust dyeing (Polyester, Polyester/Wool)	Carriers	Facilitate for dye absorption and diffusion
Skein dyeing of piece goods	Crease preventing agent	Prevent crease
Levelling	Levelling agent	Enable uniform distribution of dyestuff
Printing paste production	Emulsifying agent	Dispersion of pigment
Printing	Emulsifying agent	Remove printing thickeners
Washing	Detergent	Remove of impurities
Finishing		
Washing	Detergent	Remove impurities

(Posner 2012; Assmuth et al. 2008; BREF 2003)

In the table above the known functions for NPE in the textile manufacturing process are described. Today, there are however many 'pre-mixed options', where NPE in low concentrations is not always is recorded in the safety data sheet for a chemical product. Therefore the manufacturer of a textile article does not always know if a chemical product contains NPE (Nimkartek 2012).

[58] A dyestuff is a substance that can function as a dye or out of which dye can be derived

C.1 Identification of potential alternative substances and techniques

NPE has been used for a long time as a surfactant. One of the most important features of NPE is their excellent emulsifying and dispersing properties which enable the user to formulate very effectively stable emulsions or dispersion concentrates. NPE is very effective, can be used in a wide range of applications and is also cost-effective. Therefore it can be assumed that NPE probably still is used in those countries where no restrictions are in place.

Today it does not seem to be one single alternative that can replace NPE for all it´s uses, the alcohole ethoxylates can though be used for all purposes, but in different formulations. The different alternatives need to be evaluated on a case-by case basis in each specific process used. A number of technically viable alternative surfactants are available on the market and have been in use for quite some time.

It is not in the scope of this dossier to obtain a total picture of all the alternatives since there are so many potential replacements. Some of the alternatives are also patents and trade secrets that prevent their widespread availability to formulators. In this report we are summarizing the main group of replacers to NPE.

Physical properties to consider
The function of NPE alters depending on the number of its ethoxylate units and can therefore be used for various applications in the textile manufacturing process. Their different behaviour can be explained chemically by observing their lipophilic/hydrophilic character which differs depending on number of ethoxylate units. The balance of the polar (hydrophilic) and the non-polar (lipophilic) groups of emulsifiers, such as NPE, can be expressed as the **HLB (Hydrophilic Lipophilic Balance**[59]. An emulsifier with a low HLB value (below 9.0) has a lipophilic character while one with a high HLB value (above 11.0) is hydrophilic. Those in between are intermediates. The HLB value corresponds to the behaviour of the emulsifier when added to water. It gives an indication of potential applications of NPE with different ethoxylate units within the textile production. This can be viewed in Table 50.

[59] The HLB system was introduced by Imperial Chemical Industries, ICI, in the 1940's to assist in the selection of a suitable emulsifier. The system provides a helpful guide and is still frequently used by the industry. ICI was in 2008 acquired by Akzo Nobel.

Table 50. Solubility

Behaviour when added to water	HLB Range
No dispersibility in water	1-4
Poor dispersion	3-6
Milky dispersion after vigorous agitation	6-8
Stable milky dispersion upper end and translucent	8-10
From translucent to clear dispersion	10-13
Clear solution	13-

(Sivaramakrishnan 2009)

Therefore it is important, in the replacement of NPE, to compare the HLB value of the alternative with the specific NPE related to the requested function and application. For an optimal function in the textile manufacturing process these values should be within the same HLB-range. The general correlations can be viewed in
Table 51. For a mixture of NPEs with different ethoxylate units the HLB value of the blend can be calculated. For example a combination of 80 % NPE_7 (HLB =12.0) and 20 % NPE_{10} (HLB =13.2) gives 0.8 X 12.0 + 0.2 X 13.2 = 12.2.

Table 51. Ranges and their applications

HLB Range	Application
3-6	W/O emulsifiers
7-9	Wetting agents
8-18	O/W emulsifiers
13-15	Detergents
10-18	Solubilisers

(Sivaramakrishnan 2009)

Another parameter to consider is the **cloud point** which also should be a close match. The cloud point is the temperature of a fluid at which dissolved particles are no longer entirely soluble. A second phase is discernible in the form a cloud, hence the name.

When selecting surfactants for certain applications the ability to **foam** is important. The most desirable foaming characteristics will depend on the application of the product, where low to moderate foaming products are used in laundry detergents. It is therefore important that the foaming properties are similar when searching for alternatives for NPE (ToxEcology 2002).

Many formulations that contain surfactants also contain **electrolytes**. Any substance containing free ions[60] that make the substance electrically conductive[61] are electrolytes. It is important that alternatives are stable in the presence of commonly used electrolytes (ToxEcology 2002).

[60] An ion is an atom or molecule in which the total number of electrons is not equal to the total number of protons, giving it a net positive or negative electrical charge.

Surfactants are placed in the textile process to have a function, as been described above. Therefore to change the techniques is not applicable. The alternatives are mentioned further down as alternative as detergents and alternatives as emulsifier (in pre-treatment and in the coloring process).

C.1.2 Alternative detergents - Nonionic surfactants

The alternatives must have the characteristics of a true surfactant (i.e., a hydrophobic, micelle forming head and a hydrophilic soil-removing tail), its ability to replace an NPE surfactant will depend on a formulation's performance demands. When replacing NPE to other alternatives it is crucial that the substance has the same properties, according to those presented earlier.

Nonionic surfactants are today found in a large variety of domestic and industrial products, in powdered or in liquid formulations. There is a large variability in the structure of nonionic surfactants. The hydrophilic part may contain of many elements, for example: alcohol, phenol, ether, ester or amide. In the past decade glycoside based surfactants have been introduced on the market because of their low toxicity. Some of these surfactants are made hydrophilic by the presence of a polyethylene glycol chain, obtained from ethylene oxide.

Below is a description of the most commercially common groups of nonionic surfactants; alcohole ethoxylates (AE) and glucose based. These groups have also been pointed out in the literature and by personal contacts, as the most probable groups of nonionic surfactants to replace NPE as detergents.

Alcohol ethoxylates
Alcohol ethoxylates (AE) are composed of a hydrophobic alkyl chain (fatty alcohol[62]) which is combined with a number of ethoxylate, or ethylene oxide, units via an ether linkage. An example of the chemical structure of an alcohol ethoxylate is shown below:

$$CH_3\ (CH_2)_{x\text{-}y}\ O\ (CH_2\text{-}CH_2O)_nH$$

(n=average numbers of ethylene oxide units, x-y= range of carbon units)[63]

AE are pointed out as the most likely alternative to NPE in textiles (ToxEcology 2002, HERA 2009, Posner 2012, TEGEWA 2012). Between 1960 and 1980 the usage of AE grew rapidly in

[61] In physics and electrical engineering, a conductor is a material which contains movable electric charges.
[62] Fatty alcohols are defined as alcohols containing C12 or more per molecule and having a carbon backbone with a high degree of linearity.
[63] HERA 2009

for example laundry products (ToxEcology 2002). Since the 1930s AE has been used in significant quantities in industrial products.

The raw materials are from many different natural sources or synthetized from a petroleum cut. Many AE are based on renewable sources that derive from for example coconut or palm kerner oils.

The performance properties of these nonionic surfactants can be adjusted by the alcohol selection, which are the hydrophobic part and the length of the polyethylene glycol chain which is the hydrophilic part. Different alcohol structures and different numbers of polyethylene units with averages ranging from 2-100 gives several hundred different types of AE. Physical and chemical characteristics can therefore be very different depending on the structural variety. In Table 52 examples of linear[64] AE with CAS No are described.

Table 52. Examples of linear Alcohol Ethoxylates

Alkyl chain length	Description	CAS Number (example)
C9, C10, C11	Poly (2.5) or (6) or (8) oxyethylene C9-11 alcohol	68439-46-3
C11	Poly (3) or (5) or (7) or (9) oxyethylene C11 alcohol	34398-01-1
C12/13	Poly (1) or (3) or (5) or (6.5) oxyethylene C12-13 alcohol	66455-14-9
C12/13 – C14/15	Poly (3) or (7) or (9) or (12) oxyethylene C12-15 alcohol	68131-39-5
C14/15	Poly (2.5) or (7) or (13) oxyethylene C14-15 alcohol	68951-67-7

(ToxEcology 2002)

When AE is used as an alternative to NPE as a detergent the alcohol chain is often C12-C15 and the ethoxylation is usually between 3-7 ethoxylation units (ToxEcology 2002). It seems that the linear alcohol is a more commercially common group (HERA 2009) but there is no clear preference between linear or branched alcohols. The choice of linear or branched depends mostly on the performance, solubility and homogeneity of a formulation (TEGEWA 2012).

AE has many desirable properties for being an effective surfactant due to the resistant to water hardness, good result in cleaning synthetic fibers and rapid biodegradation. AE has also low foaming characteristics, which is similar to NPE. Linear AEs are as stable as NPE in various electrolytes used in cleaning product formulations.

[64] Also known as oxo-alcohols.

NPE is known to be effective and to have good performance in many applications but in some cases AE have better properties. Some linear AE maintain a higher cloud point than NPE which indicate that the solution stability is even better for AE. Better stability in acid and caustic cleaners has also been shown for linear AE compared to NPE (ToxEcology 2002). Many of the mid chain AEs are also greater wetting agents or detergents than NPE (TEGEWA 2012).

Glucose based surfactants§

The development of surfactants based on carbohydrates and oils is the result of a concept exclusively based on renewable resources. In the industry, glucose, sucrose and sorbitol are used as starting raw materials (IUPAC 2000). These surfactants are also mentioned as substitute for NPE as detergent in textiles. They were produced in commercial scale during the 1990´s and the current production is less than AE (Sivaramakrishnan 2009). Probably only a few percent of the alternatives to NPE are glucose based today (TEGEWA 2012).

The glucose based surfactatants include several different subgroups, for example: alkyl poly glucosides (APG), fatty acid glucose amide (FAGA), glucamides (C_{12-18}), glucamine oxides, C4-glucamide acid and alkyl glucosamides (ToxEcology 2002). Alkyl polyglycosides (APG) are used in household products like cleaning agents, liquid dishwashing agents and laundry detergents and is the most common glucose based product. Figure 17 below shows the structure of APG.

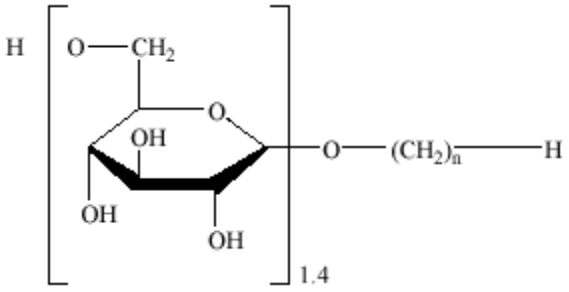


Figure 17 Structure of Alkyl poly glucosides (APG)[65](The alkyl chain is usually 8-10 or 12-14 C)

APG are composed of a linear fatty alcohol which is bound to the C-1 carbon of the glucose molecule by a glycosidic bond. When producing APG the main feed stock is oils and fats of coconut or palm kerner for the $C_{12}/_{14}$ range and tallow, rapeseed oils for the $C_{16}/_{18}$ fatty alcohols. The medium chained (C_{12}/C_{14}) APGs have their main application in detergents. The hydrophilic part of the alkyl poly glucoside molecule is derived from a carbohydrate, based on starches from corn, wheat or potatoes (Sivaramakrishnan 2009).

[65] Streber et al 1995

In general glucose based surfactants are not as good substitutes to NPE as AE. The properties of these surfactants, although they are nonionic surfactants, are better comparable to anionic surfactants. The glucose based surfactants are not so often used due to price/performance reasons (TEGEWA 2012).

Alkyl phenol ethoxylates
Within the Alkyl phenol ethoxylates group (APE) nonylphenol ethoxylates (NPE) and octylphenol ethoxylates (OPE) are the most commonly used substances as detergents and emulsifiers in the manufacturing process of textiles. NPE represents about 80-85% of the total volume in the APE group (DfE, 2011). The remaining 15-20 % constitutes of OPE and to a minor extent of APE with a longer alkyl chain as dodecylphenol etoxylates.

In the beginning of 2012 4-tert-octylfenol was considered to be a substance of very high concern according to Article 57 f in REACH due to its endocrine disrupting properties. The substance was also included in the Candidate list. In the light of the limited use of OPEs today in the manufacturing process of textiles and their ability to break down into octylphenol in the environment, a substitution of NPEs to OPEs is not considered to be likely. APEs with shorter or longer alkyl chains have a molecular size giving them properties which are not suitable for the similar areas of use as NPEs (U.S. EPA 2001). Other substances within the APE group as alternatives to NPEs will thus not be further investigated in the dossier.

C.1.5 Alternative as emulsifier – Nonionic surfactants

When the surfactant is acting as an emulsifier the two different structural groups of the molecule; the water soluble and the water insoluble parts are very important for the function as an emulsifier. The emulsifying effect of surfactants is important for both cleansing and washing of textiles. In the textile process the emulsifiers are used in the production of fibers from the pretreatment of fabrics to its dying and finishing operations. Only a small part of NPE is used as emulsifier.

NPE can be used in the pretreatment step together with a lubricant. NPE is here acting as an emulsifier for a real lubricating agent but does not provide lubricating properties by itself. In the preparation of fibres emulsifiers are needed in raw wool scouring, dispersant in viscose rayon, spin baths lubricant and antistatic in spinning of hydrophobic filaments. In the coloring process e.g. in dyeing and printing, NPEs are used for wetting penetration, solubilization, emulsification, dye leveling, detergency and dispersion of the dyes.

The ability to replace NPE as emulsifier with other alternatives will however depend on a formulation’s performance demands. Both safety profile and functional characteristics need to be evaluated on a case-by-case basis (see section C.1).

There are several different alternatives mentioned as possible replacers to NPE as emulsifiers. Since the choice of a surfactant depends on the oil to be emulsified, HLB of the oil is to be thoroughly checked before choosing a surfactant. Also in this application, fatty alcohol ethoxylates are possible to use. A combination of two alcohol ethoxylates of different moles generally solves all emulsification problems. Alkanol fatty acid amides can be used and sometimes in combination with an alcohol ethoxylate. Quaternary ammonium compounds are another group of substances that points out as alternative (BREF 2003, Posner 2012, Nimkartek 2012). Some glucose based surfactants show good emulsifying properties, for example alkyl poly glucosides (TEGEWA 2012, Nimkartek 2012) and also different sugar esters, for example sorbitan mono oleate can be used (Nimkartek 2012).

In the section concerning alternatives to detergents we have already described alcohol ethoxylates and the glucose based surfactants. In this section we have chosen to look further into the alkanol fatty acid amides. These alternatives have only been briefly described.

Alkanol fatty acid amides

This group of nonionic surfactants can be used as emulsifier but also in a wide range of personal care products. Alkanol fatty acid amides consist of a fatty acid which are usually derived from coconut oil and is linked to an amide group by a C-N bond. There are many different alkanol fatty acid amides; for example; mono and dialkylolamides, phosphoxylated alkanolamides and sulphated alkanolamides, which have different properties (NPCS 2007). Commonly occurring are N-(hydroxyethyl) cocamide (trivial name cocamide MEA) or N,N-di(hydroxyethyl) cocamide (trivial name cocamide DEA) . In Figure 18 and Figure 19 below representative structures for cocamide MEA and cocamide DEA are presented.

Figure 18. Structur formula for Cocamide MEA

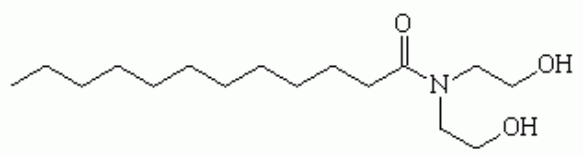


Figure 19. Struktur formula for Cocamide DEA

C.1.6 Alternatives in other applications

When NPE is used in the printing process for example as a dispersant of pigment or emulsifier, also in this application alcohol ethoxylates, in the correct HLB-range can be used as an alternative (Nimkartek 2012, Posner 2012).

C.2 Assessment of the alternatives

C.2.1 Availability of alternative

In the last 20-years there has been a rapid growth in using AE in laundry products and they are also the largest group by volume of the surfactants produced worldwide (ToxEcology 2002). In 2000, more than 435 000 tons of AE was produced in Western Europe and the North America (Modler et al 2002). For example about 1/3 of all surfactants produced in Japan is AE and in the US the production is even more (AIST 2009). The consumption in Western Europe in the year 2000 was approximately 645 000 tons (ToxEcology 2002). No further up-to-date figures of production and consumption have been found for Europe.

Several companies in the EU and multinational companies manufacture alternatives and many of them are specified for the textile process. The manufacturers for AE are more in numbers and also the number of products. The DOW Chemical Company for example manufacture ECOSURF™ which is a water-soluble modified alcohol ethoxylate based on seed oil alcohol and the TERGITOL™ TMN series which are branched nonionic surfactants. BASF manufacture a product group called Lutensol® which is predominately based on linear alcohol ethoxylate. Also Huntman manufacture a series of linear alcohol ethoxylates called SURFONIC®. AkzoNobel manufacture both linear and branched alcohol ethoxylates named Ethylan™. Several other companies such as Rudolf group, the Erca-group, SEPPIC, PulcraChemicals and the Shell group also manufacture a wide range of alternatives. There are also probably other alternatives available on the market for this purpose.
There is a greater challenge to find good stable emulsifier as replacers for NPE, but there are suitable alternatives on the market. To mention a few; Schill + Seilacher structol manufacture a series of products called LIMANOL. Huntman is producing a product called SAPAMINE® for the same purpose and Rudolf group manufacture PERRUSTOL. Also Kao chemicals, DOW Chemicals, AkzoNobel,Cognis and Rhodia manufacture one or a few different types of alternatives that can be used as emulsifiers in the textile manufacturing.

Considering the raw material situation, old figures from 1998 show that approximately 101 million tonnes of fats and oils produced were used in human foodstuffs. About 14 % of the

tonnage was available for oleochemistry[66]. In recent years the amounts produced has continuously increased by about 3% per year (IUPAC 2000).

It can be assumed that further demand for using renewable resources will continue in the future. There might be competitiveness from other interests such as food production or making environmental friendly alternatives for mineral oil-based products (IUPAC 2000).

Today there are suitable alternatives to NPEs on the market comparable in performance in the textile production. According to the contacts we have taken, the availability of alternatives as described above is not a problem. In general, there seems also to be enough alcohol capacity for supplying AE as a possible alternative (TEGEWA 2012).

There is consequently no reason to assume that alternatives would not be available in sufficient amounts to cover the increased demand caused by changes on the market, following a restriction of NPE in textiles.

C.2.2 Human health risks related to the alternative

When AE are used as a detergent contact scenarios for humans are possible. These scenarios are direct and indirect skin contact, eye contact, inhalation and oral ingestion derived from residues.

Alternatives to nonylphenol ethoxlates include; alcohol ethoxylates, glucose based surfactants and alkanol fatty acid amides these are presented below. A detailed risk assessment on the human risk from the alternatives is not in the scope of this dossier.

Alcohol ethoxylates

The eye and skin irritation properties of AE appear to be dependent on the concentration and length of the EO-units. AE with a lower degree of ethoxylation (EO-units 1-3) seem to be more irritating than AE's exceeding 4 EO- units. AE and most other surfactants give rise to eye and skin sensitization at higher concentrations (Talmage 1994). For testing eye irritation the results range from mildly to severely irritating to rabbit eyes. No relationship could be established between the chemical structures of the AEs and the eye irritation responses. AE are not considered to be skin sensitizers. A range of AE were tested with simple patch tests on human skin and that resulted in only mildly irritating to human skin (HERA 2009).

Acute toxicity tests were performed on rats/rabbit in laboratory, AE showed low order of toxicity by the oral, dermal and inhalation routes of exposure. The lowest LD_{50} value was shown in the rat with LD_{50} values ranging between 0.6 to more than 10 g/kg (HERA 2009).

[66] Oleochemistry deals with the physico-chemical transformation of fats and oils from animals and vegetables. First used in the fabrication of soaps, oleochemistry is now found in a wide variety of sectors: food, cosmetics, pharmaceutical and industrial.

None of the investigated AEs in subchronic toxicity studies caused any adverse effects on the reproductive system. Considering the developmental effects of AE, a number of studies have been conducted and the conclusion is that these chemicals are not developmental toxicants (ToxEcology 2002). According to a significant amount of toxicological data and information in *vivo* and in *vitro*, there is no evidence that AEs is genotoxic, mutagenic or carcinogenic. The majority of the available toxicity studies presented NOAELs exceeding 100 mg/kg bw/d (HERA 2009). The human health risk assessment in the HERA report demonstrated that AE is safe to use as household laundry and cleaning detergent, therefore no risk to consumers is expected.

AE are according to CESIO (2000) classified as Irritant or Harmful depending on the length of the EO-units. EO >20 is not classified.

- EO <5, Irritant (Xi) with irritation to skin (R38) and risk of serious damage to eyes (R41)
- EO >5-15, Harmful (Xn) with harmful if swallowed (R22) and irritation to skin/risk of serious damage to eyes (R38/41)
- EO >15-20, Harmful (Xn) with harmful if swallowed/ risk of serious damage to eyes (R22/R41)

Conclusion:
Available toxicological information has shown that the concentrated AE is an irritant to eyes and skin but should not be of concern at concentrations for human health. There is at present no evidence that AEs are either mutagenic, genotoxic or carcinogenic. No reproductive or developmental effects have been observed. Therefore AE should not be regarded as any serious cause for concern to human health.

Glucose based surfactants
Alkyl glucosides are not considered to cause skin irritation, but cause irritation to eyes at very high concentrations. Patch test was performed on humans at concentrations of 10% active matter of alkyl poly glucosides (APG) and no skin irritation was observed (Miljøstyrelsen 2001).

The toxicity of APG by oral administration in rats is low, LD_{50} ranges from >2 000 mg/kg bw for C_{10} APG and >35 000 mg/kg bw for n-Octadecyl-9.0-glucoside. Also the dermal toxicity is low,>2 000 mg/kg bw when C_8 alkyl glucoside was administered dermally on rabbits (Miljøstyrelsen 2001). The results from chronic toxicity studies indicated that NOEC for intact glucose based surfactants range from 0.116 mg/l to 4.3 mg/l. Their intermediates exhibit an even lower order of toxicity (NOEC >10mg/l) (ToxEcology 2002).

Alkyl glycosides are not included in Annex 1 of the list of dangerous substances of Council Directive 67/548/EEC. A general classification of 65% alkyl glucoside solution according to Dir. 67/548/EEC is Irritation (Xi) with the risk phrase; risk of serious damage to the eyes (R41) or irritating eyes (R36) according to Akzonobel 1998.

Conclusion:
The available data on glucose based surfactants does not indicate that these substances have any: carcinogenic, mutagenic or repro. toxic (CMR) properties. Glucose based surfactants show low order of acute toxicity and they are not skin irritants. Glucose based surfactants have shown to cause eye irritation at high concentrations but not be regarded as any serious cause for concern to human health.

Alternative as emulsifiers – Alkanol fatty acid amides
Acute oral and dermal toxicities from cocamide MEA in rat and rabbit are low, >5000 respectively >2000 mg/kg bw. MEA show negative result for gene mutations in bacteria *in vitro* (U.S.EPA 2012b). No genetic toxicity was shown after Ames test. Repeated dose toxicity test for 28 days on rat resulted in a NOAEL of 750-1500 mg/kg bw. MEA shows not to be irritating on rabbit skin when being exposed by a 25% solution in 24h. No signs of sensitizing were seen on guinea pig (IUCLID 2000).

Cocamide DEA: The acute oral toxicity in rats is low, LD_{50} >5000 mg/kg bw. Rats were gavage exposed for 14 days, resulted in a LD_{50} of approx. 6 300 mg/kg (U.S.EPA 2012a). The substance is harmful if swallowed and may cause slight irritation to the skin after repeated or prolonged contact to the skin.

Cocoamide DEA has not shown to be mutagenic in strains of *Salmonella typhimurium*. According to the Cosmetic directive (2000) cocamide DEA must not be used in products with nitrosating agents because of the risk of formation of N-nitrosamines. Nitrosamine contamination is possible either from pre-existing contamination of the diethanolamine used to manufacture cocoamide DEA, or from nitrosamine formation by nitrosating agents in formulations containing cocoamide DEA (Miljøstyrelsen 2001).

No alkanol fatty acid amides are included in Annex 1 of the list of dangerous substances of Council Directive 67/548/EEC.

Conclusion:
There is very limited data on alkanol fatty acid amides. It is therefore difficult to draw conclusions on the impact on human health.

C.2.3 Environmental risks related to the alternative

In the aquatic environment the hydrophobic part of the surfactant becomes oriented towards biota resulting for instance in reduced ability to balance salinity in gill breathing organisms, such as fish and aquatic invertebrates, and in reduced capillary absorption of liquid into leaves and branches of aquatic plants (Nyström, 1996).

The main route for the surfactants to reach the environment from both consumers and industrial use is via the wastewater treatment plants. Since all surfactants show more or less aquatic toxicity, the degradation resulting from wastewater treatment is important in order to reduce the negative impact on the aquatic environment.

Alternatives to nonylphenol ethoxlates include; alcohol ethoxylates, glucose based surfactants, and alkanol fatty acid amides these are presented below. A detailed environmental risk assessment from the alternatives is not in the scope of this dossier.

Alcohol ethoxylates

Monitoring

Monitoring studies from Europe; Italy, Spain, Germany, the Netherlands and UK showed an overall mean level of 4.9µg/l (range 16.8-1.1µ/l) AE from effluent waters. The highest value was observed in Spain and the lowest in Germany. The AE that was analysed were C_{12}-C_{16} and C_{18} (Eadsforth et al 2006). Environmental monitoring study from the Netherlands showed that the effluent concentrations of AE from municipal sewage treatment plants varied between 2.2 µg/l and 1.3 µg /l with an average value of 6.2 µg /l (Matthijs et al 1999).

Persistence

The alcohol ethoxylates as a class, undergo rapid primary and ultimate biodegradation under both laboratory and field conditions (Miljøstyrelsen 2001). Linear AE are normally easily degraded under aerobic conditions, with only small differences in the time needed for ultimate degradation of linear AE with different alkyl chain lengths (HERA 2009). AE with a typical alkyl chain (C_{12} to C_{15}) will normally reach more than 60% ultimate degradation in standardized tests for ready biodegradability (Miljøstyrelsen 2001). For AE containing more than 20 EO units, a reduced rate of biodegradation has been observed (Birch 1984). In the HERA report it is concluded that AE with linear hydrocarbon chain lengths from C_8 to C_{15} and mean values ranging from 3-20 EO units are readily biodegradable. AE with C_{16} or C_{18} hydrocarbon chain lengths and mean values between 2 and more than 20 ethylene oxide units are also readily biodegradable (HERA 2009).

Half-lives of 1 minute or less for removal of AE under sewage treatment conditions is expected, when a first order kinetics is assumed for the removal process. AE have also the potential to biodegrade anaerobically in sediments and during sewage treatment. At least 80% removal of AE should be expected during anaerobic digestion used as part of the sewage treatment process (HERA 2009).

Bioaccumulation

Alcohol ethoxylates are rapidly taken up and metabolized in fish (Miljøstyrelsen 2001). When fish was exposed to radiolabelled compounds of AE ($C_{12}AE_{4,}$ $C_{12}AE_{8,}$ or $C_{12}AE_{16}$) AE (200-

600µg/l) was rapidly taken up and within two hours, the parent compounds were distributed throughout the body. 24 hours later, more than 80% of the parent AE had been metabolized (ToxEcology 2002). Bioconcentration was found to be dependent on the degree of ethoxylation with bioconcentration factors being higher for the AE with shorter EO chains. Half-lives for the respective AE were 27, 70 and 75 hours (Talmage 1994). Other studies have also confirmed the rapid biotransformation and elimination of AE in fish, for example Environment Canada (2006) concluded that it is evident that the AE metabolism rates prevent any significant accumulation and that AE are not bioaccumulative (HERA 2009).

Toxicity

Nor has the parent AE compound or their breakdown products have shown endocrine disrupting properties (ToxEcology 2002).The major biodegrading intermediates are polyethylene glycols (PEG), which have shown to exhibit low aquatic toxicity (Ghirardini 2000).

The toxicity of AE to aquatic organism is linked to the chemical structure of the specific substance. Several studies have been performed to determine the acute toxic effects of AE towards aquatic organisms. In this report only the lowest values has been summarized (see Table 53).

Algae are a group of aquatic organisms which appears to be sensitive to AE. The acute toxicity of linear and branched AE to algae is similar with EC_{50} values ranging from 0.05 to 50 mg/l. Besides the differences in chemical structure, the reason for the variation may be due to different test conditions and different test species (Miljøstyrelsen 2002).

The acute toxicity of AE to invertebrates varies with EC_{50} values from 0.1 mg/l to more than 100 mg/l for the linear types and from 0.43 mg/l to 50 mg/l for the branched types. One chronic test has been found performed on daphnia, the endpoint was reproduction and the NOEC 0.790 mg/l (HERA 2009).

The acute toxicity of AE to fish varies with EC_{50} from 0.4 mg/l to more than 100 mg/l for the linear types and from 0.25 mg/l to 40 mg/l for the branched AE. Chronic toxicity test (28 days) was performed on adult fathead minnow and the NOEC value was 0.160 mg/l.

Table 53. Lowest observed toxicity data for aquatic organisms exposed to alcohol ethoxylates

Species	Compound	EC_{50} /NOEC (mg/l)	Test Duration	Reference
Algae				
Scenedesmus subspicatus	C_{15} EO7-8 (Linear)	0.05	72h	Kaluza and Taeger 1996
Selenastrum capricornutum	C_{12-15} EO7 (Linear)	NOEC:0.50	72 h	Madsen et al 1996
Scenedesmus subspicatus	C_{15} EO7-8 (1 internal CH_3-group, 25% branching)	0.05	72 h	Kaluza and Taeger 1996
Selenastrum capricornutum	C_{11-15} EO7 (4 internal CH_3-groups, quaternary C-atom) (branched)	NOEC: 4.0	96 h	Miljøstyrelsen 2001
Invertebrates				
Daphnia pulex	C_{14} EO1 (linear)	0.1	48 h	Maki and Bishop 1979
Daphnia magna	C_{12-15} EO9 (linear)	NOEC: 1.0	48 h	Kravetz et al 1999
Daphnia magna	Oxo-C_{9-15} EO2-10 (branched)	NOEC: 0.43		Schöberl et al 1988
Daphnia magna	C14-15EO7	NOEC 0.790 (reproduction)	30 days	HERA 2009
Fish				
Blue trout	Tallow E014 (linear)	0.4	96 h	Reiff et al 1979
Fathead minnnow	C_{12-15} EO9 (linear)	NOEC: 0.4	96 h	Kravetz et al 1991
Fathead minnow	C14-15EO7	NOEC: 0.160 (survival)	28 days	Miljøstyrelsen 2001
Not indicated	Oxo-C_{9-15} EO2-10 (branched)	0.25-4	-	Schöberl et al 1988
Fathead minnow	C_{11-15} EO7 (4 internal CH_3-groups, quaternary C-atom) (branched)	NOEC: 1.0	96 h	Miljøstyrelsen 2001

Conclusion:

From available information it can be concluded that AE are readily biodegradable and not bioaccumulative. No concern is expected due to exposure of AE to the aquatic environment (pelagic and benthic compartment). AE show less aquatic toxicity compared to NP (NOEC 6µg/l). No endocrine disrupting properties have been shown.

Glucose based surfactants

Monitoring

On study has been published on measured levels of glucose-based surfactants from effluent water from sewage treatment plants in Germany. The measured concentrations for alkyl glucosides and alkyl glucamides were both <0.1 µg/l (Knepper et al 1999).

Persistence

Glucoseamide surfactants have shown to be readily biodegradable in standard laboratory tests nearly and 50% degrades during transit in the effluent (Matthijs et al 1995) and is significantly further degraded during sewage treatment. Earlier studies have shown that glucosamide surfactants show >98% removal in WWTPs (Stalmans et al 1993). According to the results obtained in OECD tests for ready biodegradability, APG with alkyl chain lengths from C_8 to C_{16} are readily biodegradable. The linear APG show extensive degradation under anoxic conditions while a branched C_8 APG was only partially degraded (Madsen et al 1996).

Bioaccumulation

No experimental data describing the bioaccumulation potential of APG were found in the literature. But ToxEcology (2002) concluded that there was no concern for bioaccumulation of the parent glucose surfantants or the degradations products.

Toxicity

Results from lowest observed toxicity tests on alkyl poly glucosides (APG) and the glucose amides, ethyl glycoside fatty acid 6-O monoester, C_{12} (EGE) and fatty acid glucose amides (FAGA), are presented in Table 54. APG is the most common substance of these three and for which most data is also available. The lowest observed toxicity value for algae was shown exposed to branched APG (EC_{50} 1.5 mg/l) and Daphnia (NOEC 1.0 mg/l) exposed to linear APG fish exposed to linear APG (NOEC 1.8 mg/l).

Table 54. Lowest observed toxicity data for aquatic organisms exposed to alkyl glycosides (APG) and the glucose amides (EGE and FAGA)

Species	Compound	EC_{50} /NOEC (mg/l)	Duration	Reference
Algae				
Selenastrum capricornutum	C_8 branched APG	1.5	72 h	Madsen et al 1996
Selenastrum capricornutum	C_{12} EGE	38	72 h	Madsen et al 1996
Selenastrum capricornutum	C_{14} FAGA	NOEC: 2.9	96 h	Stalmans et al 1993
Invertebrates				
Daphnia magna	C_{14} FAGA	5.0	48 h	Stalmans et al 1993
Daphnia magna	C_{12} EGE	23	48 h	Madsen et al 1996
Daphnia magna	$C_{12\text{-}14}$ FAGA	NOEC: 4.3 (survival)	21 d	Stalmans et al 1993
Daphnia magna	$C_{12\text{-}18}$ APG	NOEC: 1.0	21 d (reprod.)	Steber et al 1995
Fish				
Zebra fish	$C_{12\text{-}14}$ APG	NOEC: 1.8	28 d	Steber et al 1995
Zebra fish	$C_{12\text{-}14}$ APG	2.5-5.0	96 h	Madsen et al 1996
Zebra fish	C_{12} EGE	11-17	96 h	Madsen et al 1996
Fathead minnow	C_{14} FAGA	2.9 (2.4-3.7)	96 h	Stalmans et al 1993

Conclusion:

From available information the glucose based surfactants presented are not persistent and there is no concern for bioaccumulation. The surfactants show less toxicity to aquatic organisms than NP (NOEC 6µg/l).

