Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Nonylphenol and **Nonylphenol ethoxylates**

ECHA/RAC/RES-O-0000005317-74-01/F

ECHA/SEAC/ RES-O-0000005317-74-02/F

Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 3 June 2014) and SEAC's opinion (adopted 9 September 2014)

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3 June 2014

ECHA/RAC/RES-O-0000005317-74-01/F

9 September 2014

ECHA/SEAC/ RES-O-0000005317-74-02/F

Opinion of the Committee for Risk Assessment

and

Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical name(s):	**Nonylphenol, Nonylphenol ethoxylate**
EC No.:	Not applicable
CAS No.:	Not applicable

This document presents the opinions adopted by RAC and SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

Sweden has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***18 September 2013***. Interested parties were invited to submit comments and contributions by ***18 March 2014***.

ADOPTION OF THE OPINION OF RAC:

Rapporteur, appointed by RAC: **Stephen Dungey**

Co-rapporteur, appointed by RAC: **Hans Christian Stolzenberg**

The RAC opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment has been reached in accordance with Article 70 of the REACH Regulation on ***3 June 2014***.

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The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The RAC opinion was adopted ***by consensus***.

ADOPTION OF THE OPINION OF SEAC

Rapporteur, appointed by SEAC: **Simone Fankhauser**

Co-rapporteur, appointed by SEAC: **Karine Fiore-Tardieu**

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***11 June 2014.***

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at ***http://echa.europa.eu/web/guest/restrictions-under-consideration*** on ***18 June 2014***. Interested parties were invited to submit comments on the draft opinion by ***18 August 2014***.

The opinion of SEAC

The opinion of SEAC on the suggested restriction was adopted in accordance with Article 71(1) and (2) of the REACH Regulation on ***9 September 2014***.

The opinion takes into account the comments of interested parties provided in accordance with Article 69(6) and 71(1) of the REACH Regulation.

The opinion of SEAC was adopted ***by consensus***.

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OPINION

THE OPINION OF RAC

RAC has formulated its opinion on the proposed restriction based on information related to the identified risk and to the identified options to reduce the risk as documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. RAC considers that the proposed restriction on **Nonylphenol ethoxylates** is the most appropriate EU wide measure to address the identified risks in terms of the effectiveness in reducing the risks provided that the conditions are modified.

The conditions of the restriction proposed by RAC are:

Nonylphenol, branched and linear, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]
($((C_2H_4O)_nC_{15}H_{24}O)$)

1. Textile articles (textile clothing, accessories and interior textiles such as: tops, underwear, nightwear, hosiery, bottoms, jackets, dresses, suits, gloves, sportwear, swimwear, scarves, shawls, ties and handkerchiefs, bags, curtains, bed linen, table linen, towels, blankets, throws, mats and rugs), or textile parts of articles, that can be washed in water during normal or reasonably foreseeable conditions of use shall not be placed on the market after [insert date 60 months after of entry into force of this Regulation] if the total concentration in the textile article, or textile parts of articles, of these substances is equal to or higher than 0.01% by weight. The limit value includes prints on the textile articles mentioned above.

2. For the purpose of this entry 'textile articles, or textile parts of articles" shall mean:

    a. Textile clothing and accessories: clothing and accessories consisting of at least 80% by weight of textile fibres in a woven, non-woven or knitted form.

    b. Interior textiles: textile articles for interior use consisting of at least 80% by weight of textile fibres in a woven, non-woven or knitted form.

    c. Fibres, yarn, fabric and knitted panels: intended for use in textile clothing and accessories and interior textiles, including upholstery fabric and mattress ticking prior to the application of backings and treatments associated with the final article.

3. By way of derogation paragraph 1 shall not apply to used articles placed on the market.

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THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document. SEAC considers that the proposed restriction on **Nonylphenol ethoxylates** is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the conditions are modified as stated in the RAC opinion.

The proposed restriction is as follows:

Nonylphenol, branched and linear, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]
($(C_2H_4O)_nC_{15}H_{24}O$))

Paragraphs 1-3 as described in the opinion of RAC.

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JUSTIFICATION FOR THE OPINION OF RAC AND SEAC

Justification for the opinion of SEAC

SEAC considers that the proposed restriction on Nonylphenol (NP) and Nonylphenol ethoxylates (NPEO) is the most appropriate EU wide measure to address the identified risks in terms of the proportionality of its socio-economic benefits to its socio-economic costs provided that the scope of the restriction is modified in a way that **Nonylphenol is excluded from the scope of the restriction** (see Explanatory note in section A.3.3 of the Background document on the direct targeting of NPEO and the indirect targeting of NP in textile articles) due to the following reasons:

As explained by the dossier submitter Nonylphenol is not used in the textile manufacturing process. However, small amounts of Nonylphenol can be found in finished textile articles possibly due to the degradation of Nonylphenol ethoxylates which are used in the textile manufacturing process or due to unintentional contamination of formulations used in textile processing. However, the exact reason and the sources are unknown. Studies (e.g. Klif 2011, Danish EPA 2013 and Greenpeace 2012a) show that only traces of Nonylphenol are detected in textiles. These small quantities are not included in the emission calculations performed by the dossier submitter because they are assumed to be negligible compared to NPEO. SEAC agrees with the dossier submitter's view that in principle even such low concentrations of NP should be avoided since the release of a unit of NP from textiles contributes relatively more to the environmental risks than a unit of NPEO (see also RAC opinion for further information). However, as stated above, NP is not identified as being intentionally used in textile processing. If NP is included in the scope, a limit value such as proposed in the current restriction would not have a considerable effect, first because the concentrations of NP are likely far below that limit value and second, because the actors in the textile supply chain are likely unable to identify intentional uses of NP that can be reduced or substituted. It is expected that actors in the textile supply chain will ensure compliance with the proposed restriction by substituting NPEO in textile processing (indicated by stakeholders consulted) – and placing a limit value on NPEO should thus achieve reduction in the concentrations of both NP (indirectly targeted) and NPEO (directly targeted). According to the dossier submitter, Nonylphenol was primarily included in the scope of the restriction in order to be consistent with the current restriction in REACH Annex XVII entry 46, which covers both, Nonylphenol and Nonylphenol ethoxylates. SEAC questions the necessity for a consistency between proposed and already existing restrictions. From a socio-economic point of view this justification does not appear to be a sufficient rationale for the inclusion of NP in the scope of the restriction. **Based on the data and the information provided in the Background document and as explained in this and the following paragraphs, SEAC considers the inclusion of Nonylphenol in the scope of the restriction not justified if evaluated against effectiveness (including proportionality), practicality (including implementability, manageability and enforceability), and monitorability.**

Effectiveness*:* the effectiveness of the restriction proposal is not expected to be significantly affected by including NP in the scope of the restriction. There is limited data available on NP concentrations in textiles. These data (studies from Klif 2011, Danish EPA 2013 and Greenpeace 2012a) show very low concentrations of NP in textiles, i.e. between 0.7 and 10 mg NP/kg textile with an average of 3.4 mg NP/kg textile. If NP is actually present in textile articles only in traces (such as the above mentioned studies indicate) the proposed limit value (0.01% by weight) would not contribute to the reduction of NP concentrations in textiles. Comments from two stakeholders received during public consultation indicate much higher NP concentrations (between 16.4 mg/kg and 660 mg/kg

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in 4% of the tested articles)[1] but these data are not conclusive and the respective stakeholders could not provide information on the sources of NP in textiles, i.e., intentional use vs contamination during the production process (see section B.2.3.1 of the Background Document). The dossier submitter does not consider the evidence given sufficient to change the overall conclusion not to include NP in the restriction proposal and SEAC agrees to that view. As stated above, if the limit value of 0.01% by weight was also set for NP, no additional risk reduction would be expected based on the few low measured concentrations (see also RAC opinion). Theoretically, an effect (at least deterring) might only be expected if the restriction would set a limit value below 10 mg/kg NP (which is the maximum concentration measured in the above-mentioned studies). However, the dossier submitter does not consider such a low limit value implementable, practicable and manageable (see evaluation of different RMOs in section E.2 of the Background document) and this view was also expressed by some stakeholders during consultation processes. SEAC agrees to that view as well: such a low limit value would cause e.g. technical difficulties, as there may be NP/NPEO traces as by-products, impurities, or intentional components (at low concentrations) in chemical formulations used in the manufacturing of textiles. This may thus result unintentionally in (low amounts of) NP/NPEO being found in the final textile article. However, when the substances are contained in the formulation at low concentrations, they are not necessarily reported in the products' safety data sheets. Thus, the sources of the substances/the reason why NP/NPEO end up in the final textile article are unknown to actors in the supply chain and would make the identification of the source/reason, in order to comply with the restriction, difficult and costly while a limit value set at 0.01% by weight (or 100 mg/kg) textile is still regarded as a ban on NPEO being intentionally used in the manufacturing process. Finally, a restriction on NPEO only is expected to result in substitution of intentional uses of NPEO in textile manufacturing and would therefore also reduce traces of NP (as the degradation of NPEO, as impurity in NPEO formulations). **For the above stated reasons, it is unlikely that the inclusion of NP would make the restriction more effective in terms of risk reduction capacity.**

Proportionality: SEAC questions the proportionality of the inclusion of Nonylphenol in the restriction scope. As stated and explained above, the effectiveness (in terms of risk reduction capacity) of the restriction proposal is not expected to be affected by the inclusion of NP (see also section A.3.3 of the Background Document). Furthermore, SEAC has no information at hand about the consequences of an inclusion of NP since it is not intentionally used in the textile manufacturing process and therefore, the reasons why NP is found in the final product as well as its sources are unknown. Identifying the reason and sources as well as identifying unintentional uses of NP may be difficult and costly for affected actors but SEAC has no information at hand to draw a conclusion on the potential difficulties and the related costs. Furthermore, testing for both NP and NPEO has to be done separately; this may imply additional costs of compliance control. Compliance control costs are regarded very unlikely by the dossier submitter and feedback received during stakeholder consultation (consultation during the preparation of the restriction proposal, as well as separately performed survey by ECHA) confirms this assumption. However, compliance control costs are one of the main determinants when discussing the proportionality of this restriction proposal and separate testing of NP would induce additional costs which would further undermine the proportionality of the restriction. Consequently, **SEAC expects the inclusion of NP to rather have a negative effect on the proportionality of the restriction.**

Practicality (including implementability, manageability and enforceability) and monitorability: Nonylphenol could not be identified as being used intentionally in the textile manufacturing processes and it is unclear how NP ends up in the final textile product.

[1] These data are based on testing of imported textiles. The tests were carried out as part of an OKOTEX-certification (see Background Document section B.2.3.1).

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As a result, the consequences of a restriction on NP for affected actors in the textile supply chain are unknown and it is unclear how actors could comply to the restriction if they do not know how NP enters the textile product. SEAC has no data at hand to draw any conclusion on potential impacts of the inclusion of NP in the scope in terms of practicality. Regarding testing, experts that have been contacted by the dossier submitter claimed that analyses for NP and NPEO have to be performed separately. If NP was included in the scope of the restriction, both substances would need to be measured by enforcement authorities and by companies, who choose to test their products for compliance reasons. Currently there is a CEN standard test method under development (by the designated group TC248/Wg26) which is expected to be available before the proposed restriction entry into force. However, this CEN standard is being developed for NPEO only. Test methods for NP exist but are not standardised yet, which makes compliance control for both, enforcement authorities and industry difficult. Consequently, in SEAC's view, an inclusion of NP would make the restriction less practicable, less manageable and less enforceable. As regards the monitorability of the proposed restriction, SEAC could not identify any major differences between restricting both, NP and NPEO, or restricting NPEO only (for more information see section on Monitorability below).

The justification in the following sections of the SEAC opinion therefore reflects on the restriction of Nonylphenol ethoxylates only.

Definition of raw and semi-finished textile articles: The Forum for Exchange of Information on Enforcement (Forum) advised that the current wording of the restriction is not clear enough as to whether it also applies to raw and semi-finished articles (R & SF articles). In the Background document, the dossier submitter defines which textile articles are covered by the restriction by referring to the definitions of textile articles inspired by the proposed criteria for the EU Ecolabel for textile products.

Comments received during the public consultation (from two stakeholders) recommended the explicit inclusion of R & SF articles into the scope of the restriction on the grounds that NPEOs have been found in some of these materials and are therefore regarded to be a source of NPEO emissions. R & SF articles were indeed implicitly included in the original scope (which was subject to public consultation) by virtue of their mention in the textile definitions of Regulation (EU) No. 1007/2011. With the modified wording of the scope, the dossier submitter still intends to include R & SF articles since the EU Ecolabel for textile products appears to provide a suitable definition for these articles stated as "*Fibres, yarn, fabric and knitted panels: intended for use in textile clothing and accessories and interior textiles, including upholstery fabric and mattress ticking prior to the application of backings and treatments associated with the final article*". This definition is proposed along with definitions of *Textile articles and accessories* as well as *Interior textiles* to be included in the Entry 46 (see in Appendix 13 of the Background Document).

The dossier submitter investigated the consequences of in-/excluding R & SF articles but no clear conclusion can be drawn either on the risk reduction capacity and the related effectiveness, or on the specific costs and the proportionality of the restriction proposal due to the lack of appropriate data (for detailed information see Appendix 13 of the Background document). However, R & SF articles were originally intended to be in the scope of the restriction (when referring to definitions in Regulations (EU) No. 1007/2011)) and this scope has undergone several stakeholder consultations where no major concern was raised regarding the restriction of such types of articles. On the contrary, comments were received during the public consultation of the original restriction proposal that explicitly recommended the inclusion of such articles. SEAC notes that R & SF articles may contain NPEO (confirmed by comments received during public consultation) and may therefore contribute to NPEO emissions when washed in water but no quantification was possible.

SEAC agrees that such emissions should be avoided in the same manner as emissions from

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finished textile articles, which contributes to the benefits of the restriction. SEAC has no data at hand to conclude specifically on costs and benefits of restricting/not restricting R & SF articles. However, SEAC agrees with the dossier submitter's evaluation that there might be somewhat higher substitution costs since in principle, NPEO used in R & SF articles should also be substituted as a result of the restriction if those articles are included into the scope (see Background document Appendix 13) but substitution costs are not considered to be a major negative factor in the evaluation of the proportionality of the restriction. Moreover, compliance control costs are not regarded to be significantly affected by including R & SF articles. The occurrence and the magnitude of compliance control costs are highly uncertain (see separate discussion in the section on costs) and the dossier submitter has accounted for these uncertainties in the performed sensitivity analysis. Based on the argumentation given in the Background document and its Appendices, SEAC agrees with the dossier submitter's view that with the revised wording of the scope raw and semi-finished articles are indeed targeted by the proposed restriction (as it was already intended in the original wording of the restriction proposal) in order to avoid emissions of NPEO during the processing of such textiles within the EU as well as to avoid NPEO in the final textile articles placed on the EU market. SEAC emphasises that no specific cost-benefit assessment could have been performed by the dossier submitter on these types of articles. However, it can be assumed that the data on textiles which have been taken into consideration in the dossier submitter's cost analysis may already include to a certain proportion R & SF articles which are used to manufacture the final textile articles.

SEAC considers that the revised wording of the scope and the proposed conditions explicitly target raw and semi-finished textile articles although it is acknowledged that no specific separate assessment of the costs and the benefits of restricting these types of articles could have been performed.

IDENTIFIED HAZARD AND RISK

Justification for the opinion of RAC

Targeting of the information on hazard and exposure

The proposed restriction is based on the following premise:

i) European water bodies are at risk from the combined effects of NPEO degradation products, i.e. NP, short chain NPEOs and nonylphenol ethoxycarboxylates (NPECs), including effects arising from their endocrine disrupting (ED) properties.

ii) A significant source of these substances is textiles (particularly those imported from outside the EU), as they can release NPEOs when they are washed in water, and these NPEOs can degrade to NP and short chain NPEOs/NPECs.

iii) Limiting the NPEO content to 100 mg/kg in textiles (equal to 0.01% by weight) that can be washed in water will not remove this source entirely, but will reduce the risk significantly, whilst still allowing the supply of textiles in which NPEO is only present from unintentional sources.

This opinion considers the evidence presented in the restriction dossier and comments submitted during the public consultation and RAC discussions. Despite the proposal to remove NP from the terms of the restriction, it should be noted that all of the hazard and risk data considered below is for NP. This is not considered to be an issue as NPEO is expected to degrade to nonyl- and shorter chain phenols in any case (see pg 53 for more details).

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Risk addressed by the proposed restriction

o Information on hazard

NP environmental hazards

Based on a large set of available studies, NP shows acute and chronic toxicity to a number of species from all trophic levels, namely algae, various invertebrates (arthropods), and fish. As the restriction proposal focuses on the freshwater and marine aquatic compartment including sediment, the RAC opinion concentrates on the corresponding information. Table 17 in the background document (BD) provides a summary of the lowest relevant and reliable data available, and this is repeated below with missing test durations added:

Table 1: *Summary of the lowest relevant and reliable acute and chronic toxicity values of nonylphenol for aquatic species (based on BD Table 17)*

Trophic level	Species	Endpoint	NP concentration	Reference
Freshwater fish	Fathead minnow (*Pimephales promelas*)	Mortality (96-h LC_{50})	128 µg/L	Brooke (1993a)
	Rainbow trout (*Oncorhynchus mykiss*)	Growth (91-d NOEC)	6 µg/L	Brooke (1993b)
Marine water fish	Winter flounder (*Pleuronectes americanus*)	Mortality (96-h LC_{50})	17 µg/L	Lussier *et al*. (2000)
	-	No marine fish long-term toxicity data are available		
Freshwater invertebrates	*Hyalella azteca*	Loss of mobility (96-h EC_{50})	20.7 µg/L	Brooke (1993a)
	Daphnia magna	Surviving offspring (21-d NOEC)	24 µg/L	Comber *et al.* (1993)
Marine water invertebrates	*Mysidopsis bahia*	Mortality (96-h LC_{50})	43 µg/L	Ward and Boeri (1990b)
	Mysidopsis bahia	Growth – length (21-d NOEC)	3.9 µg/L	Ward and Boeri (1990b)
Freshwater algae	*Scenedesmus subspicatus*	Growth rate (72-h EC_{50})	323 µg/L	Kopf (1997)
		Growth rate (72-h NOEC)	25.1 µg/L	
Marine water algae	-	No marine algae short-term toxicity data are available		
	-	No marine algae long-term toxicity data are available		
Freshwater aquatic plants	*Lemna minor*	Frond production (96-h NOEC)	901 µg/L	Brooke (1993a)
Freshwater sediment species	*Chironomus riparius*	Emergence rate (28-d EC_{10})	231 mg/kg dw	Bettinetti and Provini (2002)
Marine water sediment species	*Leptocheirus plumulosus*	Mortality, reproduction (28-d NOEC)	61.5 mg/kg dw.	Zulkosky *et al.* (2002)

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In addition, the dossier provides a large amount of information about the endocrine (namely estrogenic) effects of NP, based on the CSRs and Annex XV dossier that led to the identification of NP as a Substance of Very High Concern according to REACH article 57(f) due to its ED properties. Table 34 in the BD summarises the underlying data and qualitative information, and this is repeated below:

Table 2: *Endocrine disrupting effects of 4-nonylphenols in different taxonomic groups (BD Table 34, amended by full species names and few additional details on the mollusc Crassostrea gigas)*

Taxonomic group	**No. of species**	**Indication of hormonal activity?**	**Apical adverse effects observed?**	**Indication that apical endpoints fit to mode of action**
Fish	9	Yes In all species (increased vitellogenin level in males and females, changes in female gonadal staging, changes in sperm stages in males, testis-ova, secondary sex characteristics, elevated estradiol levels)	Yes Effects in all species with tested apical endpoints (6 species). Most sensitive adverse endpoints: Sex-ratio (*Oryzias latipes, Danio rerio, Poecilia reticulata, Gambusia holbrooki*); growth (*Onchorhynchus mykiss, Pimephales promelas*) Most sensitive fully reliable LOEC = 10 µg/L (growth *On. mykiss* and sex-ratio *D. rerio*) with some indication that effects may start at 0.75 µg/L (semen volume *On. mykiss*)	Yes, based on studies with NP clear link for four fish species 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 *Rana sylvatica* and *Rana pipiens*, Klimisch 2)	Effects observed on sex-ratio in *Xenopus laevis* in low quality study and changes in sex ratio in *R. sylvatica* and *R. pipiens* 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 a moult cycle	Yes (reproduction, development, moulting) Most sensitive fully reliable EC50 = 8 µg/L (reproduction in *Cerodaphnia dubia*)	Some indication but no clear conclusion possible due to lack of knowledge
	2 echinoderm	Effects observed are similar to those	Yes (larval malformations) Most sensitive reliable LOEC	Some indication but

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Taxonomic group	No. of species	Indication of hormonal activity?	Apical adverse effects observed?	Indication that apical endpoints fit to mode of action
	species	observed for a known anti-estrogen and thyroid active substance (pentachlorphenol)	= 0.9 µg/L (larval malformation in *Arbacia lixula*)	no conclusion possible due to lack of knowledge
	4 mussel species	Induced hermaphrodism effects fit to those observed for 17ß-estradiol and knowledge about the influence of estrogens on female sexual maturation	Yes (sex ratio skewed to females in one study, survival of offspring) Most sensitive reliable LOEC ≤ 1 µg/L (survival, sex-ratio in *Crassostrea gigas*). Less conclusive end points like sperm motility were also affected below 1 µg/L.	Some indication but no clear conclusion possible
	1 snail species		Yes (fecundity, hatching success F1 generation, growth) Most sensitive reliable LOEC 1 µg/L (embryonic toxicity in *Haliotis diversicolor*)	No conclusion possible

Compared to the information in Table 1 on the lowest relevant and most reliable acute and chronic toxicity end points, this endocrine-related information in Table 2 extends the taxonomic coverage by seven amphibian species, two echinoderm species and five mollusc species. However, some of the studies are of low or limited reliability, and may involve test methods that have not been adequately ring-tested. The data for amphibians and invertebrates are inconclusive. It is not clear whether the apical effects in invertebrates have any link with endocrine activity, or whether the observed hormonal changes themselves are adverse. The best evidence is therefore for fish.