Alternative as emulsifiers - Alkanol fatty acid amides

Monitoring
No data found for cocamide MEA.

Persistence
Cocamide MEA was found inherently biodegradable, achieving 92 % degradation in 35 days (U.S.EPA 2010).

Bioaccumulation
Bioaccumulation is regarded as low on cocamide MEA (U.S.EPA 2010).

Toxicity
A high toxicity of cocoamide MEA was reported for two tests with the green alga *Scenedesmus subspicatus* as the 96 h-EC_{50} were 1.0 and 1.1 mg/l (IUCLID 2000). A more resent study with a pure cocoamide MEA resulted in EC_{50} of 16.6 mg/l for algae. The latter data indicate that the toxicity of cocoamide MEA to algae are not markedly higher than the toxicity to daphnids and fish, and EC_{50} value above 10 mg/l are probably more representative for the toxicity towards algae (Miljøstyrelsen 2002). Acute toxicity tests on *Daphnia magna* resulted in EC_{50} values ranging from 10 mg/l and lowest observed EC_{50} for fish was in the range from 4-20 mg/l. A summary of lowest observed toxicity data can be observed in Table 55.

Table 55. Lowest observed toxicity data for aquatic organisms exposed to cocoamide MEA

Species	Compound	EC_{50}/NOEC (mg/l)	Duration	Reference
Algae				
Scenedesmus subspicatus	Cocoamide MEA	Biomass 16.6 Growth rate 36.4 NOEC: 1.0	72 h	Plum Hudsikkerhed 2000
Scenedesmus subspicatus	Cocoamide MEA	1.0; 1.1	96 h	IUCLID 2000
Invertebrates				
Daphnia magna	Cocoamide MEA	24.8; 37.5 NOEC: 10.1; 11	24 h	IUCLID 2000
Daphnia sp.	C_{12-14} amide MEA EO4	10-100	-	Schöberl et al 1988
Fish				
Unknown specie	Cocamide MEA	28.5 mg/l – 31 mg/l	96h	IUCLID 2000
Unknown specie	C_{12-14} amide MEA EO4	4-20	-	Schöberl et al 1988

Conclusion:
From available information the alkanol fatty acid amide cocamide MEA show less toxicity to aquatic organisms than NP (NOEC 6µg/l). More data is needed to draw any further conclusions.

C.2.4 Technical and economic feasibility of the alternatives

The replacement of NPE to suitable alternatives can be applied without any extensive changes in the textile production process equipment. The manufacturing process needs probably be adjusted, in the case of for example; the temperature and the chemical feed rate (Nimkartek 2012). Neither does it seem to be any need for changes in the design of the equipment from the manufacture of NPE at a transition to either alcohol ethoxylates (AE) or glucose based substances (Akzo Nobel 2011).

In this report it has not been possible to provide extensive comparative technical information on all possible alternatives to NPE for all applications in the textile process. Since AE are pointed out as the most likely alternative to NPE in textiles, available technical information thus mainly is

focused on AE. According to TEGEWA more than 90% of the alternatives to NPE belong to the AE group.

Opinions differ about whether alternatives are less effective compared with NPE. Some of the information gathered indicates that AEs seem to be slightly less effective detergents than alkyl phenol ethoxylates (APE), which means that higher concentrations and feed rates may be required for equivalent effects. Investigations carried out in the wool scouring sector showed that mills using APE used an average of 7.6 g detergent per kg greasy wool (range 4.5 - 15.8 g/kg), while the users of alcohol ethoxylates consumed an average of 10.9 g detergent per kg greasy wool (range 3.5 – 20 g/kg) (BREF 2003). Other sources maintain that generally speaking AE and glucose based detergents are comparable with NPE in terms of characteristics essential to a detergent while akanol fatty acid amides are comparable with the properties of NPE as a emulsifier (Posner 2012). The ability to replace an NPE will however depend on a formulation's performance demands (for further information see section C.1).

Significant research has been done during many years in finding cost-effective replacements for NPE within the textile section. Although there is a disagreement in the price difference between NPE and alternatives most sources though seem to agree to that the price of alternatives is higher. For example the international wool secretariat (IWS) reveled that the cost when using AE compared to the use of NPE is 20 % higher (ToxEcology 2002). In a consultation with the textile industry the consulting company AMEC Environment & Infrastructure UK Limited, found that the average price for linear AE (C_{12}-C_{14} with 2 EO units) was about 5% higher than NPE (AMEC 2012). Also TEGEWA revels that the price and in most cases also the raw material of alternative such as AE is more expensive, approximately 5-40%. According to the Indian company, Nimkartek, increases the cost of the formulation with AE by about 15-20% but prices tend to decline with time. Initially, prices are higher when new formulations are developed.

It should however be pointed out that the price might vary considerable depending on the chemical supplier (PulcraChemicals 2012) and the business relation between the supplier and the customer. For example the purchased volumes (e.g. prices for deliveries in drums are different to those in bulk) as well as on the contract made (e.g. spot business, long or mid term business, etc.) (TEGEWA 2012) .The international wool secretariat (IWS) on the other hand reveled the cost of scouring 15 000 tones of raw wool could be reduced by 24% when using AE. The saving in cost was due to the increase of efficiency in the process which reduces the use of detergent (ToxEcology 2002). Prices are also known to be heavily dependent on overall demand. If the production of AE increases this will probably lead to a lowered market price and will then result in lower prices for AE products (APERC 2002).

In Table 56 below is an attempt to show the measures of value for the difference in price between the NPE and some alternatives, having set the price for NPE to 100 for clarify the differences.

Table 56 Comparable prices between NPE and alternatives

Product, calculated to 100% active material	**Price index**
NPE	100
Alcohol ethoxylates, (natural based source)	90-120
Alcohol ethoxylates, (petrochemical based source)	80-120
Glucose based surfactants	180-260
Alkanolamides	80-130

(TEGEWA 2012)

C.4 Summary of available information on alternatives

The manufacturing of textiles is a complex process involving several different steps where many chemicals are used for different purposes. Surfactants are very important in the process and are widely used. The ability to replace NPE as detergent and emulsifier with other alternatives will depend on a formulation's performance demands and needs to be evaluated on a case-by-case basis. It is therefore difficult to replace NPE with one alternative formulation for all uses.
The alternatives must have the characteristics of a true surfactant and many physical properties need to match. We have found that this is best done with the nonionic surfactants; such as alcohol ethoxylates, glucose based, sugar esters, alkanol fatty acid amides, or quaternary ammonium compounds. In these groups there are many different kinds of surfactants depending on the chemical structure.

AE is the most investigated alternative and also the most suitable alternative in the textile process. No concern is expected due to exposure of AE to health, the aquatic environment neither has endocrine disrupting properties been shown.
Initially, alternatives seem to be a bit more expensive than NPE, it is though difficult to get a clear picture on how much. It should however be pointed out that the price might vary depending on demand and the business relation between the supplier and the customer. The replacement of NPE to suitable alternatives can be applied without any extensive changes in the textile production process equipment. Nor is there need for changes in the design of equipment from the manufacture of NPE at a transition to either AE or glucose based substances.

A number of technically alternative surfactants that perform equivalent to NPE are available on the market specified for the textile industry and they have been in use for quite some time. The availability of alternatives should not either be a problem when the demand increases.

D. Justification for action on a Union-wide basis

D.1 Considerations related to human health and environmental risks

There is concern for nonylphenol in the aquatic compartment based on the following conclusions (see section B.10):

- The risk characterisation for nonylphenol on its own results in concern (RCR 1.3) for the marine pelagic compartment based on the EU median PEC (of 90-percentile values of individual countries) from a database covering only a limited number of countries (n=4). Furthermore, there is concern for the freshwater pelagic compartment based on country specific 90-percentile values for Belgium and Germany, whereas the EU median PEC from a database covering a large number of countries (n=25 although many countries are represented by only a small number of samples, often less than 6) showed no concern (RCR 0.125).

- An assessment of the combined toxicity of nonylphenol ethoxylates, occurring in textiles, and their degradation products such as nonylphenol and nonylphenol ethoxycarboxylates has been included in this dossier since these substances emanate from textiles and will occur as mixtures in WWTP effluents and in the environment. Assessing the combined toxicity of these compounds, using Toxic Equivalency Factors and the pelagic freshwater monitoring database available, results in a RCR ratio ranging from 0.34-0.54 for the EU median PEC depending on which TEF are being used for NPnEO (n=3-8). However based on country specific 90 percentile values there is concern in 8 to 12 (RCR1.1-27) EU countries out of a total of 24 EU countries and Norway for which freshwater monitoring data is available, which corresponds to identified concern in 30 to 50 % of the countries. When in a similar way assessing the combined toxicity in the marine pelagic compartment concern is identified in three to four countries out of four countries with available monitoring data (median RCR 3.5-5.5). However, the marine RCRs are less robust as compared to the freshwater RCRs since the present database is limited and new additional data on further trophic levels would reduce the AF used when the deriving the PNEC.

- Nonylphenol is considered to be an endocrine disrupting substance and when taking the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular into account it is questionable whether the currently available knowledge and evidence can be considered sufficient to establish safe levels for the environmental compartments assessed. A few issues related to these difficulties are presented below.
    - The Reach Guidance Document on Information Requirements/Chemical Safety Assessment offers a possibility of dealing with the incomplete knowledge and

uncertainty of ED by introducing an assessment factor, AF. The present knowledge does not provide sufficient information to derive a more specific AF for endocrine disruption, but possibly set the AF to an arbitrary size of 10. If introducing this factor the RCRs derived in this assessment would increase with a factor of 10. Consequently, the EU generic RCRs for freshwater would range from 1.25 (for NP only) to 3.4-5.4 (for the combined TEF approach), respectively. When using the country specific monitoring data for freshwater the use of this extra AF=10 would result in concern in 12 Member States when assessing the toxicity of nonylphenol only and concern in all 24 Member States and Norway for which freshwater monitoring data is available when also taking the combined toxicity into account. Applying an extra AF of 10 on the marine RCRs would increase the RCR of nonylphenol on its own to 13 and the combined toxicity RCRs to 7-99.

- In the available database there are several studies of somewhat lower reliability, which therefore cannot be used when deriving the PNECs, but where the results indicate that the present freshwater and marine $PNEC_{water}$ may underestimate the toxicity of NP with one order of magnitude or more. Based on the endpoints studied the effects shown may to be due to the ED-properties of nonylphenol. This introduces further uncertainties regarding the possibilities of deriving safe levels for the endocrine properties of NP.

- It is noted that the pelagic freshwater and marine PECs based on monitoring data may be underestimated since there is a study of seasonal variation indicating that it could be expected that the entire distribution of monitoring data would shift towards higher concentration values if it would have been based on sampling performed during the summer.

Overall assessment: When assessing the toxicity of nonylphenol on its own using a standard risk assessment PEC/PNEC approach there is concern for the marine pelagic compartment at EU level. When the combined toxicity of nonylphenol and nonylphenol ethoxylates and their degradation products are assessed using Toxic Equivalency Factors there is concern in the marine compartment at EU level and in freshwater for 8 to 12 EU countries out of a total of 24 EU countries and Norway, but not for freshwater at the EU median level. If the uncertainties regarding the endocrine properties of NP would be accounted for by introducing an assessment factor arbitrarily set at 10 to the risk characterisation ratios of the combined toxicity assessment, there would be concern at the EU median level for the marine and freshwater compartments (and for marine waters in the four MS having marine monitoring data and in freshwater for all 24 Member States and Norway for which freshwater monitoring data are available).

From the above summary of the quantitative risk characterisation information in this assessment it is appropriate to conclude that there is concern for the aquatic compartment, with the combined

toxicity of NP and NPEOs and their degradation products and the uncertainty of the endocrine disruptive properties (as provisionally accounted for by the extra AF) being the most prominent contributing factors.

However, considering the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular it is questionable whether the available knowledge and evidence can be considered sufficient to establish appropriate assessment factors and safe levels for the environmental compartments assessed. Therefore, it is concluded that it is not possible in the quantitative assessment approach to determine which concentration should be regarded as safe for the environment. Thus, the assessment of the endocrine disrupting properties should be viewed in a qualitative manner rather than a quantitative manner..

Furthermore, the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

Finally, when considering the results of the quantitative risk assessment and the qualitative risk assessment of the endocrine disrupting properties, the conclusion is that there is concern for nonylphenol and nonylphenol ethoxylates in the pelagic aquatic compartment.

D.2 Considerations related to internal market

The proposed restriction covers clothing and household textile articles extensively traded and used in all Member States. The use of nonylphenol etoxylates within the textile sector in EU is restricted (if not used in closed systems) since 2005. The major part of textiles consumed within the EU is however imported from suppliers outside the Union. According to statistics from Eurostat the import of textiles was about 6 million tonnes and the imports share of the EU consumption, measured in tonnes, would likely as described in section B.9.3.4.1 be at least 75% and probably closer to 90%.

There are several voluntary actions among actors in the textile sector including limit values on NP and NPE in the finished textile article (see section 9.1.1). The effect of such current activities is hard to quantify on the EU level which makes it difficult to evaluate the effects of voluntary efforts. An optimistic scenario could be that an increasing share of imported textiles would be covered by the Oeko-Tex standard 100 and/or the EU Ecolabel. Though strictly viewed, this would only imply that NPE concentrations higher than 1000 mg/kg textile and NP concentration higher than 100 mg/kg would be avoided.

An EU-wide restriction would remove the potentially distorting effect that national restrictions or corresponding measures may have on the free circulation of goods. A union-wide restriction also

gives a clear message on the status of the requirements and is easy to communicate to the suppliers outside the EU. The proposed restriction is applied to the final article (clothing and household textile articles) and does not consider the manufacturing of textiles itself. The proposed limit value of 100 mg/kg textile would, according to comments received in stakeholder consultation, not conflict with the current REACH (Regulation No 1907/2006/EC) Annex XVII Entry 46 on NP/NPE that applies to manufacturing in the EU. Textile production in the EU should thus not be significantly affected and the restriction would imply a level playing field for textile manufacturers situated within the Union as well as abroad.

D.3 Other considerations

No other considerations.

D.4 Summary

The main reason for acting on a Union-wide-basis is the environmental impacts of nonylphenol (NP) based on the endocrine disrupting properties of nonylphenol in the aquatic environment and the combined toxicity of nonylphenol, nonylphenol ethoxylates and nonylphenol ethoxycarboxylates which typically exist together as mixtures in WWTP effluents and in the environment.The use of nonylphenol ethoxylates within the textile sector in EU is restricted (if not used in closed systems) since 2005. The major part of textiles consumed within the EU is however imported from suppliers outside the Union.

A union-wide restriction would thus be the best way of ensuring a “level playing field” among both EU producers and importers of textile articles and would also be easy to communicate to the suppliers outside the EU.

E. Justification why the proposed restriction is the most appropriate Union-wide measure

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

E.1.1.1 Risk assessment

In section B.11 it is concluded that there is concern for the aquatic compartment, with the combined toxicity of NP and NPEOs and their degradation products and the uncertainty of the endocrine disruptive properties (as provisionally accounted for by the extra AF) being the most prominent contributing factors. However, considering the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular it is questionable whether the available knowledge and evidence can be considered sufficient to establish appropriate assessment factors and safe levels for the environmental compartments assessed. Therefore, it is concluded that it is not possible in the quantitative assessment approach to determine which concentration should be regarded as safe for the environment. Thus, the assessment of the endocrine disrupting properties should be viewed in a qualitative manner rather than a quantitative manner. Furthermore, the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

When considering the results of the quantitative risk assessment and the qualitative risk assessment of the endocrine disrupting properties, the conclusion is that there is concern for nonylphenol and nonylphenol ethoxylates in the pelagic aquatic compartment.

As shown in section B.9 there are several types of uses of NP/NPE that cause releases to waste water and surface water. NP/NPE released from textiles that are imported to the EU is identified as the largest source of emissions to the environment. In order to assess the need for policy measures and the expected effect of such measures it is necessary to describe the likely trend in uses as well as the resulting emissions to the environment in the foreseeable future. In the section below a thorough discussion is given in support of formulating a plausible base-line scenario for emissions of NP/NPE.

In summary the risk assessment referred to above implies that the assessment of the future trend in risks due to emissions to the environment as well as possible risk reduction measures should focus on the relative size of emissions of NP and NPE to the environment. It would not be appropriate to solely discuss emissions that result in NP concentrations in the environment, since

other substances containing NP (in the form of NP1E, NP2E, NPnEC, NPnEO) could also cause risks. Therefore the assessment of future releases to the environment, as well as the estimated risk reduction capacity of any measures, is hereby made primarily in terms of proportional change in releases compared to emissions in the reference year 2010. This approach puts focus on the relative change in risk rather than the specific contribution to risk by different varieties of NP and NPE.

E.1.1.2 Uses and releases to the environment of NP and NPE

E.1.1.2.1 Current releases from textiles

In section 9.3.4.1 the current emission from the use phase of imported textiles is estimated based primarily on reviewed studies on NPE content in textiles combined with statistics on imports of textiles in the EU. The review of studies on NPE content in textiles shows variation in NPE concentrations from just above detection limit to 10 000 mg/kg, with a mean value of 107 mg/kg. There is no clear indication of what types of products that contain high or low concentrations of NPE. Many of the analyses of NPE content in textiles have showed concentrations below the detection limit, however a large number of tests show that NPE is intentionally used in textile manufacturing processes. It is reasonable to believe that all NPE contained in imported textile will eventually be released to waste water by washing. The EU import of finished textiles to the EU reached about 6 million tonnes in 2010. Using the mean value of 107 mg NPE per kg imported textile and the import of finished textiles at 6 million tonnes per year, and assuming that all NPE is released to waste water during the use phase, the total emission of NP-equivalents to EU waste water from imported textiles would be 257 tonnes per year. In addition there is an estimated direct release to surface water of 4 tonnes of NP_{equ} from the use phase of technical textiles manufactured in the EU.

The NP_{equ} released to waste water will eventually end up as NP in the environment It is estimated that the release to surface water is reduced to around 6,5 tonnes per year, either by treatment in WWTP or by natural processes occurring in the water environment.

In relative terms the emission from textiles is estimated to approximately half of the total estimated releases of NP and NPE to surface water in the year 2010.

E.1.1.2.2 Trend in releases from textiles under business as usual

Future trend in consumption of imported textiles in the EU

As is shown in section B.9.3.4.1 the import of finished textiles has grown considerably during the past 10-15 years. The EU import of textiles has increased dramatically and is roughly estimated to constitute somewhere between 75-90% of finished textiles consumed in the EU, assuming that most imported finished textiles are consumed within the EU. This estimate is very uncertain due to difficulties in matching statistics on EU production (EuroProm) with trade statistics (ComExt).

It is extremely difficult to make any forecast for future growth rates, both for consumption and imports, and consultation with stakeholders has not provided any reliable information in this respect. Judging from historical trends in consumption of clothing and household textiles in the EU (Eurostat 2012), the statistics indicate that clothing and household textiles have had:

- a declining share of average spending of EU households, from around 6% in 1995 to 4.7% in 2010 (of total household spending),
- a stagnant development in consumer prices, i.e. that prices have not changed considerably over the past 15 years.

There has been a relatively low growth in total EU consumption, measured in value in Euros, of clothing and textiles in the past 10 years, much due to the economic recession in recent years. However, the growth in volume is likely higher than growth in terms of value. Lower prices are expected following increasing market shares of discounters, value chains, and super-markets and increased price-competition (CBI 2009). The average import price has been declining during most of the period from 2000-2010. This trend may partly be explained by liberalization of trade restrictions on textiles imported to the EU and resulting increase in imports from countries with low cost production in primarily East Asia. Tojo et al. (2012) also describe textile consumption (in quantitative terms) as increasing in the Nordic countries included in their study, and Sweden is given as an example where the statistics show an increase of 40% from 2000 to 2009 in the quantity of products put on the market. It is unclear if the growth in textile consumption will continue to grow at such pace in the Nordic countries in the future and Tojo et al. also notes that the expenditure may not correspond to the rate of increase in the quantity of textile products consumed.

Together, the above information would indicate that during the coming 10 years:

- there will likely not be high growth rates, in value terms, in EU consumption of clothing and household textiles,
- the volume consumed may show larger growth rates as a result of lower unit prices in particular concerning imported articles,
- the imported volume of clothing and household textile will likely continue to grow at relatively high rates as EU producers loose market shares to countries with lower cost of production.

Future trend in NPE concentrations in imported textiles

Considering the concentrations of NPE found in imported textiles, the studies reviewed in section B.9.3.4.1 do not provide sufficient data for analysis of historical trends. Referring to the experience by Eurofins, there might have been some decline in the frequency of test results with relatively high concentrations (samples were 500 to 1 000 mg NPE per kg and more are found) but the evidence is not conclusive.

Taking into account that NP will likely be identified as an SVHC, and thus to be included in the Candidate list, is neither expected to have any influence on NPE concentrations in textiles, since only NP would be covered by the relevant requirements. Even if NPE is considered to be covered by the information requirement implied by NP being an SVHC, it would only affect textiles with relatively high[67] concentrations of NPE.

As shown in section B.9.1.1 there are several voluntary initiatives by textile importers that aim to reduce NPE concentrations in textiles. The effect of such current activities cannot be quantified on the EU level which makes it even more difficult to forecast future effects of voluntary efforts. An optimistic prognosis could be that an increasing share of imported textiles would be covered by the Oeko-Tex standard 100 and/or the EU Ecolabel. Though strictly viewed, this would only imply that NPE concentrations higher than 1000 mg/kg textile would be avoided if the Oeko-Tex standard is assumed to maintain current limit values. From a regulatory point of view however, it would be plausible that voluntary efforts are to a large extent driven by consumers demand and the threat of regulatory actions made by authorities. If the proposed restriction on NPE in textiles would not be carried through and no other similar initiatives by authorities would be taken to regulate NPE concentrations in imported textiles, the willingness to adopt voluntary measures would likely decrease since it would imply unnecessary costs to actors in the textile supply chain.

Considering the above, no certain statement can be made on the future trend in NPE concentrations in imported textiles. The best estimate would likely be that, in lack of an EU wide restriction, the NPE concentrations in imported textiles would generally remain at current levels until the year 2020.

Future trend in releases of NPE to EU waste water from imported textiles

When combining the conclusions drawn above, there are indications that:

- the quantity of imported textiles will continue to grow, but at low rates,
- the concentration of NPE in imported textiles will likely remain stable.

In the formulation of a baseline scenario for emissions of NPE from imported textiles a conservative assumption would be that emissions to EU wastewater will increase by 2% per year until the year 2020 This assumption constitutes a middle way with consideration to the large growth in the quantity consumed in the EU the past years, but also taking into account the possibility of lower growth rates due to the future economic situation in the EU.

The above assumptions would imply a total increase of about 22% from 2010 to 2020 in the quantity of textile products consumed, which in turn would translate into an increase in NP_{equ} emissions to waste water from imported textiles from 257 tonnes in 2010 to 313 tonnes in 2020.

[67] Taking into account the relative molecular weight of NP compared to NPE, a limit value of 0.1% NP by weight (1000mg NP per kg) would correspond to roughly 2500mg NPE per kg.

Future releases of NPE to EU waste water from EU produced technical textiles

Based on the discussion above, it is assumed that the use of NPE in production of technical textiles in the EU will continue without any further efforts by industry to substitute NPE. Considering the growth in consumed quantity of textiles in the EU, the same assumption of 2% yearly growth is applied. This would result in an increase in NP_{equ} emissions to waste water from 4 tonnes in 2010 to 4.9 tonnes in 2020.

E.1.1.2.3 Current releases from other sources than textiles

Releases of NP and NPEs to the water environment occur from a range of different sources and the main pathway is through waste water and WWTPs. In section B.9.3.4.2 current emissions to the environment are estimated in a release scenario for water recipients within the EU. The release scenario covers three main groups of dispersive uses:

1. Nonylphenols
2. Nonylphenol ethoxylates
3. Nonylphenol derivatives, other than group 2

Each of these substance groups can be subdivided into releases from chemical mixtures and release from articles. Some uses of the substances in groups 1 and 2 are restricted in concentrations ≥ 0.1% according to REACH Annex XVII.

An assessment has been made of the different dispersive uses to identify what releases of NP_{equ} that can be expected during the use phase of chemical mixtures and articles. The assessment described in B.9.3.4.2 indicates that, based on data from the Swedish product register from the year 2009, a total of 249 tonnes of NP_{equ} per year is emitted to waste water in the EU. There are several uncertainties in relation to the estimated release to waste water which could imply considerable over- or underestimation of releases.

In relative terms the emission from other sources than textiles is estimated to close to 49% of the total estimated releases of NP and NPE to surface water in the year 2010.

E.1.1.2.4 Trend in releases from other sources than textiles under business as usual

The current regulation on NP outlined by REACH (Regulation No 1907/2006/EC), where the limitation on NP and NPEO can be found in Annex XVII, Entry 46, limits marketing and use in the EU of products and product formulations that contain more than 0.1% NP or NPE. This regulation thus applies to many industries and uses of NP/NPE, but as shown above there are yet emissions occurring from various sources (other than textiles) of which many are not covered by the existing regulation. No exact estimate can be made of the effect of the regulation since it was adopted in 2005. It would be reasonable to assume that the major effects of the regulation has already occurred, before the regulation came into effect (anticipated by industry) and during the five following years until 2010 for which current releases of NP/NPE has been estimated. One viewpoint could be that the current regulation would not cause any considerable further

reductions in releases of NP/NPE. This would imply a fairly stable future development of NP/NPE emissions from such sources. Future growth in consumption of products and articles containing NP/NPE could perhaps cause increased emissions to some extent, but there is little evidence to support that conclusion.

According to section B.9.3.4.2, the combination of the emissions of nonylphenol and nonylphenol ethoxylates from these different uses sectors indicates that close to 40 % (37% more precisely) are already regulated by REACH. This is a rough estimation generated from a case by case assessment based on the information demonstrated in Annex 3. The estimated emissions from such sources that are already regulated by REACH could be affected to a larger extent by the uncertainties noted in section B.9.3.4.2, in particular in cases where a change in a product composition on the market is not followed up by an update of the composition reported to the Products register. It could be that the companies had not yet updated the information concerning e.g. concentrations of NP/NPE in their products after the implementation of the regulation on NP/NPE in REACH. This can be expected to cause an overestimation of the releases. Otherwise, if the information about these (regulated) uses in the product register is correct, it would indicate that some illegal uses (if the products used contatin NP in concentrations above 0.1%) may exist. Such illegal uses should therefore be phased down (or phased out) during the coming years as a consequence of continued enforcement and compliance within REACH. Voluntary efforts by the industries concerned may also contribute to further phase down of such sources of NP. It is therefor concluded that the 37% share of emissions from other sources than textiles that are believed to be already regulated by REACH would either be overestimated (and should thus be revised downward) or that they should be phased out in the coming years if they are in fact occurring as illegal activities. However the remaining share of emissions from other sources than textiles (63%) is not expected to change considerably. In summary the most plausible trend would thus be that emissions from other sources than textiles will be reduced by roughly 37% in the coming years.

In addition, it is expected that NP will be identified as a substance of very high concern (*SVHC*) according to article 57 of Reach, which would trigger an obligation to inform the recipient of articles if it contains more than 0.1 % of NP. It is expected that this will put further pressure on industry to move away from NP and consequently that releases from products and articles would be reduced to some extent. The extent of such effects could be discussed in light of the interim evaluation of the *Impact of the REACH Regulation on the innovativeness of the EU chemical industry* (Centre for Strategy & Evaluation Services, 2012). It is said in the report *as regards the effects of placing a substance on the candidate list on innovation, the study suggests that this is having an effect through substitution, reformulation and withdrawal. At this stage it appears that reformulation has been the most common response (60%), followed by withdrawal from portfolios (52%) and a request for substitution of such substances from suppliers (51%), and then launching of initiatives to develop new substances to substitute them with (27%). Industry is*

concerned by the uncertainty created by the candidate list. Firms are not sure if the substances they are working with to substitute substances in the candidate list with are not going to be on the candidate list themselves in due course. Premature deselect ion of substances ("blacklisting") is also a major issue. If this general finding is applied to the case of NP which will likely be idenfied as an SVHC, it seems justified to assume that emissions of NP from other uses than textiles will be reduced as a result of withdrawal, substitution, etc of products containing NP. The "blacklisting" effect could potentially also affect uses of NPE and derivatives of NP.

Following an inclusion of NP on the candidate list, it is also possible that the REACH authorisation process would be applied and thus NP could eventually be included in the Annex XIV. Through that process a sunset date would be set after which use of NP in the EU would require authorisation. The most plausible baseline scenario for NP/NPE uses (other than textiles) would thus be that, in addition to the phase out of uses that are already regulated by REACH (37% of emissions in 2010), a further reduction will occur due to NP being identified as an SVHC. The most direct effect would likely be that uses of NP would be diminished. Based on the Swedish product register the reduction would then be quite small (an estimated 4% of total releases) since the current emission mainly occur from products containing NPE or derivatives. In addition, the interim evaluation by the Centre for Strategy & Evaluation Services (2012) would suggest that there might be more profound impacts on the use of NP as well as other substances (NPE and derivatives) that may be linked to NP, but it is not possible to predict the percentagewise reduction in emissions overall. However the above discussion clearly indicates that the future emission from other sources than textiles is probably overestimated rather than the opposite.

It is very difficult to foresee the effects on NP/NPE releases if NP is eventually included in the Annex XIV. The possible authorisation requirement could also have an indirect effect on the use of NPE and other derivatives of NP, since it would not be allowed to EU producers to use NP in formulation of other products. The possibility of NP being subject to authorisation thus implies an additional factor of uncertainty with regards to future emissions from other sources than textile.

Based on the above assumptions the NP_{equ} emissions to waste water from other sources than textiles would be 150 tonnes per year in the years 2015 and 2020 (a reduction of 40% compared to 2010).

E.1.1.2.5 Future trend in waste water treatment and resulting releases of NP/NPE to the environment

In section B.10 it is shown that nonylphenol is expected to exert its toxicity in combination with nonylphenol ethoxylates and nonylphenol ethoxycarboxylates since they typically exist together as mixtures in WWTP effluents and in the environment. In section B.9.4 reference is made to the

EU risk assessment report at a worst case scenario 2.5% of the NPnE released to the environment will in time end up as nonylphenol. This estimation is therefore used in this dossier also when considering the waste water not connected to a MWWTP. The degradation of NPE when released direct to surface water will be prolonged but not considered here since this is a steady-state scenario.

Overall, the notion of combined toxicity makes it more relevant to discuss total emissions of NP and NPE (rather than only NP) when assessing the future development of risks in the water environment. In addition based on the above conclusion, the NP/NPE emission scenario for waste water being treated in WWTP would not differ from waste water being released directly to the environment without treatment (except in terms of the time required for degradation of NPE). However if WWTP:s become more efficient in reducing effluent of NP/NPEachieving lower effluent content than the abovementioned 2.5%, it would imply that the resulting NP/NPE in the environment would be affected by the share of EU households connected to WWTP:s as well as the reduction efficiency in WWTP:s. Thus in summary the discussion below concerning waste water treatment should be understood as an indication of the proportional change in risk (due to the mixture of NP/NPE released to the water environment). The numerical figures on NP emissions are thus not of primary concern in the analysis.

The most important factors determining NPE releases to the environment from waste water treatment plants in the EU in the future will probably be:

- the rate of sewage water collection,
- the rate of secondary treatment in WWTP, and
- the rate of more stringent treatment in WWTP (the latter would likely have less notable effects).

The Urban Waste Water Directive (91/271/EEC hereby UWWD) sets out requirements concerning the three factors above, and some EU countries are yet to show compliance. The UWWD requirements should already by the year 2005 have been fulfilled by most EU countries (EU-15[68]), but deadlines are extended (year 2006 to 2018) on an individual basis for new member states (EU-12[69]). The latest implementation report by the EU Commission (European Commission 2011) indicates that full compliance had only been achieved by three member states by the year 2007/2008, which would imply that some further improvement in both sewage water collection and secondary treatment should be made in coming years (or has already taken place). Considerable additional efforts are expected in the new member states (EU-12) to meet the requirements by the Directive, and the greatest improvements will thus be expected in those countries. The progress and achievements appear yet to come at a slow pace (or even showing

[68] The number of member countries in the European Union prior to the accession of ten candidate countries on 1 May 2004. The EU15 comprised the following 15 countries: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom.

[69] The member countries that have joined the EU after 1 May 2004 until 2012. These 12 countries are: Poland, Czech Republic, Cyprus, Latvia, Lithuania, Slovenia, Estonia, Slovakia, Hungary, Malta, Bulgaria and Romania.

negative trends in some aspects), though the situation has improved significantly since the implementation of the Directive over 20 years ago.

For the purpose of formulating a baseline scenario for the assessment of risk management options, the most realistic assumption would be that the UWWD would continue to spur improvements in collection of waste water and in the removal efficiency for NP/NPE by further installation of secondary treatment (along with other substances). However the trend is not clear and full and timely compliance with the Directive does not seem likely judging from the latest assessment by the EU Commission. In lack of clear projections of changes in WWTP connection rate and removal efficiency, in the baseline scenario it is assumed that the removal efficiency for NP and NPE will improve from 97.5% in the year 2010 to98% in 2015, and a less significant improvement to 98.1% in 2020. This would imply a total improvement of 25% (of the 2.5% of the intake that is released in outlet water) in emissions from WWTP in the year 2020 compared to 2010. The increased removal efficiency in WWTP would only apply to the waste water being treated and would thus not affect the NP/NPE that is being released directly to surface water from different uses.

The rate of sewage water collection is also assumed to improve by 1% per year from 2010 to 2015, and by an additional 0.5% per year from 2015 to 2020. The sewage water collection rate would thus increase from 78% in 2010, to 83% in 2015 and 85.5% in 2020.

E.1.1.2.6 Summary of future trend in emissions under business as usual

From the discussion above, the baseline scenarios for emissions of NP_{equ} to waste water in combination with an expected improvement in WWTP removal of NP/NPE, the future emissions would appear as shown in Table 57 and Figure 20 below.

Table 57. Future trend in emissions to waste water and to the environment in the baseline scenarios

	Year **2010 releases** of NP_{equ} **to waste water** (tonnes per year)	Year **2015 releases** of NP_{equ} **to waste water** (tonnes per year)	Year **2020 releases** of NP_{equ} **to waste water** (tonnes per year)	Year **2010 releases to the** water **environment** (relative to release in 2010)*	Year **2015 releases to the** water **environment** (relative to release in 2010)*	Year **2020 releases to the** water **environment** (relative to release in 2010)*
Imported textiles	257	284	313	50.4%	46.4%	48.3%
EU technical textiles	4.0	4.4	4.9	0.8%	0.9%	1.0%
Other uses	249	150	150	48.8%	24.5%	23.1%
Sum	510	438	468	**100%***	**71.8%**	**72.3%**

*The releases to the water environment are shown in percentage terms compared to the estimated total release to the water environment (taking into account reduction of NP/NPE in WWTP) in the year 2010. The proportional size of releases to the environment are deemed more relevant than numerical figures of tonnage NP/NPE released, since NP and NPE typically exist together as mixtures in WWTP effluents and in the environment and likely exert toxicity in combination.

It is notable that the total emission to waste water increases over time, from 438 tonnes in 2015 to 468 tonnes in 2020. However this is counteracted by the assumed increased removal efficiency and connection rate to WWTP, resulting in lower total emissions to the environment in 2020 compared to 2010.

The right hand part of the table above, displaying the relative change in emissions to the water environment, are also shown in the diagram below.

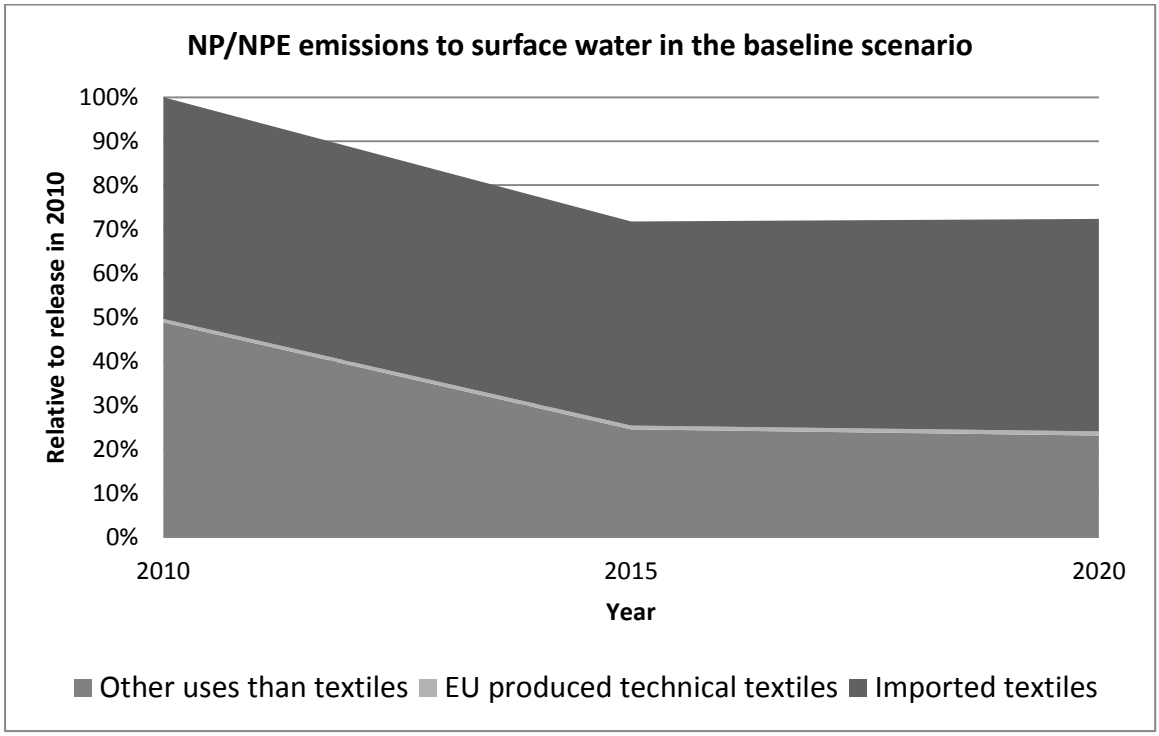


Figure 20. Future trend in emissions to surface water in baseline scenario

In summary it is expected that emissions to waste water from other sources than textiles will be reduced by 40% 2010 to 2020, and the resulting emissions to surface water would be more than halved during the same period (due to improvement in WWTP NP/NPE removal efficiency and connection rate). Though it should be noted that the expected trend in emissions from other sources than textiles are subject to considerable uncertainties that depend to a large extent on how market actors and authorities deal with the enforcement and compliance with existing regulation as well as the possible impact of NP being identified as an SVHC and thus to be included in the candidate list. The possibility of NP being subject to authorisation poses another uncertainty with regards to NP/NPE emissions from such other sources than textiles.

The emissions to surface water from textiles are expected to remain fairly stable and even show an increasing trend after 2015 as the improvements in WWTP removal efficiency and connection rate over time are assumed to be outweighed by the growth in consumption of textile products in the EU. The estimated releases from textiles are based on quite conservative assumptions of growth in the volume of imported textiles. A more positive economic development in the EU countries could very well imply higher growth in import volumes and hence emissions of NPE, assuming that the concentrations of NPE in textiles are not reduced by voluntary efforts. The emissions from textiles should be further regulated considering the concern; in particular the combined toxicity of NP and NPE and the uncertainties regarding the endocrine disrupting properties of NP that make it impossible to determine which concentration should be regarded as safe for the environment (aquatic compartment).

The estimated emissions of NP/NPE to the water environment from technical textiles are relatively small in comparison to the other identified sources.

E.1.2 Options for restrictions

Three options for restriction are assessed (see section E.2)

RMO 1 (*the proposed restriction*): Limit value of 100 mg NP/NPE per kg textile with a transitional period of 5 years

Clothing and household Textile articles that can be washed in water shall not be placed on the market 60 months after entry into force of the restriction if they contain nonylphenol or nonylphenol ethoxylat alone or in combinationin concentrations equal or higher than 100 mg/kg textile. The limit value includes prints on the textile articles comprised by the proposed restriction.

The standards adopted by the European Committee for Standardisation (CEN) shall be used as test methods for determining the content of nonylphenol or nonylphenol ethoxylate for demonstrating the conformity of the restriction. There is an ongoing work to develop a new CEN standard for textiles to detect and quantify APEOs adressed “Detection and determination of APEO in textiles by HPLC-MS” (Posner 2012).

A proposal for an addition in REACH entry 46 in Annex XVII is compiled in Table 1 in section A.1.

RMO 2: Limit value of 100 mg NP/NPE per kg textile with a transitional period shorter than 5 years

This RMO is formulated as RMO 1 except in terms of the transitional period allowed for the concerned actors to comply with the restriction. In section E.2 the option of setting the transitional period to 3 years or shorter is discussed and compared to the proposed restriction in RMO1.

RMO 3: Limit value lower than 100 mg NP/NPE per kg textile with a transitional period of 5 years

This RMO is formulated as RMO 1 except in terms of the limit value for NP/NPE in textile. In section E.2 two different limit values are discussed (20 mg/kg and 50 mg/kg) and compared to the proposed restriction in RMO1.

E.1.3 Other Union-wide risk management options than restriction

REACH Authorisation Process

Germany has prepared an Annex XV-dossier for nonylphenol identifying it as a substance of very high concern according to Article 57 f in REACH and for inclusion into the Candidate List based on its endocrine disrupting properties. Considering that its close chemical relative octylphenol already is accepted as an SVHC based on its endocrine disrupting properties using the same approach (57f), makes it most probable that also nonylphenol will be included on the candidate list as an endocrine disrupter. It is therefore assumed here that the prerequisite (NP being on the candidate list in the future) for a possible further authorisation process concerning NP would be fulfilled in the near future.

In section B.9 it is shown that a major source of NP/NPE releases to the environment are textiles. The use of NP/NPE in textile production within the EU is regulated by REACH (Regulation No 1907/2006/EC), where the limitation on NP/NPE can be found in Annex XVII, Entry 46. This regulation applies to many industries, including the textile and leather industries, except in the case of closed application systems where no release into waste waters occurs. The presence of NP/NPE in products, for example imported textiles from regions without such restrictions is not controlled by this prohibition (www.eur-lex.europa.eu).

The authorisation route only addresses use within the EU and would thus not target NP/NPE content in imported textiles. This risk management option is therefore discarded from further assessment.

Voluntary agreement

As is described in section 9.1.1 there exist a number of companies collaborations and voluntary commitments concerning e.g. NP/NPE in textiles as of today. In order for such voluntary agreements to effectively reduce NP/NPE emissions from imported textiles, there would have to be an agreement covering a vast number of importers in a sector that is partly unorganised. Imported textile products are very diverse in types and function and likewise the production chain differs greatly. The importers' possibilities to mandate standards about NP/NPE content in textiles differs, to a large extent due to unequal buyer's power and the purchasing organisation and competence available for each importer. Such factors make monitoring of compliance with voluntary agreements difficult and extensive sampling and chemical analysis, i.e. by the competent authority, would probably be necessary.

Under a voluntary agreement, the administrative costs of control of compliance within the sector would likely be similar or higher than for a Union-wide restriction. It would be more efficient for the importers to refer to a Union-wide restriction in their communication with manufacturers outside the EU. The risk management option of voluntary agreement is therefore discarded from further assessment.

Stricter requirements on end-of-pipe measures in industrial facilities and WWTP

As indicated in section B.9.1 the WFD sets out a strategy against pollution of water, including a list of prioritized dangerous substances in which NP is covered. The aim of the EU Commission is thus to reach cessation or phasing out of discharges, emissions and losses to the aquatic environment within 20 years, for NP and other prioritized dangerous substances. However it is the Member States that are responsible for taking the necessary measures to achieve this objective. It should also be noted that the EQS for NP was set as 0.3µg/l annual average and 2.0µg/l maximum allowable concentration in 2008. In light of the risk assessment made for this restriction proposal (se section B.10.1.2), the EQS might need to be revised in order for the WFD to become sufficiently stringent in relation to emissions of NP to the environment.

Assuming that the EQS for NP is revised, taking into account more recent risk assessments, there are several possible policy measures available to achieve emission reduction targets for NP (by imposing end-of-pipe measures). In particular the Industrial Emissions Directive, with its strengthened emphasis on Best Available Technology (compared to the IPPC directive), could be used as a tool for reducing emissions of NP/NPE in effluent water from industrial facilities and municipal waste water treatment plants. Additional measures in industrial plants could potentially reduce emissions from other sources than textiles. Concerning the releases of NPE from textiles, efforts in improved collection rate and removal efficiency in WWTP could reduce the release of NP/NPE to the environment. However setting stricter requirements on emissions of NP/NPE would imply large investment costs in e.g. additional waste water treatment techniques compared to the base-line scenario as outlined above.

AMEC (2012) have assessed several previous studies on measures aimed at priority substances (e.g. COHIBA 2011, ScorePP 2009, and Feenstra et al. 2009) in WWTP and discuss some possible advanced end-of-pipe measures that could be applied in order to reduce WWTP emissions of NP. Three main options are mentioned:

- Membrane filtration: Including nanofiltration (estimated removal effectiveness ranging from 70% to 100%) or reverse osmosis (estimated removal effectiveness of 98% or higher).
- Ozone oxidation: Chemical oxidation treatment efficiency for NP removal is estimated to 90%, and the cost of such treatment depends on the quality of the water and contact time for oxidation.
- Activated carbon: The effectiveness of activated carbon at WWTP depends on e.g. the concentration range of pollutants and technical parameters. At well maintained WWTP reduction rates for NP of 50% to 99% can be observed, but lower efficiencies have been observed. Activated carbon does also effectively reduce emissions of several other pollutants, e.g. TBT, PFOS, Cd and Hg.

According to AMEC (2012) the above advanced end-of-pipe measures, if they are applied across the EU to reduce NP emissions to a similar level as would a ban on NPE in textiles, would imply large investment costs and on-going operational costs. The total cost of such measures could according to AMEC be around €70 billion per year. In practice, costs will vary significantly amongst installations and according to technologies and suppliers used. In addition, wide rages of estimated costs are presented in the literature, leading to additional uncertainties. A summary of the estimated costs referred to by AMEC is given in the table below.

Table 58 Costs of techniques for abatement of NP/NPE emissions

Technology	***Reduction***	***Capital costs (€k)***	***Operational costs (€k/year)***	***Total annualised cost (€m)***	***COHIBA (2011) results (for comparison) (€/kg emitted NP/NPE)***
Activated carbon	*25-99%*	*80*	*225*	*12,026*	*12,000 – 19,000,000*
Ozone oxidation	*90%*	*1,520*	*225*	*68,853*	*93,000 – 4,200,000*
Membrane filtration	*70-100%*	*768*	*225*	*39,165*	*120,000 – 12,000,000*

Source: AMEC (2012)
Note: The cost in €/kg given in the table are not directly comparable to any estimates of emission reduction estimates made in this restriction proposal since they are based on different methodologies.

The co-benefits, i.e. removal of other pollutants, of the advanced end-of-pipe measures in WWTP are likely considerable, but would require site-specific assessment in order to be estimated. AMEC (2012) have gathered estimates of removal efficiencies for a number of priority substances and priority hazardous substances, based on information from various sources and

compiled it into a table reproduced below. AMEC notes the information as not exhaustive and present the information for illustrative purposes.

Table 59 Removal efficiencies of priority substances by three tertiary WWTP techniques

CAS Number	***Substance***	***Status***	***Reported removal efficiency (in per cent)[1]***		
			Activated carbon	***Ozone oxidation***	***Membrane filtration***
15972-60-8	*Alachlor*	*EQS Directive*			*Solar: ~40%*
120-12-7	*Anthracene*	*EQS Directive*		*>70%*	*90% (MBNDC)*
1912-24-9	*Atrazine*	*EQS Directive*		*9%*	*<10% (MBNDC) Solar: 70%*
71-43-2	*Benzene*	*EQS Directive*			*92-98% (MBNDC)*
	Brominated diphenylethers	*EQS Directive*	*90%*		
7440-43-9	*Cadmium and its compounds*	*EQS Directive*		*>90%*	
470-90-6	*Chlorfenvinphos*	*EQS Directive*			*Solar: 70%*
107-06-2	*1,2-dichloroethane*	*EQS Directive*		*71%*	
117-81-7	*Di(2-ethylhexyl)phthalate (DEHP)*	*EQS Directive*			*96% (MBNDC)*
330-54-1	*Diuron*	*EQS Directive*			*<10% (MBNDC) Solar: 70%*
206-44-0	*Fluoranthene*	*EQS Directive*			*83-98% (MBNDC)*
608-73-1	*Hexachlorocyclohexane*	*EQS Directive*			*60% (conventional)*
34123-59-6	*Isoproturon*	*EQS Directive*		*25% <10% (MBNDC)*	*Solar: 70%*
7439-92-1	*Lead and its compounds*	*EQS Directive*			*78% (MBNDC)*
7439-97-6	*Mercury and its compounds*	*EQS Directive*		*>90%*	
91-20-3	*Naphthalene*	*EQS Directive*			*95-96% (MBNDC)*
7440-02-0	*Nickel and its compounds*	*EQS Directive*			*29% (MBNDC)*
87-86-5	*Pentachlorophenol*	*EQS Directive*		*99%*	*10-50% (MBNDC)*
	Polyaromatic hydrocarbons (PAH)	*EQS Directive*			*10-90% (MBNDC)*
122-34-9	*Simazine*	*EQS Directive*		*95%*	*<10% (MBNDC)*
	Tributyltin compounds	*EQS Directive*			*10-90% (MBNDC)*
12002-48-1	*Trichlorobenzenes*	*EQS Directive*		*95%*	*<10% (MBNDC)*
1582-09-8	*Trifluralin*	*EQS Directive*		*99%*	
115-32-2	*Dicofol*	*Proposal*	*>85%[2]*		*80-58%*

1763-23-1	*Perfluorooctane sulfonic acid and its derivatives (PFOS)*	*Proposal*	*99% (historic pollution)*		
	Dioxins and dioxin-like compounds	*Proposal*	*>90% [3] (historic pollution)*		*~70% (historic pollution)*
52315-07-8	*Cypermethrin*	*Proposal*	*~98%*		*UV: ~11%*
62-73-7	*Dichlorvos*	*Proposal*	*na (insecticide: agricultural use)*	*na (insecticide: agricultural use)*	*na (insecticide: agricultural use)*
	Hexabromocyclododecanes HBCDD	*Proposal*	*99%*		*UV: 3%*
76-44-8 / 1024-57-3	*Heptachlor and heptachlor epoxide*	*Proposal*	*>90% [2]*		*70-90%*
886-50-0	*Terbutryn*	*Proposal*	*~99%*		*UV: ~24%*
57-63-6	*17alpha-ethinylestradiol*	*Proposal*	*~98% [4]*		*UV: ~25% [5]*
50-28-2	*17beta-estradiol*	*Proposal*	*96-99% [4]*		*~25% [5]*
15307-79-6	*Diclofenac [9]*	*Proposal*	*80-99%*	*22-92%*	*>95% (ozonation); UV ~59%*

Notes as referred to by AMEC (2012):

1. *ScorePP (2008) and ScorePP (2009)*
2. *Ormad (2008)*
3. *US EPA (2010)*
4. *Felebuegu et al (2006)*
5. *Defra/Water Industry EDC demonstration Programme data*
6. *Knappe (2008)*
7. *MBNDC = Mechanical, Biological, nitrifying/denitrifying, chemical treatment*

Source: AMEC (2012)

Overall the option of reducing the risk posed by NP/NPE in the environment by requiring WWTPs to implement more effective end-of-pipe treatment techniques appear far less cost effective than the proposed restriction option that would instead focus on cutting the emissions at the source. In addition to the large investment costs and operational costs implied by this RMO, there would likely be considerable costs for investigation (site-specific assessments) and administration since local authorities would have to negotiate e.g. appropriate requirements with permit holders. It would also be difficult to effectively monitor and enforce this RMO, somewhat indicated by the implementation lag experienced within the Urban Waste Water Directive (see section E.1.1). Due to these reasons this RMO is disregarded from further assessment.

E.2 Assessment of risk management options

E.2.1 Restriction option 1 (RMO 1) - Limit value of 100 mg NP/NPE per kg textile with a transitional period of 5 years

Clothing and household Textile articles that can be washed in water shall not be placed on the market 60 months after entry into force of the restriction if they contain nonylphenol or nonylphenol ethoxylat alone or in combinationin concentrations equal or higher than 100 mg/kg textile. The limit value includes prints on the textile articles comprised by the proposed restriction.

The standards adopted by the European Committee for Standardisation (CEN) shall be used as test methods for determining the content of nonylphenol or nonylphenol ethoxylate for demonstrating the conformity of the restriction. There is an ongoing work to develop a new CEN standard for textiles to detect and quantify APEOs adressed “Detection and determination of APEO in textiles by HPLC-MS” (Posner 2012).

E.2.1.1 Effectiveness

E.2.1.1.1 Risk reduction capacity

The restriction is aimed at reducing emissions of NP/NPE to the environment and subsequently reducing NP/NPE concentrations in surface waters within the EU. The reduction in emissions and concentrations of NP/NPE found in the environment will reduce the risk (as described in section B.10) due to combined toxicity of the substances as well as endocrine disrupting effects in the aquatic compartment. NP is an endocrine disrupting substance and it is therefore uncertain whether the current advancement of science and testing methodology in general and the available data base for NP in particular is sufficient to establish safe levels for the environmental compartments assessed. At the present state of knowledge, we therefore suggest to handle nonylphenol as a substance for which there exists no safe level.

As described in section B.9.3.4.1, The NPE contained in textiles is washed out during the usage phase, and NPE is released to waste water. the major part of NPE released to waste water will undergo reduction in WWTPs, but a certain percentage will be released in effluents to the environment. Some of the NPE released to waste water will be emitted straight to the environment since not all EU households are connected to WWTPs.
It is expected that NPE released to waste water will eventually end up as NP in the environment. However it is essential also to account of that nonylphenol is expected to exert its toxicity in combination with nonylphenol ethoxylates and nonylphenol ethoxycarboxylates since they typically exist together as mixtures in WWTP effluents and in the environment. Overall, the notion of combined toxicity makes it more relevant to discuss total emissions of NP and NPE (rather than only NP) when assessing the risk reduction capacity of any RMO.

The risk reduction capacity is therefore described in terms of relative change in NP/NPE emissions to the environment, thus serving as a proxy for estimating the reduction in environmental concentrations and hence reduction in risk compared to the situation in the reference year 2010 as described in the risk assessment in section B.10.

E.2.1.1.1.1 Changes in human health risks/impacts

Not relevant for NP/NPE since the risk has been assessed to be based on the environment, not on human health. However, any concerns for human health from exposure to textiles containing NP/NPEO would most probably be alleviated by the risk reduction measures proposed on the basis of the environmental risk assessment.

As indicated in section C concerning the alternatives to NPE; available toxicological information has shown that the concentrated AE is irritant to eyes and skin but should not be of concern in concentrations for consumer use. There is at present no evidence that AEs are either mutagenic, genotoxic or carcinogenic. No reproductive or developmental effects have either been observed. Therefore should AE not be regarded as any serious cause of concern to consumer use. There is limited data on glucose based surfactants. However, the data that is available does not indicate that these substances have any CMR properties. Glucose based surfactants show low order of acute toxicity and they are not irritant to the skin. Glucose based has shown to be irritant to eyes but should probably not be of concern in concentrations for consumer use.

E.2.1.1.1.2 Changes in the environmental risks/impacts

The proposed restriction will limit NP/NPE concentrations in textiles to 100 mg/kg or less. According to several of the stakeholders consulted (major brands who import textile articels to the EU) the concentration limit is expected to be implemented by the actors involved (importers and producers) by phasing out intentional use of NPE in the manufacturing of textiles. However since the restriction would only apply to textiles destined for the EU market (including textiles manufactured in the EU) there might to some extent be continued use of NPE by textile manufacturers outside the EU. Such continued use of NPE might cause unintentional contamination, e.g. by contaminated water in the manufacturing process or contamination by other fabrics during transport or storage. The stakeholder consultation has also indicated that NPE traces as impurities, by-products, or intentional components, are found in low concentrations in many chemical formulations. According to some stakeholders, in such cases NPE serves no function in the manufacturing process or in the final textile product, but are present only as traces from the chemical formulation synthesis. The use of some chemical formulations in the manufacturing of textiles may thus result (unintentionally) in NPE being found in the final textile article[70].

[70] One of the stakeholder consulted provided an example (supported by other stakeholder's comments) of a typical calculation, based on the use of a chemical formulation that contains 1000 mg/kg NPE which is in compliance with REACH (Regulation No 1907/2006/EC) Annex XVII Entry 46. The result of the calculation would indicate that in

A full reduction, to zero concentration, of the NPE in textiles is therefore not judged to be realistic within the foreseeable future, unless internationally all buyers of textiles demand NPE free articles. A full phase out of NPE concentrations in textile articles would likely also require changes in the use and/or reformulation of certain chemical formulations (that contain NPE in concentrations below 1000 ppm). This issue is further discussed in section E.2.1.1.2 below. There is no clear indication on what concentrations of NPE (in terms of average content in mg/kg textile) that could eventually be found in textiles after implementation of a limit value of 100 mg/kg. However based on the information presented in section B.9.3.4.1, the NPE content found in the reviewed studies may give an indication on the possible result of the proposed limit value. Assuming that the 251 samples (excluding 2 extreme values) of textile articles analysed are representative for the EU market, the effect of the proposed limit value could be roughly estimated by cutting all concentrations found to be above 100 mg/kg textile (and reducing those values to 100 mg/kg instead and leaving all values below 100 mg/kg unchanged). This would result in a reduced mean value of approximately 29 mg NPE per kg textile for the 251 samples analysed. This estimated NPE content in textiles would probably represent a worst case scenario as most importers and manufacturers of textiles would likely in practice reduce NPE content even more in order to achieve a sufficient margin of safety compared to the required limit value. It should be noted that this computation is far from certain in its ability to predict actual behaviour by the market actors, but it nevertheless provides a best estimate that is consistent with the information presented in previous sections of the restriction proposal.Thus it is assumed that the concentration of NPE in textiles put on the market in the EU until the year 2020 would be drastically reduced, however not to zero but to an assumed concentration of 29 mg/kg textiles.

A reduction of the NPE concentrations in textiles to 29 mg/kg would imply a reduction of NPE of roughly 73% per kg textile compared to the estimated 107 mg/kg in the baseline scenario. Compared to the estimaed total emission of NP/NPE to the environment (including all the assessed emission sources) the total annual NP/NPE emission reduction from textiles alone would constitute about 34% of the emission in 2010 as a result of the proposed restriction. Taking into account also the expected future trend in WWTP removal efficiency and connection rate and the trend in emissions from EU produced technical textiles and other sources than textiles, the total reduction of NP/NPE emissions to the water environment would be about 63% compared to emissions in 2010. In other words the identified risk in the water environment should be radically reduced in the year 2020 compared to 2010, primarily because of the proposed restriction.

The proposed restriction specifically targets clothing and household textiles that can be washed in water and identifies examples of what types of textile products that would be covered by the

some cases NPE may be found in concentrations up to 100 mg/kg fabric due to the use of such chemical formulations even though NPE is not used intentionally.

restriction on NP/NPE. The scope of the restriction thus excludes most types of technical textiles as referred to in section B.9.3.4.1. Therefore no significant reduction in emissions from such technical textiles is expected.

The reduction of NPE concentrations in textiles will have a direct effect on emissions to the environment since the NPE has been shown to be washed out during the usage phase (see section 9.3.4.1). The positive effect in the environment is thus expected to come into effect within five years after entry into force of the proposed restriction. The diagrams below show the resulting estimated emissions to the environment in the proposed restriction scenario

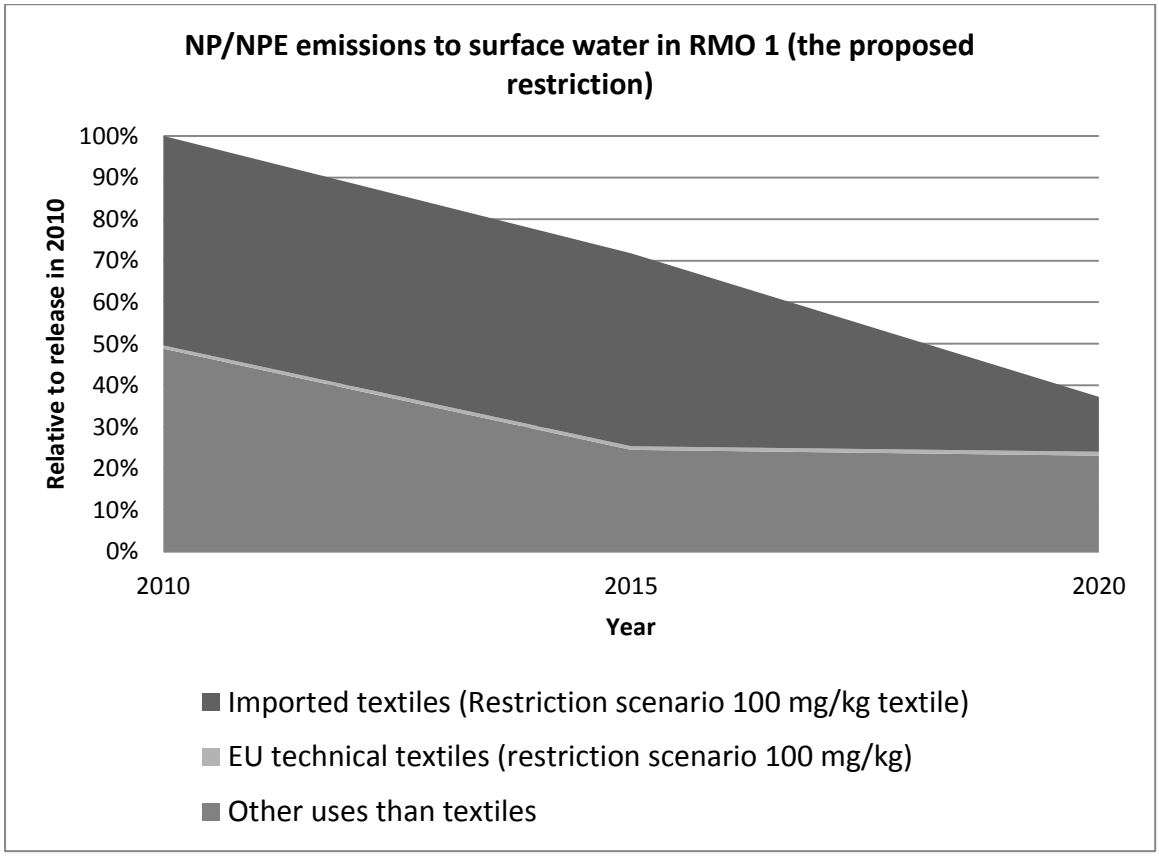


Figure 21 NP/NPE emissions to surface water in the proposed restriction scenario

As indicated by the discussion on *Future trend in waste water treatment and resulting releases of NP/NPE to the environment* above, the removal efficiency in WWTPs differs in various parts of EU. Overall it is recognized that the connection rate and occurrence of secondary treatment techniques is generally higher in the EU-15, and there remain some efforts for the other 12 Member States to comply with the targets set out by the UWWD. Lower removal rates in WWTPs means that a relatively larger share of NPE released to waste water is eventually released to surface water. The effect of the proposed restriction will thus be relatively larger in countries with lower removal rates in WWTP as the NPE load on waste water will be reduced. The variation in removal rates across EU countries and consequently the difference in effect of

the proposed restriction has not been assessed in further detail as it would require in-depth information on the current and future status of WWTPs.

The reduction in NPE concentrations in textiles is expected to occur as other alternative surfactants are used as substitutes in textile production in the EU and abroad. In section C.2.2 and C.2.3 the most likely alternative surfactants are briefly assessed in terms of risks to human health and the environment. It is expected that alcohol ethoxylates (AE) will be the major substitute for NPE and it is therefore relevant to consider the relative increase in emissions of AE to the environment. Assuming that NPE is replaced by AE by a ratio of 1:1 in textiles, and that AE is completely washed out from textiles, the reduction in NPE emissions to waste water in the EU would correspond to an equal increase in AE emissions to waste water. The emission of AE to waste water would thus increase by nearly 642 tonnes (estimated NPE content in imported textiles in the baseline year 2010 as indicated in section 9.3.2.4.1). According to the HERA report (HERA 2009) a total of 290 000 tonnes per year of AE could be assumed to be used in the EU and subsequently being released to sewage water (before any addition due to substitution of NPE in textiles). Furthermore the estimated PEC/PNEC values have been shown to be below one, ranging from 0.007 in sewage treatment plants to 0.316 in sediment. Thus the possible increase in AE emissions due to the proposed restriction would only add some 0.2% to total AE emissions to waste water, and obviously the risk assessment ratios quoted by HERA (2009) would hardly be affected and not come near the value of one.

As shown in section C other alternatives to NPE than AE will likely be used to a lesser extent due to technical and economic reasons. Judging from the information presented in section C.2.2 and C.2.3 there are no indications that increased use in textiles of those alternatives would imply risks to the human health or to the environment. Overall it is therefore expected that the risk reduction following the reduction of NPE in textiles will not be significantly counteracted by any risks associated with the alternative surfactants that replace NPE.

E.2.1.1.1.3 Other issues

No other issues.

E.2.1.1.2 Proportionality

The proposed restriction will limit NPE concentrations in textiles put on the EU market and consequently reduce emissions to the environment. The restriction is applied to the final article (clothing and household textile articles) and does not consider the manufacturing of textiles itself. The proposed limit value of 100 mg/kg textile would not conflict with the current REACH (Regulation No 1907/2006/EC) Annex XVII Entry 46 on NP/NPE that applies to manufacturing in the EU. Textile production in the EU should thus not be significantly affected. The proposed restriction also specifies that only clothing and household textile articles that can be washed in water (examples given in Table 1 in section A.1) shall be subject to the NP/NPE limit value. As described in section B.9.3.4.1 of the various technical textiles it is primarily *Clothing textiles*

(Clothtech) and Sports textiles (Sporttech) that consist of products submitted to washing in water and hence contribute to the NPE released to the waste water. Those textiles will therefore be included by the proposed restriction. This is at a worst case scenario approximately 10-15 % of the world end volume consumption. Within the other categories there can also be special products that is washed in water (e.g. among Protective textiles) but the vast majority of the technical textiles are thus handled in such a manner excluding them from the scope of this dossier.
The wording of the restriction thus excludes most technical textiles that are placed on the EU market.

The actors that are affected by the restriction are thus primarily EU importers who place clothing and household textile articles on the EU market.

The restriction does to some extent, however indirect, affect EU producers of NPE that are supplying NPE in chemical formulations to textile manufacturers in the EU and abroad. The demand for NPE by textile manufacturers will likely shrink and the demand for alternative substances will increase more or less proportionally. The effect on EU producers of NPE of this shift in demand is not considered to be of major importance since they appear to be able to change their production to instead accommodate increased demand for alternative detergents, but this issue is nevertheless discussed further below and in section F.

E.2.1.1.2.1 Technical feasibility

When assessing the technical feasibility of reducing NPE concentrations in textile articles, it is expected that the measures taken in the textile supply chain will be primarily to substitute NPEs with other alternative chemicals with similar properties. This measure would in principle reduce the NPE content in the final product to zero. But information provided in stakeholder consultation indicates that there may be NPE traces as impurities, by-products, or intentional components (at low concentrations) in some chemical formulations that are used in textile manufacturing. The use of some chemical formulations in the manufacturing of textiles may thus result (unintentionally) in NPE being found in the final textile article. This kind of unintentional NPE contamination of the final textile article could probably be also be avoided by ensuring that the chemical formulations used in manufacturing are free from NPE, e.g. by textile manufacturer's requirements aimed at suppliers of chemical products. The consultation with stakeholders, e.g. Nimkartek (2012), suggest a full phase out of NPE in such chemical products for textile manufacturing (when contained at low concentrations that are not always reported in the products' safety data sheets) to be difficult to achieve in the short or medium term. The issue of traces of NPE in chemical products could thus pose difficulties in terms of technical feasibility if the proposed limit value for NPE in textile articles is set too low. However as indicated by the stakeholder consultation a limit value of 100 mg NPE per kg textile article would avoid such difficulties as it would not be too strict towards possible unintentional contamination.

The proposed limit value will on the other hand be sufficiently stringent to deter any intentional use of NPE in the manufacturing of textile articles (such as those outlined in Table 49 in section C). This conclusion is supported by statements from several of the stakeholders consulted.