The dossier offers two alternative approaches for predicted no effect concentration (PNEC) derivation. The first option using the standard assessment factor (AF) approach in fact includes some sub-alternatives:

i) a freshwater $PNEC_{aqua}$ of 0.6 µg/L based on a rainbow trout 91-d NOEC (growth) of 6.0 µg/L and an assessment factor (AF) of 10;

ii) a marine $PNEC_{aqua}$ of 0.039 µg/L based on a marine mysid 21-d NOEC (length) of 3.9 µg/L and an AF of 100 (due to the lack of long-term data for marine organisms from the other standard trophic levels – the dossier however noted that a lower AF could take account of test results from molluscs and echinoderms);

iii) a freshwater $PNEC_{aqua}$ adjusted for "additional uncertainty" due to ED effects with an extra (arbitrary) AF of 10, resulting in $PNEC_{aqua}$ = 0.06 µg/L;

iv) a marine $PNEC_{aqua}$ based on the freshwater PNEC adjusted for additional ED-related uncertainty, applying another extra AF of 10 to extrapolate this to marine species, thus resulting in a marine $PNEC_{aqua}$ = 0.006 µg/L.

The second option uses statistical extrapolation techniques on the species sensitivity distribution (SSD) for chronic toxicity covering sensitive life stages. Determining an HC5 of 2.93 µg/L and applying an AF of 5 results in $PNEC_{aqua}$ = 0.59 µg/L. Constructing another

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SSD by adding the only marine data meeting the requirements provided by the relevant REACH guidance (Chapter R.10.3.1.3 on Information requirements and chemical safety assessment, characterisation of concentration-response for the marine compartment), i.e. the marine mysid 21-d NOEC of 3.9 µg/L, results in an HC5 of 2.12 µg/L and with the AF of 5 in a $PNEC_{aqua}$ = 0.42 µg/L. The following copy of Figure 6 in the BD displays the SSD and species from which test results are incorporated.

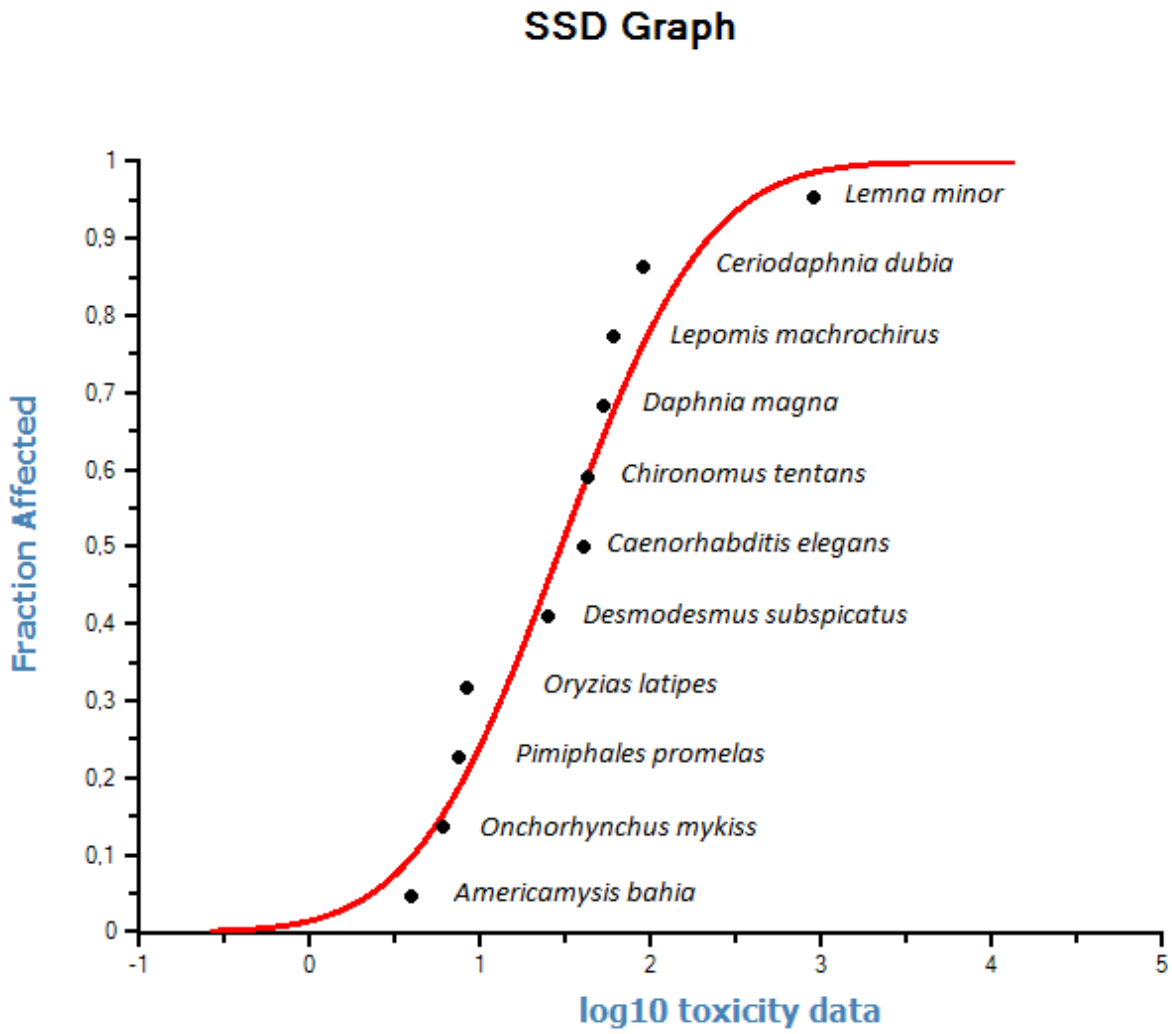

Figure 1: *Aquatic species sensitivity distribution for nonylphenol (log normal distribution) from the ETX 2.0-software with the names of the individual species inserted (BD Figure 6)*

In addition to these approaches the dossier discusses several studies reporting observations on potentially endocrine mediated effects in fish and invertebrates. These effects were observed at concentrations ranging from 0.1 to 1.0 µg/L, albeit with limited reliability in some cases (nominal concentrations; adversity of non-apical endpoints not conclusive; testing methods not adequately ring-tested, validated and standardised). Based on these observations the dossier submitter argues that the aquatic PNECs might be lower than those derived from the 91-d rainbow trout NOEC of 6.0 µg/L and the 21-d mysid NOEC of 3.9 µg/L.

In an additional general line of argument, the dossier addresses the ED properties of NP. Based on generic arguments, such as complexity of the endocrine system, risk for

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irreversible effects in sensitive life stages, potentially long delays from exposure to effect, the principal absence of effect thresholds for ED substances in active hormone systems, particular scientific difficulties to establish safe exposure levels, and scientific uncertainty in predicting the impacts caused by ED substances, the dossier submitter concludes that it is too difficult to derive a safe level for such substances and that covering ED effects by extra assessment factors in PNEC derivation would not be adequate (effectively meaning that no exposure can currently be considered acceptable).

In sections F.1.2.1 and F.1.2.2.3 the dossier indicates that ecosystem impacts by endocrine mediated effects are evidently caused by co-exposure to a number of chemicals with concordant mode of action. Specifically, the estrogenic pressure is prevalently dominated by steroid oestrogens, such as ethynylestradiol, while other chemicals with estrogenic modes of action like NP and short chain NPEOs always add to existing estrogenic pressure.

RAC has the following observations on these approaches:

a) There is a consistent data set on adverse effects from NP ecotoxicity in species from all standard trophic levels, including representatives of both fresh and marine waters (including sediment).

b) Where available, directly comparable adverse effect data for the most sensitive marine species are lower than those for related freshwater species (factor 7.5 for acute fish toxicity and factor 6 for chronic invertebrate toxicity). RAC notes that rainbow trout is known to be particularly sensitive amongst test fish species[2]. Concentrations reported for various indicative effects observed in further marine species (echinoderm, mussel and snail species) unrelated to the standard fish, algae and invertebrate taxa usually tested, are not below 0.9 µg/L (cf. point (f) below). Although the data set could be improved if reliable NOEC/EC_{10} data were available for such species, and would normally be expected before waiving the extra AF for marine PNEC derivation (cf. Table R.10-5 in ECHA's guidance on information requirements IR and chemical safety assessment CSA, characterisation of concentration-response), RAC considers that additional fully valid and conclusive chronic tests with these species (or marine algae) would not reveal significantly lower adverse effect concentrations for the traditional, apical endpoints than those in the current data set.

c) As reliable justification for community-wide measures, RAC therefore questions the proposed approaches to derive a separate marine PNEC by combining extra assessment factors. With a view to the indicative but not conclusively adverse effects observed in the same concentration range, RAC notes that the lowest relevant and reliable long-term toxicity value of 3.9 µg/L for the marine mysid *Americamysis bahia* appears to reasonably cover potential additional sensitivity due to greater diversity particularly of marine invertebrates. For the specific case of NP, RAC considers it is therefore adequate to derive a common $PNEC_{aqua}$, based on all relevant and reliable data from marine and freshwater species on traditional, apical endpoints. This is in line with the provisions outlined in Chapter R.10.3.2 of

[2] Cf. Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested. (Question N° EFSA-Q-2005-042) The EFSA Journal (2005) 301, 1-45.
In the case of NP, the 96-h LC_{50} for rainbow trout is 221 µg/L (ECB, 2002), giving an acute: chronic ratio of ca. 40 for this species. A ratio of ca. 20 can be derived using acute and chronic data for fathead minnow. The available acute toxicity data for marine fish species suggest that the winter flounder might have a NOEC below that for rainbow trout (the (speculated) long-term NOEC would be 0.4 or 0.8 µg/L based on the acute:chronic ratio for rainbow trout or fathead minnow, respectively).

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ECHA's guidance on IR and CSA for the marine compartment. Using the postulated NOEC for winter flounder (0.4 or 0.8 µg/L) as a 'representative' marine fish species makes very little difference in SSD approaches (it would decrease the HC_5-based PNEC by a factor of about 2.5[3]; this is also a precautionary approach because less sensitive data (e.g. the putative result for marine algae) should also be included).

Overall, RAC concludes that 'missing' data for standard test species representing marine invertebrates and fish does not justify a lowering of the $PNEC_{aqua}$ for traditional, apical endpoints by one or more orders of magnitude.

d) Alternative approaches derive very similar PNECs[4] for traditional, apical endpoints, thus well supporting each other: for freshwater 0.59 and 0.6 µg/L by applying SSD and AF approaches, respectively; 0.614 µg/L both for freshwater and seawater in the CSR, based on an SSD-approach; 0.39 µg/L when based on an AF of 10 for the lowest reliable marine long-term test result; 0.42 µg/L when based on an SSD incorporating this marine result into the freshwater SSD.

e) There is clear and consistent evidence for ED properties in fish at least. Indications of hormonal activity were observed in a number of species, starting from 1.0 µg/L in rainbow trout (LOEC vitellogenin [VTG] induction) and 15 µg/L in fathead minnow (LOEC secondary sex characteristics). Several of the underlying test protocols have been validated, standardised and agreed as test guidelines for specifically exploring ED properties of chemicals in fish.

f) When comparing traditional apical endpoints with indicators for endocrine mediated effects in fish, RAC notes the latter start at concentrations almost one order of magnitude lower. In an attempt to accommodate the intense discussion for developing its opinion, RAC further explored the most relevant long-term fish studies of Schwaiger et al. (2002) and Ackermann et al. (2002) in rainbow trout and the shorter duration studies of Schwaiger et al. (2000) and Pickford et al. (2003) in carp and fathead minnow. These studies appear well carried out in reputable laboratories with adequate analytical confirmation of the lowest concentration (1 µg/L in all cases). They provide insight into a range of apical and biomarker effects at a relevant low test concentration. Appendix 1 provides further details of the study evaluations. The most critical observations for developmental endpoints in the Schwaiger et al. (2002) study confirm a LOEC of 1 µg/L for F1 mortality before eyed-egg stage (Control 1.7%; 1 µg/L 10.1%; 10 µg/L 16.1%), and a NOEC of 1 µg/L for reduction of hatching rate. A presumed NOEC of 0.1 µg/L for adverse effects in rainbow trout would decrease the HC_5-based PNEC by a factor of about 5[5]. For other (particularly invertebrate) taxa, analogous evidence on relations between apical and indicative effect concentrations is less clear due to the prevalent inconclusiveness regarding endocrine related modes of action and regarding adversity of available observations at low concentrations, cf. the following observation g).

g) In tests with other taxonomic groups than fish, notably various invertebrates (e.g. echinoderms and molluscs as noted in Table 2), RAC notes a few observations for non-traditional endpoints at concentrations down to the range of 0.1 – 1.0 µg/L.

[3] See Appendix 2 for details of additional tentative SSD approaches.
[4] RAC notes that the "annual average" environmental quality standard for NP under Directive 2008/105/EC (a daughter directive of the Water Framework Directive) is also similar, at 0.3 µg/L. This value was based on an algal biomass end point that is no longer favoured for hazard assessment under REACH.
[5] See Appendix 1 for further details of RAC's additional study evaluations, Appendix 2 for details of additional tentative SSD approaches.

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These observations are not conclusively endocrine related since present knowledge prevents firm conclusions about a mechanistic link. Some observations were at the lowest test concentrations, preventing the derivation of NOECs. Validated and standardised test protocols for specifically exploring adverse ED effects are not yet available for many taxonomic groups in particular amongst invertebrate taxa. The concentrations for the aforementioned indicative observations seem to be less than one order of magnitude lower than the lowest observed adverse effect concentrations, but whether this would have also been the case when a broader data set using test protocols suitable for picking up adverse ED effects had been available, is not known. RAC notes that the DS considered the application of an extra AF when deriving a PNEC for NP as one option to deal with the uncertainties around ED.

h) RAC agrees that the ED-related generic arguments justify ED substances coming under particular scrutiny. There is however ongoing debate about how ED effects should be considered for hazard- or risk-based regulatory action. RAC is aware that the EU Commission services are currently considering the default assumption that a threshold cannot be determined experimentally due to limitations of available test systems and in understanding the underlying biology. Given this, RAC considers it premature in this specific case to give an opinion on whether or not it is possible to derive a safe exposure level for the ED effects of NP.

For traditional, apical endpoints, RAC concludes on a $PNEC_{aqua}$ of 0.4 µg/L for NP. Based on all available NP-specific test data and information from several species of fish, amphibians, algae, crustaceans (daphnids, amphipods, copepods, mysids), insects, nematodes, mussels, snails, and echinoderms, this PNEC is considered to provide sufficient coverage of additional species diversity in the marine compartment.

With a view to the ED properties of NP, RAC notes that it still appears difficult to precisely quantify the threshold for adverse ED effects of NP or to definitely exclude lower effect concentrations in taxonomic groups not yet covered by adequate testing protocols (the latter being a matter of principle that can apply to many other substances). Limited to fish, RAC efforts to further explore the evidence from available studies suggest that a PNEC lowered by about a factor of 5 (i.e. to 0.08 µg/L) might cover adverse ED effects. Even though there is currently no specific indication from any study with NP (presented in the dossier and during public consultation) that endocrine-mediated adverse effects occur at much lower concentrations than other apical effects in comparable test systems, RAC assesses the available evidence as insufficient to provide conclusive quantitative coverage of ED effects of NP for all taxonomic groups. In conclusion, RAC can not offer any opinion about whether the proposed PNEC is sufficiently protective of all relevant hazards posed by this substance.

As a pragmatic way forward for evaluating the present restriction proposal, RAC will use the 'traditional' $PNEC_{aqua}$ of 0.4 µg/L to get an indication of the possible risks. If any risks are identified for traditional, apical endpoints of NP, then the risks addressing in addition the ED effects will in all likelihood be greater, bearing in mind that the 'traditional' PNEC appears not to sufficiently cover the uncertainties identified (not only on the level of ED effects of NP, but also on the level of ED (and toxic) effects of NPEOs/NPECs (see next section) and on the combination effect of these substances with a similar mode of action).

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Environmental hazards of other relevant NPEO degradation products

In a rather general approach, the submitted dossier refers to evidence showing that ecotoxicity and estrogenicity of NPEO degradation products increase with decreasing chain length, with the most toxic substances being those with one or two ethoxylate (EO) or carboxyethoxylate units (NP1EO, NP1EC, NP2EO, NP2EC). The BD provides specific information on the underlying studies, namely four acute studies with fish (two tests), daphnids, and mysids, as well as one reproduction study with daphnids. In conclusion, the dossier highlights similar statements from two reports issued in 2002 by Environment Canada and the Environment Agency in the the UK: i) there is an inverse relationship between EO chain length and acute toxicity, for a number of different aquatic organisms, ii) the observed inverse relationship was not merely a function of the molecular weight of the NPnEOs.

In an attempt to quantify additional effects from medium (3-8 EO) and short chained (1-2 EO or EC) NPEO/NPECs, the dossier applies toxic equivalency factors (TEF) developed by Environment Canada. Table 3 provides a summary of TEFs considered for the risk characterisation of the restriction proposal, as well as figures of relative estrogenicity (RE, relative to NP) based on *in vitro* data for vitellogenin induction in trout hepatocytes, and analogous factors for octylphenol with its derivatives:

Table 3: *Summary of Toxic Equivalency Factors (TEFs) of nonylphenol and related compounds and relative estrogenicity values from Environment Canada (2001) (BD Table 22)*

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

RAC has the following observations on this approach:

a) RAC considers the TEF approach to be a rather weak basis for quantification of additional effects caused by NPEOs and NPECs, since the underlying data base is limited to a few acute studies and only one chronic study.

b) RAC notes that the Relative Estrogenicity (RE) deviates from the corresponding TEF for NP1EC and NP2EC. This sheds further doubt on the conclusiveness of the selected

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TEFs. As the REs are derived from *in vitro* data, and no corresponding information is available for medium chained NPEOs, the validity appears rather weak without further evidence.

c) RAC notes that the dossier provides two alternative scenarios to account for the medium (i.e. 3-8 EO units) chain length NPEO toxicities in the risk characterisation, either assuming the same (low) toxicity as for long chain NPEOs, or assuming the same (high) toxicity as for short chained NPEOs (shown in the table above).

d) The dossier provides no information on the relationship between chain length and toxicity / estrogenicity, be it linear or exponential.

RAC agrees that short chained NPEOs and NPECs contribute to overall toxic (including ED) effects in the environment when they are present in combination with NP. The basis for quantification however has significant uncertainties. The approach to assume the same high toxicity for NPnEO (with n = 3-8) as for NP1EO and NP2EO clearly overestimates their contribution to the effects caused by NP. As no clear experimental or other evidence is available for RAC to draw firm conclusions on adequate TEFs, RAC concludes that short-chained NPEO and NPEC, if present in combination with NP, qualitatively add to the hazards quantified for NP. While quantification for NP for the more traditional, apical endpoints is based on a well consolidated dataset, the TEF approach for NPEO and NPEC adds disproportionate uncertainty to combined quantitative hazard estimates. The latter should then be considered as indicative worst case figures only. Short chain NPEOs and NPECs, like NP, add to the existing overall estrogenic pressure on ecosystems, but lack of data preclude a quantification of the additive ED effects.