As indicated by AMEC (2012) NPE is used to some extent in manufacturing of technical textiles. AMEC's consultation with stakeholders indicate that the technical feasibility of substituting NPE in such textiles could require reformulation of chemical products and other types of adaption if technical textiles are covered by the scope of the restriction. During the preparation of the restriction proposal additional efforts have been made to identify the types of technical textiles and the how NPE might be used in the manufacture of textiles (see section B.9.3.4.). Overall it appears to be difficult to identify all uses of NPE in technical textiles and thus it would be even harder to assess the technical (and economic) feasibility of substituting NPE in such uses. Considering the lack of information about the technical feasibility of substituting NPE in such textiles and abovementioned indications of certain difficulties, and weighed against the limited risk reduction capacity of including technical textiles in the proposed restriction, it is concluded that the bulk of technical textiles should not be covered by the proposed restriction. In summary this conclusion motivates the wording of the proposed restriction to only target textiles that can be washed in water (examples given).

The wording in the proposed restriction which targets textiles that 'can be washed in water', specifically in relation to technical textiles, has been subject to stakeholder consultation. Some stakeholders do indicate that certain technical textiles may yet be affected by the proposed restriction, but the examples given were such textiles that would generally be classified as *Clothing textiles (Clothtech)* and *Sports textiles (Sporttech)* as referred to in section B.9.3.4.1. The stakeholder consultation did not show any particular difficulties in substituting NPE in such textiles, on the contrarary some stakeholder comments (from a company dealing with technical outdoor and sport textiles) suggest it to be fully feasible to phase out the use of NPE even in shorter time than the proposed transitional period of 5 years. Therefore it is expected that the proposed restriction will effectively exclude most technical textiles (that can not be washed in water) and include a minor share of such textiles (clothing textiles and sports textiles) for which it appears to be technically feasible to substitute the use of NPE in manufacturing.

The review of studies of NPE concentrations in textiles (section B.9.3.4.1) gives an indication of the share of textiles being imported to the EU that currently contain NPE concentrations above certain values. A simple assessment of the samples analysed indicates that:

- 35% of the textile articles contain NP/NPE at concentrations higher than 20 mg/kg textile
- 23% of the textile articles contain NP/NPE at concentrations higher than 50 mg/kg textile
- 19% of the textile articles contain NP/NPE at concentrations higher than 100 mg/kg textile

The above figures could provide a rough idea of the share of imported textiles that are likely produced with and without intentional use of NPE. Based on the comments received in stakeholder consultation, it could be argued that the share of textiles with NPE concentrations above 100 mg/kg should be understood as examples of intentional use of NPE in the manufacturing process. However such a strict interpretation may not be reliable considering e.g. the character of the data gathered in the review of studies. A reasonable assumption could be that 19-35% of the textile articles placed on the EU market would contain NPE from intentional uses during manufacture, which would account for a range of best to worst cases. This percentage range would thus give an indication that the use of alternative surfactants is already widespread, as the remainder 65-81% of textile articles could be assumed to not contain intentionally added NPE.

As described in section C, NPEs are used in various steps of the textile manufacturing process. NPEs primarily act as detergents and emulsifier in pre-treatment, dying/printing and finishing of textiles. The emulsifying and dispersing properties of NPE are excellent and NPE can be used in a wide range of applications. The most important physical properties of NPE (with varying ethoxylate units) is the Hydrophilic Lipophilic Balance (HLB). The HLB value corresponds to the behaviour of the emulsifier when added to water and gives an indication of what uses NPE might have in the textile production. Subsequently, the HLB value is an important factor in determining which alternative substance that may be applicable to achieve similar function. Other aspects should also be considered (see section C.1).

NPE used in textile production is added to have a function based on the properties summarized above. Thus no change in production technique should be necessary or the most feasible measure to reduce NPE concentrations in textiles.

As indicated in section C.1.2 there is a wide range of alternatives that possess the desired properties outlined above. The focus of the assessment of alternatives has been on non-ionic surfactants since they have been shown to be applicable in textile production. The most commercially common groups of non-ionic surfactants are alcohol ethoxylates (AE) and glucose based surfactants. Other alkyl phenol ethoxylates, in particular octyl phenol, have also been considered as possible alternatives but given their molecular size and properties they have been concluded unsuitable as alternative to NPE (and thus not further assessed).

AE are shown to be the most likely alternative to NPE as detergent in textiles (ToxEcology 2002, HERA 2009, AIST 2009, Poster 2012, TEGEWA 2012). About 90% of the alternatives to NPE belong to this group of surfactants. There exist several hundred different types of AE that have varying physical and chemical characteristics depending on the structural variety. AE with alcohol chain lengths C12-C15 and ethoxylation between 3-7 units are often used as alternative to NPE as a detergent. The properties of AE make it an effective surfactant and is comparable to NPE in most parameters relevant to textile production. As mentioned in section C.1.2 AE might

even surpass NPE in performance in certain aspects, e.g. higher cloud point (better solution stability), better stability in acid and caustic cleaners, and possibly better wetting properties.

Glucose based detergents provide another alternative to NPE, but according to TEGEWA (2012) this alternative only constitutes a few percentages of detergents used in textile production today. Glucose based surfactants are generally not as good alternative to NPE as AE. The properties of this type of surfactant make it more comparable to anionic surfactants, and appear to be a less viable option due to e.g. price/performance factors.

The technical feasibility to replace NPE as emulsifier is described in section C.1.5. The use of NPE as emulsifier constitutes a minor part of the total amount of NPE used in textile manufacturing today. The emulsifiers are used in the production of fibres as well as pretreatment of fabrics before dying and finishing operations. There is a greater challenge expected in finding good stable emulsifiers to replace NPE, but there are suitable alternatives on the market. The possibilities to find alternatives depend on the formulation's performance demands and needs to be considered from case-to-case. However several alternatives are available and according to consultation during the preparation of the restriction proposal the alternatives do likely belong to the non-ionic group of; alcohol etoxylates, glucose based, sugar esters or alkanol fatty acid amides.

When NPE is used in the printing process for example as a dispersant of pigment or emulsifier, also in this application alcohol ethoxylates, in the correct HLB-range can be used as an alternative (Nimkartek 2012, Posner 2012).

E.2.1.1.2.2 Economic feasibility (including the costs)

The benefits of RMO 1 are discussed in section F.

In section F.2 the costs impacts are estimated to be in the region of € 44 to 81 million in 2020. Roughly the same annualised cost will be incurred in the following 10 years after 2020.

Timing

The proposed restriction is not expected to incur any significant investments in new production equipment for textiles that are produced for exports to the EU market. The restriction will however require the actors in the textile supply chain to become informed about the restriction on NPE and to find suitable alternative surfactants.

It is recognized that the textile supply chain is very complex with many actors involved who need to be informed about the restriction on NPE if they are not already required by their customers to not use NPE. As indicated by Kogg (2009) EU importers are usually confined to business relations with the first tier of the supply chain which means that the requirements concerning

NPE must be communicated in a step-wise fashion to all relevant sub-contractors. If sufficient time is not allowed for such supply chain communication to occur under normal business to business contacts, extraordinary measures by EU importers may be necessary in order to achieve compliance with the restriction in due time. Such actions may involve e.g. information campaigns targeted to suppliers and sub-contractors as well as increased frequency of compliance checks in order to make suppliers conform. Several of the textile retailers/importers consulted give examples of their efforts in reducing the content of harmful substances in textiles, with emphasis on the long-term character of such actions. The experiences by the stakeholders consulted appear to support the view that timing, i.e. allowing for a sufficient transitional period, is indeed a major factor that would affect the economic feasibility of the proposed restriction (in addition to the limit value for NPE). As suggested by stakeholder comments, the proposed restriction with 5 years transitional period is expected to provide enough time for communication of the new requirement to occur , as well as allowing producers outside the EU to change practices in terms of e.g. surfactant purchases, without causing unproportional costs to the clothing and textile sector. However some stakeholders argue that the transitional period should be extended even further (up to 10 years) to avoid extra costs. But considering the fact that the experience in reducing NPE in textiles so far is by individual or groups of textile companies and not from exerting an EU-wide restriction (which would fascilitate communication within the supply chain), a 5 year transitional period is believed to suffice. The costs of communication and compliance control will thus be minimised, which is the main rationale for allowing 5 years for compliance after the restriction comes into force.

The timing of the proposed restriction also takes into account that manufacturers, importers, wholesalers and retailers need to sell out existing stocks of textiles (that may contain NPE above the proposed limit of 100 mg/kg textile).

The worldwide installed capacities for fatty alcohols were estimated to around 2.15 million tonnes per year in 2002 (Brackman and Hager 2004), and the production capacity has likely grown since then. The increased demand for AE due to the proposed restriction (estimated in section F.2.1 to roughly 23 000 to 42 000 tonnes in 2010, and 28 000 to 52 000 tonnes in 2020) would imply a marginal increase of total AE consumption worldwide. The proposed restriction would allow 5 years for the market to adapt in terms of supply and the impact on the market for chemicals is thus expected to be minor. The possibility of future regional shortage of AE or other alternative surfactants has not been investigated.

Because of the above reasons it is judged appropriate to allow 5 years for the actors to comply with the restriction after it comes into effect. There are no major difficulties identified for actors to comply, however the cost of communicating the new requirement to textile producers outside the EU may be substantially reduced by not pushing compliance too short. On the other hand it does not appear beneficial to further lengthen the time for actors to comply, e.g. to 10 years

instead of 5, since that would likely not reduce compliance costs significantly and it would imply a slower phase out of NPE releases to the environment.

E.2.1.1.2.3 Other issues

No other issues.

E.2.1.2 Practicality

E.2.1.2.1 Implementability

As described in section C the most likely response to the proposed restriction will be for textile producers to substitute NPE with alternative surfactants. There is a range of alternatives available and in particular alcohol ethoxylates are shown to already be widely used (and available on the market) as surfactant in textile production. Furthermore in section F it is shown that the additional cost of e.g. AE compared to NPE is relatively small, and the cost of surfactants is estimated to be very minor in comparison to total costs of producing textiles. The impact of substitution costs on the final textile article is thus expected to be insignificant.

The proposed restriction would set a limit value of 100 mg NP/NPE per kg textile, which according to information provided in stakeholder consultation, would allow not interfere with the current regulation on NP/NPE in REACH Annex XVII, Entry 46. Several major clothing and household textile companies operating in the EU are already pursuing a similar limit value for NP/NPE in textiles, however based on restricted substances lists and other types of requirements and controls. The transitional period of 5 years that is proposed would, as indicated by stakeholder comments, allow sufficient time for implementation of the new requirement for those actors who are currently not engaged in phasing out NP/NPE in textiles.

E.2.1.2.2 Enforceability

The proposed restriction is formulated with the aim of achieving efficient supervision mechanisms for the authorities responsible for enforcement. There are four main aspects worth mentioning in this respect, namely that the proposed restriction:

- Sets a clear limit for the NP/NPE content in clothing and household textile articles, i.e. it is recognized that NP/NPE should not be found in the textile above the limit value. The emphasis is thus clearly on the textile material.
- Lists examples of clothing and household articles in order to clarify the scope of the restriction, and furthermore states that the restriction shall only apply to those textile articles that can be washed in water. The wording of the restriction also makes clear that prints on the textiles articles mentioned are also subject to the limit value for NP/NPE.
- Clearly defines what is meant by ‘textile articles’ by referring to the definition in Article 3.1 a-f of the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT

AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products.

- Refers to the standards adopted by the European Committee for Standardisation (CEN) to be used as test methods for demonstrating the conformity of the articles in question. This means that authorities will be provided with EU standard test methods that will be readily available in the market for laboratory analysis services before entering into force of the proposed restriction.
- Defines the groups of substances that are covered by the restriction. The definition of NP and NPE is deliberately made so that various possible variations of the molecular structure of the substances are covered which will facilitate supervision as there are no exceptions defined.
- Allows sufficient time for the actors in the supply chain to adapt to the restriction and thus to deplete any stocks of textiles that could contain NPE concentrations above the proposed limit.

Concerning the second bullet point above, comments received during stakeholder consultation suggest that *the definition of non-washable articles should be based on accepted EU-wide or global definitions to provide a robust framework for business*. It has been suggested *that the applicability of the restriction should be aligned with voluntary European/international standards like ISO 3758 and DIN EN 23758 which apply to care symbols*. This issue is identified as a possible improvement of the clarity of the proposed restriction, however it is judged inappropriate to link the proposed restriction to a voluntary standard, both because it is not mandatory for all actors in the market and also because the standards mentioned above might change – which could in turn change the scope of the restriction. A possible solution to the issue could be to include standards concerning care symbols in the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products, since that would harmonize the use of care symbols in textile articles placed on the EU market. According to Article 24 in the abovementioned directive, the *Commission shall submit a report to the European Parliament and the Council regarding possible new labelling requirements to be introduced at the Union level.* And it is explicitly stated in Article 24 p.3 (b) that the report shall examine the option of a harmonised care labelling system. Depending on the outcome of the review the enforceability (and manageability) of the proposed restriction could thus possibly be enhanced further.

In relation to the fourth bullet point above it should be mentioned that analysing for NP/NPE in textiles today is executed in somewhat different manners. This is demonstrated when comparing reviewed studies in section B.9.3.4.1. As shown the most frequent detection limit is 1 mg NPE/kg textile. All nonylphenol ethoxylates for which there is a reference are analysed simultaneously and then summarised. Analysis for NP is performed separately. The proposed restriction refers to

the CEN standard that is currently under development by the designated working group TC248/Wg26. The standard in question is expected to be finished well in time before the restriction would come into effect (Posner 2012).

E.2.1.2.3 Manageability

The manageability of the proposed restriction is largely determined by the same aspects as mentioned above (section E.2.1.2.2). The clarity in the formulation of the restriction (in terms of scope and timing) is expected to facilitate communication of the requirement for actors in the textile supply chain.

The limit value set for NP/NPE (100mg/kg textile) has been balanced against the actors' ability to comply, taking into account the possibility of unintentional NPE contamination of textiles due to e.g. traces of NP/NPE in chemical formulations. . As indicated by several of the stakeholders consulted, setting the limit value lower than 100 mg NP/NPE per kg textile article could in fact interfere with the current regulation in REACH Annex XVII Entry 46. In effect a lower limit value than 100 mg/kg could cause confusion especially for manufacturers of textiles located withiin the Union, since there would be one regulation concerning production of textile articles and another one (more stringent) concerning articles placed on the market. This potential conflict between regulations is avoided by the proposed restriction. On the other hand the limit value is set low enough for textile producers to effectively respond to the restriction as a ban on intentional use of NPE in textiles. Thus there should be no confusion with regards to the intention behind the restriction; it is to fully steer away from intentional use of NPE in the production of textiles as it will remain in the final product and cause emissions of NP/NPE to the environment.

Since the proposed restriction clearly states what types of chlothing and household textiles that are of concern, and the whole group of substances NP and NPE are covered, the communication of the restriction should be manageable. All concerned EU importers of textiles may refer to the wording of the restriction in requiring suppliers to substitute NPEs in textile manufacturing, and similarly it will be possible to refer to coming EU standards for test methods in cases were compliance control is deemed necessary. As mentioned above, the clarity of the proposed restriction could be enhanced by referring to a common standard for care symbols, but it is outside the scope of the restriction proposal to examine that option since it is an issue to be examined by the Commission.

Furthermore, as there are already specific restrictions at the EU level for azocolourants (REACH Regulation 1907/2006/EC) and PCP (Directive 94/783/EC) in textiles, procedures in the supply chain should already exist for providing and requesting information on compliance to chemical legislation. Therefore there should be no significant additional effort of training, capacity building, development of systems for compliance control, etc. because of the proposed restriction. However it is recognized that certain efforts by actors in the textile supply chain will be required in order to inform all relevant actors about a Union-wide restriction on NP/NPE. The

5 year transitional period is expected to allow for such information spreading to occur in a manageable fashion, keeping any extraordinary measures in terms of communication and compliance control to a minimum.

E.2.1.3 Monitorability

The effects of the restriction may be monitored primarily at three levels:

- Monitoring of NPE in marketed textile articles or articles containing textiles at the Member State level.
- Monitoring of the concentrations/amounts of NPE in effluent water from WWTP within the EU.
- Monitoring of the environmental concentrations of NP within the EU.

E.2.1.3.1 Direct and indirect impacts

Monitoring of NPE in marketed textile articles or articles containing textiles

There is statistical information available from Eurostat on the quantity of imported textiles. The authorities responsible for enforcement of the restriction may perform random sampling of textile articles and use standard test methods to assess the concentration of NPE in textiles. Statistical analysis could thus be used to produce data for monitoring purposes. It is expected that the cost of compiling such information will be limited and such activities can be done concurrently with the monitoring of the restriction on azocolourants and pentachlorophenol (PCP) in textiles.

Monitoring of the concentrations/amounts of NPE in effluent water from WWTP within the EU

There is currently a reporting requirement for NP/NPE for large industrial facilities (including WWTP) in the EU according to the Regulation EC 166/2006. The information on releases of NP/NPE to the environment are updated on an annual basis and is presented in the European pollutant release and transfer register (E-PRTR) which is made publicly available by the European Environment Agency. However the information does only provide a rough estimation on total releases of NP/NPE because there might be waste water treatment plants which are below the reporting threshold (1 kg per year) of the Regulation EC 166/2006. In addition the releases of NP and NPE are reported separately which makes it a less useful tool for monitoring the effect of the proposed restriction.

There have been several monitoring programs for nonylphenol in municipal waste water treatment plants, but there is no full EU coverage expected in this respect.

Monitoring of the environmental concentrations of NP within the EU

The Water Framework Directive (WFD) requires the Member States to monitor the progressive reduction in the concentrations of priority substances (PS) and the phasing out of priority hazardous substances (PHS) (European Commission 2009). It is primarily the surveillance monitoring of priority substances that would likely contribute to the monitoring of environmental concentrations of NP. The monitoring frequencies given in WFD, Annex V 1.3.4, are once-a-month for priority substances and once-per-three-months for other pollutants. The guidance document indicates more frequent sampling may be necessary e.g. to detect long-term changes.

As indicated above, the Member States are already required to monitor the concentrations of NP in the water environment. Therefore the effect of the proposed restriction could be monitored without any additional efforts or costs. Note however that no detailed assessment has been made of any on-going or planned monitoring activities within the WFD concerning NP, i.e. it is not clear to what extent Member States will actually carry out monitoring of NP.

E.2.1.3.2 Costs of the monitoring

The monitoring of NPE in marketed textile articles or articles containing textiles can be done concurrently with the monitoring of the restriction on azocolourants and pentachlorophenol (PCP) in textiles.

The monitoring activities described above, concerning NP in effluent water from WWTP and NP concentrations in the environment, are part of on-going activities as required by current EU regulation.

In summary there are no significant additional costs to be expected due to the above monitoring activities.

E.2.2 Restriction option 2 (RMO 2): Limit value of 100 mg NP/NPE per kg textile with a transitional period shorter than 5 years

This RMO is formulated as RMO 1 except in terms of the transitional period allowed for the concerned actors to comply with the restriction.

In order to discuss the effectiveness, practicality and monitorability of RMO 2, a transitional period of 1-3 years is suggested and compared to the 5 year transitional period in the proposed restriction.

E.2.2.1 Effectiveness

E.2.2.1.1 Risk reduction capacity

Same as RMO 1.

E.2.2.1.1.1 Changes in human health risks/impacts

Same as RMO 1.

E.2.2.1.1.2 Changes in the environmental risks/impacts

Compared to RMO 1, this restriction option would imply a similar reduction in NPE releases to the environment. But the reduction in NPE releases would occur approximately 2-4 years earlier due to the shorter time (12-36 months) allowed for actors to comply with the restriction. The positive effect in the environment is thus expected to come into effect within one to three years after entry into force of the restriction.

However, based on comments received in stakeholder consultation there is reason to believe that the actors in the textile supply chain would have difficulties in complying with the restriction within such a short time frame for adaption (this is further discussed in the section on *Practicality* below). RMO 2 could thus to some extent be expected to show a lag in actual compliance and it less certain that the targeted reduction will in fact be achieved by the target date, in particular in the case of 1 year transitional period but also in the 3 year alternative.

Another possible negative impact in the environment (which is hard to substantiate and predict) of allowing a shorter transitional period, is that there would be less time to find optimal chemical formulations to substitute all uses of NPE in textile manufacturing. As described in section C.2.1 there are already alternatives on the market that can be used to substitute NPE, and there has been a rapid growth particularly in the use of alcohol ethoxylates during the last 20 years. In general, chemical formulations based on AE and other alterantive surfactans can effectively replace NPE but it may depend on the formulation's performance demands. Certain adjustments in the manufacturing process, e.g. in terms of temperature and the chemical feed rate may also be necessary in some cases. Thus overall, allowing a shorter transitional period could potentially influence the use of water, energy and other resources (because NPE free chemical formulations have not yet been fully optimized for all uses). Such possible negative effects in the environment would likely occur in the manufacturing countries and not within the Union.

E.2.2.1.1.3 Other issues

No other issues.

E.2.2.1.2 Proportionality

Same as RMO 1, except differences due to timing (see section E.2.2.1.2.1 below).

E.2.2.1.2.1 Technical feasibility

Same as RMO 1, except differences due to timing (see section E.2.2.1.2.1 below).

E.2.2.1.2.2 Economic feasibility (including the costs)

The estimated benefits of RMO 2 would be similar to RMO 1, however they would occur sooner (see section E.2.2.1.1.2).

Due to the shorter time allowed for actors in the textile supply chain to comply with the restriction, the costs impacts could become significantly higher. As shown in section F.2 the major costs due to a restriction on NPE in textiles would be those for compliance control. For RMO 1 it is estimated that EU importers will primarily rely on on-going communication, with suppliers and subsequent information to sub-contractors in the textile supply chain, in order to ensure that textile articles put on the EU market are in compliance. Thus in RMO 1 it is not expected that EU importers will have to drastically increase the testing frequency with regards to NPE concentrations in imported textiles. However in RMO 2 it could be that extraordinary measures would have to be taken by EU importers, e.g. by increasing the testing frequency or by extensive communication activities aimed at textile producers abroad. The costs of compliance control under RMO 1 are estimated to be in the region of €135-140 million in the years 2015-2020. A worst case scenario for RMO 2 could be that the testing frequency would have to be increased, perhaps as much as ten times the frequencies suggested under RMO 1. This would increase the compliance costs by almost equal proportion, i.e. the cost could reach €1.4 billion per year. Even if such extraordinary measures are taken by EU importers it would not make certain that the marketed articles are in compliance, i.e. there could be a higher degree of non compliance which would imply that the emission reduction target would not be achieved in due time.

Compared to RMO 1, the timing of RMO 2 would also make it more difficult for manufacturers, importers, wholesalers and retailers to sell out existing stocks of textiles (that may contain NPE above the proposed limit of 20mg/kg textile). Such problems would likely occur if a transitional period as short as 1 year is chosen, but stakeholder consultation has not indicated this to be an issue if at least 3 years transitional period is given. Strictly enforced, this restriction option could thus mean that some existing stocks would have to be put on sale (before the time for compliance), destroyed or otherwise disposed of e.g. by export from the EU. The cost of such actions would likely be substantial (note – this only applies to the case of 1 year transitional period).

E.2.2.1.2.3 Other issues

No other issues.

E.2.2.2 Practicality

E.2.2.2.1 Implementability

See the discussion in section E.2.2.1.2.2 above.

E.2.2.2.2 Enforceability

The enforceability of RMO 2 would be similar to RMO 1, except in terms of:

- The availability of EU standards for test methods: It is not certain that the now on-going development of EU standards for test methods will finish in time (in the case of 1 year transitional period) before RMO 2 would become effective. This would make it harder for authorities to perform compliance checks according to common standards which could increase the administrative costs of enforcing the restriction.
- The time allowed for actors in the supply chain to adapt to the restriction: As indicated in section E.2.2.1.2.2 allowing just 12 months allowed for compliance could imply certain difficulties for actors in the textile supply chain to empty remaining stocks of textiles that could contain NPE concentrations above the proposed limit value. Due to the likely substantial costs of disposing any remainder of non-compliant textiles, there could potentially occur marketing of non-compliant articles in substantial volumes. To counteract this effect the authorities would likely have to increase enforcement activities (if the aim is full compliance). The cost to enforcement authorities would thus be relatively higher.

E.2.2.2.3 Manageability

Similar to RMO 1 except regarding the timeframe allowed for actors in the supply chain to comply with the restriction.

E.2.2.3 Monitorability

The monitorability of RMO 2 would overall be comparable to RMO 1. However the monitoring of the environmental concentrations of NP within the EU could possibly be less well developed as the Member States are yet not fully operational in terms of surveillance programs.

E.2.3 Restriction option 2 (RMO 2): Limit value lower than 100 mg NP/NPE per kg textile with a transitional period of 5 years

This RMO is formulated as RMO 1 except in terms of the limit value for NP/NPE in textile. In order to discuss the effectiveness, practicality and monitorability of RMO 3, two different limit values are discussed (20 mg/kg and 50 mg/kg) and compared to the proposed restriction in RMO1.

E.2.3.1 Effectiveness

E.2.3.1.1 Risk reduction capacity

Similar to RMO 1, but the total risk reduction capacity would be relatively greater in RMO 3 (see section E.2.3.1.1.2 below).

E.2.3.1.1.1 Changes in human health risks/impacts

Similar to RMO 1.

E.2.3.1.1.2 Changes in the environmental risks/impacts

In section E.2.1.1 the risk reduction capacity of RMO 1 is estimated, by calculating the change in NP/NPE content in textiles, based on the samples gathered in the review of studies on NPE concentrations in textiles. The calculation is based on the assumption that all NP/NPE concentrations above the limit value would be reduced (to the limit value). This estimated NPE content in textiles would probably represent a worst case scenario as most importers and manufacturers of textiles would likely in practice reduce NPE content even more in order to achieve a sufficient margin of safety compared to the required limit value. It should be noted that this computation is far from certain in its ability to predict actual behaviour by the market actors, but it nevertheless provides a best estimate that is consistent with the information presented in previous sections of the restriction proposal. If the same method for calculating emission reduction used in section E.2.1.1 is applied in the case of RMO 3, the relative reduction in emissions would appear as in the figure below.

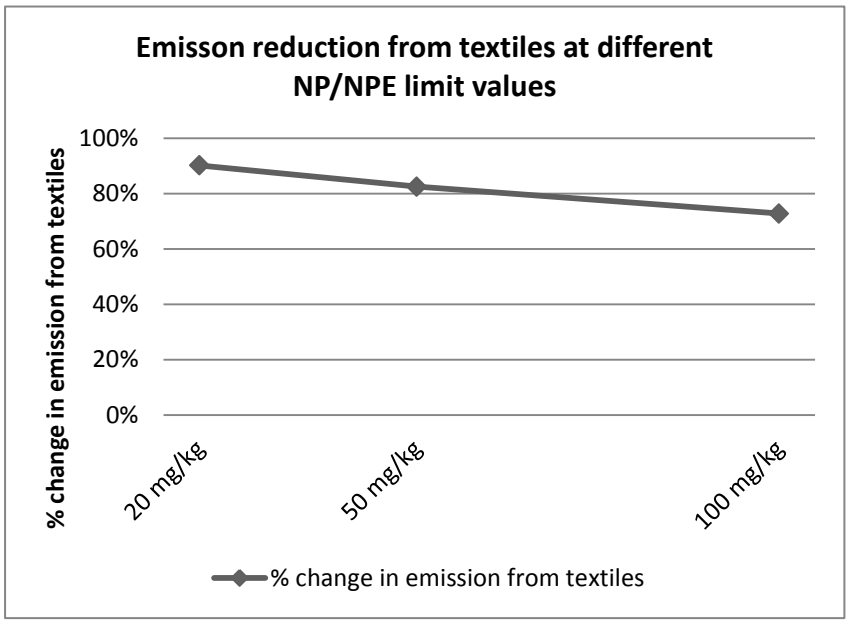


Figure 22 Emission reduction from textiles at different NP/NPE limit values

The limit values 20 and 50 mg NP/NPE per kg textile would, according to the calculation, result in reduced mean values of about 11 and 19 mg/kg respectively for the 251 samples analysed. According to the calculation, about 90% of NP/NPE emissions from textiles would be reduced if

the limit value is set to 20 mg/kg textile, and about 82% would be reduced with a limit value of 50 mg/kg textile.

Of the estimaed total emission of NP/NPE to the environment (including all the assessed emission sources) the total annual NP/NPE emission reduction from textiles alone would constitute about 44% (20 mg/kg limit value) or 39% (50 mg/kg limit value) of the emission in 2010 as a result of the proposed restriction. Taking into account also the expected future trend in WWTP removal efficiency and connection rate and the trend in emissions from EU produced technical textiles and other sources than textiles, the total reduction of NP/NPE emissions to the water environment would be about 71% (20 mg/kg limit value) or 66% (50 mg/kg limit value) compared to emissions in 2010. Clearly the risk reduction capacity would thus be greater in RMO 3 compared to RMO 1, but the difference would probably not be greater than between 3-8% based on the calculation method chosen.

In addition, as indicated by comments received in stakeholder consultation, setting the limit value lower than 100 mg/kg for the final textile article could imply that textile manufacturers within the Union would have to implement additional measures compared to what is currently required according to REACH annex XVII entry 46 (which concerns the use of chemical formulations). Such measures would thus likely lead to a further reduction in NP/NPE content in textiles produced within the Union (which is not expected in RMO 1), and subsequently reduce emissions water to some extent. However the size of such possible emission reduction has not been assessed in detail, as it would be expected to be relatively small compared to the total emission from imported textiles.

E.2.3.1.1.3 Other issues

No other issues.

E.2.3.1.2 Proportionality

Similar as RMO 1, except differences technical and economic feasibility (see sections below).
E.2.3.1.2.1 Technical feasibilityRMO 1, but RMO 3 would imply certain difficulties in achieving suffient reduction of NP/NPE concentrations in textiles in order to comply with a lower limit value. Information provided in stakeholder consultation indicates that there may be NPE traces as impurities, by-products, or intentional components (at low concentrations) in some chemical formulations that are used in textile manufacturing. The use of some chemical formulations in the manufacturing of textiles may thus result (unintentionally) in NPE being found in the final textile article. This kind of unintentional NPE contamination of the final textile article could probably be also be avoided by ensuring that the chemical formulations used in manufacturing are free from NPE, e.g. by textile manufacturer's requirements aimed at suppliers of chemical products. The consultation with stakeholders, e.g. Nimkartek (2012), suggest a full phase out of NPE in such chemical products for textile manufacturing (when contained at low concentrations that are not

always reported in the products' safety data sheets) to be difficult to achieve in the short or medium term. Since there is currently not full information available (to neither authorities or actors in the textile supply chain) about the occurrence of NP/NPE as traces in chemical formulations, it is impossible to assess the technical feasibility of fully phasing out NP/NPE to the extent required by RMO 3. The issue of traces of NPE in chemical products could thus pose difficulties in terms of technical feasibility if the proposed limit value for NPE in textile articles is at 20 or 50 mg/kg textile.

E.2.3.1.2.2 Economic feasibility (including the costs)

The estimated benefits of RMO 3 would be somewhat greater than in RMO 1, as indicated by the risk reduction capacity estimated in section E.2.3.1.1.2.

The costs of RMO 3 would likely be significantly higher than in RMO 1 primarily because:

- Additional information about the chemical composition (even for traces at low concentrations in chemical formulations) would have to be compiled by actors in the textile supply chain both within the Union and abroad.
- In cases where NP/NPE is found as traces in low concentrations in chemical formulations, and where such traces could result in too high NP/NPE concentrations in the final textile article, there would have to be reformulation of some chemical products. This would likely lead to some reformulation costs and to a lesser extent substitution costs (if NP/NPE would have to be replaced by other substances in the formulations).
- Additional compliance control, by means of e.g. higher testing frequency on textile articles placed on the market, would likely have to be implemented by actors in the textile supply chain. The cost of such additional compliance control would likely be great, possibly in the same order of magnitude as in the case of RMO 2, but cannot be quantified in lack of reliable estimates of what test frequencies that would apply.
- The limit value would affect a larger number of actors in the textile supply chain, since there are very few companies that are currently pursuing limit values of 20 or 50 mg/kg textile under voluntary efforts. There could thus be significant costs also to those actors that are currently pro active in phasing out NP/NPE from textile products.

If the same assessment is made as in section E.2.1.1.2.1 (regarding the share of textile articles on the market that would be affected by the limit value on NP/NPE), it would indicate that

- 49% of the textile articles contain NP/NPE at concentrations higher than 5 mg/kg textile (which could be a plausible scenario for mean NP/NPE concentrations in textile if the limit value is set to 20 mg/kg textile)
- 35% of the textile articles contain NP/NPE at concentrations higher than 20 mg/kg textile
- 23% of the textile articles contain NP/NPE at concentrations higher than 50 mg/kg textile

Comparing the percentage range above (23-49%) to the range suggested for RMO 1(19-35%) would indicate that a larger share of the textiles placed on the market today would be affected by the limit value; however it does not seem relevant to put emphasis on any exact proportions considering the uncertainty in such relative figures. Overall, comments provided in stakeholder consultation suggest that a limit value of 20 mg/kg textile would likely have severe repercussions on trade in textile products and that it would force the greater majority of actors in textile supply chain to engage in extensive compliance control.

E.2.3.1.2.3 Other issues

No other issues.

E.2.3.2 Practicality

E.2.3.2.1 Implementability

See the discussion in section E.2.2.1.2.2 above.

E.2.3.2.2 Enforceability

The enforceability of RMO 3 would be similar to RMO 1, except in terms of the possible conflicting standards regarding the use of chemical formulations containing NP/NPE in textile manufacturing withing the Union (REACH annex XVII entry 46) and a limit value of 20 or 50 mg NP/NPE in the final textile article. According to several stakeholders consulted, a lower limit value than 100 mg/kg textile would imply inconsistencies and thus confusion to corporations operating in many jurisdictions.

E.2.3.2.3 Manageability

See above.

E.2.3.3 Monitorability

The monitorability of RMO 2 would overall be comparable to RMO 1.

E.3 Comparison of the risk management options

The three risk management options assessed differ in terms of:
the timing of compliance for actors in the textile supply chain (60 months in RMO 1 compared to shorter transitional period of 12-36 months in RMO 2). The time allowed for compliance would primarily affect the economic feasibility (including the costs) and the enforceability of the restriction.

- the limit value to be achieved (100 mg/kg textile in RMO 1 compared to 20-50 mg/kg textile in RMO 3). The level of the limit value would primarily affect the risk reduction capacity, the technical feasibility and the economic feasibility of the restriction.

Table 60 Comparison of the risk management options assessed

	RMO 1 (Limit value of 100 mg NP/NPE per kg textile with a transitional period of 5 years)	**RMO 2 (Limit value of 100 mg NP/NPE per kg textile with a transitional period shorter than 5 years)**	**RMO 3 (Limit value lower than 100 mg NP/NPE per kg textile with a transitional period of 5 years)**
Risk reduction capacity	(++) Reduction of NPE of roughly **73%** compared to the estimated 107 mg/kg textile in the baseline scenario. The total reduction of NP/NPE emissions to the water environment would be about **63%** compared to emissions in 2010, and the proposed restriction would constitute **34%** reduction alone.	(++) Same as in RMO 1 but the reduction would occur 2-4 years earlier.	(+++) Reduction of NPE of roughly **82-90%** compared to the estimated 107 mg/kg textile in the baseline scenario. The total reduction of NP/NPE emissions to the water environment would be about **66-71%** compared to emissions in 2010, and RMO 3 would constitute **39-44%** reduction alone.
Technical feasibility	(+++) RMO 1 is expected to be technically feasible in terms of e.g. availability of suitable alternatives to NP/NPE. The wording of the restriction effectively excludes most technical textiles and will thus not cause isses of feasibility that could otherwise occur.	(+++) Same as RMO 1.	(-) There may be NPE traces as impurities, by-products, or intentional components (at low concentrations) in some chemical formulations that are used in textile manufacturing, which could cause concentrations of NP/NPE above 20-50 mg/kg textile. The consultation with stakeholders strongly suggest a full phase out of NPE traces in such chemical products for textile manufacturing to be difficult to achieve in the short or medium term.
Economic feasibility	(-) The costs of RMO 1 are expected to consist primarily	(---) The costs of RMO 2 is expected to be significantly	(---) The costs of RMO 3 is expected to be significantly

	of costs for compliance control in the textile supply chain, and a minor part of costs for substitution. The total annualised cost is estimated to roughly € 44 to 81 million in the years 2020 to 2030. There is great uncertainty in the cost estimates due to e.g. uncertainties in the test frequency to be applied as a mean of compliance control	higher than in RMO 1. This is mainly because textile importers/retailers would not be allowed sufficient time to inform and communicate the restriction on NP/NPE to all relevant parts of the supply chain which would likely result in extraordinary measures to ensure that textile products placed on the market in the Union are in compliance. Such measures would likely include higher test frequencies by textile importers and possibly targeted information campaigns to textile suppliers. Stakeholder consultation has indicated that the costs to textile businesses could be substantial if the transitional period for the restriction is set too short.	higher than in RMO 1. This is mainly because of the likely difficulties in acquiring full information about traces of NP/NPE (at low concentrations) in all chemical formulations used in textile manufacturing, and there could also be some costs of reformulating some products to make them NP/NPE free. In addition, comments from stakeholders suggest that a limit value as low as 20 mg NP/NPE per kg textile would be impossible to achieve even with a transistional period of 5 years. A limit value of 20-50 mg/kg could imply significant extra costs for compliance control and possibly repercussions on trade in textile articles.
Enforceability and manageability	(+++) RMO 1 is formulated so that clothing and household textile articles are clearly targeted, giving examples of what types of textiles that are covered by the restriction and specifically stating that prints are also included. The proposed restriction refers to an agreed definition of what is meant by a 'textile article' and to a common standard for testing NP/NPE. Overall RMO 1 is therefore expected to be enforceable and manageable.	(+) Similar to RMO 1, but allowing a transistional period as short as 12 months could imply certain issues with regards to the readiness of the common standards for testing methods as well as difficulties to ensure that current stocks of textile articles placed on the market are emptied before the restriction comes into effect. Also, there are indications from stakeholder consultation that 12-36 months would not be sufficient time for actors in the supply chain to become fully informed about the restriction, which could reduce the manageability of the restriction.	(++) Similar to RMO 1, except in terms of the possible conflicting standards regarding the use of chemical formulations containing NP/NPE in textile manufacturing withing the Union (REACH Annex XVII Entry 46) and a limit value of 20 or 50 mg NP/NPE in the final textile article. According to several stakeholders consulted, a lower limit value than 100 mg/kg textile would imply inconsistencies and thus confusion to corporations operating in many jurisdictions.

E.4 Main assumptions used and decisions made during analysis

The assessment of the appropriateness of risk management options is based on a range of calculations and estimates that are based to a large extent upon uncertain assumptions. It is recognised that some of these assumptions may significantly alter the result of the analysis if they were to be changed e.g. in light of new evidence from further stakeholder consultation. The main assumptions to consider in terms of uncertainty are believed to be:

- The exposure assessment for emissions from textiles, in particular the representativity of the samples used to estimate NP/NPE concentrations in imported textiles as described in section B.9.3.4.1. The uncertainty in NP/NPE concentrations in textile articles affects not only the estimation of current emissions but largely also determine the risk reduction capacity of the proposed restriction. This uncertainty could be reduced by taking additional samples for analysis of NP/NPE content in textiles, in a randomized and statistically sound manner in order to ensure representativity for the whole market.
- The uncertainty in the exposure assessment for emissions from other sources than textiles, as described in section B.9.3.4.2. There may be over- and underestimations of current emissions and consequently the relative share of total emissions made up by textiles could be different than estimated. Overall the representativity of the data from the Swedish product register for the whole market in the Union could be questioned. Those same uncertainties are reproduced and strengthened in the reference scenario where the future trend in emission from other sources than textiles is assessed. However, the future trend in those sources will not alter the conclusion with regards to the risk reduction capacity of the proposed restriction (in terms of emissions from textiles) since it is dicussed in relation to current emissions.
- As shown in section B.9.3.4.3 there may be additional other sources that are currently not possible to quantify but which could potentially constitute some portion of the estimated current emissions of NP/NPE. If e.g. the emisisons from cosmetics were to be quantified and shown to constitute a significant portion of current emissions, the estimated relative size of emissions from textiles would be reduced and subsequently the risk reduction capacity of the proposed restriction would be lower.
- The assumptions used to calculate compliance costs in section F.2 and referred to in section E.2, in particular assumptions about how actors in the supply chain may react to a restriction on NP/NPE in textile articles. The assumed testing frequency by textile importers, which is thought to serve as a proxy for efforts made in the textile supply chain to comply with the restriction, may be either over- or underestimated which could significantly change the result of the cost computation. The stakeholder consultation has not provided any useful information in this respect, which is not surprising as it would not serve the interests of importers/retailers to reveal such information to suppliers. In effect, revealing the testing frequency could give rise to moral hazard among suppliers in the textile supply chain, i.e. that e.g. textile suppliers would recognise the risk of getting

caught with NP/NPE levels above the limit value would be low (hence low expected costs of non-compliance) and non-compliance could thus become more frequent.

E.5 The proposed restriction(s) and summary of the justifications

In order to reduce the risk identified in the water environment a restriction on NP/NPE concentrations in textile articles is proposed as follows:

Clothing and household textile articles that can be washed in water shall not be placed on the market 60 months after entry into force of the restriction if they contain nonylphenol or nonylphenol ethoxylat alone or in combinationin concentrations equal or higher than 100 mg/kg textile. The limit value includes prints on the textile articles comprised by the proposed restriction.

The standards adopted by the European Committee for Standardisation (CEN) shall be used as test methods for determining the content of nonylphenol or nonylphenol ethoxylate for demonstrating the conformity of the restriction. There is an ongoing work to develop a new CEN standard for textiles to detect and quantify APEOs adressed "Detection and determination of APEO in textiles by HPLC-MS" (Posner 2012).

A proposal for an addition in REACH entry 46 in Annex XVII is compiled in Table 1 in section A.1.

The proposed restriction is expected to prompt substitution of NPE used in textiles destined for the EU market. The limit value of 100 mg NPE per kg textile will, according to the stakeholders consulted, be interpreted as a ban on intentional use of NPE in textiles and subsequently there should only remain unintentional contamination of NPE in textiles (if any).

The proposed restriction is expected to reduce the mean concentrations of NP/NPE in textile articles to approximately 29 mg/kg, i.e. about 73% lower in the year 2020 compared to the estimated 107 mg NP/NPE per kg textile in the reference year 2010. Compared to the estimated total emission of NP/NPE to the environment (including all the assessed emission sources) the total annual NP/NPE emission reduction from textiles alone would constitute about 34% (as a result of the proposed restriction) of the total emission in 2010. Taking into account also the expected future trend in WWTP removal efficiency and connection rate and the trend in emissions from EU produced technical textiles and other sources than textiles, the total reduction of NP/NPE emissions to the water environment would be about 63% in the year 2020 compared to the estimated emissions in 2010. In other words the identified risk in the water environment should be radically reduced in the year 2020 compared to 2010, primarily because of the proposed restriction.

There are no indications that the available alternative chemicals in textiles production would cause concern for human health or the environment if used to substitute NPEs.

The restriction is applied to the final article (clothing and household textile articles) and does not consider the manufacturing of textiles itself. The proposed limit value of 100 mg/kg textile would according to comments received in stakeholder consultation not conflict with the current REACH (Regulation No 1907/2006/EC) Annex XVII Entry 46 on NP/NPE that applies to manufacturing in the EU. Textile production in the EU should thus not be significantly affected and the restriction would imply a level playing field for textile manufacturers situated within the Union as well as abroad.

The proposed restriction also specifies that only clothing and household textile articles that can be washed in water (examples given in Table 1 in section A.1) shall be subject to the NP/NPE limit value. As described in section B.9.3.4.1 of the various technical textiles it is primarily *Clothing textiles (Clothtech) and Sports textiles (Sporttech)* that consist of products submitted to washing in water and hence contribute to the NPE released to the waste water. Those textiles will therefore be included by the proposed restriction. The vast majority of technical textiles are however excluded from the scope of the proposed restriction.

The actors that are affected by the restriction are thus primarily EU importers who place clothing and household textile articles on the EU market.

It is expected that the actors in the textile supply chain will comply to the proposed restriction by substituting NPEs with other alternative chemicals with similar properties. The restriction will likely not imply any significant investment in new production techniques or machinery. The assessment of alternatives to NPE indicates that there is already a range of alternatives available in the market and they are widely used in textile production. The most likely replacements for NPEs are various forms of alcohol ethoxylates and glucose based detergents. The alternatives to NPEs are generally shown to be comparable to NPE in terms of effectiveness as surfactants, however the prices for alternatives might be somewhat higher.

The cost of substituting NPEs with alternative surfactants is estimated to be minor in comparison to e.g. the total EU import value for textiles. However the costs of compliance control for EU importers and retailers might be considerable (estimated to roughly €44 to 81 million in the years 2020 to 2030) depending on how the actors in the textile supply chain react to the restriction. Though overall the costs impacts are not significant in relation to consumer's prices for the final textile article. The proposed restriction allows 5 years for compliance in order to minimize any costs impacts and allow smooth adaption for all concerned actors. The need for a transitional period of at least 5 years has been emphasized in stakeholder consultation since it is considered

essential for sufficient communication to occur among the range of actors in the textile supply chain.

The proposed restriction is formulated so that interpretation is facilitated for actors in the textile supply chain as well as for authorities responsible for enforcement, i.e. the restriction is expected to be enforceable and manageable. The proposed restriction sets a clear limit for the NP/NPE content in clothing and household textile articles, i.e. it is recognized that NP/NPE should not be found in the textile above the limit value. The emphasis is thus clearly on the textile material. A list of examples of clothing and household articles is given in order to clarify the scope of the restriction, and furthermore it is stated that the restriction shall only apply to those textile articles that can be washed in water. The wording of the restriction also makes clear that prints on the textiles articles mentioned are also subject to the limit value for NP/NPE. The restriction clearly defines what is meant by 'textile articles' by referring to the definition in Article 3.1 a-f of the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products. Furthermore the restriction refers to the standards adopted by the European Committee for Standardisation (CEN) to be used as test methods for demonstrating the conformity of the articles in question. This means that authorities will be provided with EU standard test methods that will be readily available in the market for laboratory analysis services before entering into force of the proposed restriction. the groups of substances that are covered by the restriction are defined and is deliberately made so that various possible variations of the molecular structure of the substances (NP and NPE) are covered which will facilitate supervision as there are no exceptions defined. Finally the proposed restriction allows sufficient time for the actors in the supply chain to adapt to the restriction and thus to deplete any stocks of textiles that could contain NPE concentrations above the proposed limit.

F. Socio-economic Assessment of Proposed Restriction

F.1 Human health and environmental impacts

The causal relationship between NP/NPE emissions to and concentrations in the environment may not always be direct. Nonetheless in section E.2.1.1 it is assumed that the reduction in NP/NPE emissions to the environment serves as a good proxy for estimating the reduction in environmental concentrations and hence reduction in risk. Thus the reduction in releases of NP/NPE to the environment is expected to reduce concentrations of NP/NPE in the water environment.

The proposed restriction is expected to reduce the mean concentrations of NP/NPE in textile articles to approximately 30 mg/kg, i.e. about 73% lower in the year 2020 compared to the estimated 107 mg NP/NPE per kg textile in the reference year 2010. Compared to the estimated total emission of NP/NPE to the environment (including all the assessed emission sources) the total annual NP/NPE emission reduction from textiles alone would constitute about 34% (as a result of the proposed restriction) of the total emission in 2010. Taking into account also the expected future trend in WWTP removal efficiency and connection rate and the trend in emissions from EU produced technical textiles and other sources than textiles, the total reduction of NP/NPE emissions to the water environment would be about 63% in the year 2020 compared to the estimated emissions in 2010. In other words the identified risk in the water environment should be radically reduced in the year 2020 compared to 2010, primarily because of the proposed restriction.

F.1.1 Human health impacts

As indicated in section B.10 a risk characterisation for human health is not accounted for in this targeted risk assessmentsince the risk has been assessed based on the environmental concerns, not for human health. However this topic might come under new discussion in coming years and thus there may be reason to reconsider the need for a human health risk assessment in the future. It is already recognized (see section B.5.9.5) that nonylphenol exposure over several generations can cause disruptions in the reproductive system of offspring which are compatible with the effects of exogenous estrogenic activity. Effects may be in terms of reduction in e.g. sperm count and sperm quality in males, and changes in the estrous cycle, timing of vaginal openings and ovarian weights in women. But human exposure to NP has so far not been shown to occur at such levels that would incur the abovementioned effects. However the United Kingdom has announced their intention to evaluate NP in 2014 as part of the Community Rolling Action Plan (CoRAP). The motives for the evaluation are said to be due to the concern that NP is a suspected endocrine disruptor with risk characterisation ratios close to 1 (human health).

Drawing from the above, it appears justified (however speculative) to at least mention the possibility that human health impacts might in fact occur. The type and extent of such possible impacts is not clear. But it could be argued that any impacts on the reproductive capacity of humans could indeed imply substantial negative impacts on individuals (in terms of physiological and psychological health) as well as costs to society (in terms of e.g. health care services related to reproductive health).

However, any concerns for human health from exposure to textiles containing NP/NPEO would most probably be alleviated by the risk reduction measures proposed on the basis of the environmental risk assessment. There could thus be benefits in terms of avoided human health impacts that are currently not possible to identify or quantify.

F.1.2 Environmental impacts

There is concern for nonylphenol in the aquatic compartment based on the following (see section B.10):

An assessment of the combined toxicity of nonylphenol ethoxylates, occurring in textiles, and their degradation products such as nonylphenol and nonylphenol ethoxycarboxylates has been included in this dossier since these substances emanate from textiles and will occur as mixtures in WWTP effluents and in the environment. Assessing the combined toxicity of these compounds, using Toxic Equivalency Factors and the pelagic freshwater monitoring database available, results in concern in 8 (RCR 1.1-17) to 12 (RCR 1.3-27) EU countries out of a total of 24 EU countries and Norway for which freshwater monitoring data is available, which corresponds to identified concern in 30 to 50 % of the countries. In relation to the assessment of combined toxicity of NP and NPE it is worth noting that:

- The proposed restriction will target NP and NPE in textile articles or articles containing textiles. The expected reduction in NP/NPE concentrations in textiles would thus not only achieve a reduction in NP concentrations in the water environment, but it would effectively reduce the concern for the combined toxicity of NP and NPE of various mixtures.
- Based on the assessment method applied in section B.10 (which indicates concern in 8-12 countries out of 24 EU countries), the expected reduction of NP/NPE emitted to the water environment in the proposed restriction scenario (roughly 63% reduction compared to the year 2010) would result in concern in about 2 to 4 EU countries, assuming that the emission reduction occurs in the same proportion across the whole Union. Note however that the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

Considering the current advancement of science and testing methodology for endocrine disruptors in general and the available data base for NP in particular it is questionable whether the available knowledge and evidence can be considered sufficient to establish appropriate assessment factors and safe levels for the environmental compartments assessed. Therefore, it is concluded that it is not possible in the quantitative assessment approach to determine which concentration should be regarded as safe for the environment. Thus, the assessment of the endocrine disrupting properties should be viewed in a qualitative manner rather than a quantitative manner. In relation to the endocrine disrupting properties of NP it is worth noting that:

- Under other circumstances, in particular if the restriction proposal had been based primarily on a standard risk assessment approach, one possibility would have been to follow the suggested environmental impact assessment method proposed by Verhoeven et al. (Verhoeven et al. 2012). According to this methodology toxicity data for NP (and for other substances that may replace NP/NPE) may be used to estimate a Species Sensitivity Distribution (SSD) which is then used to compute the Potentially Affected Fraction (PAF) of aquatic species at different concentrations of NP. The result of such a procedure would be an estimated impact in terms of the proportion of a generic assembly of species potentially affected by the predicted environmental concentrations of NP (and any alternative substance that is similarly assessed) in different policy scenarios. However considering the conclusion about NP being an endocrine disrupting substance and the uncertainties that make it impossible to quantitatively establish a safe level for the environmental compartments assessed, the abovementioned approach for assessing environmental impact would fail to identify and quantify the impact.
- As noted e.g. in The Weybridge+15 (1996-2011) report (European Environment Agency 2012) few studies link endocrine effects at the individual level to the population level, and there are no studies that address the ecological impacts of endocrine disrupters. It could thus be that populations of certain aquatic species (and potentially large parts of aquatic ecosystems in the EU) are affected negatively by NP but it has not yet been studied sufficiently.

In summary, the risk characterisation approach chosen in this dossier based on the assumption on lack of safe levels for the endocrine disrupting properties of NP/NPEO make it impossible to assess the environmental impact in quantitative terms and clearly the valuation of benefits cannot be performed based on current knowledge.

In addition to the (unquantified) reduction in environmental impacts within the Union, it should be recognized that the proposed restriction will likely also imply a significant reduction in emissions of NP/NPE in many textile manufacturing countries. The proposed restriction is expected to cause substitution of NPE currently used as a surfactant in textile manufacturing. Since the major share of textiles imported to the Union originate from countries with less well

developed environmental regulation and less effective sewage water treatment (if any), the environmental improvement in relative terms will likely be largest were textile articles destined for the Union are produced.

F.2 Economic impacts

F.2.1 Compliance costs

As indicated in section C.2.4 surfactants are used in the textile production process for certain functions, and changing the production technique does not appear to be a viable option to reduce the use (and subsequently concentration in textiles) of NPE. There are no indications that the production process would have to be altered to fit usage of alternatives to NPE. Neither is there any significant costs expected for EU producers of NPE that might be indirectly affected by the change in demand for NPE and alternative surfactants. As indicated by stakeholder consultation, Producers of NPE are generally believed to be able to shift production to e.g. alcohol ethoxylates or glucose based substances without major changes in the design of production equipment. Therefore the compliance costs that are described here cover:

- Substitution of NPE as detergent and emulsifier in textile production (for EU imported textiles)
- Compliance control by importers and retailers, i.e. testing of articles of textiles for NPE content.

F.2.1.1 Cost of substitution

As shown in section C there are a variety of possible alternatives to NPE in textiles production. Not all alternatives have been assessed in detail due to lack of comparative technical information. The assessment of alternatives shows that alcohol ethoxylates are the most likely alternative to NPE as detergents in textiles, and owing to the substantial current use of AE there is technical information available on which to assess substitution costs.

The effectiveness of the alternatives compared to NPE varies depending on the use in question (further discussed in section C.2.4). Thus there might be certain uses where AE is less efficient than NPE and vice versa. However the general conclusion is that AE (and glucose based) detergents are comparable with NPE in terms of characteristics essential to a detergent (Posner 2012). Drawing from this, substituting NPE with alterantive detergents would imply no significant change in the quantity of detergents used in textile production.

The prices of the alternatives to NPE also vary considerably depending on e.g. the chemical supplier and the business relation between the supplier and the customer. The volume purchased as well as contract (short/long term) might also affect prices. Comparable price ranges for some alternatives are summarized in Table 56 in section C.2.4. It seems reasonable to assume that the

price of the most cost-effective alternative would be somewhat higher than for NPE. Considering the future trend in prices there is no clear indication of neither upward nor downward price development of e.g. alcohol ethoxylates. However given the transitional period of 5 years in the proposed restriction, the price gap could potentially be reduced. It is nevertheless assumed, in line with AMEC (2012), that the price of alternatives (using alcohol ethoxylates as proxy) will be about 0-10% higher than for NPE throughout the scenario period 2010-2020. AMEC refer to consultation with industry when quoting an average price for NPEs of €2/kg, which would imply an average price difference of €0.1/kg for alternative surfactants compared to NPEs.

There is scarce information on the amounts of NPE used in textile production outside the EU. The application rate will likely differ considerably depending on type of textile material, dying procedures etc. The only information source found quoting a specific value for application rate of NPE in textiles production is the OECD Emission Scenario Document on textile finishing industry (OECD 2004). The emission scenario document suggests that, in dyeing and pre-treatment processes surfactants are used in a concentration of 2 g/L, and a typical liquor ratio in exhaust processes of 1:10, which would imply that 20 g surfactant per kg of textile are used. It is not clear if this estimate would also apply to textile production in general outside the EU, but it appears to be the best available estimate and is therefore used in calculation of the quantity of surfactants required in manufacturing.

Considering that NPE has already been replaced by other surfactants in many textile manufacturing activities outside the EU, an estimate of total surfactant use must be targeted on the share of EU imported textiles where NPE is intentionally applied in textile production. AMEC (2012) refer to consultation with Eurofins in doing a similar assessment and their estimate point to about 55% of EU imported textiles being produced with NPE as input chemical. the review of studies of NPE concentrations in textiles (section B.9.3.4.1) gives an indication of the share of textiles being imported to the EU that currently contain NPE concentrations above certain values. A simple assessment of the samples analysed indicates that:

- 35% of the textile articles contain NP/NPE at concentrations higher than 20 mg/kg textile
- 23% of the textile articles contain NP/NPE at concentrations higher than 50 mg/kg textile
- 19% of the textile articles contain NP/NPE at concentrations higher than 100 mg/kg textile

The above figures could provide a rough idea of the share of imported textiles that are likely produced with and without intentional use of NPE. Based on the comments received in stakeholder consultation, it could be argued that the share of textiles with NPE concentrations above 100 mg/kg should be understood as examples of intentional use of NPE in the manufacturing process. However such a strict interpretation may not be reliable considering e.g. the character of the data gathered in the review of studies. A reasonable assumption could be that 19-35% of the textile articles placed on the EU market would contain NPE from intentional uses during manufacture, which would account for a range of best to worst cases. This percentage range would thus give an indication that the use of alternative surfactants is already widespread,

as the remainder 65-81% (19-35%) of textile articles could be assumed to not contain (contain) intentionally added NPE. This estimate is based on best available information and is consistent with other parts of this restriction proposal and is therefore used in calculation of costs of substitution.

As indicated in section B.9.3.4 the quantity of EU imported textiles was about 6.04 million tonnes in 2010. Assuming a yearly growth rate of 2% (see section E.1.1.) in import quantity in the baseline scenario, the tonnage would be about 6.7 million tonnes in 2015 and 7.4 million tonnes in 2020.

The key assumptions for estimating substitution costs for NPE in imported textiles are thus:

- No significant difference in effectiveness of alternative surfactants compared to NPEs
- An average price difference of €0.1/kg surfactant (alternatives compared to NPEs)
- Surfactant input use of 20g per kg textile produced
- 19-35% of the (current) imported textile quantity is produced with intentional use of NPE as surfactant
- An EU imported quantity of textiles of 6.04 million tonnes in 2010, with yearly growth rate of 2% until the year 2020.

Combining the above assumptions, the quantity of NPE to be replaced by alternative surfactants would be about 23 000 to 42 000 tonnes in 2010, and 28 000 to 52 000 tonnes in 2020. This would imply an operational substitution cost of roughly €2.8 to 5.2 million in the year 2020. Similar to AMEC (2012) it is assumed that the cost of substitution for textiles producers outside the EU is fully passed on to EU importers. For illustrative purposes the cost of substitution may be compared to the total import value for clothing in the EU, reaching €61 billion in 2010 (Eurostat 2012), which shows that substitution costs in production would constitute roughly 0.005-0.09% of the import value.

F.2.1.3 Costs of compliance control

It is expected that the major cost to textile importers in the EU will be that for compliance control. The issue of assessing such costs is far from easy given the complexity of the textile industry (Kogg 2008) and it is not clear to what extent additional control efforts will actually be necessary, e.g. in terms of additional testing of NPE concentrations in imported textiles. The cost of compliance control is therefore based on several more or less well founded assumptions and qualitative reasoning that make the overall cost estimates subject to considerable uncertainties.

To begin with, it is recognised that specific restrictions at the EU level already exist for azocolourants (REACH Regulation 1907/2006/EC) and PCP (Directive 94/783/EC) in textiles. Thus procedures in the supply chain should already exist for providing and requesting information on compliance to chemical legislation. Similar to the Annex XV report on chromium

VI in leather articles (Danish Environmental Protection Agency 2012), it is estimated that there will be no extra costs of training, capacity building, development of systems for compliance control, etc. of the proposed restriction.

Based on AMEC's findings from consultation with testing laboratories (AMEC 2012) the cost would currently be about €200 per test for NPE in textiles. However AMEC comment this estimate as uncertain since stakeholders were of different opinion regarding who in the supply chain would absorb the extra cost of testing.

As described in section 9.1.1 there are several larger retailers that already require their suppliers to not intentionally use NPEs in textile production. Some companies include NPEs in their restricted substance lists (RSLs) and require documentation from suppliers demonstrating that the NPE concentrations are below certain limits. Spot testing is conducted either in the companies' own laboratories or by commercial test laboratories. Other companies rely on certification (e.g. the Bluesign, OEKO-TEX Standard). Most RSLs (as referred to above) and the Bluesign require NPE concentrations to be below 100 mg/kg while OEKO-TEX Standard 100 sets a NP limit of 100mg/kg and total nonylphenol(1-9)ethoxylate limit of 1000 mg/kg textile. Thus overall there are indications that many textile importers, but far from all, set requirements for NPE in textiles and also perform some kind of checks of NPE concentrations either in their own regime, by means of certification or by requiring suppliers to do tests. In such cases, testing for NPE is often done in concurrence with testing for other chemicals (as a test package) and the cost of each test may thus be reduced.

However no actors consulted during the preparation of this restriction proposal (including the consultation carried out by AMEC) have been able to provide any general statement on what test frequencies that might apply for NPE in textiles, and even less known is the possible increase in testing frequency following the proposed restriction. It is not surprising that textile importers and retailers are reluctant to reveal details of their testing regimes as it would not serve their interests to give such information to suppliers. In effect, revealing the testing frequency could give rise to moral hazard among suppliers in the textile supply chain, i.e. that e.g. textile suppliers would recognise the risk of getting caught with NP/NPE levels above the limit value would be low (hence low expected costs of non-compliance) and non-compliance could thus become more frequent.

The global supply chain for textiles can be very complicated and the production process for a piece of clothing may take place in several different countries with various sub-contractors involved. As indicated by e.g. Kogg (2008) EU importers or retailers often have limited direct contacts with sub-contractors in the supply chain and must generally rely on information from the first tier of their supply chain. Posner (2012) indicate that control by means of contractual agreements, communication and mutual confidence between buyer and supplier may sometimes reduce the need for testing to zero. But under some circumstances testing might be necessary, at

least during initial phases of contractual agreements, to ensure that suppliers live up to requirements in e.g. RSLs. This view is also indicated by the *AFIRM Supplier Toolkit* (AG Afirm Group, 2012) which provides guidance on how to begin to implement an RSL program. In Appendix C (*Model Brand Program Protocol for Testing clothing*) of the guidance it is suggested that analytical testing should be performed based on risk assessment with regards to the supplier, type of product, substances in question etc. Hence the appropriate frequency of analytical testing is determined on a case by case basis and cannot be known in advance for any particular textile article, and even less so for the whole market. Furthermore the buyer's position in the market, e.g. being a large or small importer in terms of value and quantity, may also affect the possibilities to require suppliers to follow certain standards (and impose sanctions if standards are not followed) with regards to chemical content in textiles.

In absence of clear information on testing frequency it is hence necessary to make certain assumptions based on best guesses. In doing so, it is worth mentioning some factors that might be important in determining the need for companies' own compliance checks:

1. The current occurrence of NPE in imported textiles and possible on-going spot testing performed by importers
2. Technical and economic feasibility to replace NPE as surfactant in textile production (the extra costs avoided if suppliers do not comply with requirements)
3. Business relations between EU importers and suppliers abroad, especially in terms of buyers power and contractual arrangements
4. Clarity in formulation of requirements and thus simplicity in communicating requirements concerning chemical content in textiles
5. The likelihood for textile suppliers outside the EU to be found not in compliance with the buyer's requirements (testing frequency by EU importers)
6. The likelihood for EU importers and retailers to be inspected by authorities (and independent parties) and possibly found to be not in compliance with regulation

If the above factors are assessed in relation to the proposed restriction, the following comments are worth mentioning:

1. Not all EU importers would have to increase the frequency of spot testing as they have already ensured that the imported textile articles do not contain NPE. As indicated above (based on the review of studies on NPE in textiles) roughly 19-35% of the tested textiles contained NPE concentrations above 20-100mg/kg, which would indicate that increased testing frequency would not be necessary for the major part of imported textiles that are currently well below the proposed restriction limit of 100mg/kg textile. Thus testing would only have to increase for about 19-35% of the textiles being imported to the EU.
2. There exist alternatives and the cost to substitute NPE in textile production is very small compared to the EU import value (roughly 0.005-0.09%). Thus there seems to be no significant reason why suppliers outside the EU would not comply with requirements set

out by buyers, i.e. the suppliers have little to gain (avoided extra production costs) by not complying.

3. An EU-restriction would impose the same requirement for NPE concentrations for all textiles destined to the EU market. The collective buyer's power of EU importers is considerable and will likely imply that suppliers accept the change in terms concerning usage of NPE. The proposed implementation time of 3 years will allow smooth adaption for textile producers in terms of e.g. chemical input purchases.
4. Unlike today, the proposed restriction will clearly define a general applicable concentration of NP/NPE that is dis-allowed in the final textile article put on the EU market. The clarity and unity in the imposed restriction will facilitate the formulation of contractual terms between buyers and suppliers and the requirements can be clearly communicated to sub-contractors by referring to EU legislation instead of a variety of voluntary requirements (RSLs, certification etc). Communication costs will thus be relatively low. The proposed implementation time of 5 years for the restriction would allow buyers to communicate the new requirements during regular business to business contacts and it is expected that essentially all relevant actors in the supply chain will be informed in due time for the restriction to become legally binding in the EU.
5. Even if the non-EU suppliers' risk of getting caught in spot testing would be very low, i.e. a low testing frequency by EU importers, the potential cost to the supplier could be considerable. Possible sanctions by the buyer could be non-payment, reductions in future payments, or other non-monetary types of sanctions. As an experiment for thought, a simplified calculation of risk (for the supplier being found non-compliant) and possible export value lost would indicate a break-even point[71] at test frequency of roughly 1 per 30 000 articles when compared to the extra production cost due to substitution of NPE with alternative surfactants.
6. The proposed restriction would make it possible for authorities across the EU to inspect and if necessary perform testing for NPE in textiles based on a common testing standard. Likewise the possibilities for other independent parties to do similar spot testing would be simplified. However it is not expected that the rate of inspection and testing of textiles will increase considerably. Rather it is expected that the proposed restriction will have a general deterring effect and that actors within the EU will comply. Even if the test frequency by inspection authorities (and others) would be low, the possible losses to retailers/importers could be substantial in terms of fines, loss in consumers' trust and goodwill etc.

[71] The break-even point is computed by assuming a weight of 500kg for each batch of clothes exported to the EU, a total of 5.4 million tonnes clothing and a total EU import value of €62.5 billion in 2010 (Eurostat 2012, CN codes 61+62). The average export value (assumed same as import value) per batch would then be €5800. If the test frequency is 1 per 30000 articles the exporter would risk loosing 0,00017*€5800=€1. This would be the same value as the extra cost of substituting NPE with alterantive surfactants for 500kg of clothes produced.

In summary it would thus seem reasonable to assume the companies' own efforts in testing for NPE in textiles to be relatively minor. The time allowed for adjusting to the proposed restriction would allow buyers to inform suppliers, and the cost of substituting NPE with alternatives will be insignificant. Testing will likely be used primarily by those importers and retailers that clearly lack confidence in their suppliers abroad (concerning NPE in textiles). Over time it is expected that the need for such testing will eventually be further reduced as the restriction becomes fully known and producers' practises adapt.

Based on the above discussion a rough estimate of potential costs of compliance control may be estimated by assuming:

- The cost of testing for NPE to be €200 per test,
- The testing frequency by EU importers and retailers to be 1 per 30 000 articles in the first year after the restriction becomes legally binding (5 years after entry into force of the restriction). This testing frequency is assumed to apply to 19-35% of the imported quantity of textiles.
- The testing frequency will then be reduced to 1 per 100 000 in subsequent years 2016-2020. This testing frequency is assumed to apply to 19-35% of the imported quantity of textiles.
- The typical weight per item of clothing to be 0.15kg, similar to AMEC (2012), meaning that a total of about 40 billion pieces of clothing were imported in 2010
- The one-off cost of testing in the first year following the restriction is assumed is to be amortised over a 10 year period, similar to AMEC (2012). The testing costs during subsequent years are counted as operational costs, gradually increasing as growth in import quantity is expected.

The above assumptions would result in a total annualised cost €41 to 76 million in 2020. The cost of testing for NPE would thus constitute roughly 0.05 to 0.1% of the total EU import value of clothing and textiles considered in this restriction proposal. Clearly this cost estimate is very uncertain due to the range of assumptions made. The actual cost of compliance control may become considerably larger if EU importers/retailers use spot testing as their primary tool for compliance control. On the other hand the need for compliance checks by EU importers might also be gradually phased out as the use of alternative surfactants become generally acceptable, meaning that the cost of testing would diminish over time.

It is important to note also that, based on the cost estimates above, the impact on consumer prices would be lower than the impact on import price, since there is generally a considerable price mark-up from import price to the final retail stage in the EU. For illustrative purposes, similar to AMEC (2012), the table below shows an indication of the relative price impact on articles due to costs of compliance control, taking into account possible variations in testing frequency for NPE in textile articles.