Environmental hazards of alternatives for NPEO

Based on the available information provided in the BD (Section C.2.3), RAC agrees with the dossier submitter that alcohol ethoxylates, glucose based surfactants (alkyl glucosides and alkyl glucamides), and alcanol fatty acid amines show lower toxicity, no indications of endocrine activity, and pose a lower level of environmental risk when used as alternatives for NPEO as surfactants or emulsifiers. RAC notes that there are some limitations in the available hazard information for some of these substances.

- Information on emissions and exposures

NP exposure in EU water bodies

NP is a Water Framework Directive Priority Hazardous Substance, so is subject to monitoring by the EU Member States. Relevant data have been reported to the European Commission and summarised in a database maintained by EIONET[6] and a report by the Joint Research Centre (2008). The dossier submitter referred to these data to draw conclusions about risk in the original dossier, and additional data were provided for several countries during the PC. Only measured data from 2006 or later are considered relevant (since earlier years reflect higher use prior to the introduction of the existing restriction for NP/NPEO[7]), and results reported to be below the limit of detection (LoD) or limit of quantification (LoQ) are assumed to be half that value for statistical purposes (in accordance with EU technical guidance). Measurements from urban regions are considered

[6] http://cdr.eionet.europa.eu/
[7] Entry 46 of REACH Annex XVII, originally published as Directive 2003/53/EC of the European Parliament and of the Council of 18 June 2003, Official Journal of the European Union L 178/24, 17.7.2003.

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more relevant than concentrations in rural regions.

If several measurements are available for the same water body, the dossier submitter uses the 90th percentile as a representative value. A surface water PEC is then calculated for 25 individual EU countries and Norway using the median value of 90th percentiles of monitoring data for water bodies in each country (see Table 4, derived from Tables 1 & 35 in the BD, updated using information received during PC). A PEC for marine waters was similarly estimated using the median value of 90th percentiles of monitoring data from combined brackish and marine waters from four Nordic countries.

Table 4: *Values used to derive surface water PECs based on monitoring data (BD Tables 34 & 35)*

Country	**PEC (90P) µg NP/L**	
	Freshwater	***Marine***
Austria	0.331	-
Belgium	0.05*	-
Bulgaria	0.265	-
Cyprus	0.453	-
Czech Republic	0.169	-
Denmark	0.025* - 0.34 (Min 90P – Max 90P)	0.051
Estonia	0.025*	-
Finland	0.12	0.089
France	0.15	-
Germany	0.136 – 0.33 (Min 90P – Max 90P)	-
Greece	0.59	-
Hungary	0.025*	-
Ireland	0.01*	-
Italy	0.200	-
Lithuania	0.062	0.115
Luxembourg	0.05*	-
Malta	0.01*	-
The Netherlands	0.095	-
Norway	0.036	0.017
Poland	0.025*	-
Romania	0.33	-
Slovakia	0.05*	-
Slovenia	0.02	-
Spain	0.43 – 0.54 (Min 90P – Max 90P)	0.19
Sweden	0.05*	0.05*
United Kingdom	0.32§	-
Median	**0.08 – 0.11**	**0.07**

Note: * means the substance was below the limit of detection.

§ This value is based on measurements at 10 English sites. Other data indicate that the 90th percentile in 162 WWTP effluents across the country was 0.37 µg/L (so with dilution/partitioning in the receiving water, the final surface water concentration would be lower).

These values were used for risk characterisation in the dossier in preference to other estimates (e.g. based on effluent monitoring or product register data). RAC agrees that this monitoring database provides a good starting point for considering the level of NP exposure, but cautions that it may be misleading about the scale and extent of that exposure for risk assessment purposes, for the following reasons:

- It is very difficult to compare data between countries, due to potential analytical differences (e.g. limits of detection (LoD)) and the limited amount of data available. For example, 16 out of 26 countries from which freshwater measurements are reported

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appear to involve six or fewer water bodies (the PEC for Cyprus is based on data for two water bodies only, of which one is below the LoD).
- Very few data are summarised for marine waters, and the very close similarity between the overall freshwater and marine PECs is not intuitively logical given that the available dilution in marine environments is usually significantly greater than in freshwaters.
- There are a large number of non-detects for some water bodies, and the assumption that the true concentration is half the LoD in such cases may introduce some bias.
- There are significant conflicts in the data between EIONET and JRC (2008) for some countries (e.g. Belgium), and the reasons for these differences are not clear.

Nevertheless, with a few exceptions, national Competent Authorities have not provided any comment about the choice of data for their countries, and so presumably accept that the 90th percentiles are reasonable. Modelled data provided by the UK during PC suggest that around five per cent of English water bodies are at risk of exceeding an annual average concentration of 0.3 µg/L (the proportion exceeding 0.4 µg/L will be lower). England is a relatively densely populated and industrialised region with a good degree of tertiary wastewater treatment but relatively small rivers. RAC considers that this conclusion is likely to be applicable to broadly similar parts of Europe, with higher concentrations likely where the level of wastewater treatment is lower.

Several articles cited during PC indicate that marine and freshwaters might be exposed to NP concentrations above 0.4 µg/L in Spain and Greece (e.g. Sánchez-Avila *et al*. (2013), Sánchez-Avila *et al*. (2012) and Stasinakis *et al*. (2012)).

In conclusion, NP is present in some European fresh waters at a concentration exceeding 0.4 µg/L. The majority of water bodies appear to be exposed to lower concentrations.

Short chain NPEO/NPEC exposure in EU water bodies

The dossier submitter reviews a number of studies that demonstrate that the degradation of NPEOs in wastewater treatment plant (WWTP) will result in the co-release of NP, short chain NPEOs and NPECs (some further degradation of the NPEOs to NP may also occur following release) (Section B.9.4 of the BD). However, it does not present any comprehensive monitoring data for short chain NPEOs or NPECs in receiving waters. Instead, a tentative estimate of the proportion of NP1EO and NP2EO that can be expected to be released with NP has been made based on degradation studies (the assumption of distribution in a WWTP is taken from the Existing Substances Regulation assessment (ECB, 2002)[8], combined with the ratio of NP1EO/NP2EO to NP1EC/NP2EC (approximately 1:2) observed in the study by Ahel *et al.* (1994), and then assuming, as a worst case, that all of the longer chain NPEO released to effluent has 3-8 ethoxy units). The estimated relationship is then used with the NP PEC originally selected for risk characterisation purposes to estimate a 'worst case' concentration for the short chain NPEOs and NPECs (Table 41 in the BD, repeated below).

Table 5: *Predicted concentrations of NPEOs and NPECs in fresh and marine waters*

Chemical species	Proportion relative to NP	Concentration (µg/L)	
		Fresh water	Marine water
NP	1	0.085	0.05

[8] Of the total NPEO input, 2.5 per cent is released as NP in effluent, 25 per cent is released as mono-/ di-ethoxylates and NPEC and 8 per cent as longer chain ethoxylates. The remainder is mineralised or adsorbs to sludge.

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NP1EO/NP2EO	3.3	0.28	0.165
NPnEO (n = 3-8)	3.2	0.27	0.16
NP1EC/NP2EC	6.7	0.57	0.335

The dossier submitter recognises that the exact proportions in fresh and marine water will vary, and that the true environmental concentrations may differ in reality. However, the dossier submitter claims that support for the estimated relative proportions of NP versus NP1EO/NP2EO is provided by a review article by Bergé *et al.* (2012): WWTP effluent concentrations from 32 individual studies in the period 1985 – 2012 from 15 countries resulted in median NP and NP1EO concentrations of 1.28 µg/L and 4.50 µg/L, respectively, i.e. a relative proportion of 1:3.5; surface water concentrations from 32 individual studies in the period 1991 – 2011 from 17 countries resulted in median NP and NP1EO concentrations of 0.33 µg/L and 0.99 µg/L, respectively, i.e. a relative proportion of 1:3.

RAC has the following observations:

a) The assumptions about the degradation pathways of NPEOs in WWTP in the risk assessment report under the Existing Substances Regulation (EU, 2002) were intended to reflect a reasonable worst case situation. Available data suggest that the formation of small amounts of NP from NPEO occurs primarily under anaerobic conditions, with little if any formed under aerobic conditions. The dossier includes brief summaries of a number of additional studies that have been performed since that assessment was completed, but it is not clear if this is a comprehensive review, and none of the studies is directly relevant to the behaviour of NPEOs in WWTP. The dossier submitter does not discuss whether the worst case assumptions are still valid, or how this degradation rate may vary. They point out that an NPEO fate study by Loyo-Rosales et al. (2007) in three American WWTP, two of which involved advanced treatment, indicated an overall NPEO removal efficiency of 61–80 %, but this does not describe whether NP was formed.

   On this basis, RAC can accept that the 2.5 % conversion rate of NPEO to NP is a worst case assumption, but it is possible that a more thorough analysis might modify this.

b) The calculation relies on a single study (Ahel *et al.*, 1994) for the assumption of the ratio of NP1EO/NP2EO to NP1EC/NP2EC in WWTP effluent, and does not consider how this may vary.

c) The paper by Bergé *et al.* (2012) appears to support the estimated distribution but this might be coincidental. It is difficult to be sure of the reliability of the cited studies without further details. RAC notes that some are nearly thirty years old, and may therefore reflect different types of WWTP treatment practice or NP/NPEO loads than are typically found today. For example, data for ten UK WWTPs in 2013 (provided during PC) indicate that the geometric mean NP effluent concentration was 0.29 µg/L; the ratio assumed in the dossier suggests that the NP1-2EO effluent concentration should be 0.96 µg/L, whereas it was in fact 0.07-0.13 µg/L[9] (i.e. at least seven times lower). In contrast, other studies cited by Bergé *et al.* (2012) or provided during PC show that Spanish WWTP can have an NP:NP1-2EO ratio in effluent of 2:3 (Sánchez-Avila *et al*. (2012)[10], based on mean data for eight WWTP), approximately 1:3 (Sánchez-Avila *et al*., 2009[11]; based on sampling over two days only, for one WWTP),

[9] Geometric mean, where non-detects were assumed to represent concentrations at half the LoD.
[10] Sánchez-Avila, J, Tauler, R and Lacorte, S (2012). Organic micropollutants in coastal waters from NW Mediterranean Sea: Sources distribution and potential risk. Environment International, 46, 50–62.
[11] Sánchez-Avila, J, Bonet, J, Velasco, G and Lacorte, S (2009). Determination and occurrence of phthalates, alkylphenols, bisphenol A, PBDEs, PCBs and PAHs in an industrial sewage grid discharging to a municipal wastewater treatment plant. Science of the Total Environment, 407, 4157-4167.

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or 1:25 (Vega-Morales *et al.*, 2010[12], for one WWTP). The samples were collected post-2006.

It is therefore likely that the NP1-2EO concentration may be higher than the NP concentration in some, but not necessarily all, receiving waters. The data are too few to allow a clear conclusion to be drawn about which situation is more typical.

d) The fate and partitioning behaviour of short chain NPEOs and NPECs is not discussed in the dossier. They are likely to have a lower degree of lipophilicity compared to NP, and so will probably remain in the water column longer than NP (assuming that they are not themselves rapidly degraded). It therefore seems to be a reasonable assumption that they will co-exist with NP in receiving waters until the NP has sedimented out with particulates.

e) The approach is an extrapolation dependent on the choice of NP PEC (see above), and assumes that the NP in the receiving water is entirely derived from NPEO degradation. This is an over-simplistic assumption, since WWTP influent contains significant quantities of NP, as described in the dossier and confirmed by UK data provided during PC. It is possible that some of the NP in the influent arises from NPEO degradation in the sewer system before it arrives at the WWTP but there is no information to confirm this (it would have to be an anaerobic process, so this degradation is unlikely to happen during textile washing). If NPEO degradation were a significant source, the levels of short chain NPEOs would be expected to be relatively high as well (as they would be precursors), but this does not appear to be the case (for example, the combined geometric mean NP1-2EO concentrations in the influent of ten UK WWTPs was 0.14 µg/L, thirteen times lower than that for NP (1.92 µg/L)). Given the relative amounts, it seems more likely that the NP is derived from other sources. This is an important point that is also relevant to the risk reduction potential of the proposal.

RAC considers the approach to estimate concentrations of short chain NPEOs in receiving waters to be useful as a screening tool, but is likely to result in a significant over-estimation.

o Risk characterisation

The dossier addresses risks to surface water, sediment, wastewater treatment plant micro-organisms, soil and secondary poisoning of predators. No risks have been identified for any compartment other than surface waters, so they are not discussed further in this opinion.

The dossier submitter takes a deterministic approach to risk assessment. Based on the median PECs for fresh and marine waters derived in the dossier and a 'traditional' $PNEC_{aqua}$ of 0.4 µg/L derived for this opinion, the 'minimum' risk characterisation ratios (RCR) for NP are below 1, suggesting a relatively low risk overall (the freshwater RCR is highest, at 0.20–0.28). Three countries have a 90th percentile NP concentration higher than 0.4 µg/L, indicating a risk for NP in freshwater (Cyprus, RCR = 1.2, based on measurements from two locations; Greece, RCR = 1.5, based on measurements from ten locations; and Spain, RCR = 1.1 – 1.4, based on measurements from 46 locations). Looking further into the underlying data, 50% (= 1/2), 20% (= 2/10) and 13% (= 6/46) of the available Cypriot, Greek and Spanish freshwater locations, respectively, have measured NP concentrations above the $PNEC_{aqua}$.

[12] Vega-Morales, T, Sosa-Ferrera, Z and Santana-Rodríguez, J J (2010). Determination of alkylphenol polyethoxylates, bisphenol-A, 17α-ethynylestradiol and 17β-estradiol and its metabolites in sewage samples by SPE and LC/MS/MS. Journal of Hazardous Materials, 183, 701-711.

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There are also indications that there may be concern for freshwaters in other parts of the EU. For example, 20% (1/5) of Austrian waters and 15% of the waters in the Netherlands (2/26) have measured concentrations exceeding the $PNEC_{aqua}$ (even though the 90th percentile PECs are below the $PNEC_{aqua}$). In addition, modelled data provided by the UK during PC suggest that around five per cent of English water bodies are at risk of exceeding an annual average NP concentration of 0.3 µg/L (the proportion exceeding 0.4 µg/L will be lower). Finally, academic studies indicate risks in Spanish marine waters (RCR up to 15).

Based on these findings, and noting the limitations in the monitoring data set, RAC assumes that at least a small proportion of freshwater bodies in several EU Member States, and some marine waters, are at risk due to NP exposure. The majority of EU water bodies appear likely to be exposed to NP concentrations below 0.4 µg/L and so will not be at risk from this substance alone (ignoring the overall estrogenic pressure arising from this substance and short chain NPEO/NPEC and other substances that may also be present). Surface water concentrations and therefore risks appear to be higher in southern Europe. RAC notes that ED biomarkers could still be induced at this concentration (e.g. VTG could be induced in fish at concentrations below the lowest reported LOEC of 1.0 µg/L), and that the suggested 'traditional' $PNEC_{aqua}$ might need to be lowered by a factor of about 5 for coverage of possibly adverse ED-mediated effects in fish, which would however require further confirmatory studies, still not covering other taxonomic (particularly invertebrate) groups. However, many more sites would be at risk if the tentative $PNEC_{aqua}$ of 0.08 µg/L were used (the 90th percentile concentrations would be exceeded in Austria, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Italy, The Netherlands, Romania and the UK).

The dossier presents an approach to assess the additional risk arising from co-release of NPEO degradation products, using Toxic Equivalence Factors (TEFs) and an assumption that the levels of NP reported in water bodies can be extrapolated to levels of short chain NPEOs that may also be present. Based on the median NP PECs for fresh and marine waters, there is no risk when the contribution of these degradation products is considered. Similar calculations are presented based on the 90th percentile NP concentrations for various EU Member States, and Norway, using a scaling factor. When this is done, a risk is identified for up to thirteen countries, with a maximum RCR of 17. As discussed above, RAC considers this to be a screening assessment only, due to the lack of reliable chronic ecotoxicity data for the TEFs and unreliable assumptions about the levels of degradation products that may be present in receiving waters. RAC assumes it is sufficient to acknowledge that the level of risk represented by the NP monitoring data is likely to be an underestimate when the presence of other NPEO degradation products is taken into account. The actual degree of underestimation cannot be assessed with confidence at present.

It can be assumed that at least a small proportion of freshwater bodies (and some marine waters) in more than one EU Member State are at risk due to NP exposure (the risk is more extensive if a lower $PNEC_{aqua}$ is selected). Co-release of other NPEO degradation products will add to this risk, and there is also some residual uncertainty about the margin of safety for possible ED effects covered (or not) by the 'traditional' PNEC. The magnitude of the additional risk cannot be determined with any certainty on the basis of the available data, so this means that only a 'minimum' risk can be identified using data for NP alone.

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JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Justification for the opinion of RAC

Monitoring data provided by the UK during PC show that release of NP and NPEOs to WWTP is ubiquitous, and that a high percentage of the NP load (up to ca. 75%) is believed to arise from domestic sources (the percentage for NPEOs arising from domestic sources is not known with any uncertainty, but might be expected to be at a similar level). NP is present in fresh waters in several areas of Europe at concentrations exceeding the 'traditional' $PNEC_{aqua}$ of 0.4 µg/L. It therefore poses an environmental risk at a European-wide scale. Co-release of NPEO degradation products will add to the risk, although the actual increase in risk is not possible to establish reliably based on the data presented in the dossier.

RAC concludes that action to reduce the risks arising from NP exposure needs to be taken on an EU-wide basis.

Justification for the opinion of SEAC

SEAC agrees that action is required on an EU-wide basis. The proposed restriction covers textile articles or textile parts of articles, where those articles comprise of textile clothing and accessories as well as interior textiles (for further information on the articles covered by the restriction see section A.1.2 of the Background Document as well as Appendix 13)[13]. Such products are extensively traded and used in all Members States. The use of Nonylphenol and Nonylphenol ethoxylates as substances or in mixtures, which are not used in closed systems, is already restricted in the EU within the textile sector since 2005 (REACH Annex XVII, Entry 46). However, the dossier submitter investigated that these substances are still used primarily outside the EU as detergents and auxiliaries in the manufacturing of textile articles. Furthermore, the major part of textiles consumed within the EU is imported from outside the Union. According to statistics from Eurostat the import of textiles was about 6 million tonnes in 2010 and the import share of EU consumption is assumed to be at least 75 % and probably close to 90 % (see sections B.9.3.4.1 and E.1.1.2.2 of the Background Document). This assumption is supported by data from the EUROSTAT PRODCOM database, which indicate that the textile import share of EU consumption was approximately 82% in 2010. SEAC agrees that an EU-wide restriction would remove potentially distorting effects that national restrictions or other national risk management measures may have on the free circulation of goods. Moreover, it would reduce the existing uncertainty for international suppliers regarding regulatory requirements, since it provides a clear statement of the requirements in the EU and can therefore easily be communicated to suppliers outside the EU (confirmed by stakeholders).

Action on an EU-wide basis is also regarded to be justified based on the assessment of the EU-wide nature of environmental impacts, economic impacts as well as the availability of alternatives for the concerned substances throughout the EU. Furthermore, it is regarded as ensuring equal treatment among both, EU producers and importers of textile articles as listed in the restriction scope.

[13] The definition of textile articles within the scope of the restriction uses the definitions in the proposed criteria document for Commission decision establishing the ecological criteria for the award of the EU Ecolabel for textile products.

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JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Justification for the opinion of RAC

It is clear that there are several sources of NP in wastewater. The justification for the restriction relies on assumptions about the overall amounts of NP thought to arise from NPEO released by textile washing in comparison with other sources.

Occurrence of NPEO in textiles

NPEOs are used as surfactants for various purposes in the textile manufacturing process, e.g. for dispersion, emulsification, cleaning, etc., so it is not unexpected that residual amounts may remain on textile articles at the end of processing. No comprehensive collection of data exists about the levels of NPEO in textile articles on the European market. The BD summarises results from twelve published studies. These are considered relevant because they are recent (i.e. performed after 2005) and describe the method of chemical analysis. Items were apparently chosen at random from commercial retail sources, and across different price ranges in some cases. A summary of the available information is presented in Table 9 of the BD. Arithmetic and geometric means and median concentrations were calculated by the dossier submitter for each study, assuming that samples for which NPEO was not detected had a concentration that was half the reported limit of detection (LoD). The dossier submitter has calculated an overall arithmetic mean of 211 mg NPEO/kg textile (reducing to 97 mg/kg if two outliers are removed from the data set) ("Scenario A"), a geometric mean of 9 mg/kg ("Scenario B"), and a median of 5 mg/kg ("Scenario C") (see Section B.2.3 of the BD). Figures 2 and 3 illustrate the distribution of the reported results.

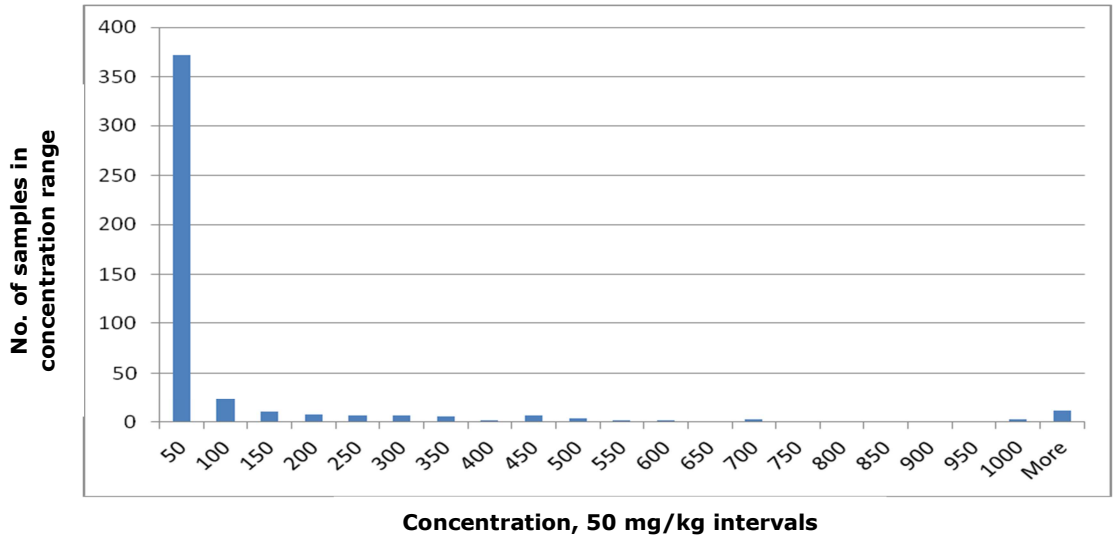

Figure 2: *Frequency of reported NPEO textile concentrations, n = 474*

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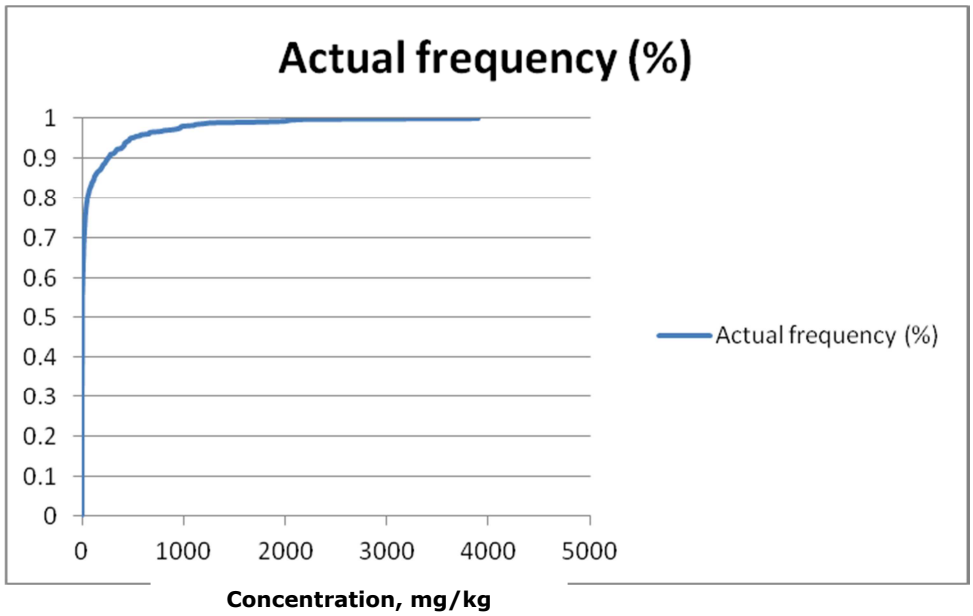

Figure 3: *Cumulative frequency of reported NPEO textile concentrations (three outliers removed)*

Anecdotal information from one test laboratory (Eurofins) that has experience of analysing textiles suggests that the NPEO concentration is below 10 mg/kg in about a third of tested samples. Around half the samples have NPEO concentrations in the range of 10 to 500 mg/kg (with an average of 100 – 150 mg/kg), thought to reflect intentional use of NPEO in the manufacturing process. Levels in the range 500 – 1,000 mg/kg or more are found in about five per cent of samples, although such high levels have occurred less often in recent years. It is thought that these higher levels may be due to use of NPEO in colouring processes. It is not clear whether the laboratory's statements are representative of the entire textile market. The dossier submitter also notes that a previous study (COHIBA, 2012) assumed that half of all imported textiles contain NPEO.

Based on back-calculations from NPEO monitoring data for ten UK WWTP and assuming that all the NPEO originates from textile washing, the NPEO concentration in textiles is estimated to be in the range 17 – 43 mg/kg[14], which is a similar order of magnitude to the values derived from the twelve studies. The dossier submitter suggests that the actual NPEO concentration in textiles lies somewhere between the calculated geometric and the arithmetic mean, and selects an 'average' concentration of 53 mg/kg textile for subsequent calculations.

RAC has the following observations on this information:

a) Imported textile articles on the EU market can clearly contain NPEO, with some individual items containing levels above 100 mg/kg (78/474 (16 per cent) from the studies reported, although the proportion may be higher for some specific product types (e.g. children's winter overalls); the proportion from the anecdotal source is unclear).

b) A large proportion of individual items of clothing have NPEO levels below a detection limit of around 1 – 10 mg/kg (221/474 or 47 per cent from the studies reported

[14] The range reflects the result of calculations based on either the geometric mean (assuming that non-detects represent concentrations of half the LoD) or the arithmetic mean of the NPEO influent concentrations.

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(although this might be misleading given the number of samples involving a single garment type (underwear)); the proportion may be around thirty-three per cent according to an anecdotal source).

It is logical to assume that textiles produced in countries without any specific regulatory controls on the use of NPEO may contain higher levels than those made within the EU. It is, however, still possible for EU-manufactured textiles to contain residual amounts of NPEO, since its use in textile processing has not been restricted completely. There is insufficient information to comment further (mainly due to lack of information about countries of origin in the original reports).

c) There tends to be an order of magnitude difference between the arithmetic mean and median values for most of the studies, indicating a significant skew in the data. The choice of the best statistic for expressing 'average' concentrations is therefore open to question. The dossier says that when dealing with diverging data it is preferable to use the median rather than a mean value. However, since the sample size is considered to be small, the median is not considered to be more reliable than the average. RAC acknowledges this fact, but notes that the arithmetic mean will give more weight to high values, and that subsequent calculations may therefore be biased. RAC also notes that if the confidence intervals of the means had been estimated in the BD (e.g. using boot strapping methods), they could have provided a useful measure of the uncertainty in the cited values. Overall, RAC suggests that the geometric mean (9 mg/kg) would be a more appropriate measure in this case since it takes into account the large number of non-detects, but is still precautionary.

d) The total number of items analysed (474) is very small compared to the number of textile articles on the EU market (both finished and part-finished). Most of the studies also involved a limited variety of clothing (approximately 40% of the analyses were performed on underwear). They therefore do not represent a truly randomised sample of all textile goods, and it is not known whether some textile types will normally contain significantly more NPEO than others. Comments received during PC suggest that the lack of standardisation in analytical methods (including sampling and extraction techniques) can also introduce substantial variability in reported values.

e) The back-calculation from NPEO concentrations in WWTP influent is a useful 'reality' check. Although the calculations are based on data for only ten UK WWTP, and so might not be representative, the WWTP were chosen because they were known to have high levels of NP in influent, and textile consumption patterns are likely to be broadly similar across Europe. The assumption that all of the NPEO present is derived from textile washing is conservative (as recognised in Annex 12 of the dossier), and if there are other sources (e.g. paints) then the calculated concentrations in textiles will be lower than suggested. On the other hand, the analytical method was only capable of detecting substances with up to fifteen ethoxylate units, and since textiles may contain NPEO with up to thirty ethoxylate units, the overall NPEO concentration could be underestimated. RAC recognises that the back-calculation itself is based on a number of assumptions (e.g. in terms of the quantity of textiles on the market, population size served by the WWTP and flow rates). However, it suggests that the arithmetic mean textile concentration derived in the dossier (Scenario A) might be too high, and that the 'average' concentration is possibly closer to the geometric mean (Scenario B). The assumption of an average mid-way between the geometric and arithmetic means is therefore still likely to be conservative.

Based on a limited amount of published information for small numbers of specific textile article types (mainly clothing) on the EU market, it appears that around 20 per cent of such articles may contain NPEO concentrations exceeding 100 mg/kg

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(sometimes above 1,000 mg/kg or occasionally even 10,000 mg/kg), but a significant proportion (perhaps around 50 per cent) may have NPEO concentrations below 1 – 10 mg/kg. The overall 'average' concentration of NPEO in textiles estimated as 53 mg/kg in the dossier is a reasonable worst case, but a more realistic value is probably lower (in the range 10-50 mg/kg); it is not known if this is typical of all textile articles on the market.

Three of the twelve studies also analysed for NP in addition to NPEO. Klif (2011) did not detect any NP in 31 products randomly chosen from the categories children's clothing, leisure/sports equipment shoes and dog toys (the LoD is not stated in the dossier). Greenpeace (2012) found NP at a concentration of 8 mg/kg textile in two out of fourteen items of outdoor clothing (LoD: 3 mg/kg textile). Danish EPA (2012-2013) analysed fifteen items of children's clothing and detected NP with an arithmetic mean of 1.6 mg/kg textile (the detection frequency and LoD are not stated in the dossier). In contrast, stakeholder comments submitted during PC (Fedustria (2014), followed up subsequently by the dossier submitter) indicate that higher NP concentrations can sometimes be measured. For example, tests carried out in Belgium on textiles manufactured outside the EU found that NP concentrations exceeded 10 mg/kg in about four per cent of samples (number of samples not stated); the NP concentrations in the non-compliant samples ranged from 16.4 mg/kg to 790 mg/kg.

This suggests that low levels of NP may be present in at least some textiles, although a reliable 'average' concentration cannot be estimated based on the limited data available. Since NP is not known to be intentionally used in textile processing, the source of the NP is unclear – it may be due to degradation of NPEOs at some point in the manufacturing process, or (perhaps more likely) it could be an impurity in some grades of NPEO (or other substances used in the manufacturing process).

NPEO releases from textile washing

The dossier submitter notes that the extent of NPEO release during laundering may vary depending on the type of textile article and the NPEO content of the fabric, although as NPEO is easily dissolved in water, it is likely that all NPEO is washed out after repeated washing, regardless of textile type (Månsson et al., 2008). Three studies (Greenpeace, 2012, EA, 2012 & Danish EPA, 2013) have analysed several clothing types (n = 35) before and after simulated laundry tests. The Greenpeace and Danish EPA studies demonstrated that a single wash is sufficient to release 9 – 94 per cent, or 22 – 99 per cent, respectively, of the NPEO content, depending on the article (the EA study indicated initial wash-off rates at the upper end of this range for underwear). These studies conclude that effectively all NPEO will be washed out after two or more washes under normal conditions. Although this is a very small sample, RAC agrees that it is reasonable to assume that NPEO can be readily washed out of textiles in the absence of information to the contrary.

A second consideration is whether washing frequency varies with different article types. Since the majority of textile articles that can be washed would be expected to be subjected to laundering at least once a year, the dossier assumes that all NPEO present in textile articles that can be washed will be released to waste water over the course of a year. RAC agrees that this is a reasonable worst case approach in the absence of better information.

The dossier presents data on annual amounts of textile imports into the EU (6,037,526 tonnes in 2010), and uses this together with the 'average' content of NPEO estimated to be present in textiles (53 mg/kg) as the basis of its emission calculation, resulting in a total potential NPEO release of 320 tonnes/year at the continental level (see Section B.9.3.4.1 of the BD). If the geometric and arithmetic means of the textile

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concentrations are considered, the range is 53 – 585 tonnes/year.

The dossier indicates that the import of semi-finished textiles was about 4.1 million tonnes in 2010 (EU Statistical Database, 2012). These textiles are likely to be processed by textile industries within the EU, and can contain NPEO so are a potential source of release. However, the dossier suggests that most of the products covered by the statistics will either not be subject to washing, or only contain small quantities of NPEO (without presenting further evidence to explain why). The dossier states that this source could increase the 'relevant' textile tonnage by up to 10 per cent, although this is not included in the final release estimates.

RAC has the following observations:

a) The source of the data on textile imports is "EU statistics on import and export of certain textiles, produced by the administrative agency Statistics Sweden 2011 on behalf of the Swedish Chemicals Agency". The dossier submitter has clarified that this tonnage figure refers to Taric codes covering: knitted or crocheted fabrics; articles of apparel and clothing accessories, knitted or crocheted; articles of apparel and clothing accessories, not knitted or crocheted; other made-up textile articles; sets, worn clothing and worn textile articles; sports footwear; tennis shoes, basketball shoes, gym shoes, training shoes and the like; toys representing animals or non-human creatures-stuffed. The amount of imported textiles over the period 2005-2010 varies between 5.3 million and 6.2 million tonnes/year. RAC is unclear whether the entire amount of each category can be assumed to be subject to laundering with water.

   In the absence of any other data, RAC accepts a figure of about 6 million tonnes as representing the best estimate of the total amount of imported textiles that may be subject to washing in water, but notes that the actual amount that may be washed with water could be different.

b) Given the comments made on NPEO levels in textiles above, combined with uncertainties in the tonnage of textiles subject to washing, RAC concludes that extrapolating the available data to estimate NPEO levels in all textile articles may lead to significant under- or over-estimates compared to the actual situation. For use in subsequent calculations of releases from washing, RAC presumes that the range of 53 – 585 tonnes/year provides an appropriate range for consideration, but notes that the lower end of this range may be more realistic (i.e. based on the geometric mean concentration in textiles).

c) Since it cannot be excluded that NPEO may also be present in textile articles produced within the EU, RAC believes that it would be better to use the total amount of relevant textile articles on the market for the calculation, if reliable data are available. Section E.1.1.2.2 of the BD indicates that tonnage figures are not available, but suggests that the total EU consumption of relevant textiles was in the range of 6.7 – 8.1 million tonnes in 2010 (most likely in the lower part of the range). In the absence of additional information on the extent to which EU-produced textiles contain NPEO, RAC recognises this as an unquantifiable uncertainty.

The dossier submitter recognises that technical textiles not covered by the proposed restriction can still be exposed to water (e.g. rain) allowing leakage of NPEO to the environment. Based on consultation with Industry, AMEC (2012) indicates that 5,000 tonnes of NPEOs can be used annually in the EU for the production of technical textiles. If it is assumed that 20 kg of NPEO is used per tonne of textile (based on the OECD emission scenario document for the textile industry (OECD, 2004)), this would suggest that the finished articles may contain up to 100 tonnes of NPEO as a worst case. However, the dossier uses the estimated arithmetic and geometric mean concentrations of NPEO in

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clothing (9 – 97 mg/kg) to assume that 0.05 – 0.5 per cent of the NPEO could stay in the textile after the process, with potential releases to surface water over a ten year period resulting in an annual emission of approximately 1 – 10 tonnes of NPEO to surface water. RAC does not think this calculation is sufficiently substantiated, and believes that it is better to simply acknowledge that this is another potential source of NPEO in the environment, albeit not adequately quantified.

RAC considers that the assumed quantity of NPEO released from textile laundering on an annual basis is highly uncertain. The figure derived in the dossier of 320 tonnes (range: 53 – 585 tonnes) appears to be the best estimate currently available, but RAC assumes that the lower end of this range is possibly more realistic, while noting that the contribution of EU-produced textiles is unknown. RAC recognises that other textiles that are not intentionally laundered in water may still contribute to environmental emissions of NPEOs.

Comparison of the textile washing scenario with other sources of NP/NPEO

Many other sources of NPEO and NP exist besides textiles (e.g. paints, adhesives, in the construction industry, and as impurities in other derivatives). The dossier summarises available information on these, along with predicted release estimates based on Swedish Product Register data and modified Environmental Release Categories (ERCs) (Section B.9.3.4.2 of the BD). The transformation rate of derivatives to NP in a WWTP is assumed to be the same as for NPEO (i.e. 2.5 per cent), so releases are expressed as 'NP equivalents' for comparative purposes. The estimated release data are then scaled up to EU level using a factor of 53, on the basis of population size. The results are indicated in Table 31 of the BD (repeated below). No comparison is made with exposure scenarios in the CSRs.

Table 6: *Releases to WWTP of NP from use in the EU, based on data in chemical mixtures in Sweden in 2009*

Product group*	**NP equivalents in products (tonnes)**	**LIFE CYCLE RELEASES TO WWTP**					
		Formulation (tonnes)	**End product use (tonnes)**	**Processing (tonnes)**	**Service life (tonnes)**	**Total (tonnes)**	**Total (%)**
Emulsifier	2,595	26.30		64.93		91.2	**36**
Cleaning agent	119	0.65	60.24			60.9	**24**
Plastic product	8,866	31.08		1.07	13.77	45.9	**18**
Paint	1,784	9.04		7.89	9.38	26.3	**10**
Adhesive	541	2.81		3.39	4.66	10.9	**4.3**
Lubricant	270	0.78	0.16		5.12	6.1	**2.4**
Pharmaceutical	11	0.05	4.90			5.0	**2.0**
Constr. material	92	0.40		0.75	2.30	3.5	**1.4**
Printing ink	8,325	0.83		0.42	0.42	1.7	**0.7**
Other	178	1.53		0.61	0.50	2.6	**1.0**
Total (tonnes)	22,781	73.48	65.31	79.05	36.15	254	**100**
Total (%)		**29**	**26**	**31**	**14**	**100**	

*Imported cosmetics and pharmaceuticals are not included.

The total estimated annual releases to waste water at the continental level are: NP 6.4 tonnes, NPEO 176 tonnes (as 'NP equivalents') and NP derivatives 72 tonnes (254 tonnes total, as 'NP equivalents'). The dossier recognises that there could be some non-compliance with the existing Annex XVII restriction, although such releases are not taken into account because they are believed to be relatively small (if they occur at all).

The dossier includes a qualitative description of some of the uncertainties involved in these

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release estimations. Not all products on the market are included in the Product Register, and it does not include details for all end product uses. The release rates are based on conservative assumptions, and the contribution from long-life articles is assumed to have reached a steady state, which may not be the case.

The dossier then uses the estimated annual NPEO release from textiles and other sources to calculate an average NPEO concentration in WWTP influent of 10.1 – 18.1 µg/l, using parameters for Sweden (waste water volume) as an example (Section B.9.4.1 in the BD). In this calculation, the 'NP equivalents' released to waste water from other sources are converted to NPEO (assuming a conversion ratio of 2:5 based on a specific NPEO chain length) to allow comparison (Sections B.9.3.4.1 and B.9.3.4.2 of the BD). Assuming that 2.5 per cent of the influent NPEO concentration is released from the WWTP as NP, the resulting NP effluent concentration is 0.3 – 0.5 µg/L. A default dilution factor of ten gives a predicted local surface water concentration of about 0.03 – 0.05 µg/L (ignoring any partitioning to solids), which the dossier suggests compares well with the overall median of the 'country-specific PECs' (0.085 µg/L in the original dossier). The calculated concentration is however an approximation and there are potential sources of errors. Release from end use of NP is not considered in the estimated influent/effluent concentrations, which might lead to an underestimation. The dossier submitter points out that approximately 18 per cent of households in the EU are not connected to a WWTP (EC, 2013), but this source is not considered in the calculations. Other unquantified sources released to the wastewater (e.g. cosmetics) are not considered in the calculations either.

Overall, the dossier submitter suggests that textile laundering may contribute approximately 7 – 44 per cent of the amount of NP in EU surface waters (Table 33 of the BD), and a value of 30 per cent is selected for modelling purposes in Section E.