Table 61. Relative impact of test frequency on the price of textile articles

Test frequency	Relative impact on the price of articles in %*	
	Average price of articles: €15	**Average price of articles: €100**
1 per 100 articles	13%	2%
1 per 1,000 articles	1.33%	0.2%
1 per 10,000 articles	0.13%	0.02%
1 per 30,000 articles (assumed for first year)	0.044%	0.007%
1 per 100,000 articles (assumed for subsequent years)	0.013%	0.002%

*Note that the percentages in the table only apply to the articles that require additional testing of NPE compared to the current frequency of testing, i.e. there should not be any impact on the price of the estimated 50% of imported articles that are likely already well in compliance with the proposed restriction.

F.2.2 Total costs impacts

Based on the cost estimates described above it is clear that the bulk of total cost impacts will probably consist of compliance control for textiles that are imported to the EU, estimated to about €41 to 76 million in 2020. These costs will be shared among a large number of EU importers of textiles. The total number of textile importers in the EU is estimated to around 56 000 by AMEC (2012), but not all companies are expected to increase the testing frequency for NPE following the proposed restriction. The cost to each company is estimated to be proportional to the quantity of textiles imported, i.e. that the cost impacts will be fairly proportional for small and large companies. However as indicated by comments given in stakeholder consultation many of the smaller importers are less likely to currently check for the presence of NPEs in textiles, which could mean that the cost impact might become relatively more significant for those companies.

The cost of substitution of NPE in imported textiles is estimated to roughly €2.8 to 5.2 million in the year 2020. It is assumed that the cost of substitution for textiles producers outside the EU is fully passed on to EU importers. Overall this cost impact is considered to be small in relative terms, constituting roughly 0.005-0.09% of the EU import value for clothing. The cost of substitution will only be borne by those importers that currently import textiles with NPE concentrations above the limit value in the proposed restriction, i.e. less than 19-35% of the quantity of imported textiles.

The total cost impacts amount to an annualised cost of about € 44 to 81 million in 2020. Roughly the same annualised cost will be incurred in the following 10 years after 2020.

It is expected that the main cost impacts will occur starting from the year when the proposed restriction becomes effective, i.e. in the year 2020. However the actors affected by the restriction will likely gradually adapt to the new regulation and the cost impacts would therefore start to occur before 2020. This simplified assumption about the actors' gradual adaption would imply a linear increase in annualised costs impacts from 2015-2020. It is also important to mention that the cost impacts in the long term (after 2020) have not been assessed in any detail. It is very difficult to foresee the developments within the textile business and it could be that costs, in particular costs of compliance control, are substantially reduced over time.

F.3 Social impacts

No significant social impacts are expected due to the proposed restriction, since:

- The cost impacts are likely spread among a large number of actors in the textile supply chain and costs are relatively minor in comparison to the total value of the textiles imported to- or manufactured in the EU.
- The cost to EU manufacturers, importers and retailers is expected to be passed on to consumers but then showing even less significant impacts on consumer prices.

F.4 Wider economic impacts

No major wider economic impacts are expected due to the proposed restriction. However it may be mentioned that:

- The costs impacts of the restriction will only marginally affect actors in the textile supply chain
- The current EU regulation on NP/NPE in textile manufacturing only concerns EU producers which may imply certain competitive disadvantages vis-à-vis non-EU manufacturers of textiles. The proposed limit value of 100 mg/kg textile would, according to comments received in stakeholder consultation, not conflict with the current REACH (Regulation No 1907/2006/EC) Annex XVII Entry 46on NP/NPE that applies to manufacturing in the EU. Textile production in the EU should thus not be significantly affected and the restriction would imply a level playing field for textile manufacturers situated within the Union as well as abroad.

F.5 Distributional impacts

No significant distributional impacts are expected due to the proposed restriction.

F.6 Main assumptions used and decisions made during analysis

Main assumptions are discussed throughout the sections above.

F.7 Uncertainties

Major uncertainties are discussed throughout the sections above.

F.8 Summary of the socio-economic impacts

The proposed restriction is expected to reduce the mean concentrations of NP/NPE in textile articles to roughly 29 mg/kg, i.e. about 73% lower in the year 2020 compared to the estimated 107 mg NP/NPE per kg textile in the reference year 2010. Compared to the estimated total emission of NP/NPE to the environment (including all the assessed emission sources) the total annual NP/NPE emission reduction from textiles alone would constitute about 34% (as a result of the proposed restriction) of the total emission in 2010. Taking into account also the expected future trend in WWTP removal efficiency and connection rate and the trend in emissions from EU produced technical textiles and other sources than textiles, the total reduction of NP/NPE emissions to the water environment would be about 63% in the year 2020 compared to the estimated emissions in 2010. In other words the identified risk in the water environment should be radically reduced in the year 2020 compared to 2010, primarily because of the proposed restriction.

Nonylphenol is expected to exert its toxicity in combination with nonylphenol ethoxylates and nonylphenol ethoxycarboxylates since they typically exist together as mixtures in WWTP effluents and in the environment. In relation to this it is worth noting that:

- The proposed restriction will target NP and NPE in textile articles or articles containing textiles and thus it would effectively reduce the concern for the combined toxicity of NP and NPE of various mixtures.
- Based on the method applied in section B.10 (which indicates concern in about 8-12 countries out of 24 EU countries), the expected reduction of NP/NPE emitted to the water environment in the proposed restriction scenario (roughly 63% reduction compared to the year 2010) would result in concern in about 2 to 4 EU countries, assuming that the emission reduction occurs in the same proportion across the whole Union. However the levels of concern identified (when taking the combined exposure toxicity into account) should only be regarded as an estimate of minimum toxicity levels as they do not sufficiently take the ED properties of nonylphenol into account.

NP is an endocrine disrupting substance and it is therefore uncertain whether the current advancement of science and testing methodology in general and the available data base for NP in particular is sufficient to establish safe levels for the environmental compartments assessed. At the present state of knowledge, we therefore suggest to handle nonylphenol as a substance for

which there exists no safe level. In relation to the endocrine disrupting properties of NP it is worth noting that:

- Under other circumstances, in particular if the restriction proposal had been based primarily on a standard risk assessment approach, one possibility would have been to follow the suggested environmental impact assessment method proposed by Verhoeven et al. (Verhoeven et al. 2012). However considering the conclusion about NP being an endocrine disrupting substance and the uncertainties that make it impossible to establish a safe level for the environmental compartments assessed, the abovementioned approach for assessing environmental impact would fail to identify and quantify the impact.
- As noted e.g. in The Weybridge+15 (1996-2011) report (European Environment Agency 2012) few studies link endocrine effects at the individual level to the population level, and there are no studies that address the ecological impacts of endocrine disrupters. It could thus be that populations of certain aquatic species (and potentially large parts of aquatic ecosystems in the EU) are affected negatively by NP but it has not yet been studied sufficiently.

In summary, the above indications make it impossible to assess the environmental impact in quantitative terms and clearly the valuation of benefits cannot be performed based on current knowledge.

The costs impacts of the proposed restriction are expected to consist primarily of compliance control costs (to EU importers and retailers) and substitution costs (to non-EU producers that supply textiles to the EU market). The total costs impacts are estimated to € 44 to 81 million in 2020 per year in the years 2020-2030. The cost estimates are subject to considerable uncertainty. Several of the underlying assumptions are based on reasoning and best guesses. The most important factor determining the size of costs impacts is likely the frequency of testing for NP/NPE in textiles, as carried out by actors in the textile supply chain to ensure compliance.

The net benefit of the proposed restriction has not been estimated since the benefit in terms of reduced environmental impact has not been quantified.

G. Stakeholder consultation

G.1 Stakeholder meeting at the Swedish Chemicals Agency

In December 2011 the Swedish Chemicals Agency invited Swedish stakeholders to a meeting with the aim to gather information. A questionnaire including the following issues was sent together with the invitation:

- Function(s) of NP/NPE in the manufacturing of textiles

- Content of NP/NPE in the textiles at delivery
- Possibilities for control and to ensure a limit value in a restriction
- Test methods to be used to ensure compliance
- Expected business impact of a restriction depending on the limit value of NP/NPE
- Alternatives in use or planned
- The impact on production cost and quality of the textile

The stakeholders represented textile importers, companies with experience from analyses of NP/NPE in textiles and waste water treatment plants (Stockholm Water).

Information gathered from the meeting has been taken into account in section C, E and F in the dossier.

G.2 Industry

G.2.1 Actors within the EU

AMEC

In the context of the European Chemicals Agency´s (ECHA) project on "abatement costs for certain hazardous chemicals", a stakeholder consultation was undertaken by the consulting company AMEC Environment & Infrastructure UK Limited. A questionnaire, which was developed in collaboration with ECHA and the Swedish Chemicals Agency[72], was sent to:

- manufacturers, formulators and importers using NP/NPE and their trade organisations
- European textile producers using NP/NPE or alternatives
- European textile importers and retailers
- Key trade associations representing textile industry

The questionnaire (AMEC, 2012, Appendix A) asked for information on EU production, import and export of NP/NPEs as well as current use (and trend in use) of the NPEs in textile industries. Textile producers, retailers, importers and trade associations representing the textile industry were also asked about the possibilities to reduce or replace the use of NPEs in textile production, such as technical and economic aspects of substitution as well as experiences from monitoring NPE content in textiles.

Of the in total 41 organisations that were contacted 24 organisations provided information, but only 2 organisations returned a completed questionnaire (AMEC 2012, Appendix B). Information was also provided from the Swedish Chemicals Agency and the Anglo-Welsh Environment Agency.

[72] The Swedish Chemicals Agency was invited to collaborate with ECHA in the planning and performing of the project on NP/NPEs.

The result from the data collection made by AMEC has been taking into account in section B, C, E and F in the dossier.

Others
In order to obtain information on alternatives two European trade organisations; TEGEWA (German association of textile auxiliaries suppliers), CEPAD (European Council for Alkylphenols and Derivatives) and two producers of chemicals (Akzo Nobel and PulcraChemicals) were contacted and provided information on the following issuses:

- Alternatives to NPE in the functions as detergent and emulsifier
- Avalibility, price and effectiviness of alternatives compared to NPE

Also other suppliers of chemicals as DOW, BASF, Rhodia and Huntsman were contacted in the same issues but no response was received.

Questionnaire concerning feasibility issues in an EU-wide restriction on NPE in textile articles
An extended stakeholder consultation with the aim to obtain more information on the definition of textile articles, the scope of the restriction and a feasible concentration limit value for NPE within a suggested transitional period was carried through. A questionnaire was established and distributed to 17 European trade organisations, 8 Swedish companies and their European networks and 4 companies carrying out textile analyses. The questionnaire was also sent to "Roadmap to zero[73]", Greenpeace and Afirm[74]. The questionnaire is published in Annex 6 and the send list is published in Annex 7.

Of the organisations/companies contacted, a completed questionnaire was returned from 8 of them. The organisations/companies which have responded to the questionnaire represent European trade organisations, members of the Affirm network, Swedish companies, and a company carrying out analyses of chemicals in textile articles. Contributions from the consultation have been taking into account (see section B, E and F in the dossier) in the establishment of a:

- proposed limit value for NP/NPE in the textile article not being in conflict with the current restriction of NPE/NPE set out in REACH Annex XVII, Entry 46 in
- a proposed appropriate transitional period

[73] A group of major apparel and footwear brands and retailers made a shared commitment to help lead the industry towards zero discharge of hazardous chemicals by 2020.
[74] Apparel & Footwear International RSL Management Group

Study trip to Akzo Nobel and two textile producers in Sweden
In December 2011, three members of the NP/NPE restriction dossier group went on a study trip to the Akzo Nobel production site in Stenungsund, Sweden. The aim of the trip was to learn about the production of NPE and to obtain adjacent information concerning NPE. Examples of questions asked: how much NPE can be produced, what happens to the produced NPE, is Akzo Nobel producing alternatives to NPE and what are the alternatives? It was also important to create contacts for the further work with the dossier, which subsequently have been very useful.

Two members of the restriction dossier group continued to two textile manufactures in Sweden; ludvig svensson and Almedahls, both located in Kinna. The aim of these study trips was to learn how the textile process works and to ask questions on textile production. Area topics discussed were for example: their work with chemical issues, how they prevent problems with chemicals, where problems in textile making may occur and questions concerning alternatives to NPE.

G.2.2 Request for Information from Member States and EEA

In September 2011 Sweden published a questionnaire at CIRCABC with the aim to gather information on:

- Import of textile (and leather articles) and analytical methods
- Alternatives in use
- National risk management measures and monitoring programs
- Unpublished information on hazards, risks and exposure
- Estimated contributions to the occurrence in the environment from derogated uses in the current restrictions in REACH Annex XVII
- Industry stakeholders

Information was provided from Slovakia, the Netherlands, Spain, Germany and the United Kingdom.

G.3 Actors outside the EU

NIMKARTEK Technical Services Pvt. Ltd, established in India, was invited to the Swedish Chemical Agency with the aim to discuss and collect information on issues related to the use of NPE in the manufacturing of textiles in India. NIMARTEK among others conduct training programs for textile suppliers. On the agenda for discussing were suitable alternatives, technical and economic feasible limit value which also ensures a margin between intentionally and unintentionally added NPE to the textile, transitional period, compliance cost and the definition of technical textiles. The outcome of the discussion has been taken into account in section C, E and F in the dossier

H. Other information

No additional information included.

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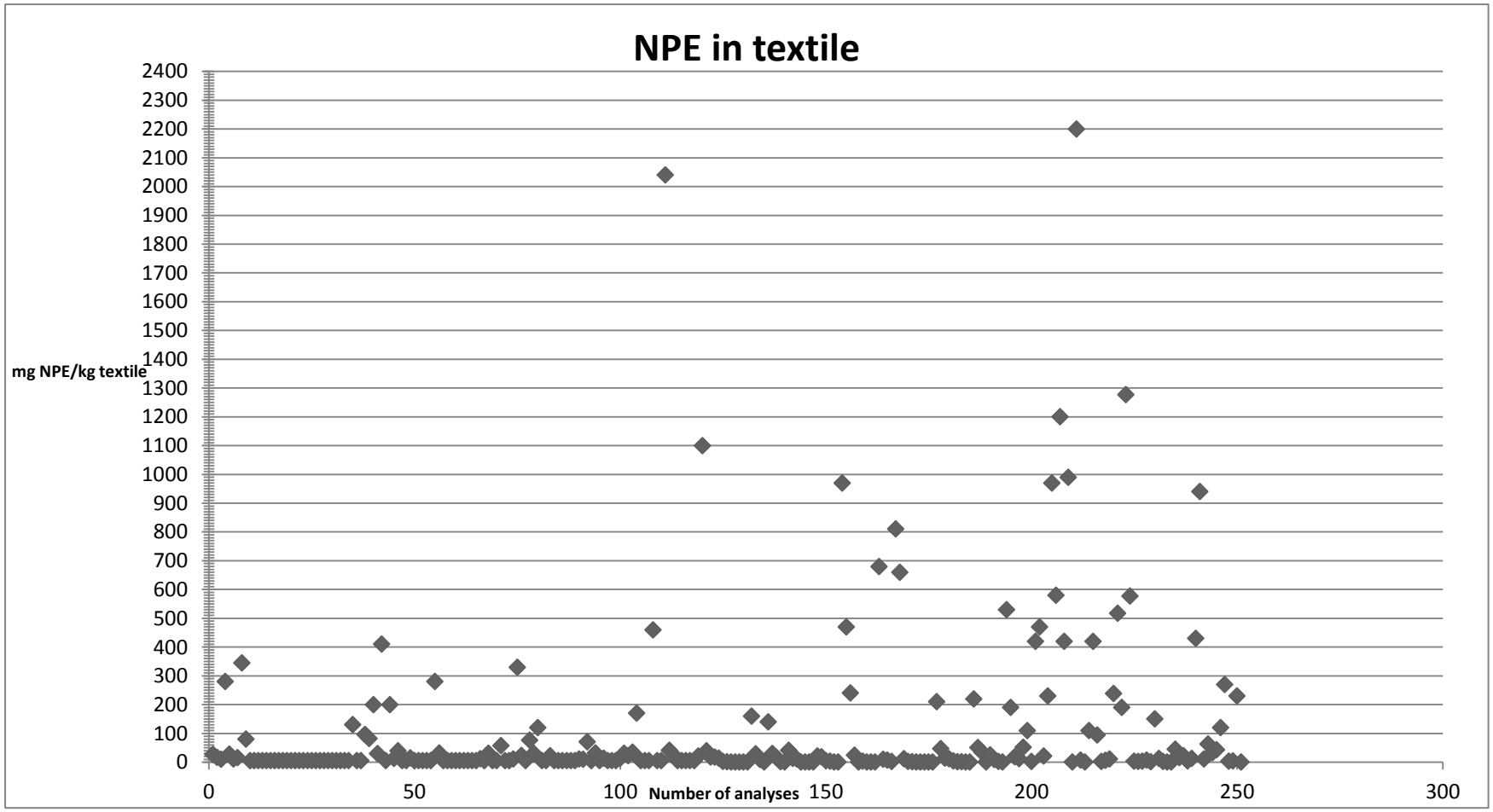
Annex 1 NPE concentrations in textiles (from 7 reviewed studies)



Annex 2 Release rates for NP, NPE and other NP derivatives

Release rates for different general release scenarios for nonylphenol (NP), nonylphenol ethoxylates (NPE) and other nonylphenol derivatives (NP-der.) applied to data from the Swedish product register (KemI 2012).

ERC	ERC No.	ERC mod.	Scenario	Release rate (fraction)	Chemical group
Formulation of mixtures	2	modified	Hardener for paint, solvent based	0.0001	NP
Formulation of mixtures	2	modified	Pharmaceutical additive, water based	0.01	NP-der.
Formulation of mixtures	2	modified	Paint/Printing ink/Adhesive, solvent free or solvent based	0.01	NP, NP-der.
Formulation of mixtures	2	default	Casting agent	0.02	NP
Formulation of mixtures	2	default	Plastic/Paint/Sealant/Adhesive/Oil/Cleaning agent, partly water based	0.02	NPE, NP-der.
Industrial use of processing aids	4	modified	Printing ink, solvent free +cleaning losses	0.005	NP-der.
Industrial use of processing aids	4	modified	Paint/Printing ink, coloring + solvents/cleaning losses	0.02	NP-der.
Industrial use of processing aids	4	modified	Plastic +H_2Osolu.	0.02	NPEO
Industrial use of processing aids	4	modified	Surface active agent/Paint/Cutting oil + H2Osolu. + cleaning losses	0.05	NPEO
Industrial inclusion into or onto a matrix	5	modified	Plastic, inclusion into matrix (plastic)	0.01	NP, NPE, NP-der.
Industrial use of auxiliaries for polymerization	6d	default	Plastic, auxiliaries for polymerization	0.00005	NPE, NP-der.
Industrial use of substances in closed systems	7	modified	Motor oil, system processing + cleaning losses	0.02	NPE
Industrial use of substances in closed systems	7	default	Oil/Metal surface treatment agent, system processing agent	0.05	NPE, NP-der.
Wide dispersive indoor use of processing aids, open	8a	modified	Glue/Lubricant/Hydraulic oil etc. + cleaning losses	0.005	NP-der.
Wide dispersive indoor use of processing aids, open	8a	modified	Paint/Glue/Sealant, ? based + cleaning losses	0.01	NP,NPE,NP-der.
Wide dispersive indoor use of processing aids, open	8a	modified	Paint, water based +cleaning losses	0.02	NPE, NP-der.
Wide dispersive indoor use of processing aids, open	8a	modified	Glue, water based + cleaning losses	0.05	NPE, NP-der.
Wide dispersive indoor use of processing aids, open	8a	modified	Anticorrosion agent, partly indoor	0.05	NPE
Wide dispersive indoor use of processing aids, open	8a	modified	Cleaning agent, partly outdoor	0.5	NPE
Wide dispersive indoor use of processing aids, open	8a	modified	Cleaning agent	0.9	NPE, NP-der.
Wide dispersive indoor use of processing aids, open	8a	modified	Pharmaceutical additive, use, water based	0.9	NP-der.
Wide dispersive indoor use of reactive substances , open	8b	default	Casting agent	0.02	NP
Wide dispersive indoor use, inclusion into or onto a matrix	8c	default	Hardener for paint, private/professional uses	0.01	NP-der.
Wide dispersive indoor use, inclusion into or onto a matrix	8c	default	Plastic, construction material +cleaning of dust & equipment's	0.01	NPE
Wide dispersive outdoor use of reactive substances, open	8e	modified	Reactive processing agent, outdoor-partly connected to STP	0.005	NPE
Wide dispersive indoor use in closed systems	9a	modified	Lubricant/Fuel additive, end use, partly indoor	0.01	NPE, NP-der.
Wide dispersive indoor use of long-life articles, low release	11a	default	Plastic	0.0005	NPE, NP-der.
Wide dispersive indoor use of long-life articles, low release	11a	modified	Adhesive/Plastic + wear	0.001	NP-der., NP
Wide dispersive indoor use of long-life articles, low release	11a	modified	Paint/Printing ink/Adhesive + film + wear	0.005	NP, NP-der.
Wide dispersive indoor use of long-life articles, low release	11a	modified	Plastic/Adhesive/Sealant + H2Osolu. + wear	0.01	NPE, NP-der.
Wide dispersive indoor use of long-life articles, low release	11a	modified	Paint/Plastic/Adhesive/Putty + H2Osolu. + film + wear	0.05	NPE, NP-der.
Industrial processing of articles with abrasive techniques (no release)	12b	modified	Stripping of surface coating + film, partly indoor	0.5	NPE

Annex 3 Release rates for dfifferent uses sectors

Release rates for different combinations of product types and sector of uses for the uses of nonylphenol and relevant derivatives to waste water before STP (Sweden 2009). (data source: The Swedish Product register, KemI 2012).

Product Category	Sector of Use	ERC	Release rate **(fraction)**	Chemical group
Adhesive, curing agent for industrial use	Construction industry	11a mod.	0.001	NP
Adhesive, curing agent for industrial use	Construction industry	8a mod.	0.01	NP
Adhesive, solvent free for industrial use	Industry for pulp, paper and paper products	11a mod.	0.005	NP-der.
Adhesive, solvent free for industrial use	Industry for pulp, paper and paper products	2 mod.	0.01	NP-der.
Adhesive, water based for consumer use	Construction industry	11a mod.	0.01	NPE
Adhesive, water based for consumer use	Construction industry	8a mod.	0.05	NPE
Adhesive, water based for consumer use	Industry for glues	11a mod.	0.01	NP-der.
Adhesive, water based for consumer use	Industry for glues	2	0.02	NP-der.
Adhesive, water based for consumer use	Industry for glues	8a mod.	0.05	NP-der.
Adhesive, water based for industrial use	Construction industry	11a mod.	0.01	NP-der.
Adhesive, water based for industrial use	Construction industry	2	0.02	NP-der.
Adhesive, water based for industrial use	Construction industry	8a mod.	0.05	NP-der.
Adhesive, water based for industrial use	Industry for pulp, paper and paper products	11a mod.	0.01	NP-der.
Adhesive, water based for industrial use	Industry for pulp, paper and paper products	11a mod.	0.05	NPE
Adhesive, water based for industrial use	Industry for pulp, paper and paper products	2	0.02	NP-der.
Adhesive, water based for industrial use	Industry for pulp, paper and paper products	2	0.02	NPE
Adhesive, water based for industrial use	Industry for wood and products of wood	11a mod.	0.01	NPE
Adhesive, water based for industrial use	Industry for wood and products of wood	8a mod.	0.05	NPE
Adhesive, water based for industrial use	Surface treatment and coating of metals	11a mod.	0.01	NPE
Adhesive, water based for industrial use	Surface treatment and coating of metals	2	0.02	NPE
Base oils	Industry for fabricated metal products	2	0.02	NP-der.
Base oils	Industry for fabricated metal products	7	0.05	NP-der.
Base oils	Tanneries; industry for leather goods	7	0.05	NPE
Binders for paints, adhesives	Industry for dyes and pigments	2	0.02	NPE
Binders for paints, adhesives	Industry for glues	11a mod.	0.05	NP-der.
Binders for paints, adhesives	Industry for glues	11a mod.	0.05	NPE
Binders for paints, adhesives	Industry for glues	2	0.02	NPE
Binders for paints, adhesives	Industry for glues	8a mod.	0.005	NP-der.
Binders for paints, adhesives	Paint industry	11a mod.	0.005	NP-der.
Binders for paints, adhesives	Paint industry	11a mod.	0.05	NPE
Binders for paints, adhesives	Paint industry	2	0.02	NP-der.
Binders for paints, adhesives	Paint industry	2	0.02	NPE
Binders for paints, adhesives	Paint industry	8a mod.	0.01	NP-der.
Binders, other than these intended for sand, paint, adhesives	Paint industry	11a mod.	0.05	NP-der.
Binders, other than these intended for sand, paint, adhesives	Paint industry	8a mod.	0.02	NP-der.
Blowing agents (plastics, rubber etc.)	Industry for plastics in primary forms	11a mod.	0.001	NP-der.
Blowing agents (plastics, rubber etc.)	Industry for plastics in primary forms	5 mod.	0.01	NP-der.
Car shampoo	Retail sale, except for such with motor vehicles	8a mod.	0.5	NPE

Cast compounds	Industry for stone products	2	0.02	NP
Cast compounds	Industry for stone products	8b	0.02	NP
Catalysts	Industry for plastic products	11a	0.0005	NP-der.
Catalysts	Industry for plastic products	2	0.02	NP-der.
Catalysts	Industry for plastic products	6d	0.00005	NP-der.
Cleaner, others	Jeweler’s shop	8a mod.	0.9	NPE
Cleaner, others	Sale, maintenance and repair of motor vehicles	2	0.02	NPEO
Cleaner, others	Sale, maintenance and repair of motor vehicles	8a mod.	0.9	NPE
Cleaner, others	Services	8a mod.	0.9	NPE
Curing agent for plastics	Industry for plastic products	11a mod.	0.01	NPE
Curing agent for plastics	Industry for plastic products	8c	0.01	NPE
Cutting oil	Sale, maintenance and repair of motor vehicles	4 mod.	0.9	NPE
Degreasing agents	Industry for fabricated metal products	2	0.02	NPE
Degreasing agents	Industry for fabricated metal products	8a mod.	0.9	NPE
Degreasing agents	Wholesale of chemical products	2	0.02	NPE
Degreasing agents	Wholesale of chemical products	8a mod.	0.9	NPE
Dyestuffs	Manufacture of textiles, paints, wood products	11a mod.	0.005	NP-der.
Dyestuffs	Manufacture of textiles, paints, wood products	4 mod.	0.02	NP-der.
Electroplating agents, other	Surface treatment and coating of metals	7	0.05	NP-der.
Emulsifiers	Industry for cleaning and polishing preparations	8a mod.	0.9	NP-der.
Emulsifiers	Industry for glues	11a mod.	0.01	NP-der.
Emulsifiers	Industry for glues	2	0.02	NP-der.
Emulsifiers	Industry for glues	2	0.02	NPE
Emulsifiers	Industry for medical, precision and optical instruments	8a mod.	0.9	NP-der.
Emulsifiers	Industry for pharmaceutical preparations	2 mod.	0.002	NP-der.
Emulsifiers	Industry for pharmaceutical preparations	8a mod.	0.9	NP-der.
Explosives	Construction industry+Mines and quarries+Industry for stone products	8e mod.	0.005	NPE
Filling, filler	Construction industry	11a mod.	0.001	NP-der.
Filling, filler	Construction industry	2	0.02	NP-der.
Filling, filler	Construction industry	6d	0.00005	NP-der.
Friction reducing agents	Paint industry	11a mod.	0.05	NPE
Friction reducing agents	Paint industry	2	0.02	NPE
Fuel additives, others	Production of other chemical products but synthetic fibers	2	0.02	NP-der.
Fuel additives, others	Production of other chemical products but synthetic fibers	9a/9b mod.	0.01	NP-der.
Hardeners, others	Paint industry	11a mod.	0.005	NP-der.
Hardeners, others	Paint industry	11a mod.	0.05	NPE
Hardeners, others	Paint industry	2	0.02	NP-der.
Hardeners, others	Paint industry	4 mod.	0.05	NPE
Hardeners, others	Paint industry	8c mod.	0.01	NP-der.
Heat stabilizer	Industry for plastic products	2	0.02	NP-der.
Insulating materials, heat-cold	Construction industry	11a mod.	0.05	NPE
Insulating materials, heat-cold	Construction industry	8c	0.01	NPE
Lubricants, other+Motor oil	Petrol stations+Maintenance and repair garages for motor vehicles	9a mod.	0.01	NP-der.
Lubricants, Rust removing agents, Base oils, hydraulic oil, Fuel additives, Coolants and lubricants for metal processing	Several ind. sectors	2	0.02	NP-der.
Lubricants, Rust removing agents, Base oils, hydraulic oil, Fuel additives, Coolants and lubricants for metal processing	Several ind. sectors	8a mod.	0.005	NP-der.

Metal surface treatment agents, others	Surface treatment and coating of metals	7	0.05	NPE
Motor oil	Retail sale, except for such with motor vehicles	7 mod.	0.02	NPE
Motor oil	Retail sale, except for such with motor vehicles	9a mod.	0.01	NPE
Multi-purpose cleaners	Manufacture of food products	8a mod.	0.9	NPE
Multi-purpose cleaners	Manufacture of food products	2	0.02	NPE
Paint, curing paint for other use	Construction industry	11a mod.	0.005	NP
Paint, curing paint for other use	Construction industry	8a mod.	0.01	NP
Paint, curing paint with anti-corrosive effect for other use	Industry for fabricated metal products	11a mod.	0.005	NP
Paint, curing paint with anti-corrosive effect for other use	Industry for fabricated metal products	8a mod.	0.01	NP
Paint, other curing paint for interior use	Construction industry	11a mod.	0.005	NP
Paint, other curing paint for interior use	Construction industry	8a mod.	0.01	NP
Paint, other curing paint for interior use	Paint shop + Industry for fabricated metal products	11a mod.	0.05	NPE
Paint, other curing paint for interior use	Paint shop + Industry for fabricated metal products	8a mod.	0.01	NPE
Paint, other solvent free for interior use	Construction industry	11a mod.	0.005	NP
Paint, other solvent free for interior use	Construction industry	8a mod.	0.01	NP
Paint, other water based for exterior use	Construction industry	2	0.02	NPE
Paint, other water based for exterior use	Construction industry	8a mod.	0.02	NPE
Paint, other water based for exterior use	Paint shop	2	0.02	NP-der.
Paint, other water based for exterior use	Paint shop	2	0.02	NPE
Paint, other water based for exterior use	Paint shop	8a mod.	0.02	NP-der.
Paint, other water based for exterior use	Paint shop	8a mod.	0.02	NPE
Paint, other water based for industrial use	Industry for wood and products of wood	11a mod.	0.005	NP-der.
Paint, other water based for industrial use	Industry for wood and products of wood	2	0.02	NP-der.
Paint, other water based for industrial use	Industry for wood and products of wood	8a mod.	0.02	NP-der.
Paint, other water based for interior use	Paint shop	11a mod.	0.005	NP-der.
Paint, other water based for interior use	Paint shop	11a mod.	0.05	NPE
Paint, other water based for interior use	Paint shop	2	0.02	NP-der.
Paint, other water based for interior use	Paint shop	8a mod.	0.02	NP-der.
Paint, other water based for interior use	Paint shop	8a mod.	0.02	NPE
Paint, other water based paint	Services	11a mod.	0.05	NPE
Paint, other water based paint	Services	8a mod.	0.02	NPE
Paint, solvent based anti-corrosive for industrial use	Surface treatment and coating of metals	11a mod.	0.005	NP
Paint, solvent based anti-corrosive for industrial use	Surface treatment and coating of metals	11a mod.	0.05	NP-der.
Paint, solvent based anti-corrosive for industrial use	Surface treatment and coating of metals	2 mod.	0.0001	NP
Paint, solvent based anti-corrosive for industrial use	Surface treatment and coating of metals	2 mod.	0.01	NP-der.
Paint, solvent based anti-corrosive for industrial use	Surface treatment and coating of metals	8a mod.	0.01	NP
Paint, solvent based anti-corrosive for industrial use	Surface treatment and coating of metals	8a mod.	0.01	NP-der.
Paint, water based with flame retardant effect for interior use	Paint shop	11a mod.	0.05	NPE
Paint, water based with flame retardant effect for interior use	Paint shop	2	0.02	NPE
Paint, water based with flame retardant effect for interior use	Paint shop	8a mod.	0.02	NPE
Pigment paste	Paint shop	2	0.02	NPE
Pigments for paints and inks	Industry for dyes and pigments	2	0.02	NPE
Printing ink remover	Publishers and printers; other industry for reproduction	2	0.02	NPE
Printing ink remover	Publishers and printers; other industry for reproduction	8a mod.	0.9	NPE
Printing ink, solvent-free for off-set print on paper	Publishers and printers; other industry for reproduction	11a mod.	0.005	NP-der.
Printing ink, solvent-free for off-set print on paper	Publishers and printers; other industry for reproduction	2 mod.	0.01	NP-der.
Printing ink, solvent-free for off-set print on paper	Publishers and printers; other industry for reproduction	4 mod.	0.005	NP-der.