These calculations are important for two reasons. They provide a reality check of the assumptions used in the dossier by allowing the estimated concentrations in WWTP influent and effluent to be compared with measured data (although this has not been done in any detail in the dossier). They should also give an estimate of the relative contribution of textile washing to NP/NPEO concentrations in receiving waters in comparison with other sources. RAC has the following observations:

a) RAC notes that the calculation of total releases of NPEO to waste water depends on the estimated release of NPEO from textiles, which as described above is highly uncertain, and could vary over an order of magnitude.

b) The estimate of NP/NPEO releases from non-textile sources is complicated and based on a large number of untested assumptions:

- Information on tonnages linked to specific uses and recommended risk management measures appears to be missing[15]. The dossier therefore makes arbitrary modifications to the ERCs for various product types, which are acknowledged to be conservative assumptions that have not been checked with relevant industrial sector representatives. This builds substantial uncertainty into their reliability.

- RAC considers that the assumed breakdown rate for NP derivatives to NP in WWTP is unsubstantiated, and may significantly over- or under-predict releases for some product types.

[15] RAC notes that NP is listed on the CoRAP for 2014, with the intention of clarifying sources and pathways to the environment.

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- It is not known whether the chemical market for Sweden is representative for the rest of Europe. The scaling up of releases from Sweden to the EU based on population size is therefore uncertain.

- The predicted releases for some product types considered in the dossier only occur during formulation and processing. Although the magnitude of these releases are important for comparison with the textile releases, they will not necessarily contribute to local concentrations in WWTP as they will only take place at relatively few (almost certainly industrial) sites. It could therefore be misleading to include them in combination with textile releases.

- Based on the approach adopted in the dossier, "cleaning agents" contribute 24 per cent to the total releases of 'NP equivalents' from non-textile sources to waste water. RAC notes that Annex XVII of REACH restricts the use of NPEOs for domestic cleaning, metal working and industrial/institutional cleaning (except where the washing liquid is recycled or incinerated). In theory there should be no release from this source, which casts some doubt on the approach, unless the term 'cleaning agent' refers to other applications.

c) RAC thinks that a more reliable estimate of the contribution of textile washing to NPEO and NP levels might be obtained by estimating influent/effluent concentrations, and comparing these with measured influent/effluent data. In this way, no assumptions need to be made about the origin of the other sources. This calculation has not been performed in the dossier, so is included here.

   As previously noted in this opinion, WWTP influent contains significant quantities of NP, as described in the dossier[16] and confirmed by UK data provided during PC, and it seems likely that this NP comes from sources other than NPEO (although based on the limited data available, textiles could still be a small direct source). To estimate the relative contribution of NPEO to NP levels in effluent, an illustrative calculation can be based on the geometric and arithmetic mean influent concentrations of 1.92 & 2.85 µg/L for NP and 1.60 & 4.03 µg/L for NP1-15EO from the UK data set:

   - Assuming, *as a worst case*, that around 35% of the influent NP concentration is emitted in the effluent (based on SIMPLETREAT modelling quoted in the dossier), and around 2.5% of the influent NPEO concentration is converted to NP in the WWTP, the NP effluent concentration is predicted to be 0.7 or 1.1 µg/L (based on the geometric or arithmetic mean, respectively), suggesting that the influent NPEO will account for up to 10% of the NP in the final effluent.

   - UK data provided during PC suggests that the average removal level of NP could be higher than 65%[17]. If the removal level of NP is assumed to be 80%, the predicted NP effluent concentration would be 0.4 or 0.7 µg/L, and the influent NPEO concentration would account for up to ca. 15% of this concentration. Clearly this estimate would change if the actual formation of NP from NPEO degradation was lower than 2.5%.

[16] The median 90th percentile of NP in WWTP influent is reported to be 5.43 µg/L, based on a very small data set (Table 38, Figure 11 and Table 3 of Annex 8 of the BD).

[17] The average removal efficiency for ten WWTP sampled during February – May 2013 was 85%, although one had a removal efficiency of 66% (the highest level of removal was 93%). The average removal efficiency for a larger sample of 28 WWTP over one year in a separate study was >80%. This suggests that 65% removal is a reasonable worst case assumption, but might not reflect typical conditions. The way that removal efficiency is calculated (dividing the effluent NP concentration by the influent concentration) may underestimate the level of removal since it does not take into account the possible formation of NP from NPEO in the WWTP. Nevertheless, since this is only expected to make a small contribution (2.5% as a worst case), the overall removal efficiencies are probably fairly reliable.

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- Similarly, an average NP removal level of 90% would give a predicted NP effluent concentration of 0.2 – 0.4 µg/L, and the influent NPEO concentration would account for up to ca. 25% of this concentration.

The geometric and arithmetic mean NP effluent concentrations for these ten WWTP were actually 0.29 and 0.32 µg/L, respectively, which is closest to the third scenario. Clearly, a different transformation rate for NPEO to NP, as well as the fact that the monitoring data do not include NP>15EO, could make a difference to these calculations. However, the UK data suggest a higher level of NP removal than the SIMPLETREAT prediction, and that NPEO may account for up to around 25% of the final NP effluent concentration. This figure is in good agreement with the range of 7 – 44% estimated in the dossier, as well as the choice of 30% as a reasonable worst case. However, RAC notes that since there will be other sources of NPEO in the influent, it seems likely that the actual contribution of textile laundering to NP levels in effluent will be somewhat below this figure (i.e. probably in the bottom half of the range).

d) RAC also notes that the measured concentration of NP in water bodies might be influenced by other sources than WWTP discharges. For example, the dossier notes that run-off from car parks, roads, storm water, etc., can contain measurable amounts of NP (data are summarised in Figure 8 and Table 1 of Annex 8 of the BD). The relative importance of these sources is difficult to judge based on the data provided in the dossier, but it adds to the difficulties in assessing the relative contribution of a single source (textile washing) to NP levels observed in the environment.

e) Calculations of 'NP equivalents' are made on the basis of an "NPEO with eight ethoxy units (where the NP/NPEO ratio is 2:5)". RAC understands that this calculation is based on a ratio of weights only, and whilst this might represent an average for NPEOs there is no justification for this in the dossier (some NPEO products contain a lot more than eight ethoxy units). It certainly cannot be used to estimate releases of NP to the environment for any particular product type because it effectively translates into 100 per cent conversion (whereas instead the actual degradation behaviour needs to be known). RAC notes that some of the statements in the dossier (e.g. the estimate of a release of 21-234 tonnes NPequ from textile washing, and also release of 10 tonnes/year of NPEO from technical textiles "corresponding to 0.25 tonnes NP") are potentially misleading because of this.

Given the large number of untested assumptions in the release estimates from non-textile sources, RAC concludes that the the comparison of releases of NP/NPEO from different sources is highly uncertain. Textile laundering appears to contribute up to approximately 30% (range: 7 – 44%) of the amount of NP in EU surface waters.

Effectiveness in reducing the identified risks

Justification for the opinion of RAC

The dossier submitter has modelled a baseline 'business as usual' (BaU) scenario for the period 2010 to 2031, based on assumed future trends in emissions to waste water combined with expected improvements in waste water treatment practice. The main assumptions are for an annual increase in textile consumption of 2% with no change in NPEO concentrations, a reduction of emissions from "other" uses of NP/NPEO by 37% prior to 2015 (compared to 2010), and some improvements in overall WWTP removal efficiency

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and connection rate (Section E.1.1.2.6 of the BD provides a summary).

It is not known how textile manufacturers will react to the implementation of a limit value of 100 mg NPEO per kg of textile. However, the proposed restriction is not intended to completely remove NPEO as a source of NP (and other NPEO degradation products) from textile articles, since stakeholder comments indicate that it is difficult to completely remove non-intentional sources from the production process. Based on the existing studies of NPEO concentrations in textiles, the dossier submitter has attempted to model the change in 'average' concentration by assuming that all textile articles with concentrations currently above the proposed limit value would in future be placed on the market with an NPEO concentration *equal to* 100 mg/kg. Textile articles with concentrations currently below 100 mg/kg are assumed to remain unchanged. With a transitional period of 5 years, the dossier submitter estimates that the 'average' NPEO concentration will therefore reduce from 53 mg/kg (range: 9 – 97 mg/kg) to 16.3 mg/kg by 2021. This transitional period is thought to provide a reasonable amount of time for the market to adjust and for suppliers to test and implement substitutes (especially as many suppliers outside the EU are involved, and supply chains may be long).

The dossier submitter estimates that this change in NPEO textile concentrations would lead to an NP emission reduction of 21% based on 2010 figures, and 32% compared to the BaU scenario for 2021. Taking into account the expected future trend in WWTP removal efficiency/connection rate and the trend in emissions from other sources, total NP emissions to the water environment are predicted to have roughly halved by 2021 compared to the situation in 2010.

The dossier submitter has also considered a possible variation to the proposed restriction involving a lower NPEO concentration limit in textiles (20 or 50 mg/kg rather than 100 mg/kg) with the same transitional period of 5 years. Assuming that all NPEO concentrations currently above the limit value would be reduced to the limit value (and that concentrations currently below the limit remain unchanged), a limit value of 20 or 50 mg/kg textile would result in mean NPEO concentrations of about 7 or 11 mg/kg in textiles (compared to 53 mg/kg in the baseline scenario). The dossier submitter estimates that this would reduce NP emissions to surface water by 36-40% compared to the BaU scenario in 2021 (or about 58-61% if improvements in WWTP efficiency are included). However, this option is considered to be disproportionate because although the risk reduction potential will be greater, comments received from stakeholders (including during PC) suggest that it may be difficult to meet a lower limit because of unintentional contamination of textiles by NPEO during the production process and transportation (e.g. from lubricants).

RAC has the following observations on this information:

a) RAC agrees with the dossier submitter that future projections of NP emissions are uncertain. The assumptions about improvements in wastewater treatment and textile consumption appear reasonable, but the effect of Candidate Listing on the market for NP/NPEO is unknown and could be significant. The assumption in the dossier of a 37% reduction in emissions from non-textile sources of NP/NPEO is based on the belief that some of these sources are in fact already currently restricted and so they will be removed entirely from the market by 2015. RAC has already noted the significant uncertainty in the estimated emissions from non-textile sources, and considers that the emissions from restricted uses are probably a lot lower than supposed in the dossier (presumably already close to zero, given that the original restriction was introduced in 2005). However, a reduction of 37% (by 2021 rather than 2015) may be a better reflection of changes caused by Candidate Listing. RAC can therefore accept the modelling presented in the dossier with this caveat.

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b) The actual change in textile NPEO levels following implementation of the restriction is also uncertain, but RAC considers that the dossier submitter has chosen the best approach currently possible. As already noted, the actual 'average' concentration of NPEO in textiles might be lower than 53 mg/kg. The average concentration following restriction could therefore be lower than 16.3 mg/kg by 2021, but given the uncertainties, the selected concentration seems to be a reasonable assumption (representing a reduction of about 70%).

c) As discussed above, textiles currently appear to contribute up to approximately 30% (range: 7 – 44%) of the amount of NP released to EU surface waters, so a reduction in textile NPEO concentrations of about 70% should reduce overall NP surface water concentrations by around 21% (range: 5 – 31%) based on the scenario for 2010.

d) The dossier does not indicate how the change in emission will affect the NP RCRs. A 21% reduction in NP concentrations would give RCRs at 79% of their current level (assuming that the textile washing contribution is consistent across Europe and nothing else changes). Current NP RCRs above 1 (based on 90th percentile freshwater concentrations, the highest RCR is 1.5 for Greece) would therefore be reduced, but risks could still remain for Spain and Greece based on the monitoring data in the dossier (and also marine waters for Spain), bearing in mind that this is a minimum level of risk (extensive risks would still remain if a lower $PNEC_{aqua}$ were selected). If overall NP emissions are halved by 2021 (due to both the restriction and other trends in use and wastewater treatment), a risk could still be identified in Spanish marine waters (highest RCR of ca. 7.5) (ignoring any additional contribution of estrogenic pressure and other NPEO degradation products to the overall risk).

e) The proposed restriction will therefore contribute to a reduction in aquatic risks from NP and other NPEO degradation products, but it does not seem sufficient to eliminate them entirely. Stakeholder comments suggest that a limit value lower than 100 mg/kg would not be practically possible for all textiles, due to unintentional uses of NPEO in the production process. It therefore seems important to investigate additional control measures (RAC recognises that actions arising from Candidate Listing will contribute to this).

f) RAC notes that a transitional period of 5 years is proposed. A shorter timescale would enable risks to be reduced more rapidly. RAC also notes that a lower NPEO concentration limit in textiles has a greater risk reduction capacity than the proposed restriction. The calculations presented in the dossier are subject to the same uncertainties as for the calculation assuming a 100 mg/kg limit. However, given the relatively high proportion of articles with NPEO concentrations apparently less than 20 mg/kg already, reducing the limit below 100 mg/kg does not reduce emissions in proportion (e.g. reducing the limit by a factor of five (to 20 mg/kg) only increases emission reduction capacity by a factor of about 1.25, i.e. the reduction in NP surface water concentrations would be about 26% compared to 21% for the 100 mg/kg limit).

   Socio-economic considerations are also relevant for a final decision on the transitional period and limit value. The need for a lower limit could be reconsidered at a later date once experience has been obtained with analytical method standardization, and more comprehensive information has been collected on NPEO concentrations in textiles following the introduction of a restriction.

The proposed restriction is likely to significantly reduce aquatic risks from NP and other NPEO degradation products in Europe. Future changes in NP and NPEO emissions are very hard to predict because of uncertainties around the impact of Candidate Listing. Average textile NPEO concentrations are expected to be

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reduced by about 70% following the implementation of the proposed restriction, and it is likely that this will reduce current 'minimum' RCRs by approximately 21% (range: 5 – 31%). A shorter transitional period than 5 years and/or lower limit than 100 mg/kg would provide faster and/or marginally improved risk reduction capacity, although there are socio-economic considerations about whether these are viable options. Improvements in wastewater treatment are also expected to contribute to reducing NP emissions in future. Nevertheless, it seems possible that risks will remain for some parts of Europe even after the restriction is introduced, while the estrogenic pressure would in any case be reduced by implementing the proposal.

If the EU adopts a different paradigm to the risk assessment of endocrine disrupting chemicals in future, the wording of this conclusion may need to be reconsidered, but the overall conclusion will remain unchanged.

Justification for the opinion of SEAC

Several risk management options have been considered by the dossier submitter in order to determine the most appropriate EU-wide measure to manage the environmental risks arising from the presence of Nonylphenol and Nonylphenol ethoxylates in imported textiles as defined and described in the proposal (see section E.1 of the Background document).

EU-wide risk management measures such as the REACH Authorisation process, voluntary agreements by industry and stricter requirements on end-of-pipe measures in industrial facilities and WWTP have been discarded due to the following reasons:

- The **REACH authorisation process** only addresses uses within the EU and would thus not target the concerned substances likely to be released from imported textile articles.

- **Voluntary actions by industry** have not been considered to be an appropriate risk management option by the dossier submitter, although there are already a number of company collaborations and voluntary commitments concerning Nonlyphenol and Nonylphenol ethoxylates in textiles (see section B 9.1.1 of the Background Document). However, in order for such measures to effectively reduce emissions of the substances of concern in imported textiles, an agreement would be necessary covering a vast number of importers in a sector that is highly segmented (imported textile products are diverse in types and functions and the production chains differ). The effectiveness of voluntary agreements might be much lower than a REACH restriction as there might be little incentive and/or willingness for importers to comply. Furthermore, the stakeholders consulted stated that it is easier and more efficient for textile importers to refer to legal requirements such as an EU-wide restriction than to communicate voluntary agreements to their suppliers and oblige them to comply with those. During consultations carried out with stakeholders it was revealed that, e.g., importers ensure that suppliers comply with EU legislation by stipulating the applicable regulations in their contracts and by providing information to non-EU suppliers about these requirements. SEAC agrees that a REACH restriction would therefore be a clear statement to non-EU suppliers and reduce any (potentially) existing lack of clarity on regulatory requirements in the EU.

- **Stricter requirements on end-of-pipe measures in industrial facilities and WWTP** (Waste Water Treatment Plants) have been evaluated by the dossier submitter and have been found to be less cost effective than controlling emissions at the source.

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- According to the dossier submitter's research, end-of-pipe measures, in order to reduce NPEO emissions, would imply large investment and on-going operational costs, which could be around € 70 billion per year. Costs may vary significantly among installations and according to technologies used. The literature shows a wide range of estimated costs for this type of measures (based on AMEC 2012 report, presented by the dossier submitter in section E.1.3 of the Background Document).
- SEAC acknowledges that such measures - if implemented in order to reduce NPEO emissions - may create substantial co-benefits as they would remove other pollutants than the substances of concern as well. But these co-benefits are difficult to estimate and would require site-specific assessment. It was not possible to perform such an assessment, neither by the dossier submitter, nor by SEAC.
- The UK Environment Agency provided a large amount of data on NP and NPEO during the public consultation (UK Environment Agency 2013c). In summary, the data show that releases of NP and NPEO to waste water treatment works (WWTW) is ubiquitous and widespread. The UK WWTW show good removal rates for NP (> 80%) but NP is still present in WWTW effluent in relatively high concentrations (see section E.1.3. of the Background Document). The UK Environment Agency stated that high percentages of the NP load to UK WWTW (up to ~ 75%) are believed to arise from domestic sources (it has to be noted that no similar analysis has been performed for NPEO). Under the assumption that the UK findings are representative for other MS as well, many WWTPs across the EU would need to improve existing treatment processes or upgrade to additional treatment steps in order to achieve an overall emission reduction of NP/NPEO. Based on the UK data on influent/effluent concentrations in WWTPs with different treatment processes, it may be difficult to predict the effectiveness of any additional treatment measures for NPEO since there are other factors than the treatment technique itself that determine the amount of releases mitigated (see section E.1.3 of the Background document). The UK Water Industry Research Chemicals Investigation Programme[18] provides estimates on the cost-effectiveness of additional measures to achieve the EQS (Environmental Quality Standard) for NP in the UK[19]. Nonetheless, these studies are not directly comparable to the current case since the measures are assessed against the Water Framework Directive EQS which is lower than the PNEC identified in section B.10 of this restriction proposal. However, in SEACs view the results of these studies seem to support the conclusion that the implementation of end-of-pipe measures would imply significant investment costs and in addition, external damage costs due to increased CO_2 emissions associated with these investments. The CIP results indicate (for the UK) that additional treatment would have to be introduced at approximately 144 of the UK WWTPs in order to achieve NP concentrations of maximum 100% of the EQS. According to the report, the same result could be achieved if source control measures reduced influent by approximately 60%. The net present value of the investment in extra treatment (in the UK) would be in the region of £ 0.3 billion with an annual CO_2 emission of 22,000 tonnes. This cost estimate cannot be

[18] Between 2010 and 2013 the UK WIR has been conducting a Chemicals Investigation Programme (CIP), which has generated a large amount of data on the sources of chemicals in the environment including NP. The CIP included three major investigations of (1) risk of chemicals, (2) WWTP performance and (3) source investigations.

[19] NP is one of the priority substances listed in Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy. The Directive sets out environmental quality standards concerning the presence in surface water of certain pollutants and substances or groups of substances identified as priority on account of the substantial risk they pose to or via the aquatic environment.

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extrapolated to any reliable estimate for the EU level without extensive further investigations. Neither the dossier submitter, nor SEAC was able to perform such investigations. However, the dossier submitter still performed a simple illustrative calculation that gives an indication of the potential cost of such measures: the total annual cost in the EU would be estimated to € 214 million plus € 4 million external damage cost per year (for further information see section E.1.3, footnote 83 of the Background document). A further example on the cost-effectiveness of end-of-pipe measures is given in section E.1.3 of the Background document, dealing with the case of 17 alpha-ethinylestradiol (EE2). This evaluation indicates high costs of the measures (including external damage costs, increased energy production and an increase in sludge production that could imply additional costs of disposal) whilst being ineffective at reducing emissions from sources that are not connected to WWTP. Lastly, the implementation of end-of-pipe measures to reduce emissions of NPEO from textile articles would not reflect the principles that environmental damage should – if possible - be rectified at source, according to the "polluter pays"-principle (which is one of the guiding principles in EU policy – see European Parliament and the Council, 2013). Further information on the evaluation of end-of-pipe measures is provided in section E.1.3 of the Background Document and in Appendix 12.

Overall, based on the above listed arguments as provided by the dossier submitter in the Background document (section E.1.3, Appendix 12) and backed up by UK information provided during the public consultation, **SEAC agrees with the dossier submitter's conclusion that these RMOs are not considered as the most appropriate for managing the risks of Nonylphenol ethoxylates released from textile articles**.

Regarding the **REACH restriction process,** the following restriction options with different limit values have been discussed in the dossier:

- A restriction with a limit value of **0.01% by weight** textile and a transitional period of **5 years (the proposed restriction - RMO 1);**

- A restriction with a limit lower than 0.01% by weight textile (i.e. 0.002% by weight textile and 0.005% by weight of textile) and a transitional period of 5 years (RMO 2a and 2b);

Both, the limit value and the transitional period have been subject to stakeholder consultation during the development of the restriction proposal as well as during the subsequent public consultation on the restriction proposal. A limit value of 0.01% by weight textile and a transitional period of 5 years were confirmed by most stakeholders to be the most appropriate. Stakeholders that claimed support for a higher/lower limit value or for a longer/shorter transitional period didn't provide sufficient information that substantiated their claim.

- **The limit value:** As already mentioned above, it has to be noted that the limit value proposed by the dossier submitter targets NPEO only and not NP (for further details, see the explanatory note in section A.3.3 of the Background Document). The dossier submitter proposes a limit value for NPEO of 0.01% by weight textile. Additionally, two lower limit values (0.002% by weight for RMO2a and 0.005% by weight for RMO2b) are discussed in the restriction proposal. The level of the limit value primarily affects the risk reduction capacity, the technical feasibility and the costs of each restriction option. It was indicated by stakeholders that a limit value of 0.01% by weight textile is achievable and sufficiently stringent to deter any intentional use of NPEO in the manufacturing of textile articles. Furthermore, it was indicated that the proposed value would not conflict with the current REACH Annex XVII entry 46

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on NP/NPEO, which applies to manufacturing of textiles in the EU. However, in SEAC's view consistency between existing and newly introduced restrictions is not a necessary condition for the choice of the limit value. Moreover, information provided by stakeholders further indicates that, even though NPEO is substituted, there may still be NPEO traces as impurities, by-products, or intentional components (at low concentrations) in some chemical formulations that are used in textile manufacturing. The use of such chemical formulations during the processing of textiles may thus result (unintentionally) in NPEO being found in the final textile article. The issue of traces of NPEO in chemical products could thus pose difficulties in terms of technical feasibility if the proposed limit value for NPEO in textile articles is set too low (see section E.2.1.1.2.1 of the Background document, confirmed by Stakeholders during public consultation).

- The duration of the **transitional period:** the dossier submitter proposes a transitional period of 5 years. The dossier submitter has chosen the transitional period considering that it is manageable and practicable in terms of timing and costs (i.e. better manageable than, e.g., a 3 years transitional period) also for SMEs. The transitional period mainly affects the ability for industry to communicate the restriction down the supply chain and the costs of each restriction option. This was confirmed by the stakeholders consulted (see section E.2.1.1.2.1 of the Background document).

    - The dossier submitter presents several arguments in favour of a shorter transitional period and explains that 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 (confirmed during the public consultation). Hence, no considerable transition time is needed in this respect. Considering the relatively quick turnaround time of textile articles in the market, in particular for clothing textiles and accessories, it is likely that a transition time of one year would suffice to sell out existing stocks. Furthermore, the dossier submitter investigated that alternatives are available in sufficient amounts and their production has likely grown since 2002 worldwide, indicating that the market should be able to adapt in terms of supply within one year transition time and the impact on the market for chemicals is expected to be minor (see section E.2.1.1.2.1. of the Background Document). Two stakeholders argued during the public consultation (one NGO and one organisation representing manufacturers of auxiliaries and colorants used in textiles) that a three years transitional period would indeed be feasible or even too long. However, they based their argumentation mainly on the availability of alternatives and the time needed for shifting from NPEO based detergents to alternative detergents. SEAC acknowledges that this shift is technically feasible and might be performed rather quickly.

    - The above stated arguments seem to indicate the feasibility of a shorter than the proposed transition period of 5 years. However, the choice of 5 years is in line with comments received by almost all stakeholders during the different consultations that have been performed. It was indeed indicated by stakeholders that a 5 years transitional period is needed in order to have sufficient time to communicate the new legal requirement down the (global) supply chain. A period shorter than 5 years would be difficult to implement by actors in the supply chain and would therefore raise costs due to the need for more extensive communication strategies and possibly testing of products, which is stated by stakeholders to be likely not performed in case sufficient time for the implementation would be allowed. The dossier submitter qualitatively assessed the consequences of implementing a shorter transitional period (i.e. 3 years) and stated that it is not possible to make

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generalised statements about the form and magnitude of the involved compliance control costs (see section E.2.1.1.2.1 of the Background document). SEAC acknowledges that further quantitative assessment was not feasible, due to lack of relevant data. However, SEAC agrees that the issue of timing is closely related to the occurrence and magnitude of compliance control costs. Some stakeholder responses indicate that a shorter transitional period may imply significant extra efforts by textile importers and other actors in the textile supply chain. Section E.2.1.1.2.1 of the Background document stated there are indications that 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 (further arguments are in detail listed in the relevant section under the heading "Timing"). Major concern about a shorter transition period raised by most of the respondents was not about technical issues, but about the communication of the legal requirement down the rather complex global supply chains connected with higher costs. The suggested time period of 5 years is expected to provide enough time for communication of the restriction and will allow actors outside the EU to react accordingly. Almost all stakeholders (except the two above mentioned) stated that the five-year period is considered to minimise compliance control needs, and that costs of such controls are even considered unlikely to occur, which will positively affect the proportionality of the restriction.

SEAC acknowledges that it is difficult to conclude on the above discussed values as it is difficult to verify what is technically achievable and manageable for industry and how long it actually takes to communicate a new legal requirement down the respective supply chains. The limit value and duration period are mainly based on industry's declarations, received during the development of the restriction proposal, during a separately performed survey by ECHA[20] as well as during public consultation. From a technical point of view a lower limit value as well as a shorter transitional period might be achievable but SEAC has no information at hand that would support the choice of such values. In the public consultation the proposed setting was confirmed by almost all stakeholders to be the most appropriate. Stakeholders who claimed the feasibility of a lower limit value and/or a shorter transitional period during public consultations did not provide sufficient information (such as costs or other quantitative data) which substantiated their claim. Furthermore, from the perspective of proportionality (see separate discussion on proportionality below), without further or any contradictory information from stakeholders, SEAC does not have information to disagree with the dossier submitter that the proposed limit value and transitional period are the most appropriate ones.

Alternatives have been discussed within the restriction report and are considered to be available (see section C of the Background document). Although the dossier submitter acknowledges that it is difficult to replace NPEO with one alternative formulation for all uses, a number of technically feasible alternative surfactants that have the same/similar performance characteristics as NPEO are presented as being available on the market. The dossier submitter's investigation has shown that non-ionic surfactants are able to fulfil the properties needed: alcohol ethoxylates, glucose-based surfactants and alkyl phenol ethoxylates (when used as detergent) and sugar esters, alkanol fatty acid amides,

[20] ECHA 2014, survey with 14 respondents, among them members of Finatex and EURATEX, complemented by a personal interview with a representative for the Association of Textiles and Fashion Business in Finland.

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quaternary ammonium compounds and again, alcohol ethoxylates and glucose-based surfactants (when used as emulsifier). Such alternatives have been in use by the textile industry for quite some time. Alcohol ethoxylates (AE) are the most investigated alternatives and also the most suitable alternatives in the textile process according to the dossier submitter. No concern is expected due to exposure of AE to health or the environment. Neither did RAC identify any concern associated with the alternatives evaluated in the restriction proposal (see RAC opinion for more details). Alternatives seem to be slightly more expensive than NPEO (their prices indicated to be 0-10% higher) although it is difficult to determine the exact extra cost, as prices vary depending on demand and business relations between suppliers and customers. The replacement of NPEO by suitable alternatives is considered to be applicable without any major changes in the textile production process as indicated during the public consultation. Furthermore, interested parties stated that alternatives are already used in the textile manufacturing process in- and outside the EU. As stated in section B.9.1.1 of the Background document, there already exist a number of company collaborations and voluntary commitments concerning the substitution of Nonylphenol and Nonylphenol ethoxylates in textiles, i.e. companies already voluntarily substitute NPEO in the textile manufacturing process. SEAC agrees to the dossier submitter's assessment, which is backed by feedback received in stakeholder consultation that suitable alternatives are available and are technically and economically feasible.

The dossier submitter also analyses the "extra washing" of textile articles as a possible consequence of the restriction proposed (see section E.2.1.1.1.2 of the Background Document). However, the dossier submitter considers that the proposed restriction is not expected to lead to extra washing and subsequent increase in emissions of NPEO in textile manufacturing countries. Theoretically this could be an issue if textile producers choose extra washing as a measure to ensure compliance with the proposed restriction instead of substituting NPEO in the manufacturing process. There is no indication from the stakeholders consultation that extra washing would indeed be practised as a measure to reduce NPEO concentrations in textiles. Even though SEAC considers "extra washing" of textile articles as a rather unlikely and therefore non-plausible alternative, it has no information at hand to decide on whether or not this is considered to be a realistic alternative by actors in the textile supply chain.

Overall, the proposed by RMO1 (limit value of 0.01% by weight and five-year transitional period) is considered as the most appropriate. During consultations performed by the dossier submitter, by ECHA[21] and during the public consultation on the restriction proposal no major concern was raised by industry about restricting NP and NPEO in textiles under this setting. Moreover, the setting of the proposed restriction has been found to be effective in reducing NPEO emissions, technically feasible and achievable to relatively low cost (see discussion below and section F.2.1 of the Background document). The proposed restriction effectively reduces the major part of NPEO that is estimated to be emitted from imported textile articles (during the washing process) (for more details see RAC opinion). There are technically feasible alternatives available with similar effectiveness although at marginally higher prices compared to NPEO. The proportionality of the restriction proposal is discussed in the section below.

[21] ECHA 2014, survey with 14 respondents, among them members of Finatex and EURATEX, complemented by a personal interview with a representative for the Association of Textiles and Fashion Business in Finland.

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Proportionality to the risks

Benefits: Imported textile articles are identified as a major source of NPEO emissions to the aquatic compartment when such articles are washed in water. The restriction proposal will lead to a reduction of NPEO concentrations in textiles (by approximately 69%, see section E.2.1.1.1.2 of the Background document as well as Appendix 11) and therefore to a reduction of emissions to the environment since the substances have been shown to be washed out during the usage phase. The proposed restriction is expected to reduce NPEO emissions from textiles by 32% compared to the baseline scenario in the year 2021 (see section E.2.1.1.1.2 of the Background document as well as Appendix 11). Since contributions from other uses than textiles are also expected to be reduced (independently from the proposed restriction), along with more efficient waste water treatment, the total reduction in emissions to the water environment in the year 2021 may be around 55 % lower compared to emissions in 2010. Compared to the estimated total emission of NP/NPEO to the environment (including all the assessed emission sources) in 2010, the proposed restriction alone would provide for an emission reduction by 21%. Different scenarios have been established by the dossier submitter in order to account for uncertainties regarding the concentration of NPEO in textiles (see section B.2.3.1, B.9.3.4.1 and E.2.1 of the Background Document as well as Appendix 11). Back-calculations from monitored NPEO concentrations in UK WWTP influents indicate that the dossier submitter's estimations can be considered reliable (see Appendix 12 of the Background document). Since the restriction would reduce emissions of NP/NPEO, it would generate positive impacts (namely 'benefits') for the environment. The dossier submitter considers the benefits of the restriction to be substantial (however not quantitatively assessed) based on the fact that the negative impacts in the water environment (in particular on biodiversity and subsequent functions and services provided by water ecosystems) will be reduced (see section E.2.1.1.3 of the Background Document). However, SEAC notes that quantification of these benefits was not possible for the dossier submitter and therefore neither a direct comparison whether benefits outweigh costs. A pure description of expected benefits without direct links to the substances of concern makes it very difficult for SEAC to draw an opinion on the magnitude of benefits and therefore, on the proportionality of the restriction proposal via a cost-benefit approach. Still, the dossier submitter included information on several evaluation studies (see section F.1.2.2 of the Background document) that give indications of the value that people place on improved water quality and biodiversity, based on the use and non-use values and the ecosystem functions and services approach. SEAC emphasizes that restricting NPEO will lead to improvements of the quality of water bodies and will therefore contribute to achieving the Environmental Quality Standards. In the economic literature, there are studies available that link the increase in environmental quality standards of water bodies to improvements in human welfare. **Therefore, SEAC concludes that there are benefits from the restriction.**

Costs: Surfactants are used in the textile production process for certain functions (see Background document for any details, especially sections B and C). Alternatives to NPEO are available and based on information provided by the dossier submitter and stakeholders (through different consultation processes carried out) SEAC considers them to be technically and economically feasible. Furthermore, there is no indication that the production process would be significantly altered when moving to alternative substances. It is not expected that EU producers of NPEO face any significant costs due to a change in demand (decreasing) for NPEO. This is because, according to stakeholder consultation, producers of NPEO should be able to easily shift production to other substances such as alcohol ethoxylates or glucose-based substances without major changes in the production equipment. Costs that are further discussed and assessed by the dossier submitter are costs arising through

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substitution of NPEO as detergent and emulsifier in the extra-EU[22] production of imported textiles (in the Background document and hereafter referred to as **substitution costs**), and costs for importers and retailers, e.g. for analytical testing of the NPEO content in imported articles which are intended to be placed on the EU market (in the Background document and hereafter referred to as **compliance control costs**).

- Based on the analysis of the dossier submitter, the bulk of total costs would most probably consist of **substitution costs.** Substitution costs are calculated based on the price difference between NPEO and its substitutes (no reformulation or other potential associated costs are included, as e.g. reformulation costs are not to be expected for uses of NPEO in textile articles that are within the scope of the restriction proposal (according to the stakeholders consulted, such costs would be relevant for technical textile production processes only)). It is assumed that the costs of substitution of NPEO by alternative substances would be fully passed on to EU importers by the extra-EU textile producers. These costs are estimated to be around € 2.9 million per year (in present value) from 2021 to 2031 (see section F.2.1 of the Background document as well as Appendix 11). The cost increase is due to the relatively higher price (per unit of input) of alternative surfactants, as indicated during stakeholder consultation. SEAC agrees to consider this cost as relatively small compared to the total import value for clothing in the EU (€ 61 billion in 2010, Eurostat 2012) which shows that substitution costs would constitute about 0.005% of the import value (see section E.2.1.1.2.2. of the background document).

- Furthermore **compliance control costs** may be incurred for actors in the supply chain, e.g. for importers and retailers when testing for the NPEO content in the imported textiles. The dossier submitter considers this type of cost very uncertain and dependent on how actors in the supply chain choose to implement any control measures to ensure compliance with the proposed restriction. During stakeholder consultations, it was indicated that importers primarily make use of contractual arrangements with their non-EU suppliers to ensure compliance with EU legislation, and provide information regarding these regulatory requirements to their non-EU suppliers, who in turn test for restricted substances in products. Some costs might be expected to be borne by non-EU suppliers related to these tests. However, neither the dossier submitter nor SEAC has any indication that these costs would be passed on the importers. Moreover, only a few responses were received during consultations on this particular issue which makes an extrapolation to the whole EU difficult. Furthermore, when an EU regulation is in place (e.g. a restriction) the manufacturers outside the EU tend to know about it and comply with such legal requirements. No feedback from industry was received indicating any major concerns due to the restriction proposal, either during public consultation or during separately performed consultations regarding this type of costs. This could additionally be understood as an indication that the costs for EU textile industry could be regarded as an insignificant barrier to the implementability of the restriction. However, there was only limited feedback during consultation processes on this issue and it is not clear whether these findings and conclusions can be extrapolated to the whole EU. There are already existing information requirements for Nonylphenol ethoxylates as these substances have been identified as substances of very high concern and are included in the Candidate List for Annex XIV. However, these pieces of information remain uncertain and compliance control costs thus still may occur. The dossier submitter considered such costs as a worst case scenario for cost impacts and estimated them to be about €43 million per year from the year 2021 to 2031. As a whole, the total estimated costs of substitution and compliance control are estimated to approximately €46 million per year from the year 2021 to 2031 (see sections

[22] Extra-EU production refers to production of textiles outside the EU.

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E.2.1.1.2 and F.2.1 of the Background document).

The cost estimates described above have been subject to sensitivity analysis (see section E.2.1.1.2.4 of the Background Document as well as Appendix 11). This analysis shows that the **total costs** of the restriction proposal, if both substitution and compliance control costs are taken into account, are highly sensitive to which input values are used to calculate the costs of compliance control. The most uncertain input values – the test frequencies applied by textile importers in particular – largely determine the scale of the estimated compliance control costs. The estimate of the share of textile articles that are produced with intentional use of NPEO (range between 16-31%) is also highly uncertain and affects the share of textiles that may be subject to tests as well. The range of variability in these input values may cause the resulting total costs to change considerably (from €14 million to €80 million per year from the year 2021 to 2031). Changing other input values (relating to compliance costs) are less likely to alter the results significantly.

Proportionality:

- **Cost-benefit approach:** As described above, the restriction is expected to cause relatively low cost increases to actors in the textile supply chain if only substitution costs are considered, since there are technically feasible and available alternatives although at marginally higher prices compared to NPEO. The proposed implementation time of 5 years ensures sufficient time for adaptation in terms of dissemination of information and hence should minimise any additional cost impacts in terms of e.g. compliance control. The dossier submitter concludes that the total cost of reducing the exposure to NPEO is considered to be small in comparison to the total import value for clothing in the EU and in comparison to the expected described benefits. It is concluded that the improvements in use and non-use values related to the ecosystems in question are likely to be of substantial benefit to society in the European Union. In addition to this, it should be recognized that the proposed restriction, which motivates a shift to alternative surfactants in textile production, will likely also imply a significant reduction in emissions of NPEO and subsequent positive environmental impacts in many textile manufacturing countries.

  On one hand, the dossier submitter considers the benefits of the proposed restriction to be substantial, continuing in the long term since it avoids future negative impacts in the aquatic environment (see section F.1.2.2 of the Background Document). On the other hand, the costs of the proposed restriction are regarded to be small, if only substitution costs are considered. If the potential costs of compliance control are taken into account as well, in particular if more pessimistic assumptions are made in the estimation of such costs (as shown by the sensitivity analysis), the dossier submitter acknowledges that it appears difficult to demonstrate that benefits outweigh costs and thus difficult to conclude about the proportionality of the restriction proposal (see section E.2.1.1.3 of the Background Document).

  From this assessment, SEAC's view is that there are no data at hand that would allow a conclusion on the magnitude of benefits. An attempt was made to better define the benefits of the proposed restriction in connecting them to improvements in meeting the Environmental Quality Standards applicable to surface water. However, the monitoring data set is not sufficient for such an assessment and the actual degree of improvement will depend on several factors currently being considered by individual Member States. Nonetheless, NP is a Priority Hazardous Substance under the Water Framework Directive, so the current restriction proposal will contribute to achieving a phase out of NP emissions, released to the environment due to the degradation of NPEO. SEAC agrees that costs are relatively small compared to the total import value for clothing in the EU in 2010 (the respective figures are stated above) if only substitution costs are considered. The situation is

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more difficult to judge if compliance control costs are considered as well, especially if more pessimistic assumptions (e.g. low NPEO concentrations in textiles, high test frequencies) are made. SEAC thus concludes that for the current restriction proposal it is not possible to decide on the proportionality of the restriction proposal based on a cost-benefit comparison, although it is acknowledged that benefits indeed will occur.