Putty	Construction industry	11a mod.	0.05	NPE
Putty	Construction industry	8c mod.	0.05	NPE
Putty	Construction industry+ Retail sale, except for such with motor vehicles	11a mod.	0.05	NPE
Putty	Construction industry+ Retail sale, except for such with motor vehicles	8c mod.	0.05	NPE
Raw material for cosmetics and hygienic articles	Industry for basic pharmaceutical products	2	0.02	NP-der.
Raw material for cosmetics and hygienic articles	Industry for basic pharmaceutical products	8a mod.	0.9	NP-der.
Raw material for production of plastics	Construction industry	11a mod.	0.01	NPE
Raw material for production of plastics	Construction industry	6d	0.00005	NPE
Raw material for production of plastics	Paint industry	11a mod.	0.005	NP-der.
Raw material for production of plastics	Paint industry	2	0.02	NP-der.
Raw material for production of plastics	Paint industry	5 mod.	0.01	NP-der.
Raw material for production of plastics	Wholesale of chemical products	11a mod.	0.001	NP-der.
Raw material for production of plastics	Wholesale of chemical products	2	0.02	NP-der.
Raw material for production of plastics	Wholesale of chemical products	6d	0.00005	NP-der.
Release agents, others	Industry for plastic and rubber products	11a mod.	0.05	NPE
Release agents, others	Industry for plastic and rubber products	4 mod.	0.02	NPE
Rolling oil	Industry for basic metals	7	0.05	NPE
Rust preventive, others	Surface treatment and coating of metals	12b Mod.	0.5	NPE
Rust preventive, others	Surface treatment and coating of metals	8a mod.	0.05	NPE
Screw-cutting oils	Wholesale of chemical products	4 mod.	0.5	NPE
Sealant	Construction industry	11a mod.	0.001	NP-der.
Sealant	Construction industry	11a mod.	0.01	NPE
Sealant	Construction industry	2	0.02	NP-der.
Sealant	Construction industry	2	0.02	NPE
Sealant	Construction industry	8a mod.	0.01	NP-der.
Sealant	Construction industry	8a mod.	0.01	NPE
Solvent	Paint industry	11a mod.	0.005	NP
Solvent	Paint industry	8a mod.	0.01	NP
Stabilizers	Industry for plastic products	11a mod.	0.001	NP
Stabilizers	Industry for plastic products	5 mod.	0.01	NP
Stabilizers, others	Industry for plastic products	11a	0.0005	NP-der.
Stabilizers, others	Industry for plastic products	11a mod.	0.01	NP-der.
Stabilizers, others	Industry for plastic products	2	0.02	NP-der.
Stabilizers, others	Industry for plastic products	6d	0.00005	NP-der.
Stabilizers, others	Paint industry	11a mod.	0.05	NP-der.
Stabilizers, others	Paint industry	2	0.02	NP-der.
Surface active agents, other	Industry for organic basic chemicals	2	0.02	NPE
Surface active agents, other	Industry for organic basic chemicals	4 mod.	0.05	NPE
Surface active agents, other	Industry for plastics in primary forms	11a	0.0005	NPE
Surface active agents, other	Industry for plastics in primary forms	6d	0.00005	NPE
Surface active agents, other	Paint industry	2	0.02	NPE
Thickeners	Paint industry	2	0.02	NPE

Annex 4 Possible NP derivatives in cosmetics

Nonylphenol releasing derivatives which can be used as ingredients in cosmetics (source: INCI 2012)

No	CAS No.	EC No.	Trivial name	Substance name	Cosmetic function
1	27986-36-3	248-762-5	NONOXYNOL-1	2- (nonylphenoxy)ethanol	emulsifying agents
2	27176-93-8	248-291-5	NONOXYNOL-2	2- [2- (nonylphenoxy)ethoxy]ethanol	emulsifying agents / surfactants
3	9016-45-9		NONOXYNOL-3	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents
4	9016-95-9	230-770-5	NONOXYNOL-4	2- [2- [2- [2- (4- nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol	emulsifying agents / surfactants
5	7311-27-5	230-770-5	NONOXYNOL-4	2- [2- [2- [2- (4- nonylphenoxy)ethoxy]ethoxy]ethoxy]ethanol	emulsifying agents / surfactants
6	26264-02-8	247-555-7	NONOXYNOL-5	14- (nonylphenoxy)- 3, 6, 9, 12- tetraoxatetradecan- 1- ol	emulsifying agents / surfactants
7	9016-45-9	247-555-7	NONOXYNOL-5	14- (nonylphenoxy)- 3, 6, 9, 12- tetraoxatetradecan- 1- ol	emulsifying agents / surfactants
8	9016-45-9		NONOXYNOL-6	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
9	27177-03-3	248-292-0	NONOXYNOL-7	20- (nonylphenoxy)- 3, 6, 9, 12, 15, 18- hexaoxaicosan- 1- ol	emulsifying agents / surfactants
10	9016-45-9	248-292-0	NONOXYNOL-7	20- (nonylphenoxy)- 3, 6, 9, 12, 15, 18- hexaoxaicosan- 1- ol	emulsifying agents / surfactants
11	9016-45-9	248-293-6	NONOXYNOL-8	23- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21- heptaoxatricosan- 1- ol	emulsifying agents / surfactants
12	9016-45-9	247-816-5	NONOXYNOL-9	26- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21, 24- octaoxahexacosan- 1- ol	emulsifying agents / surfactants
13	27177-05-5	248-293-6	NONOXYNOL-8	23- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21- heptaoxatricosan- 1- ol	emulsifying agents / surfactants
14	26571-11-9	247-816-5	NONOXYNOL-9	26- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21, 24- octaoxahexacosan- 1- ol	emulsifying agents / surfactants
15	9016-45-9	248-294-1	NONOXYNOL-10	29- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21, 24, 27- nonaoxanonacosanol	emulsifying agents
16	27177-08-8	248-294-1	NONOXYNOL-10	29- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21, 24, 27- nonaoxanonacosanol	emulsifying agents
17	9016-45-9		NONOXYNOL-11	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
18	9016-45-9		NONOXYNOL-12	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
19	9016-45-9		NONOXYNOL-13	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
20	9016-45-9		NONOXYNOL-14	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
21	9016-45-9		NONOXYNOL-15	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
22	9016-45-9		NONOXYNOL-18	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents / surfactants
23	9016-45-9		NONOXYNOL-35	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents
24	9016-45-9		NONOXYNOL-120	Poly(oxy- 1, 2- ethanediyl), a- (nonylphenyl)- ?- hydroxy-	emulsifying agents
25			DINONOXYNOL-4 PHOSPHATE		emulsifying agents
26	9014-93-1		NONYL NONOXYNOL-5	Poly(oxy- 1, 2- ethanediyl), a- (dinonylphenyl)- ?- hydroxy-	emulsifying agents
27	63351-73-5	264-108-1	AMMONIUM NONOXYNOL-4 SULFATE	Ammonium 2- [2- [2- [2- (nonylphenoxy)ethoxy]ethoxy]ethoxy]ethyl sulphate	emulsifying agents / surfactants
28	31691-97-1	264-108-1	AMMONIUM NONOXYNOL-4 SULFATE	Ammonium 2- [2- [2- [2- (nonylphenoxy)ethoxy]ethoxy]ethoxy]ethyl sulphate	emulsifying agents / surfactants
29	66197-78-2	266-231-6	NONOXYNOL-9 PHOSPHATE	26- (nonylphenoxy)- 3, 6, 9, 12, 15, 18, 21, 24- octaoxahexacosan- 1- yl dihydrogen phosphate	Surfactants

Annex 5 Tables from chapter B.9.7 Measured levels

Table 62 Measured nonylphenol concentrations in European freshwaters, brackish and marine waters and surface run-offs.

Location	Concentration (µg NP/L)	Period	Remark	Reference
Lakes, rivers, water courses				
Austria		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Danube (Hainburg)	0.025*		Flow 2000 m^3/s	
Drau (Lavamund)	0.025*		Flow 200 m^3/s	
Enns (Steyr-Pyburg)	0.025*		Flow 200 m^3/s	
Mur (Speilfeld)	0.025*		Flow 150 m^3/s	
Traun (Edelberg)	0.535		Flow 150 m^3/s	
Belgium		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Gaverbeek (Deerlijk)	3.492		Observation: foam, yellow, particles	
Grote Spierebeek (Dottignies)	0.025*		Observation: foam, yellow, particles	
Kanaal Gent-Terneuzen (Zelzate)	0.082		Observation: yellow, particles	
Leie (Wevelgem)	0.782			
Mandel (Wielsbeke)	0.390		Observation: yellow	
Scheldt (Hemiksem)	0.048			
Scheldt (Oudenaarde)	4.489			
Zenne (Drogenbos)	1.173			
Bulgaria		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)

Iskar (Novi Iskar)	0.220		Flow 12.5 m^3/s	
Lesnovka (Dolni Bogrov)	0.270		Flow 0.45 m^3/s	
Cyprus		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Garyllis (Lemesos)	0.50		Flow 0.005 m^3/s Observation: brown, foam	
Kargotis (Lefkosia)	0.025*		Flow 0.08 m^3/s	
Czech Republic		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Elbe (Valy)	0.025*		Flow 25 m^3/s	
Lusatian Neisse/Nisa (Hradek nad Nisou)	0.230		Flow 2.7 m^3/s	
Odra (Bohumin)	0.025*		Flow 27.4 m^3/s	
Svratka (Zidlochovice)	0.025*		Flow 7.6 m^3/s	
Vltava (Zelcin)	0.025*		Flow 92.2 m^3/s	
Denmark		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Gudenaa (Tvilum Bro)	0.025*		Flow 13.7 m^3/s	
			Analysis: LC IT-MS	COHIBA (2011a)
Small river (Copenhagen)	0.025* 1.2		Small river with several upstream urban run-offs and combined sewer overflows Discharge: South of Copenhagen Harbour 4-NP (mix) No precipitation Precipitation	
Estonia		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Emajogi (Kavastu)	0.025*		Flow 70 m^3/s Observation: yellow	
Narva (Narva)	0.025*		Flow 400 m^3/s	
Purtse	0.025*			

(Tallinn)				
Finland		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Kokemäen (Pori)	0.025*		Flow 235 m^3/s	
Vantaa (Helsinki)	0.025*		Flow 16.5 m^3/s	
France		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Ardieres (St Jean, Moulin de Thuaille)	0.088		Observation: yellow	
Bourbre (Pont de Cheruy, Chavanoz)	0.243			
Drac (Vercors bridge in Grenoble)	0.025*			
Saone (Ille Barbe – upstream Lyon)	0.025*			
Rhone (Solaize)	0.120		Flow 1524 m^3/s	
Seine (Conflans Saint Honorine)	0.025*		Flow 264 m^3/s	
Germany		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Elbe (Geestacht)	0.025*		Flow 614 m^3/s	
Elbe (Wittenberg)	0.025*		Flow 243 m^3/s	
Fulda (Hannoversch Münden)	0.025*		Flow 92.1 m^3/s	
Havel (Ketzin)	0.025*		Flow 45.5 m^3/s	
Isar (München)	0.025*		Flow 33.6 m^3/s	
Lahn (Lahnstein)	0.025*		Flow 75.4 m^3/s	
Main (Kostheim)	0.025*		Flow 166 m^3/s	
Mosel (Koblenz/Mosel)	0.025*		Observation: sediments, dirty Flow 224 m^3/s	

Mulde (Dessau)	0.025*		Flow 287 m^3/s	
Neckar (Manheim)	0.025*		Flow 239 m^3/s	
Oder (Eisenhüttenstadt)	0.025*		Observation: sediments, dirty Flow 238 m^3/s	
Oder (Schwedt)	0.025*		Flow 477 m^3/s	
Saale (Bernburg)	0.025*		Flow 205 m^3/s	
Saar (Lisdorf)	0.025*		Flow 18 m^3/s	
Rhine (Burkheim)	0.025*		Flow 655 m^3/s	
Rhine (Koblenz/Rhein)	0.025*		Flow 1820 m^3/s	
Rhine (Wesel)	0.100		Flow 1170 m^3/s	
Rhine (Worms)	0.025*		Flow 1380 m^3/s	
Weser (Langwedel)	0.025*		Flow 307 m^3/s	
German monitoring data	 0.1 0.3 0.21 0.69 0.11 0.36 0.13 1.1	2006 2007 2008 2009	 n = 42 mean max n = 117 mean max n = 93 mean max n = 85 mean max	BAUA (2011)
Greece		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Evrotas (Sparta)	0.025*			
Hungary		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)

Hosszureti Patak (Kamaraerdo) Pecsi viz (Kemes) Raba (Gyor) Sajo (Kesznyeten) Sio (Szekszard) Tisza (Tiszasziget)	0.025* 0.025* 0.025* 0.025* 0.025* 0.025*		Flow 0.21 m^3/s Observation: yellow Flow 1.7 m^3/s Flow 83 m^3/s Observation: yellow Flow 17.5 m^3/s Flow 13 m^3/s Flow 830 m^3/s	
Ireland Liffey (Lucan Bridge)	 0.075	2007, autumn	Analysis: SPE-LC-MS Flow 7.9 m^3/s Observation: yellow, dirty	Joint Research Center (2008)
Italy Tevere (Rome)	 0.200	2007, autumn	Analysis: SPE-LC-MS Flow 233 m^3/s	Joint Research Center (2008)
  Lake Maggiore Tributary affected rivers Creek Ballarante (Arolo) River Bardello (Bozza) Creek Aqua Nera (Ispra) Creek Vévera (Arona) Creek Tiasca (Meina) Creek Erno (Lesa) Creek S. Spessa (Baveno) River Strona (Gravellona Toce) River Toce (Gravellona Toce) Tributary mountain rivers Creek San Bernadino (Verbania) Creek S. Spessa (Baveno) River Toce (Villa-dossola)	 0.05* (n=8) 0.05*-0.14 (n=9) 0.05* (n=3)	2006, February - April	Analysis: SPE-LC-MS-MS	Loos *et al.* (2007)
Lithuania Nemunas (Kaunas)	 0.025*	2007, autumn	Analysis: SPE-LC-MS Flow 192-220 m^3/s	Joint Research Center (2008)

Nemunas (Kaunas, downstream)	0.025*		Flow 316-468 m^3/s	
Neris (Kaunas, downstream)	0.025*		Flow 173-184 m^3/s	
Neris (Kaunas, upstream)	0.025*		Flow 173-184 m^3/s	
Luxembourg		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Alzette (Ettelbruck)	0.025*			
Moselle (Grevenmacher)	0.025*			
Sûre (Amont Erpendange)	0.025*			
Malta		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Bahrija Valley	0.025*			
Wied il-Luq	0.025*			
Wied tal-Lunzjata	0.025*		Observation. insects	
The Netherlands		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Meuse (Eijsden at border NL-Belgium)	0.025*		Flow 211 m^3/s	
Rhine (Lobith)	0.025*		Flow 2200 m^3/s	
Rhine/Meuse estuary (Maassluis)	0.050			
Scheldt (Schaar, estuary at border NL)	0.025*		Flow 110 m^3/s	
Norway		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Alna (Oslo)	0.025*			
Glomma (Sarpsfoss)	0.025*			
Hamar, Mjøsa	0.0226	2006-09-11	Analysis: GC-MS WWTP recipient water NP-mix[§]	Nordic Council of Ministers (2008)
Vansjø, Vanemfjorden	0.0465	2006-10-19	WWTP recipient	

			water NP-mix[§]	
Poland		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Vistula	0.025*			
Vistula	0.025*			
Vistula	0.025*			
Romania		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Somez Mare (before Dej)	0.060		Flow 20 m^3/s	
Somez Mic (after Cluj)	0.440		Flow 15 m^3/s	
Somez Mic (before Cluj)	0.025*		Flow 35 m^3/s	
Somez Mic (after Gherla)	0.050		Flow 20 m^3/s	
Slovenia		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Drava (Maribor 1)	0.025*		Observation: yellow	
Drava (Maribor 2)	0.025*		Observation: particles	
Krka (After Mun Novo Mesto)	0.025*		Flow 51 m^3/s	
Krka (Before Mun Novo Mesto)	0.025*		Flow 51 m^3/s	
Krka (Otocec Ob KrKi)	0.025*		Flow 51 m^3/s	
Ljubljanica (Ljubljana)	0.025*			
Ljubljanica (Ljubljana)	0.025*			
Sava (Kresnice)	0.250			
Spain		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Besos (Barcelona)	0.548		Flow 5 m^3/s	
Ebro (Mora la Nova)	0.025*		Flow 166.8 m^3/s	

Llobregat (Barcelona)	0.305		Flow 17 m^3/s	
Sar (Bertamirans)	0.158		Flow 2.5 m^3/s	
Sweden		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Dalälven (Älvkarleby)	0.025*		Flow 340 m^3/s	
Emån (Emsforo)	0.025*		Flow 28 m^3/s	
Fyrisån (Flottsund)	0.025*		Observation: dirty, particles, yellow Flow 12.8 m^3/s	
Göta Älv (Alelyckan)	0.025*		Flow 556 m^3/s	
Motala ström (Norrköping)	0.025*		Observation: yellow Flow 3.4 m^3/s	
Norrström (Stockholm)	0.025*		Flow 157 m^3/s	
Viskan (Åsbro)	0.025*		Flow 35 m^3/s	
			Analysis: GC-MS	Nordic Council of Ministers (2008)
Stockholm, Lake Tärnan	0.0683	2006-11-19	Background site NP-mix[§]	
Gothenburg, Lille Öresjön	0.107	2006-01-13	Background site NP-mix[§]	
		2006-01-01	Analysis: GC-MS	SWECO (2007)
Gothemsån, agricultural region	0.05* 0.31		Anthropogenic influence: Urban background Filtrated Total	
Visby STP, outlet into the Baltic Sea	0.7 0.88		Point source (STP) Filtrated Total	
Lill-Gösken, inlet	0.15		Point source Total	
Storsjön, outlet (below nedre säljet, Gavleån)	0.16		Point source Total	
Testeboåns delta, outlet	0.2		Point source Total	

Göta älv	0.16		Urban background Total	
Munksjön, inlet	0.19		Urban background Total	
Munksjön, outlet	0.20		Urban background Total	
Lillån, Bankeryd	0.24		Urban background Total	
Vättern, Southern part	0.05*		Background Total	
Vättern, Northern part	0.05*		Background Total	
Svartån, downstream of Tranås	0.05* 0.05*		Urban background Filtrated Total	
Gnosjöån, downstream of Gnosjö	0.42		Point source Total	
Eksjöån, downstream of Eksjö STP	0.21		Urban background Total	
Emån, downstream of Vetlanda	0.24		Urban background Total	
Emån, Rosenfors	0.05*		Urban background Total	
Emån, Emsfors	0.05* 0.05*		Urban background Filtrated Total	
Emån, Åsebo, downstream of Högsby	0.25		Urban background Total	
Huskvarnaån, outlet	0.05*		Urban background Total	
Bruzaån, downstream Hjältevad	0.13		Background (urban area) Total	
Emån, Storgölen	0.17		Point source Total	
Lagan, donstream of Värnamo	0.20 0.28		Urban background Filtrated Total	

Anderstorpsån, inlet to Nissan	0.3		Urban background Total	
Varnan, upstream of Kristinehamn	0.2		Urban background Total	
Varnan, downstream of Kristinehamn	0.21 0.20		Urban background Filtrated Total	
Klarälven, Skoghallsådran	0.05*		Point source Total	
Borlänge, Fågelmyra landfill	0.91		Point source Total	
Dalälven, Borlänge, STP effluent	1.1		Point source Total	
Mässingboån, agricultural farming area	0.17		Urban background Total	
Tjärna vattentäkt	0.05*		Urban background Total	
Petersburg vattentäkt	0.05*		Urban background Total	
Tandån, STP recipient	0.16		Urban background Total	
Stråfulan	0.19		Background Total	
Dalälven, Långhag	0.15 0.20		Urban background Filtrated Total	
Dalälven, Näs Bruk	0.05* 0.14		Urban background Filtrated Total	
Stångjärnsbäcken, deponi	0.20		Point source Total	
Lusbobäcken, dagvatten	0.14		Urban background Total	
Svartån, industry	0.05* 0.20		Point source Filtrated Total	
Eskilstunaån outlet	0.05* 0.05*		Urban background Filtrated Total	

Hjälmaren outlet, Hyndevad	0.05*		Urban background Total	
Mälaren, Arnöfjärden	0.05*		Urban background Total	
Nyköpingsån, Kristineholm	0.11		Urban background Total	
Fyrisån, nedre föret	0.42		Point source Total	
Kolbäcksån	0.05*		Urban background Total	
Svartån	0.18		Urban background Total	
Riddarfjärden	0.05*		Urban background Total	
Drevviken	0.05*		Urban background Total	
Brunnsviken	0.05*		Urban background Total	
Stora Envättern	0.23 0.34		Background Filtrated Total	
Fysingen	0.05* 0.14		Point source Filtrated Total	
Motala Ström, outlet Bråviken	0.05* 0.27		Point source Filtrated Total	
Stångån, outlet Roxen	0.05*		Point source Total	
Svartån, outlet Roxen	0.3		Point source Total	
Dovern, outlet Glan	0.78		Urban background Total	
Kallholmsfjärden	0.05*		Point source Total	
Vormbäcken	0.05*		Urban background Total	
Tvärån	0.05*		Point source Total	

Umeälven, lower part	0.1		Point source Total	
Kalixälven, outlet	0.05*		Point source Total	
Luleälven, outlet	0.05*		Point source Total	
Piteälven, outlet	0.05*		Background Total	
Boskvarnasjön, outlet	0.16		Urban background Total	
Åsnen outlet, Hackekvarn	0.12		Urban background Total	
Kråkesjön, outlet	0.24		Urban background Total	
Mörumsån, Forsbacka, 2 km upstream of the outlet into the Baltic Sea	0.2 0.2		Point source Filtrated Total	
Stockvik, point source	0.05* 0.11		Point source Filtrated Total	
Kalixälven, mining	0.05* 0.05*		Background Filtrated Total	
Krageholmssjön	0.05* 0.3		Background Filtrated Total	
Reference lake North, Abisko	0.05* 0.05*		Point source Filtrated Total	
Ursviksfjärden, downstream	0.05*		Background Total	
Örefjärden	0.05*		Point source Total	
Sagån	0.05* 0.19		Urban background Filtrated Total	
Mölndalsån	0.05 0.28		Urban background Filtrated Total	

			Urban background	
Säveån	0.18		Filtrated	
	0.23		Total	
			Point source	
Häggån	0.2		Filtrated	
	0.31		Total	
			Point source	
Jordhammarsviken	0.05*		Filtrated	
	0.16		Total	
			Analysis: GC-MS	SWECO (2009a)
Abiskojaure (lake)	0.05*	2007-12-09	Anthropogenic	
	0.05*	2008-01-10	influence:	
	0.05*	2008-02-10	Background	
	0.05*	2008-03-10		
	0.05*	2008-04-13		
	0.05*	2008-05-10		
	0.05*	2008-06-17		
	0.11	2008-07-27		
	0.05*	2008-08-24		
	0.05*	2008-09-23		
	0.05*	2008-10-20		
	0.05*	2008-11-26		
Göta Älv (river)	0.12	2007-12-20		
	0.21	2008-01-28	Urban, Port	
	0.18	2008-02-20		
	0.35	2008-03-25		
	0.18	2008-04-29		
	0.15	2008-04-28		
	0.05*	2008-06-25		
	0.69	2008-07-14		
	0.20	2008-08-25		
	0.05*	2008-09-25		
	0.05*	2008-10-23		
	0.05*	2008-11-12		
Hjulstafjärden (lake)	0.14	2007-12-12		
	0.11	2008-01-17	Diffuse, urban	
	0.20	2008-02-14	background	
	0.17	2008-03-12		
	0.22	2008-04-17		
	0.21	2008-05-13		
	0.89	2008-06-17		
	2.40	2008-07-15		
	0.12	2008-08-12		
	0.25	2008-09-16		
	0.05*	2008-10-16		
	0.05*	2008-11-13		
Stora Envättern (lake)	0.05*	2007-12-12		
	0.10	2008-01-17	Low, regional	
	0.22	2008-02-14	background	
	0.31	2008-03-12		

	0.27	2008-04-17		
	0.20	2008-05-13		
	0.61	2008-06-18		
	1.80	2008-07-15		
	0.24	2008-08-13		
	0.22	2008-09-16		
	0.05*	2008-10-16		
	0.05*	2008-11-08		
Storsjön (lake)	0.05*	2007-12-18		
	0.05*	2008-01-17	Urban	
	0.13	2008-02-20		
	0.17	2008-03-17		
	0.25	2008-04-23		
	0.15	2008-05-13		
	0.16	2008-06-23		
	0.18	2008-07-30		
	0.16	2008-08-20		
	0.46	2008-09-23		
	0.05*	2008-10-21		
	0.05*	2008-11-10		
The inlet to Vänern at Karlstad (river)	0.18	2007-12-19		
	0.12	2008-01-15	Industry point source, urban	
	0.29	2008-02-18		
	0.20	2008-03-18		
	0.21	2008-04-16		
	0.20	2008-05-20		
	0.54	2008-06-18		
	2.50	2008-07-09		
	0.12	2008-08-21		
	0.15	2008-09-25		
	0.13	2008-10-21		
	0.05*	2008-11-12		
The outlet of Vättern, to Motala Ström (lake)	0.05*	2007-12-16		
	0.05*	2008-01-16	Diffuse, urban	
	0.13	2008-02-18		
	0.05*	2008-03-17		
	0.05*	2008-04-14		
	0.05*	2008-05-13		
	0.05*	2008-06-18		
	0.05*	2008-07-14		
	0.14	2008-08-14		
	0.05*	2008-09-16		
	0.05*	2008-10-14		
	0.05*	2008-11-13		
Älvkarleby (river)	0.14	2007-12-11		
	0.18	2008-01-16	Diffuse	
	0.25	2008-02-13		
	0.05*	2008-03-12		
	0.10	2008-04-14		
	0.22	2008-05-13		
	0.46	2008-06-17		
	3.50	2008-07-15		

	0.23 0.22 0.05* 0.05*	2008-08-12 2008-09-15 2008-10-16 2008-11-12		
		2009-06-21 – 2009-06-29	Analysis: GC-MS	SWECO (2009b)
Ulvsundsjön	0.05*			
Gröndal	0.05*			
Årstaviken (Årstadal)	0.05*			
Klubben	0.05*			
Turingen, outlet	0.05*			
Fysingen (south part)	0.05*			
Södertälje channel, Guest harbor	0.05*			
Edsbro, directly downstream, Söderängsåns inlet	0.05*			
Drevviken, outlet	0.05*			
Magelungen, outlet	0.05*			
Tämnaren	0.05*			
Trehörningen	0.05*			
Funbosjön	0.05*			
Strömaren	0.05*			
Finnsjön	0.05*			
Enköpingsån	0.05*			
Fyrisån	0.05*			
Tämnaren	0.05*			
Råcksta å	0.05*			
Trosaån	0.05*			
Svärtaån	0.05*			
Kilaån	0.05*			
Nyköpingsån	0.05*			
Hedenlundaån				

Malmån	0.05*			
Husbyån	0.05*			
Garhytteån	0.05*			
Dalkarlshytteån	0.05*			
Storån	0.05*			
Nittälven	0.05*			
Väringen	0.05*			
Kvismare kanal	0.05*			
Arbogaån through Ställdalen	0.05*			
Garphytteån	0.05*			
Laxån	0.05*			
Lillån through Örebro	0.05*			
Stora Aspen (downstream Fagersta)	0.05*			
Downstream Arboga	0.05*			
Nedre Vättern (Skinnskatteberg)	0.05*			
Östersjön (downstream Surahammar)	0.05*			
Lien	0.05*			
Hedströmmen (downstream Kolsva)	0.05*			
Kolbäcksån (downstream Hallstahammar)	0.05*			
Snytboån/Trätten (downstream Norberg)	0.05*			
Kvicksund	0.05*			
Vågsjön				
UK		2007, autumn	Analysis: SPE-LC-MS	Joint Research Center (2008)
Clyde (Glasgow)	0.200			

Forth (Edingburgh) Humber (Hull) Lune (Lancaster) Mersey (Runcorn) Ouse (Naburn Lock) Severn (Haw Bridge, Stafford) Tees (Middlesbrough) Wyre (Fleetwood)	0.025* 0.230 0.025* 0.230 0.025* 0.025* 0.025* 0.320		Flow 47 m^3/s Flow 10.4 m^3/s Observation: yellow Flow 33.4 m^3/s	
Brackish and marine waters				
Denmark Brackish, Limfjorden Brackish, Roskilde Fjord Marine, Copenhagen, Øresund Marine, Faroe Island, Klaksvik Marina Marine, Faroe Island, Torshavn, Vagsbotn Marine, Kattegat, St. 905-1 Marine, Kattegat, St. 905-2	 0.005* 0.0179 0.0188 0.0075* 4.199*** 0.0421 0.0222	 2006-11-14 2006-10-03 2006-10-04 2007-01-12 2007-01-12 2006-09-21 2006-10-18	Analysis: GC-MS WWTP recipient water NP-mix§ o WWTP recipient water NP-mix§ WWTP recipient water NP-mix§ WWTP recipient water NP-mix§ WWTP recipient water NP-mix§ Background site NP-mix§ Background site NP-mix§	Nordic Council of Ministers (2008)
			Analysis: LC IT-MS	COHIBA (2011a)

			4-NP (mix)	
Baltic Sea	0.05*	2009-08-27	Reference sample	
The Sound	0.05*	2009-11-17	Reference sample	
	0.025*	2010-06-29		
Finland			Analysis: GC-MS	Nordic Council of Ministers (2008)
Brackish, Espoo, near pipeline outlet, 1 m depth	0.0204	2006-10-04	WWTP recipient water NP-mix§	
Brackish, Espoo, near pipeline outlet, 16 m depth	0.0479	2006-10-04	WWTP recipient water NP-mix§	
Brackish, Helsinki, near shipping port	0.0936	2006-10-04	WWTP recipient water NP-mix§	
Norway			Analysis: GC-MS	Nordic Council of Ministers (2008)
Marine, Oslo Fjorden, Inner part of	0.010*	2006-10-25	WWTP recipient water NP-mix§	
Marine, Oslo Fjord, St. 36	0.010*	2006-11-08	Background site NP-mix§	
Marine, Tromsø, St. 42	0.010*	2006-08-30	Background site NP-mix§	
Marine, Varangerfjord, St. 10	0.010*	2006-09-07	Background site NP-mix§	
Sweden			Analysis: GC-MS	SWECO (2009a)
Askö (coastal)	0.05*	2007-12-11	Anthropogenic influence: Diffuse	
	0.05*	2008-01-23		
	0.05*	2008-02-12		
	0.05*	2008-03-26		
	0.05*	2008-04-22		
	0.05*	2008-05-22		
	0.05*	2008-06-01		
	0.66	2008-07-15		
	0.11	2008-08-12		
	0.05*	2008-09-11		
	0.05*	2008-10-07		
	0.05*	2008-11-29		
Fladen	0.13	2007-12-12	Anthropogenic influence: Low	
	0.05*	2008-01-15		
	0.05*	2008-02-19		
	0.05*	2008-03-19		
	0.05*	2008-04-15		
	0.05*	2008-05-13		
	0.05*	2008-06-14		
	0.05*	2008-07-08		
	0.16	2008-08-19		

	0.05*	2008-09-16		
	0.05*	2008-10-08		
	0.05*	2008-11-29		
Gaviksfjärden (coastal)	0.05*	2007-11-05	Anthropogenic	
	0.05*	2007-12-03	influence: Low,	
	0.05*	2008-01-15	regional background	
	0.15	2008-02-11		
	0.05*	2008-03-24		
	0.05*	2008-04-21		
	0.05*	2008-05-19		
	0.53	2008-06-01		
	0.11	2008-07-30		
	0.05*	2008-08-25		
	0.05*	2008-09-24		
	0.05*	2008-10-21		
Hasslö (arcipelago)	0.05*	2007-12-18	Anthropogenic	
	0.05*	2008-01-16	influence: Diffuse,	
	0.15	2008-02-20	urban background	
	0.05*	2008-03-26		
	0.12	2008-04-16		
	0.05*	2008-05-20		
	0.05*	2008-06-23		
	0.29	2008-07-16		
	0.29	2008-08-25		
	0.05*	2008-09-25		
	0.05*	2008-10-16		
	0.05*	2008-11-17		
Rånefjärden (coastal)	0.20	2007-11-05	Anthropogenic	
	0.05*	2007-12-05	influence: Low,	
	0.21	2008-02-12	regional background	
	0.17	2008-03-12		
	0.05*	2008-04-23		
	0.14	2008-05-21		
	1.50	2008-06-11		
	0.10	2008-07-30		
	0.24	2008-08-27		
	0.05*	2008-09-25		
	0.05*	2008-11-05		
	0.05*	2008-12-03		
Skagerack	0.05*	2007-12-13	Anthropogenic	
	0.05*	2008-01-14	influence: Low	
	0.05*	2008-02-18		
	0.05*	2008-03-20		
	0.05*	2008-04-14		
	0.05*	2008-05-12		
	0.19	2008-06-09		
	0.05*	2008-07-28		
	0.05*	2008-08-18		
	0.05*	2008-09-15		
	0.05*	2008-10-09		
	0.05*	2008-11-07		

Öresund	0.05* 0.05* 0.05* 0.05* 0.05* 0.05* 0.28 0.23 0.12 0.05* 0.05* 0.05*	2007-12-13 2008-01-16 2008-02-13 2008-03-12 2008-04-16 2008-05-15 2008-06-12 2008-07-16 2008-08-13 2008-09-17 2008-10-15 2008-11-12	Anthropogenic influence: Diffuse, boat traffic	
		2009-06-10, 2009-06-11, 2009-06-23, 2009-06-24	Analysis: GC-MS	SWECO (2009c)
Karlholmfjärden, Uppsala	0.05*			
Karlholmsfjärden (Lötfjärden), Uppsala	0.05*			
Lövstabukten, Uppsala	0.05*			
Kallrigafjärden, Uppsala	0.05*			
Ängsfjärden (Northern part), Uppsala	0.05*			
Galtfjärden, Uppsala	0.05*			
Östhammarfjärden, Uppsala	0.05*			
Hargsviken, Uppsala	0.05*			
Skutskärsfjärden (Western part), Uppsala	0.05*			
Skutskärsfjärden (Eastern part), Uppsala	0.05*			
Marsviken	0.05*			
Furöområdet	0.05*			
Ålöfjärden	0.05*			
Stadsfjärden	0.05*			
Sjösafjärden	0.05*			
Trosafjädern	0.05*			
Tvären	0.05*			
Risöområdet	0.05*			

Fågelöfjärden	0.05*			
Gunnarbofjärden	0.05*			
Strömmen, Stockholm Blockhusudden	0.05*			
Askrikefjärden	0.05*			
Trälhavet, Stockholm Trälhavet II	0.05*			
Mysingen, Stockholm Mysingen, outside of ARV(1)	0.05*			
Himmerfjärden, Stockholm Himmerfjärden H5	0.05*			
Norrtäljeviken, Norrtäljeviken 6	0.05*			
Edsboviken, Stockholm Edeboviken H	0.05*			
Lilla Värtan, Stockholm Fjäderholmarna	0.05*			
Hallsfjorden, Stockholm Igelstaviken, railroad bridge	0.05*			
Norra Vaxholmsfjärden, Stockholm Norra Vaxholmsfjärden, Blynäs	0.05*			
Stora Värtan, Stockholm Hägernäsviken	0.05*			
Askrikefjärden, Stockholm Askrikefjärden	0.05*			
Edsviken, Stockholm Edsviken Landsnora	0.05*			
Brunnsviken, Stockholm Brunnsviken	0.05*			
Lilla Värtan, Stockholm Värtahamnen	0.05*			
Skurusundet, Stockholm Lännerstasunden, Fisksätraholmen	0.05*			
Baggenfjärden, Stockholm	0.05*			

Farstaviken, Kattholmen Edeboviken, Stockholm Edeboviken Strömmen, Stockholm Valdemarsudde (Hamnbassängen) Norrtäljeviken, Stockholm Norrtäljeviken, Tjuvholmen	 0.05* 0.05* 0.05*			
Surface run-offs				
Denmark Shredder Plant Copenhagen Copenhagen	 0.025* 0.025* 0.19 0.19 0.025* 0.025*	 2010-05-15 2010-05-15 2009-11-06 2010-06-07 2010-06-07 2010-05-30	Analysis: LC IT-MS Industrial run-off Discharge: Copenhagen Harbour 4-NP (mix) Run-off north Run-off south Storm water Roads and parking lots Filter treatment of run-offs Inlet Outlet Storm water Paved areas in an industrial area	COHIBA (2011a)
Estonia 0.23 0.05*			Analysis: LC IT-MS Storm water 20 m from the shoreline, Gulf of Finland 4-NP (mix)	COHIBA (2011b)
Finland Porolahti creek 0.38 0.25			Analysis: LC IT-MS Storm water 4-NP (mix)	COHIBA (2011c)
Germany Wismar 0.17 0.05*			Analysis: LC IT-MS Storm water 4-NP (mix)	COHIBA (2011d)
Norway Lier			Analysis: GC-MS Surface point source	Nordic Council of Ministers (2008)

St. 1	0.0075*	2006-10-27	NP-mix§	
St. 2	0.0075*	2006-10-27	Surface point source NP-mix§	
Latvia			Analysis: LC IT-MS	COHIBA (2011e)
Riga, urban area	2.6	2009-09	Storm water 4-NP (mix)	
Lithuania			Analysis: LC IT-MS	COHIBA (2011f)
Klaipėda	0.19 0.05*	2009-11 2010-06	Storm water 4-NP (mix)	
Poland			Analysis: LC IT-MS	COHIBA (2011g)
Szczecin and Swinoujscie Seaport	0.42 0.29	2009-12 2010-10	Storm water 5 different sampling points pooled together Discharge: Szczecin Lagoon 4-NP (mix)	
Sweden			Analysis: GC-MS	Nordic Council of Ministers (2008)
<u>Stockholm</u>,				
Båtbyggargatan	0.272	2006-12-06	Storm water point source, NP-mix§	
Lugnets Allé	0.235	2006-12-06	NP-mix§	
Sveavägen	0.359	2006-12-06	NP-mix§	
Styrmansgatan	0.186	2006-12-06	NP-mix§	
Lill-Jansskogen	0.010*	2006-12-06	Storm water diffuse source NP-mix§	
Årstafältet	0.0418	2006-12-06	NP-mix§	
Hammarby Sjöstad	0.0075*	2006-12-06	Surface point source NP-mix§	
Riddarfjärden	0.0075*	2006-12-06	NP-mix§	
Stora Essingen	0.0454	2006-12-06	Surface diffuse source NP-mix§	
Stockholm	0.12 2.0	2009-11 2010-06	Analysis: LC IT-MS Storm water Traffic related area Discharge: Lake Mälaren, Årstaviken 4-NP (mix)	COHIBA (2011h)

*Half detection limit
**Estimate, outside calibration range
***BPA used for estimating recovery
§Various nonylphenol isomers

Table 63 Measured nonylphenol concentrations in European sediments.

Location	Concentration (mg NP/kg dw)	Period	Remark	Reference
Freshwater sediment				
Denmark			Analysis: LC IT-MS	COHIBA (2011a)
Small river (Copenhagen)	0.30*	2010-06-29	Small river with several upstream urban run-offs and combined sewer overflows Discharge: South of Copenhagen Harbour 4-NP (mix)	
Norway			Analysis: GC-MS	Nordic Council of Ministers (2008)
Hamar, Mjøsa	0.0434	2006-10-25	Recipient environment DW (%): 10.0 NP-mix**	
Vansjø, Vanemfjord	0.0214	2006-10-19	Recipient environment DW (%): 20.1 NP-mix**	
Sweden			Analysis: GC-MS	Nordic Council of Ministers (2008)
Västmanland, Övre Skärsjön	0.0543	2006-12-05	Background environment DW (%): 15.6 NP-mix**	
Skåne, Krageholmssjön	0.249	2006-11-23	Background environment DW (%): 11.1 NP-mix**	
			Analysis: GC-MS	SWECO (2009a)
Abiskojaure (lake)	0.064	2008-09-15	Anthropogenic influence: Background	
Storsjön (lake)	0.005*	2008-09-22	Anthropogenic influence: Urban	
Älvkarleby	0.005*	2008-11-12	Anthropogenic influence: Diffuse	
Stora Envättern	0.005*	2008-11-08	Anthropogenic influence: Regional background	
Hjulstafjärden	0.005*	2008-11-13		

Vänerns inlopp utanför Karlstad	0.06	2008-09-22	Anthropogenic influence: Urban background	
Vätterns utlopp i Motala Ström	0.036	2008-09-25	Anthropogenic influence: Point source	
Göta Älv	0.35	2008-09-25	Anthropogenic influence: Urban background	
			Anthropogenic influence: Urban background	
Brackish and marine water sediment				
Denmark			Analysis: GC-MS	Nordic Council of Ministers (2008)
Kattegat, St.905	0.0092	2006-09-21	Background environment DW (%): 37.5 NP-mix**	
Copenhagen, Øresund	0.00175*§	2006-10-04	Recipient environment DW (%): 82.1 NP-mix**	
Roskilde, Roskilde Fjord	0.0856	2006-11-14	Recipient environment DW (%): 15.9 NP-mix**	
Faroe Islands, Klaksvik, Pollurin	0.0015	2006-06-15	Recipient environment DW (%): 46.1 NP-mix**	
Faroe Islands, Götuvik, Bekkafrost	0.00136	2006-06-15	Recipient environment DW (%): 59.3 NP-mix**	
Faroe Islands, Torshavn, Harbour	0.340	2007-01-12	Recipient environment DW (%): 32.5 NP-mix**	
			Analysis: LC IT-MS	COHIBA (2011a)
Copenhagen harbour	0.30*	2010-06-29	CSO in Harbour (middle)	
	0.70	2010-06-29	CSO in Harbour (south)	
The Sound	0.30*	2010-06-29	Reference sample	
Finland			Analysis: GC-MS	Nordic Council of Ministers (2008)
Espo, coastal sea (Baltic Sea)	0.440	2006-10-03	Recipient environment DW (%): 4.8 NP-mix**	

Helsinki, City bay	0.390	2006-10-03	Recipient environment DW (%): 38.2 NP-mix**	
Norway			Analysis: GC-MS	Nordic Council of Ministers (2008)
Oslo Fjord, St.360	0.0237	2006-06-14	Background environment DW (%): 33.9 NP-mix**	
Tromsø, St.42	0.00175*§	2006-08-30	Background environment DW (%): 33.9 NP-mix**	
Varangerfjorde, St.10	0.00175*§	2006-09-07	Background environment DW (%): 33.9 NP-mix**	
Oslo, Oslo Fjord - inner	0.00175*§	2006-10-25	Recipient environment DW (%): 33.9 NP-mix**	
Sweden			Analysis: GC-MS	Nordic Council of Ministers (2008)
Stockholm, Stora Essingen	0.449	2006-12-05	Recipient environment DW (%): 17.8 NP-mix**	
Stockholm, Årstaviken	0.390	2006-12-05	Recipient environment DW (%): 13.5 NP-mix**	
Stockholm, Hammarby Sjöstad	0.485	2006-12-05	Recipient environment DW (%): 26.2 NP-mix**	
Stockholm, Riddarfjärden	0.257	2006-12-05	Recipient environment DW (%): 33.5 NP-mix*	
			Analysis: GC-MS	SWECO (2009a)
Råne fjärden	0.005*	2008-11-05	Anthropogenic influence: Regional background	
Askö	0.005*	2008-09-18	Anthropogenic influence: Diffuse	
Öresund	0.012	2008-09-17	Anthropogenic influence: Diffuse	
Hasslö	0.017	2008-09-25	Anthropogenic influence: Urban background	

*Half detection limit

**Various nonylphenol isomers
§All data have been determined on the basis of wet wet weight (ww) and subsequently converted to dry weight (dw) basis using reported dry weight (DW %) values. The detection limit of 0.0035 (NP-mix) has not been converted to dry weight basis.

Table 64 Measured nonylphenol concentrations in samples from WWTP influent and effluent water, suspended particles/solids and sludge within the EU and Norway.

Location	Concentration	Period	Remark	Reference
Water (µg NP/L)				
Denmark			Analysis: GC-MS	Nordic Council of Ministers (2008)
Copenhagen, Lynetten			750 000 peq NP-mix*	
	3.55**	2007-10-17	Influent water	
	0.116		Effluent water	
Roskilde, WWTP Bjørgmarken			50 000 peq NP-mix*	
	0.0075*	2006-11-13	Effluent water	
	0.0513	2007-02-15	Effluent water	
Faroe Island, Torshavn, Hospitalet			Relatively small NP-mix*	
	0.923	2006-11-12	Influent water	
	2.173**		Effluent water	
Faroe Island, Torshavn, WWTP Sersjantvikin			Relatively small, mostly domestic waste NP-mix*	
	0.969	2006-12-29	Influent water	
	0.169		Effluent water	
			Analysis: LC IT-MS	COHIBA (2011a)
Municipal WWTP 1			750 000 peq Discharge: Sound outside of the Copenhagen Harbour approx 1.5 km from the coast line 4-NP (mix)	
	2.7	2009-09-15 - 22	Influent water	
	0.005*	2009-09-15 - 22	Effluent water	
	0.005*	2009-09-15 - 22	Effluent water	
	0.29	2009-09-15 - 22	Effluent water	
	0.025*	2010-05-12	Bypass	
Municipal WWTP 2			350 000 peq Discharge: Sound outside of the Copenhagen Harbour approx 1.5 km from the coast line 4-NP (mix)	
	9	2009-09-21 - 26	Influent water	

	0.22	2009-09-21 - 26	Effluent water	
	0.05*	2009-09-21 - 26	Effluent water	
	0.32	2009-09-21 - 26	Effluent water	
	0.025*	2010-05-12	Bypass	
			After treatment technology (floc formation and settling plus activated carbon) tested on the effluent 4-NP (mix)	
	0.22	2009-11-11 - 13	Influent water	
	0.16	2009-11-11 - 13	Effluent water	
	0.05*	2009-11-17 - 19	Influent water	
	0.12	2009-11-17 – 19	Effluent water	
Industrial WWTP 1			Waste Incineration Plant Industrial wastewater from cleaning of the plant and cooling of slag Discharge: Copenhagen Harbour 4-NP (mix)	
	0.05*	2009-08-26 – 28	Outlet from slag pool, 48 h sample	
	0.14	2010-04-22	Grab sample	
Industrial WWTP 2			Power Plant Industrial wastewater 4-NP (mix)	
	0.05*	2009-11-11 – 13	Internal WWTP, outlet	
	0.025*	2010-03-22	Internal WWTP, outlet Discharge: MWWTP 1	
	0.23	2009-11-11 – 13, 2009-11-25 – 26, 2009-11-27 – 2009-12-1	Neutralisation/ sedimentation	
	0.025*	2009-11-12,	Discharge:	
	0.05*	2009-11-25	Copenhagen Harbour	
	0.025*	2010-03-18		
Industrial WWTP 3			Sedimentation Cooling water conc.	
	0.025*	2010-05-21	Hospital Discharge: MWWTP 1	
Industrial WWTP 4			4-NP (mix) Outlet	

Combined sewer overflow	0.05* 0.05*	2009-09-03 2010-03-15	Gas works site Discharge: MWWTP 1 (possible leaching to Copenhagen harbour) 4-NP (mix) Internal WWTP, outlet Borehole K6	
	0.05* 0.51	2009-10-03 2010-06-07	Large CSO located in the southern end of Copenhagen Harbour Discharge: Copenhagen Harbour 4-NP (mix) Outlet	
	0.39 0.22 0.23	2010-06-07 2010-11-23 2010-11-23	Large CSO located in the northern end of Copenhagen Harbour Discharge: Copenhagen Harbour 4-NP (mix) Inlet Outlet	
Estonia Municipal WWTP 1			Analysis: GC-MS after acylation 223 333 peq Discharge: Deep-sea outlet, Gulf of Finland	COHIBA (2011b)
	0.05* 0.33 0.54 0.42 0.05* 0.25	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08	Effluent water 4-NP (mix)	
Municipal WWTP 2			140 00 peq Discharge: River, 12 km from shoreline, Gulf of Finland	
	0.52 0.20 0.29 0.23 0.24 0.25	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08	Effluent water 4-NP (mix)	

Municipal WWTP 3			15 217 peq Discharge: River, 18 km from shoreline, Gulf of Finland Effluent water	
	0.75	2009-09	4-NP (mix)	
	0.47	2009-11		
	1.75	2010-01		
	2.62	2010-04		
	0.64	2010-06		
	1.12	2010-08		
Municipal WWTP 4a			10 000 peq Discharge: Gulf of Finland	
	0.22	2009-09	Effluent water	
	0.26	2009-11	4-NP (mix)	
	0.38	2010-01		
Municipal WWTP 4b			15 000 peq Discharge: Deep-sea outlet, Gulf of Finland Effluent water	
	0.73	2010-04	4-NP (mix)	
	0.15	2010-06		
	0.34	2010-08		
Finland			Analysis: GC-MS	Nordic Council of Ministers (2008)
Espoo, Suomenoja			500 000 peq NP-mix*	
	3.146**	2006-10-04	Influent water	
	0.189		Effluent water	
Helsinki, Viikinmäki			1000 000 peq NP-mix*	
	5.688**	2006-10-04	Influent water	
	0.374		Effluent water	
Pornainen, Pornainen			<1000 peq NP-mix*	
	0.065	2006-10-04	Effluent water	
			Analysis: LC IT-MS	COHIBA (2011c)
Municipal WWTP 1			280 000 peq Discharge: Harbour near coastline into the Gulf of Finland Effluent water	
	0.29	2009-09	4-NP (mix)	
	0.17	2009-11		
	0.22	2010-01		
	1.19	2010-04		

	0.28	2010-06		
	0.45	2010-08		
Municipal WWTP 2			295 000 peq Discharge: Approx 9 km from coastline into the Gulf of Finland Effluent water	
	0.05*	2009-09	4-NP (mix)	
	0.15	2009-11		
	0.58	2010-01		
	0.63	2010-04		
	0.28	2010-06		
	0.32	2010-08		
Municipal WWTP 3			780 000 peq Discharge: Approx 7 km from coastline into the Gulf of Finland Effluent water	
	0.05*	2009-09	4-NP (mix)	
	0.35	2009-11		
	0.46	2010-01		
	0.54	2010-04		
	0.39	2010-06		
	0.36	2010-08		
Industrial WWTP 1			Discharge: Coastline into the Gulf of Finland Effluent water	
	0.05*	2009-09	4-NP (mix)	
	0.05*	2009-11		
	0.70	2010-01		
	0.36	2010-04		
	0.26	2010-06		
	0.23	2010-08		
Germany			Analysis: LC IT-MS	COHIBA (2011d)
Municipal WWTP 1			Effluent water	
	1.14	2009-09	4-NP (mix)	
	0.25	2009-11		
	0.13	2010-01		
	0.21	2010-04		
	0.22	2010-06		
	0.37	2010-08		
Municipal WWTP 2			Effluent water	
	2.24	2009-09	4-NP (mix)	
	0.15	2009-11		
	0.12	2010-01		
	0.31	2010-04		
	0.15	2010-06		
	0.25	2010-08		
			Effluent water	

Industrial WWTP 1	2.11 0.45 0.65 0.31 1.80	2009-09 2009-11 2010-01 2010-04 2010-08	4-NP (mix)	
Industrial WWTP 2	1.15 0.18 0.42 0.40 0.05* 0.48	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08	Effluent water 4-NP (mix)	
Latvia			Analysis: LC IT-MS	COHIBA (2011e)
Municipal WWTP 1	0.36 0.66	2010-06 2010-08	717 371 peq Effluent water 4-NP (mix)	
Municipal WWTP 2	0.43 0.41	2010-06 2010-08	90 000 peq Effluent water 4-NP (mix)	
Industrial WWTP 3	0.12 0.27	2010-06 2010-08	Effluent water 4-NP (mix)	
Industrial WWTP 4	0.26 0.32	2010-06 2010-08	Effluent water 4-NP (mix)	
Lithuania			Analysis: LC IT-MS	COHIBA (2011f)
Municipal WWTP 1	0.18 0.19 0.75 0.59 0.24 0.16	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08	21 452 peq Discharge: Tenzė (tributary of river Akmena-Danė – approx 17 km from the Curonian lagoon) Effluent water 4-NP (mix)	
Municipal WWTP 2			20 945 peq Discharge: Šyša (tributary of river Nemunas – approx 12 km from the Curonian lagoon)	

			Effluent water	
	0.05*	2009-09	4-NP (mix)	
	0.17	2009-11		
	0.20	2010-01		
	0.46	2010-04		
	0.10	2010-06		
	0.16	2010-08		
Industrial WWTP 1			Discharge: Into a MWWTP and then, after treatment	
			Effluent water	
	0.05*	2009-09	4-NP (mix)	
	0.05*	2009-11		
	0.33	2010-01		
	0.50	2010-04		
	0.05*	2010-06		
	0.16	2010-08		
Industrial WWTP 2			Discharge: Smiltelė stream (approx 2.5 km from the Curonian lagoon)	
			Effluent water	
	0.05*		4-NP (mix)	
	0.16			
	0.30			
	0.37			
	0.05*			
	0.12			
Norway			Analysis: GC-MS	Nordic Council of Ministers (2008)
Oslo, Bekkelaget			250 000 peq	
			NP-mix*	
	0.266	2006-09-06	Influent water	
	0.189		Effluent water	
Oslo, VEAS			500 000 peq	
			NP-mix*	
	1.108	2006-09-13	Influent water	
	0.105		Effluent water	
Poland			Analysis: LC IT-MS	COHIBA (2011g)
Municipal WWTP 1			99 100 peq	
			Discharge: Świna Strait approx 5 km from the coast line into the Baltic Proper	
			Effluent water	
	0.39	2009-09	4-NP (mix)	
	0.44	2009-11		
	0.21	2010-01		
	0.13	2010-04		
	0.44	2010-06		
	0.45	2010-08		

Municipal WWTP 2			573 720 peq Discharge: Bay of Gdańsk approx 2.4 km from the coast line into the Baltic Proper Effluent water 4-NP (mix)	
	0.76	2009-09		
	0.61	2009-11		
	0.26	2010-01		
	0.27	2010-04		
	0.73	2010-06		
	0.20	2010-08		
Municipal WWTP 3			420 000 peq Discharge: Bay of Puck approx 2 km from the coast line into the Baltic Proper Effluent water 4-NP (mix)	
	0.97	2009-09		
	0.37	2009-11		
	0.30	2010-01		
	0.12	2010-04		
	0.60	2010-06		
	1.33	2010-08		
Industrial WWTP 1			Discharge: Vistula River (Martwa Wisla) Effluent water 4-NP (mix)	
	0.93	2009-09		
	0.41	2009-11		
	0.41	2010-01		
	0.65	2010-04		
	****	2010-06		
	0.35	2010-08		
Sweden			Analysis: GC-MS after acylation	COHIBA (2011h)
Municipal WWTP 1			656 000 peq Discharge: Baltic Sea, inner archipelago of Stockholm (Saltsjön) Effluent water 4-NP (mix)	
	0.025*	2009-09		
	0.025*	2009-11		
	0.025*	2010-01		
	0.025*	2010-04		
	0.097	2010-06		
	0.025*	2010-08		
Municipal WWTP 2			131 800 peq Discharge: Umeälven Effluent water 4-NP (mix)	

	0.025* 0.025* 0.094 0.10 0.11 0.025*	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08		
Municipal WWTP 3			340 000 peq Discharge: Baltic Sea, inner archipelago of Stockholm (Himmerfjärden) Effluent water 4-NP (mix)	
	0.025* 0.025* 0.025* 0.025* 0.087 0.025*	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08		
Municipal WWTP 4			Discharge: Baltic Sea, Kalmarsund Effluent water 4-NP (mix)	
	0.025* 0.025* 0.064 0.055 0.051 0.077	2009-09 2009-11 2010-01 2010-04 2010-06 2010-08		
Particulate phase/Sludge (mg NP/kg dw)				
Denmark			Analysis: GC-MS	Nordic Council of Ministers (2008)
Copenhagen, Lynetten	4.878**	2007-10-17	750 000 peq DW (%): 20.3 NP-mix*	
Roskilde, Bjørg	3.658**	2007-02-15	50 000 peq DW (%): 28.4 NP-mix*	
Faroe Island, Torshavn, Hospital	1.46**	2007-01-12	Relatively small DW (%): 13.7 NP-mix*	
Faroe Island, Torshavn, Sersjantvikin	2.388**	2006-12-29	Relatively small, mostly domestic waste DW (%): 18.0 NP-mix*	
			Analysis: LC IT-MS	COHIBA (2011a)
Municipal WWTP 1 (Lynetten)			750 000 peq Discharge: Sound	

			outside of the Copenhagen Harbour approx 1.5 km from the coast line	
	8.6 6.1	2009-09-14 2010-02-09	4-NP (mix)	
Municipal WWTP 2 (Damhusåen)			350 000 peq Discharge: Sound outside of the Copenhagen Harbour approx 1.5 km from the coast line	
	2.3 1.8	2009-09-21 2010-02-09	4-NP (mix)	
Industrial WWTP 1	<0.60		Waste Incineration Plant Sediment	
Estonia			Analysis: LC IT-MS	COHIBA (2011b)
Municipal WWTP 1			223 333 peq Discharge: Deep-sea outlet, Gulf of Finland Sludge	
	3.88	2010-01	4-NP (mix)	
Municipal WWTP 3			15 217 peq Discharge: River, 18 km from shoreline, Gulf of Finland	
	24.2 2.01	2010-01 2010-06	4-NP (mix)	
Finland			Analysis: GC-MS	Nordic Council of Ministers (2008)
Espo, Suomenoja			500 000 peq DW (%): 13.5	
	28.360**	2006-10-04	NP-mix*	
Helsinki, Viikinmäki			1000 000 peq DW (%): 49.9	
	14.583**	2006-10-04	NP-mix*	
Pornainen, Pornainen	8.932**	2006-10-04	1000 peq DW (%): 15.0 NP-mix*	
Germany			Analysis: LC IT-MS	COHIBA (2011c)
Municipal WWTP 1			Effluent water	
	2.7 2.23	2010-01 2010-06	4-NP (mix)	

Municipal WWTP 2	3.04	2010-01	4-NP (mix)	
Latvia			Analysis: LC IT-MS	COHIBA (2011d)
Municipal WWTP 1	10.52 15.02	2010-06 2010-08	717 371 peq 4-NP (mix)	
Municipal WWTP 2	0.89 0.95	2010-06 2010-08	90 000 peq 4-NP (mix)	
Lithuania			Analysis: LC IT-MS	COHIBA (2011e)
Municipal WWTP 2	4.28 0.95	2010-01 2010-06	21 452 peq Discharge: Tenzė (tributary of river Akmena-Danė – approx 17 km from the Curonian lagoon) 4-NP (mix)	
Norway			Analysis: GC-MS	Nordic Council of Ministers (2008)
Bekkelaget	3.556**	2006-09-07	250 000 peq DW (%): 4.3 Wet sludge from inlet NP-mix*	
	4.078**	2006-09-07	DW (%): 88.2 Stabilized dry sludge from the outlet NP-mix*	
Oslo, VEAS	1.46**	2006-09-13	500 000 peq DW (%): 58.2 Wet sludge from outlet NP-mix*	
	3.005**	2006-09-13	DW (%): 6.2 Stabilized dry sludge from outlet NP-mix*	
Poland			Analysis: LC IT-MS	COHIBA (2011g)
Municipal WWTP 2	15.9 36.77	2010-01 2010-06	573 720 peq Discharge: Bay of Gdańsk approx 2.4 km from the coast line into the Baltic Proper 4-NP (mix)	
Sweden			Analysis: GC-MS	Nordic Council of Ministers (2008)
Stockholm, Henriksdal			750 000 peq DW (%): 15.0	

Stockholm, Hammarby Sjöstad	7.570** 14.328**	2006-10-18 2006-10-18	NP-mix* 15 000 peq, mainly domestic waste DW (%): 13.5 NP-mix*	
Municipal WWTPs in Södermanland County	120 (22-350, 5) 64.5 (17-215, 10) 35 (20-158, 11) 23 (8-128, 11) 31.5 (4-120, 10) 22 (7-51, 10) 22.5 (3-53, 10) 13 (3-33, 11) 16 (2-32, 11) 10 (2-23, 11) 12 (2-24, 11) 14 (2-28, 11) 14 (2-30, 11) 8.5 (2-22, 12) 8.5 (2-29, 12) 6.5 (3-22, 10) 5 (2-17, 11) 5 (1-13, 11) 6 (3-15, 11)	1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009	Analysis: Median (min – max, n)	Länststyrelsen Södermanslands län (2010)
Göteborg, Ryaverket	28 21 23 16 15 12 11 14 14	2003 2004 2005 2006 2007 2008 2009 2010 2011	825 000 peq Mean values	Gryaab (2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011)
Stockholm, Bromma WWTP	140 76 79 62 59 63 26 17 17 32 27 30 23 23 23 24	1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006	310 000 peq Mean values	Stockholms stad (2012)

Stockholm, Henriksdal WWTP	20 18 16 20 14 150 99 94 62 76 62 30 17 23 24 26 24 23 20 21 22 16 16 15 15 11	2007 2008 2009 2010 2011 1991 1992 1993 1994 1995 1996 1997 1998 1999 2000 2001 2002 2003 2004 2005 2006 2007 2008 2009 2010 2011	750 000 peq Mean values	
Helsingborg, Öresundsverket	46 23 16 18 18 18 18 13 11 9.5	1995 2000 2003 2004 2005 2006 2007 2008 2009 2010	130 000 peq Mean values	Helsingborg stad (2012)
Municipal WWTP 2	 6.5 9.7	 2010-01 2010-06	Analysis: GC-MS after acylation 340 000 peq Discharge: Baltic Sea, inner archipelago of Stockholm (Himmerfjärden) Effluent water 4-NP (mix)	COHIBA (2011h)

*Various nonylphenol isomers
**Estimate, outside calibration range
***High uncertainty due to low recovery
****Very low recovery
N/A: Not available

Table 65 Measured nonylphenol concentrations in samples from landfill within the EU and Norway**.**

Location	Concentration	Period	Remark	Reference
Water (NP µg/L)				
Denmark			Analysis: GC-MS	Nordic Council of Ministers (2008)
Faroe Island, Torshavn, Husahagi	0.0272	2006-12-29	NP-mix** Effluent water	
Landfill	1.7 1.39	2009-10 2010-06	Analysis:LC IT-MS 4-NP (mix) Effluent water	COHIBA (2011a)
Waste deposit 1	0.05* 0.025*	2009-08-24 2010-03-10	Analysis: LC IT-MS Industrial waste Discharge: MWWTP 2 4-NP (mix)	COHIBA (2011a)
Waste deposit 2	0.05* 0.025 0.33	2009-10-19 2010-05-25 2010-05-25	Industrial and public waste Discharge: Secondary groundwater – possible leaching to Copenhagen Harbour 4-NP (mix) Borehole 1 Borehole 2	
Estonia			Analysis:LC IT-MS	COHIBA (2011b)
Landfill	0.99 0.39	2009-10 2010-06	4-NP Effluent water	
Finland			Analysis: GC-MS	Nordic Council of Ministers (2008)
Espoo, Ämmässuo	16.997***	2006-10-04	NP-mix** Effluent water	
Landfill	1.7 1.39	2009-10 2010-06	Analysis:LC IT-MS 4-NP Effluent water	COHIBA (2011c)
Germany			Analysis:LC IT-MS	COHIBA (2011d)
Landfill	0.10 0.05*	2009-11 2010-08	4-NP Effluent water	
Latvia			Analysis: LC IT-MS	COHIBA (2011e)

Landfill	0.05*		Discharge: River Daugava 4-NP (mix)	
Lithuania			Analysis: LC IT-MS	COHIBA (2011f)
Landfill	0.23 0.20	2009-11 2010-06	Discharge: Drainage channel – approx 9 km from the Curonian lagoon 4-NP (mix)	
Poland			Analysis: LC IT-MS	COHIBA (2011g)
Landfill	15 15	2009-12 2010-10	Pooled samples taken from two different walls Discharge: Return to Municipal WWTP 4-NP (mix)	
Sweden			Analysis: GC-MS after acylation	COHIBA (2011h)
Landfill	0.24 0.20	2009-11 2010-06	4-NP (mix)	
Soil (mg NP/kg dw)				
Denmark			Analysis: GS MS	Nordic Council of Ministers (2008)
Faroe Islands, Húsahagi	0.047	2006-12-29	DW (%): 44.2 NP-mix**	
Faroe Islands, Havnadalur	0.002*	2006-12-29	Old waste deposit DW (%): 44.2 NP-mix**	
			Analysis: LC IT-MS	COHIBA (2011a)
Waste deposit 2	0.03*	2009-10-14	Industrial and public waste N-NP (mix)	

*Half DL
**Various nonylphenol isomers
**Estimate, outside calibration range

Kemikalieinspektionen
Swedish Chemicals Agency

2012-10-19

Annex 6 - Questionnaire concerning feasibility issues in an EU-wide restriction on NPE in textile articles

The Swedish Chemicals Agency is preparing a proposal for an EU-wide restriction on nonylphenol (NP) and nonylphenol ethoxylates (NPE) in textile articles within the REACH regulation. More information on the restriction process under REACH can be found at the ECHA website (http://echa.europa.eu/sv/support/restriction).
The use of nonylphenol and nonylphenol ethoxylates is already prohibited within the EU, with the exception of a few use areas. We are concerned about these substances since NPE may transform to NP in the environment where the substance has low degradability. NP is very toxic to aquatic organisms and may cause harmful long-term effects in the aquatic environment. In addition, nonylphenol has suspected hormone-disrupting properties.
The Swedish Chemicals Agency is in need of feed-back on the appropriate wording of the restriction to be proposed. In particular we are investigating issues related to technical and economic feasibility of a possible restriction on NPE in textiles, such as; the definition of textile articles, the scope of the restriction and a feasible concentration limit value for NPE within a suggested transitional period.
We would very much appreciate if you have the opportunity to answer the questions below. Please indicate if you have any confidentiality claims with regards to particular information provided in your response. **Please provide your response to Inger Cederberg, Inger.Cederberg@kemi.se, +46 (0)8 519 41 447, no later than 7 November 2012**.
In order for us to validate the responses given to the questionnaire, we kindly ask you to provide:
The name of your organisation:
Your name and title:

Questions:

Definition of textile articles

The term "Textiles" is very wide and in the restriction to be proposed it is necessary to define what kinds of textiles that are covered. In order to facilitate the interpretation and the practical application, the restriction to be proposed includes a definition of the term "textile articles" as meaning textile articles defined in article 3.1 a-f of the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products (see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:272:0001:0064:en:pdf).

- *Is this definition of textiles from the above mentioned directive suitable to use in a restriction on chemicals in textiles?*

Your response (please motivate):

The scope of the proposed restriction

The main release of NPE from textiles to the environment in the EU is by washing in water. The restriction to be proposed will therefore only apply to textiles that "**can be washed in water**". The restriction will therefore not affect suppliers of textiles that are not washable in water.

- *Is it appropriate to define the scope of the restriction to only include textiles that "can be washed in water"?*

Your response (please motivate):

- *Could you name some types (if any) of "technical textiles" (according to your own understanding of this term) that can be washed in water and which would therefore be covered by the suggested scope?*

Your response (please motivate):

Concentration limit and transition period

There is a need to balance the reduction of the discharge of NP/NPE to the environment against a practical application of the restriction in terms of technical and economic feasibility. In order to balance the need for a reduction of the discharge of NP/NPE to the environment and to ensure a margin between intentionally (when NPE is used with a purpose in the textile manufacturing process) and unintentionally (when NPE is not used with a purpose in the textile manufacturing process but is yet detected as a contaminant in the textile) added NP/NPE to the textile, the limit value of 20 mg NPE/kg textile is proposed.

A transitional period is needed for enabling the market to adjust in terms of possibility to deal with textile articles in existing stocks, inform and educate EU-suppliers as well as non EU-suppliers about the regulation, and other needs for adaptation. It is here assumed that any transitional period for a restriction would start in the year 2015.

- *If the aim is to stop all intentional use of NPE in the manufacturing of textiles destined for the EU market, do you believe that 20 mg NPE/kg textile is a suitable limit value, to be achieved in a 5 year* transitional period*?*

Your response (please motivate):

- If your response to the above question is NO, what other limit value do you consider to be technically and economically feasible in a five years transitional *period?*
Your response (please motivate):

- According to your experience and considering that the restriction to be proposed would be EU-wide, how would a transitional period of <u>three years instead of five years</u> be to achieve a limit value of 20 mg NPE/kg textile compare in terms of feasibility for actors in the textile supply chain?
Your response (please motivate):

- *Please feel free to also comment on other issues regarding the restriction to be proposed.*

Annex 7 Send list - Questionnaire concerning feasibility issues in an EU-wide restriction on NPE in textile articles

Organisation	**E-mail adress**
Fédération Belge de l'Industrie Textile, du Bois et de l'Ameublement - FEDUSTRIA	info@fedustria.be
CREAMODA – Belgian fashion	info@creamoda.be
Federazione Tessile Moda – SMI - Sistema Moda Italia	info@sistemamodaitalia.it
ssociaçao Têxtil e Vestuàrio de Portugal - ATP	atp@atp.pt
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Turkish Clothing Manufacturers'Association	tgsd@tgsd.org.tr
International Association of Users of Artificial and Synthetic Filament Yarns and of Natural Silk - AIUFFASS	pierre.vanmol@fedustria.be
European Linen and Hemp Confederation - C.E.L.C.	celc.sg@wanadoo.fr
European Man-made Fibres Association - CIRFS	info@cirfs.org
European Association for Textile Polyolefins - EATP	info@eatp.org
International Association Serving the Nonwovens & Related Industries - EDANA	info@edana.org
European Federation of the Cotton and Allied Textiles Industries - EUROCOTON	michele.anselme@eurocoton.org
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FESI	The Federation of the European Sporting Goods Industry

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