- **Cost-effectiveness approach:** From a **cost-effectiveness** perspective, the dossier submitter regards the restriction to be cost-effective compared to other types of measures, in particular compared to improved end-of-pipe abatement techniques in WWTP (although not directly comparable – see discussion in the respective section above), which are the most likely alternative measures at hand. Such measures may be effective in reducing emissions (along with emissions of many other pollutants) but are likely less cost-effective than a REACH restriction due to expected high costs connected to the technical requirements (see the section above "Justification that the suggested restriction is the most appropriate EU wide measure" as well as sections E.1.3 and E.2.1.1.3 of the Background Document). Additionally, the dossier submitter compared the **cost-effectiveness** of the proposed restriction to previous measures that have been implemented in the EU to reduce emissions of NP/NPEO, in particular the restriction on the use of NP/NPEO in concentrations equal or higher than 0.1 % implemented in 2005 (see REACH Annex XVII, entry 46). The cost-effectiveness of the existing restriction on NP/NPEO was estimated (ex ante) in the Nonylphenol Risk Reduction Strategy by RPA (1999). The impact assessment in this strategy includes substitution, reformulation and commercialisation costs. Furthermore, the report states that the proposed measures would require some degree of monitoring, however limited, but no quantified costs of compliance control or monitoring are reported. The risk reduction potential is estimated in terms of percent reduction in continental NP burden. By converting the costs to a chosen year of comparison and assuming the costs to be annual ongoing costs (costlier substitute) or one-off investment costs (reformulation and commercialisation), the cost-effectiveness of this previous measure may be compared to the proposed restriction (see Appendix 11 of the Background Document for information on methodology used and for detailed results of the comparison). As shown in the figure below (Figure 26 of the Background Document), the cost per percent reduction in NP load is relatively low for the proposed restriction compared to the estimated costs of the existing restriction, if only substitution costs of the proposed restriction are considered (€ 0.5 million). However, if the 'worst case' situation (i.e. inclusion of compliance control costs) is considered, the cost per percent reduction in NP load becomes almost 4 times higher (€7.3 million) for the proposed restriction compared to the least cost-effective measure (metals). In this case, the proposed restriction does not appear cost-effective compared to the previous measure. However, SEAC would like to emphasise that in the evaluation of the previous measure on NP/NPEO no quantified costs of compliance control or monitoring are reported. This may induce some bias in the comparison with the cost-effectiveness of the restriction proposed for the 'worst case' situation.

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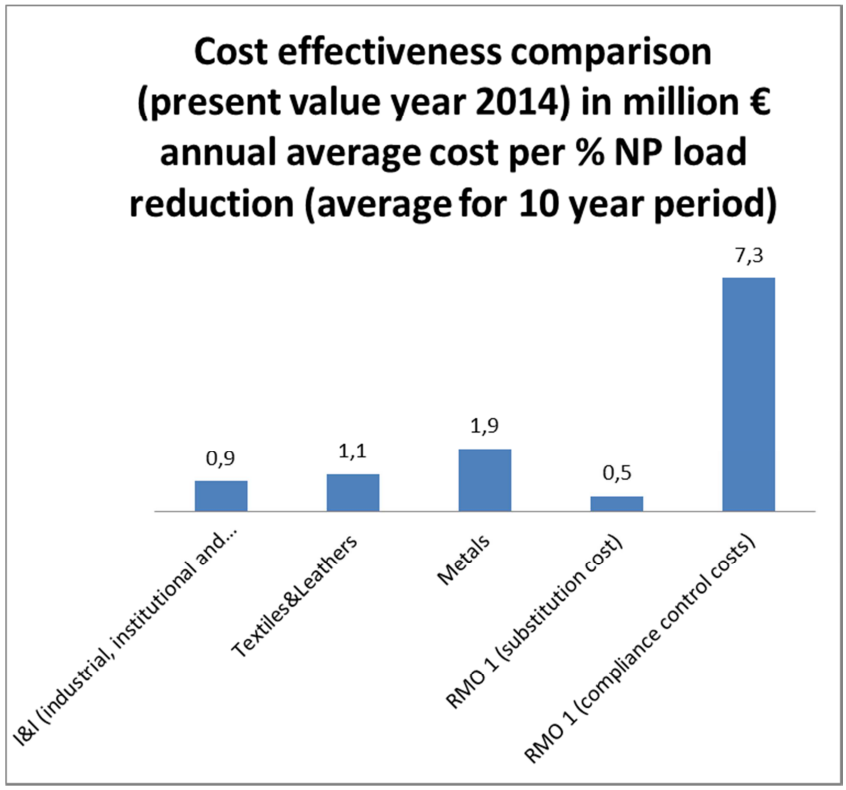

Figure 4 Cost-effectiveness of previous measures to reduce NP/NPEO emissions compared to the proposed restriction[23]

The cost-effectiveness comparison has been subject to sensitivity analysis (see section E.2.1.1.3 and Appendix 11 of the Background document), where a number of input parameters were altered in order to identify the most sensitive ones. It appears that the results are mostly sensitive to the following parameters: the NPEO concentration in textiles and the inclusion/exclusion of compliance control costs as well as the test frequencies applied. The sensitivity analysis shows that the conclusion on cost-effectiveness as regards substitution costs is robust except where very low NPEO concentrations (in textiles) are used as input parameters. If compliance control costs are additionally considered, the analysis indicates that the proposed restriction is relatively cost effective – compared to the existing restriction – only in scenarios where very high NPEO concentrations in textiles are used as input parameters. Thus the result of the cost-effectiveness comparison is highly sensitive to the assumptions made about concentrations of NPEO in textile articles. Experimentation in sensitivity analysis additionally shows that the test frequencies used in estimation of compliance control costs greatly outweigh other uncertainties in the cost estimates. The result does not change substantially if any of the other input parameters are altered.

SEAC concludes that a decision on proportionality mainly depends on the above mentioned input factors, i.e. the **concentration of NPEO in textile articles** (and therefore the risk reduction capacity of the proposal) and the **amount of total costs,** where the frequency of testing is the input factor with the highest uncertainty and

[23] I&I (industrial, institutional and domestic cleaning), Textiles&Leathers (textiles and leader processing), and Metals (metal working) refer to measures restricting the use of NP and NPE in concentrations equal or higher than 0,1 % within the EU since 2005 (REACH Annex XVII, Entry 46). RMO1 (substitution cost) and RMO1 (compliance control costs) refer to the restriction proposal as discussed in this opinion. Annex 11 of the Background document contains description of the methodology and results of the comparison of the proposed and existing restriction.

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sensitivity. It is expected that benefits will occur due to the proposed restriction; however, the magnitude is unknown to SEAC. Still, NP is a Priority Hazardous Substance under the Water Framework Directive, so the current restriction proposal will positively contribute to achieving a phase-out of NP emissions, released to the environment due to the degradation of NPEO. SEAC considers the costs to be small if only substitution costs are taken into account. Although compliance control costs could reach quite an extensive amount (subject to the uncertainty of the testing frequency), they seem rather unlikely and the actual amount is highly uncertain. The consultations performed confirm this assumption and no major concern was raised by industry due to the proposed restriction, either during public consultation or during separately performed stakeholder consultation. Furthermore, feedback by companies showed that primarily contractual arrangements with non-EU suppliers are set in order to ensure compliance with EU law. However, it has to be emphasised that only a few responses were received during consultations on this particular issue which makes an extrapolation to the whole EU difficult. Uncertainties exist also when it comes to concentrations of NPEO in textiles. These uncertainties could only be reduced by taking additional samples for analysis of the NPEO content in textiles, in a randomized and statistically sound manner in order to ensure representativeness for the whole market in the Union, which cannot be performed by SEAC. **In summary, on the grounds that the substitution costs assessed by the dossier submitter may better reflect the expected costs of the restriction proposed than the 'worst-case' situation (substitution plus compliance control costs), SEAC concludes that the proposed restriction is expected to be a low cost way of reducing any actual or potential environmental impacts of NP/NPEO. In this respect, SEAC regards a restriction on NPEO in textile articles not being disproportionate.**

Practicality, incl. enforceability

Justification for the opinion of RAC

The BD suggests that the proposed restriction is technically feasible since other substances can effectively substitute NPEO in the production of textiles, as has clearly happened in Europe following the introduction of the existing restriction for NP/NPEO. The proposed implementation time of 5 years should give sufficient time for companies to adapt in terms of dissemination of information along supply chains (which can sometimes be complex). The proposal also provides a level of consistency with REACH Annex XVII Entry 46 as the limit is the same (although it applies to mixtures rather than articles in that case). This limit will target intentional use of NPEO in textile manufacturing, but not unintentional contamination. Examples of textile types are provided to clarify the scope of the restriction, with a definition of what is meant by "textile articles". It is also explained that the scope is confined to those textile articles that can be washed in water. Finally, the proposal notes that a standard test method is in development for NPEO analysis that will be available before entry into force.

RAC agrees that the proposal should be practical to implement. Some further explanation is needed to ensure that all stakeholders fully understand what is included within the scope, in terms of what is meant by washing, and the definition (dealt with under Basis for the Opinion). RAC notes that there are some issues if NP is retained within scope, in terms of both proportionality (dealt with under Basis for the Opinion) and practicality of chemical analysis (dealt with under Monitorability).

RAC agrees that the proposal should be enforceable via chemical analysis. Companies may choose to introduce contractual obligations for the levels of NPEO in textiles in their supply

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chain, which could be an alternative approach to ensuring compliance.

Subject to some modifications of the wording of the restriction, RAC agrees that the proposal should be both practical and enforceable.

Justification for the opinion of SEAC

Implementability: SEAC agrees to the dossier submitter's assessment that a restriction on NPEO in textile articles is implementable. The most likely response to the regulatory action will be a substitution of NPEO with alternative surfactants. There is a range of alternatives available and considered to be technically and economically feasible. In particular alcohol ethoxylates are shown to be already widely used as surfactants in textile production (see section C and F of the Background document). The limit value of 0.01% by weight textile is achievable and manageable but would in fact imply a ban on intentional use of NPEO in the textile manufacturing process as confirmed by stakeholders consulted. Several major clothing and interior textile companies operating in the EU are already pursuing a similar limit value for NP/NPEO in textiles, which indicate no difficulties for the implementation of this limit under REACH. Stakeholders consulted confirmed that the transitional period of 5 years would allow sufficient time for the implementation and communication of the new requirements without creating major problems or needs for intensive compliance control or changes in technical equipment in the supply chain (see also respective section on the transitional period above).

Enforceability: SEAC agrees that the proposed restriction on NPEO in textile articles, as formulated in section A.1.2 of the Background document, is as clear as possible in order to be enforceable for the respective authorities:

- The restriction sets a clear limit for the NPEO content in textile articles, or parts of textile articles, i.e. it is recognised that those substances shall not be found in the textile above the limit value. The emphasis is thus clearly on the textile material.

- The entry includes a non-exhaustive list of articles (examples of articles covered by the scope) that will be affected by the restriction in order to clarify the scope as much as possible. The restriction shall only apply to those textile articles that can be washed in water during normal or reasonably foreseeable conditions of use, such as specified by the dossier submitter. The wording furthermore clarifies that prints on the textile articles are also subject to the limit value.

  Comments were received during stakeholder consultation suggesting 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 SEAC agrees with the dossier submitter's view that it is inappropriate to link the proposed restriction to a voluntary standard, both because the latter 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 is

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to submit a report to the European Parliament and the Council regarding possible new labelling requirements to be introduced at the Union level. It is explicitly stated in Article 24 p.3 (b) that the report will 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.

- SEAC agrees that the restriction defines to the extent possible what is meant by "textile articles" or "textile parts of articles" (it refers to already existing definitions[24]) as well as other phrases used such as "washed in water".

  The restriction includes a derogation for 'used' articles placed on the market. Such articles are not expected to contribute to emissions of NP/NPEO since they have been washed already a couple of times. Furthermore, given that these articles are not expected to contain any NP/NPEO above the proposed limit value, testing is not deemed to be necessary for those articles in order to comply with the restriction. SEAC acknowledges Forum's advice that there might be enforcement difficulties due to the fact that also articles that haven't been washed yet and could therefore contain NP/NPEO above the limit value end up in the second-hand market for which no clear definition is available. However, SEAC regards the proportion of unwashed articles ending up in this market rather small. SEAC agrees with the dossier submitter's approach to introduce a derogation on used articles placed on the market.

- The restriction defines the groups of substances that are covered.

- SEAC agrees that the proposed transitional period allows sufficient time for actors in the supply chain to adapt to the restriction and thus to deplete any stocks of textiles that contain NPEO concentrations above the limit (confirmed by stakeholders consulted). It also allows sufficient time for enforcement authorities for preparation work, if necessary.

- There are currently several analytical methods for measuring NPEO content in textiles but there is a need for standardisation. A standard test method for testing NPEO in textile articles to be adopted by the European Committee for Standardisation is currently under development (by the designated group TC248/Wg26) and is expected to be available before the restriction enters into force.

The Forum brought forward some reservations as regards the wording of the entry and the term "can be washed in water". Based on comments and suggestions provided by the Forum, the scope of the proposed restriction was rearranged by the dossier submitter in order to be as clear as possible. Furthermore, examples of articles are listed (non-exhaustive list). SEAC thinks that the aim and the scope of the restriction proposal are well and clearly explained in the Background Document. The proposal targets NPEO in textile articles that are / can be washed in water and subsequently the substances are released to waste water. NPEO is released to waste water from a number of sources of which the release from washing of textiles contributes to an average of close to 30 % compared to other quantified sources (see section B.9.4 of the Background Document). The definition of textile articles within the scope of the restriction is based on the definitions used in the proposed criteria document for Commission decision establishing the ecological criteria for the award of the EU Ecolabel for textile products. With this, SEAC thinks that unclarity and uncertainty for both, industry and authorities are reduced to the extent possible. Furthermore, the exact final wording of the REACH Annex XVII entry is decided by the

[24] Similar to the definition proposed in article 1.1 a-b in criteria document (final clean version for EUEB vote) for Commission decision of XXX establishing the ecological criteria for the award of the EU Ecolabel for textile products (available at http://susproc.jrc.ec.europa.eu/textiles/whatsnew.html).

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Commission.

Additionally, concern was raised by the Forum that there is not an analytical standard method for testing of NPEO in textiles available yet. Forum states that specific sampling and preparation methods are necessary as well. However, the development of a CEN standard test method is currently under development by the European Committee for Standardisation which is expected to be available once the restriction enters into force. SEAC agrees that the availability of standard testing methods is an important issue but it is not seen as a task of the Committee to guarantee the availability of such methods in advance.

Manageability: SEAC agrees that the proposed restriction on NPEO in textile articles is manageable, whereas manageability is largely determined by:

- 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 NPEO (0.01% by weight textile) has been balanced against the actors' ability to comply, taking into account the possibility of unintentional NPEO contamination of textiles due to e.g. traces of NPEO in chemical formulations
- Furthermore, NPEO is included in the Candidate list and there are already specific restrictions at the EU level for azocolourants (REACH Regulation 1907/2006/EC) and pentachlorophenol (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
- The types of textile clothing, fabric accessories and interior textiles that are of concern have been specified to the extent possible (see also section on Enforceability above as well as section A.1.2 of the Background document), and the whole group of NPEO substances are covered, the communication of the restriction should be manageable.

Monitorability

Justification for the opinion of RAC

The BD suggests that the restriction may be monitored at three levels:

- Monitoring of NPEO in textile articles or articles containing textiles at the Member State level (e.g. concurrently with the monitoring of the existing restriction on azocolourants in textiles).
- Monitoring of the concentrations/amounts of NPEO in effluent water from WWTP within the EU (e.g. under Regulation EC 166/2006 for large industrial facilities, although it is recognised that some WWTP are below the reporting threshold of 1 kg/year).
- Monitoring of the environmental concentrations of NP within the EU (for example as already done for the Water Framework Directive).

RAC suggests that the most direct way of assessing compliance will be random sampling of articles by companies and authorities; although the use of contractual obligations is also an option for companies. A range of textiles are already analysed for NPEO and NP content by commercial laboratories, using a variety of analytical techniques and extraction methods. It is therefore clear that an analytical method exists in principle. Comments from stakeholders

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during PC and from the Forum for Exchange of Information on Enforcement (Forum), emphasise the need to establish a standardised analytical technique to overcome variability between laboratories, and work is underway at the European Committee for Standardisation (CEN) to deliver such a method for NPEO within the next year or so. RAC points out that this method must cover the whole range of ethoxylate chain lengths that may be present in textiles (some current methods only give results for up to 15 ethoxylate units).

Work may also be needed to ensure that sampling strategies and techniques are appropriate, and this is not covered by a CEN standard. The distribution of the substance within the article may vary depending on the article type and even between individual articles, so it is not possible to define a generic strategy that could apply to all articles. However, RAC suggests that several samples are analysed for each article because of this heterogeneity. Alternatively, it may be preferable to take a mixed sample of the article with an even distribution of the different textile materials.

RAC notes that different analytical methods would be required if both NP and NPEO are included in the restriction. It is possible that a method that cleaves the ethoxylate groups could be developed to allow reporting of both NP and NPEO together using a single method (as used by Greenpeace, although it is not currently being investigated by CEN). In any case, inclusion of NP would present some complications in the way the results are reported. It appears that there are several options:

- To sum based on total mass of NP and NPEO together.
- To sum based on mole weight, although this would require knowledge of the mass of individual ethoxylate chain lengths in the sample (which could be difficult given the range).
- To base the sum on some sort of Toxic Equivalency Factor, although this would need further development as the data set is weak.
- If a cleavage method were available, NP could be measured in one sub-sample prior to the cleavage step, resulting in effectively a sum of "NP equivalents", both already present as NP and coming from any precursor in the sample. This would have the advantage of not being complicated by varying NPEO molecular weights.

It would be simplest, therefore, to target NPEO alone since that is the substance actually used in textile processing, and NP concentrations appear to be much lower in general. If NP were to be included, the restriction would perhaps need to specify its limit separately from NPEO to avoid summing ambiguities. In addition, a standard analytical method for NP would need to be developed.

Monitoring of effluent and surface waters could be used to indicate trends following the introduction of the restriction, and might provide additional intelligence about hotspots of NP/NPEO exposure for follow-up by enforcement authorities. However, as the actual contribution of textile washing to NPEO releases is uncertain compared to other sources, this would not provide direct evidence of non-compliance.

RAC notes that more comprehensive EU monitoring of NPEO concentrations in the environment (including specific measurements for short chain ethoxylates and carboxylates) would allow a more refined assessment of combination risks at a future date.

RAC concludes that the proposed restriction is monitorable. It would be simplest to target NPEO alone when measuring textiles, which has implications for the wording of the restriction.

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Justification for the opinion of SEAC

SEAC notes that the effects of the restriction on NPEO in textile articles can be monitored primarily at three levels, as described in section E.2.1.3 of the Background document:

- Monitoring of NPEO in marketed textile articles or articles containing textiles at the Member State level: as explained by the dossier submitter, the authorities responsible for enforcement of the restriction may perform random sampling of textile articles, based on statistical information available from Eurostat on the quantity of imported textiles, and use standard test methods to assess the concentration of NPEO in textiles. It is expected that the cost of compiling such information will be limited and such activities can be done concurrently with the monitoring of existing restrictions, such as those on azocolourants and pentachlorophenol (PCP) in textiles.

- Monitoring of the concentrations and/or amounts of NPEO in effluent water from WWTP within the European Union: the dossier submitter indicates that there is currently a reporting requirement for NP/NPEO for large industrial facilities (including WWTP) in the EU according to the Regulation EC 166/2006, whereby information on releases of NP/NPEO to the environment is updated on an annual basis 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/NPEO and the releases of NP and NPEO are reported separately which makes it a less useful tool for monitoring the effect of the proposed restriction. Additionally, there have been several monitoring programs for NP in municipal WWTP, but there is no full EU coverage expected in this respect.

- Monitoring of the environmental concentrations of NP within the EU: the dossier submitter reminds that the 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), such as NP concentrations in the water environment. Even though SEAC does not have sufficient evidence to support a restriction on NP, a restriction on NPEO only will also contribute to a reduction of NP concentrations in the environment due to the degradation of NPEO to NP. However, 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.

Overall, regarding these three different levels of monitoring, SEAC considers that there might not be significant additional costs. Emissions of NP/NPEO are indeed already measured and well reported by existing information systems on pollutants releases. Moreover, NP in effluent water from WWTP is already controlled through other EU regulations and the control of NPEO content in textiles can easily be carried out concurrently with other substances already restricted in textiles.

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BASIS FOR THE OPINION

Basis for the opinion of RAC

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by Sweden are:

a) *Removal of references to NP*: NP was included in the original proposal to provide some consistency with the existing Annex XVII restriction, which applies to several other use areas as well as textile processing. RAC considers that the available information does not allow any meaningful estimate of 'average' NP concentrations in textiles. It appears that NP levels are usually substantially lower than NPEO levels. Any NP present in a textile that is washed could contribute to the aquatic risk, so inclusion of NP in the scope would ensure that any unforeseen contamination is reduced. However, NP is not known to be intentionally used in textile manufacture. The restriction is expected to result in substitution of intentional uses of NPEO in textile manufacturing, which should reduce related levels of NP anyway (from impurities in formulations, etc.). RAC also notes that inclusion of NP would possibly require additional testing (as different analytical methods are usually needed for NP and NPEO) and introduce issues about the interpretation of the concentration limit when the substances are present in combination. Therefore for reasons of practicality and proportionality, RAC suggests that the restriction should target NPEO only. A decision to include NP could perhaps be taken at a later date if more comprehensive textile monitoring data become available.

b) *Reformatting of the limit from 100 mg/kg to 0.01 % by weight*: This is simply to make the restriction consistent with the format of existing Annex XVII entries.

c) *Clarification of the scope, by*:

   i) *Adding the words "textile articles, or parts of textile articles"*: This follows advice from the Forum and comments from stakeholders during PC asking whether the restriction applies to the total concentration in the finished article or to specific components of the article. It removes ambiguity by ensuring that all relevant parts of articles are within scope (including toys and printed pictures).

   ii) *Replacement of the reference to Regulation (EU) No. 1007/2011 with more specific wording for the definition of textile articles*: This follows comments from the Forum, which queried whether the Regulation definition would cover all relevant textile types. A textual description based on the proposed revised criteria for the EU ecolabel for textiles seems to be appropriate. It is beyond RAC's mandate to suggest a detailed list of all CN/TARIC codes that are within the scope of the restriction.

   iii) *Adding text to ensure raw and semi-finished goods (i.e., fibres, yarns, fabric and knitted panels) are covered*: These were included in the original scope by virtue of their mention in the textile definitions of Regulation (EU) No. 1007/2011. With the removal of this reference, it is important to explicitly mention them because such goods might contribute to the release of NPEO

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to European surface waters through washing (e.g. at textile processing sites even if the final article might be exported outside Europe). RAC notes that there is inadequate quantitative information on their actual levels of NP/NPEO, although stakeholder comments during PC suggest that they can exceed the proposed limit.

iv) *Adding the words "during normal or reasonably foreseeable conditions of use" for articles that can be washed in water*: This follows comments from Forum. The restriction is based on risks arising from textiles washed using water, and NPEO emissions are likely to be highest when the article is submerged in water and agitated with detergents above room temperature. The wording "in" rather than "with" water defines the enforcement scope by excluding textile articles that are washed by simply wiping or dabbing with a wet sponge/cloth (e.g. some types of footwear or furniture in which the textile parts are not detachable). However, further clarification is needed for cases where articles have labels that do not recommend washing in water, but people do so anyway. The additional phrasing has been used in other EU legislation including REACH restrictions and is explained in the ECHA guidance on requirements for substances in articles. Instructions on the label of the article are an example of "normal conditions of use" and the term "reasonably foreseeable conditions of use" would cover such cases when washing can be anticipated as likely to occur because of the function and appearance of the article even though they are not normal conditions of use. RAC recognizes that this wording might still be ambiguous for aqueous carpet cleaning equipment (for example), and recommends that this issue is considered further prior to the adoption of the restriction.

d) *Inclusion of a derogation so that the restriction does not apply to used articles placed on the market*: This follows advice from the Forum. The restriction is aimed at reducing NPEO emissions from textile washing. Second-hand textiles have usually been washed several times prior to re-sale, and so will contain substantially lower amounts of NPEO (the proportion of unwashed textile articles reaching the second-hand market is likely to be relatively small). This is a practical modification to provide legal certainty for the second-hand market. The wording is similar to that used for the proposed restriction of lead and its compounds in consumer articles.

To ensure that new articles can continue to be produced using recycled textiles containing NP/NPEO made prior to the restriction's entry into force (e.g. surplus unsold stock), further wording could be added to say "[the restriction]...shall not apply to articles produced by recycling finished articles that were placed on the market for the first time before ... (the date of entry into force)." Such uses of recycled textiles are not expected to contribute significantly to the release of NP/NPEO to the environment, since the proportion is likely to be very small compared to the amount of articles made using new fibres.

e) *Removal of the reference to a specific CEN standard*: This is based on advice from the Forum, to avoid problems should better or alternative analytical techniques become available in future. If reference to a specific standard method is desired, the wording should be suggestive rather than directive (i.e. the method "may" be used rather than "shall" be used).

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Basis for the opinion of SEAC

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

The main changes introduced in the restriction as suggested in this opinion compared to the restriction proposed in the Annex XV restriction dossier submitted by Sweden are the same as described in the RAC opinion.

The basis for these changes is information received during the public consultation and the advice of the Forum for Exchange of Information on Enforcement.

References not included in the BD

Sánchez-Avila, J, Bonet, J, Velasco, G and Lacorte, S (2009). Determination and occurrence of phthalates, alkylphenols, bisphenol A, PBDEs, PCBs and PAHs in an industrial sewage grid discharging to a municipal wastewater treatment plant. Science of the Total Environment, 407, 4157-4167.

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Appendix 1

Further evaluation of fish toxicity

Species	Duration and stage of life-cycle	Effect observed	Concentration	Ref. Comments
Schwaiger et al. (2002) *Onchorhynchus mykiss* Rainbow trout	One generation study: 3 year old F0 fish exposed prior to spawning for 10 days per month for 4 months at 1 and 10 µg/L; F1 not exposed to NP, reared for up to 3 years	Stage of maturation F0 Vitellogenin (males) F0 Sex ratio F1 Intersex gonads Vitellogenin (males) F1 Vitellogenin (females) F1 Mortality before eyed-egg stage F1 Mortality during embryo stage F1 Hatching rate F1 Testosterone (female) F1	No effect LOEC/NOEC <1 µg/L*** No effect 1-2% (also in controls) No effect LOEC 10 µg/L*a LOEC/NOEC <1 µg/L***b No effect LOEC 10, NOEC 1 µg/L* LOEC 10 µg/L**a a: 1µg/L not measured/-able b: Control, 1.7%; 1µg/L, 10.1% and 10 µg/L, 16.1%	Intersex: *"Whether the low percentage of intersex, showing both feminising and masculinising features, really represents a trans-generational effect of NP due to sex steroid levels or just a normal feature within the frame of physiological variability remains unclear"*
Ackermann et al. (2002) *Onchorhynchus mykiss,* Rainbow trout	Embryos exposed through: hatching, sexual differentiation, juvenile stage and adulthood for 1 year at 1.05 and 10.17 µg/L (EE2 as positive control; DMSO as carrier control)	Hatching rate Sex reversal Ovotestis Stage of sexual development Zona radiata protein (liver). Vitellogenin	No effect No effect No effect No effect LOEC 10.17, NOEC 1.05 µg/L LOEC/NOEC <1.05 µg/L	*"Based on our data, on expression of VTG, the NO(A)EL level of NP lies below 1.05 µg/L NP and this fact should be considered in the risk assessment of this environmental pollutant."*
Schwaiger et al. (2000) *Cyprinus carpio,* Carp	5 month old juveniles exposed for 70d primarily to look for low dose, apical effects (EE2 as positive control)	Severe anaemia - Tot. no. of leucocytes - Tot. no. of erythrocytes - Differential red blood cell count	LOEC 5 µg/L** NOEC 1 µg/L (clearly lowered) LOEC 10 µg/L** NOEC 5 µg/L LOEC 10 µg/L * NOEC 5 µg/L	*"…under field conditions, the NP-induced, general toxic effects, might outbalance the relatively weak estrogenic effects of this substance…"* The latter part of this statement was not substantiated in this experiment; it seems to be true when compared to other studies

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Species	Duration and stage of life-cycle	Effect observed	Concentration	Ref. Comments
Pickford et al. (2003) *Pimephales promelas,* Fathead minnow	2 week exposure of fish via the waterphase (1, 10 and 50 µg/L)	Vitellogenin, mRNA Vitellogenin, plasma	LOEC 50 µg/L*** NOEC 10µg/L a LOEC 10 µg/L*** NOEC 1 µg/L a: Not significant at p <0.001 but clearly elevated (several hundred vs <10 attomol Vtg/g totRNA in controls - probably still significant)	

*p<0.05, **p<0.01, ***p<0.001

The long-term studies of Schwaiger et al. (2002) and Ackermann et al. (2002) in rainbow trout and the shorter duration studies of Schwaiger et al. (2000) and Pickford et al (2003) in carp and fathead minnow respectively seem well carried out in reputable laboratories with adequate analytical confirmation of the lowest concentration (1µg/L in all cases). They provide insight into a range of apical and biomarker effects at a relevant, low tested concentration.

Where developmental endpoints are concerned, the Schwaiger et al. (2002) study showed significant effects at the embryo-larval stage in the offspring of exposed parent rainbow trout, i.e. post spawning, the offspring were not exposed themselves, with a LOEC of 1 µg/L (mortality before eyed egg stage). The hatching rate was significantly reduced at 10 µg/L, resulting in a NOEC at 1 µg/L (please note the relatively wide spacing of test concentrations study design), i.e. Vitellogenin and some reproductive hormone levels were measured, and found to be significantly raised in the same exposure concentration range in the F0 but also the F1. Ackermann et al. (2002), also using rainbow trout exposed for a year from embryo to adulthood, showed no effect on hatching rate, sex reversal, ovotestis or stage of sexual development at either 1 or 10 µg/L. However, for the biomarker *zona radiata* protein in the liver, a NOEC of 1 µg/L was recorded, while for vitellogenin, the NOEC was <1.05 µg/L, i.e. being found significantly elevated at the lowest concentration tested. The rainbow trout studies cover all essential parts of the fish lifecycle in possibly one of the most sensitive species, albeit they were not designed to provide continuous exposure from F0 through to adult F1 stages. It is worth noting that a reliable measured NOEC for egg mortality is not available, and the relevance of this parameter has not been assessed alongside all the other end points for this species, including the findings of another early life-stage test that did not indicate mortality at the egg stage (Brooke, 1993b). This apparent difference could be due to a transgenerational effect, but RAC does not consider it appropriate to use this value as a direct replacement for the growth NOEC used for the SSD in the BD in the absence of a more thorough review. However, it does suggest that the derived traditional PNEC of 0.4 µg/L may not be fully protective.

The haematological and pathological investigations of Schwaiger et al (2000) in carp reveal significant changes in the blood of carp at 5 and 10 µg/L (3 parameters), leaving NOECs of 1 and 5 µg/L for a condition described as severe anaemia in the absence of tissue lesions in liver, kidney and spleen.

Where vitellogenin is concerned, the study by Pickford et al (2003) confirms a NOEC of 1µg/L for significantly elevated plasma vitellogenin in fathead minnow, i.e. slightly higher than that for rainbow trout.

Bearing in mind that one of the effects described in three of these studies, vitellogenin can change rapidly within hours/days depending on the conditions prevailing and is thus not necessarily regarded as adverse, it might be tempting to dismiss the findings were it not for the clear developmental and haematological effects described in two of the studies.

However, just as importantly, these studies indicate where effects are not found and provide a clear impression that reproductive and other effects are unlikely to be found at lower concentrations. Thus in terms of risk assessment, NOECs around or not much lower than 1 µg/L for development in (parentally exposed) rainbow trout seem realistic. The endpoints where effects were found at the lowest tested concentration of 1 µg/L, especially increased egg mortality in non-exposed F1, may need to be considered in terms of concentration response (rather than any assessment factor) to determine an overall NOEC; it is appreciated that this is not made easy by the wide spacing in test concentrations.

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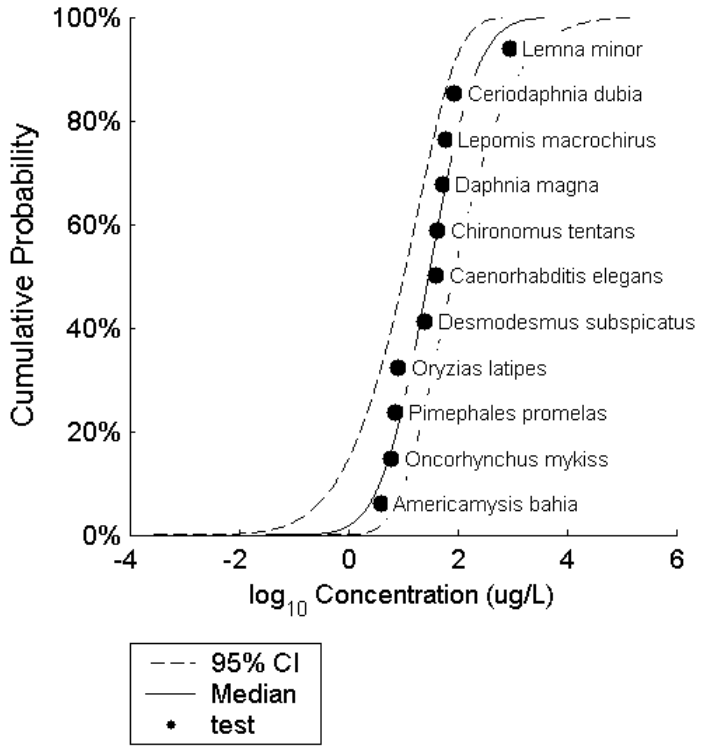
Appendix 2

Influence of additional data on species sensitivity distributions

The following information was derived using http://www.webfram.com/home.aspx.

CURRENT PROPOSAL IN OPINION

Species Name	NOEC, µg/L
Caenorhabditis elegans	40.2
Ceriodaphnia dubia	88.7
Chironomus tentans	42
Daphnia magna	53
Desmodesmus subspicatus	25.1
Lemna minor	901
Lepomis macrochirus	59.5
Americamysis bahia	3.9
Oryzias latipes	8.2
Pimephales promelas	7.4
Oncorhynchus mykiss	6



Median HC_5: 2.11 (90th % CI: 0.37-5.86) µg/L, so PNEC = 0.42 µg/L

N.B. BD derives HC_5 as 2.12 µg/L.

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Goodness of Fit (GoF) Results

Kolmogorov Smirnov

P-Values	Critical Values For Test Statistic	Calculated Test Statistic	Accepted or Rejected
0.1	0.819	0.5666	Accepted
0.05	0.895	0.5666	Accepted
0.025	0.995	0.5666	Accepted
0.01	1.035	0.5666	Accepted

Cramer Von Mises

P-Values	Critical Values For Test Statistic	Calculated Test Statistic	Accepted or Rejected
0.1	0.104	0.0510	Accepted
0.05	0.126	0.0510	Accepted
0.025	0.148	0.0510	Accepted
0.01	0.179	0.0510	Accepted

Anderson Darling

P-Values	Critical Values For Test Statistic	Accepted or Rejected
0.1	0.631	Accepted
0.05	0.752	Accepted
0.025	0.873	Accepted
0.01	1.035	Accepted

AD Stat: 0.4241
AD P-Val: 0.6819

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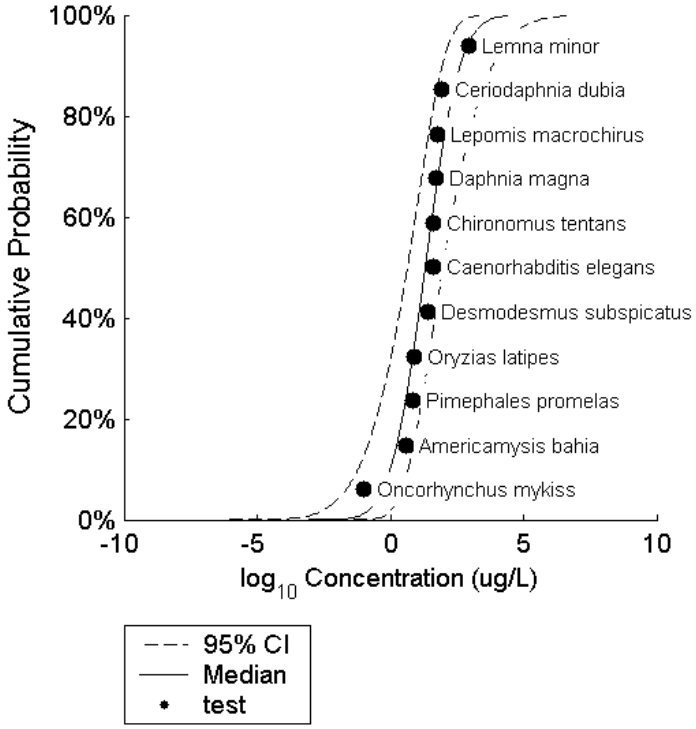
FIRST ALTERNATIVE

The LOEC for egg mortality (F1) for *O. mykiss* is 1 µg/L. We don't know what the NOEC would be. As an approximation, if we divide the LOEC by 10, we would have a speculative NOEC of 0.1 µg/L (it could of course be higher or lower than this).

Replacing the growth NOEC for this species (6 µg/L) with this value in the SSD gives a median HC_5 of 0.42 (90th % CI: 0.03-1.87) µg/L, so a PNEC of 0.08 µg/L, i.e. taking account of this additional information would lower the PNEC by about a factor of 5.



GoF Results

Kolmogorov Smirnov

P-Values	Critical Values For Test Statistic	Calculated Test Statistic	Accepted or Rejected
0.1	0.819	0.6147	Accepted
0.05	0.895	0.6147	Accepted
0.025	0.995	0.6147	Accepted
0.01	1.035	0.6147	Accepted

Cramer Von Mises

P-Values	Critical Values For Test Statistic	Calculated Test Statistic	Accepted or Rejected
0.1	0.104	0.0809	Accepted
0.05	0.126	0.0809	Accepted
0.025	0.148	0.0809	Accepted
0.01	0.179	0.0809	Accepted

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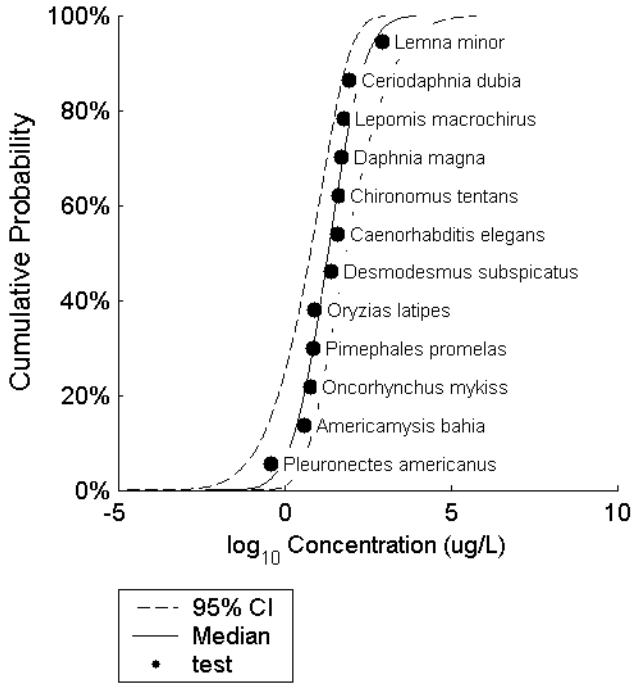
Anderson Darling

P-Values	Critical Values For Test Statistic	Accepted or Rejected
0.1	0.631	Accepted
0.05	0.752	Accepted
0.025	0.873	Accepted
0.01	1.035	Accepted

AD Stat: 0.5583
AD P-Val: 0.8506

SECOND ALTERNATIVE

Winter Flounder *Pleuronectes americanus* appears to be more acutely sensitive than the Rainbow Trout. We don't have a NOEC, but could estimate one based on the acute: chronic ratio for other species. Rainbow Trout appears to be the most sensitive of the fish species tested, but the acute: chronic ratio depends on the choice of NOEC. If we take the growth NOEC of 6 µg/L, the ratio is 40 (it would be 2,400 based on the putative egg mortality NOEC of 0.1 µg/L, or 240 based on the LOEC). Applying a ratio of 40 to the Winter Flounder LC_{50} gives a speculative NOEC of 0.4 µg/L. Adding this data point to the original SSD gives a median HC_5 of 0.78 (90th % CI: 0.10-2.64) µg/L, giving a PNEC of 0.16 µg/L, i.e. taking account of the potentially higher chronic sensitivity of Winter Flounder lowers the PNEC by a factor of about 2.5. If the acute: chronic ratios for this species were lower or higher, a different result would be obtained.



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GoF Results

Kolmogorov Smirnov

P-Values	Critical Values For Test Statistic	Calculated Test Statistic	Accepted or Rejected
0.1	0.819	0.5265	Accepted
0.05	0.895	0.5265	Accepted
0.025	0.995	0.5265	Accepted
0.01	1.035	0.5265	Accepted

Cramer Von Mises

P-Values	Critical Values For Test Statistic	Calculated Test Statistic	Accepted or Rejected
0.1	0.104	0.0469	Accepted
0.05	0.126	0.0469	Accepted
0.025	0.148	0.0469	Accepted
0.01	0.179	0.0469	Accepted

Anderson Darling

P-Values	Critical Values For Test Statistic	Accepted or Rejected
0.1	0.631	Accepted
0.05	0.752	Accepted
0.025	0.873	Accepted
0.01	1.035	Accepted

AD Stat: 0.3516
AD P-Val: 0.5311

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