Committee for Risk Assessment (RAC)

Opinion

on an Annex XV dossier proposing restrictions on

Nonylphenol and **Nonylphenol ethoxylates**

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

Adopted

3 June 2014

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Opinion of the Committee for Risk Assessment

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 on the proposal for restriction of

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

This document presents the opinion adopted by RAC. 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.

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.

OPINION

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 ethoxylates ($(C_2H_4O)_nC_{15}H_{24}O$))

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.

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

JUSTIFICATION FOR THE OPINION OF RAC

IDENTIFIED HAZARD AND RISK

Description of and justification for 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 nonylphenol ethoxylate (NPEO) degradation products, i.e. nonylphenol (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 fourth draft opinion considers the evidence presented in the restriction dossier and comments submitted during the public consultation and RAC discussions.

Description of the risk to be addressed by the proposed restriction

o Information on hazard(s)

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)

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 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 species	Effects observed are similar to those observed for a known anti-estrogen and thyroid active substance (pentachlorphenol)	Yes (larval malformations) Most sensitive reliable LOEC = 0.9 µg/L (larval malformation in *Arbacia lixula*)	Some indication but no conclusion possible due to lack of knowledge
	4 mussel species	Induced hermaphrodism effects fit to those observed for 17ß-	Yes (sex ratio skewed to females in one study, survival of offspring)	Some indication but no clear

Taxonomic group	No. of species	Indication of hormonal activity?	Apical adverse effects observed?	Indication that apical endpoints fit to mode of action
		estradiol and knowledge about the influence of estrogens on female sexual maturation	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.	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 inTable 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 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.

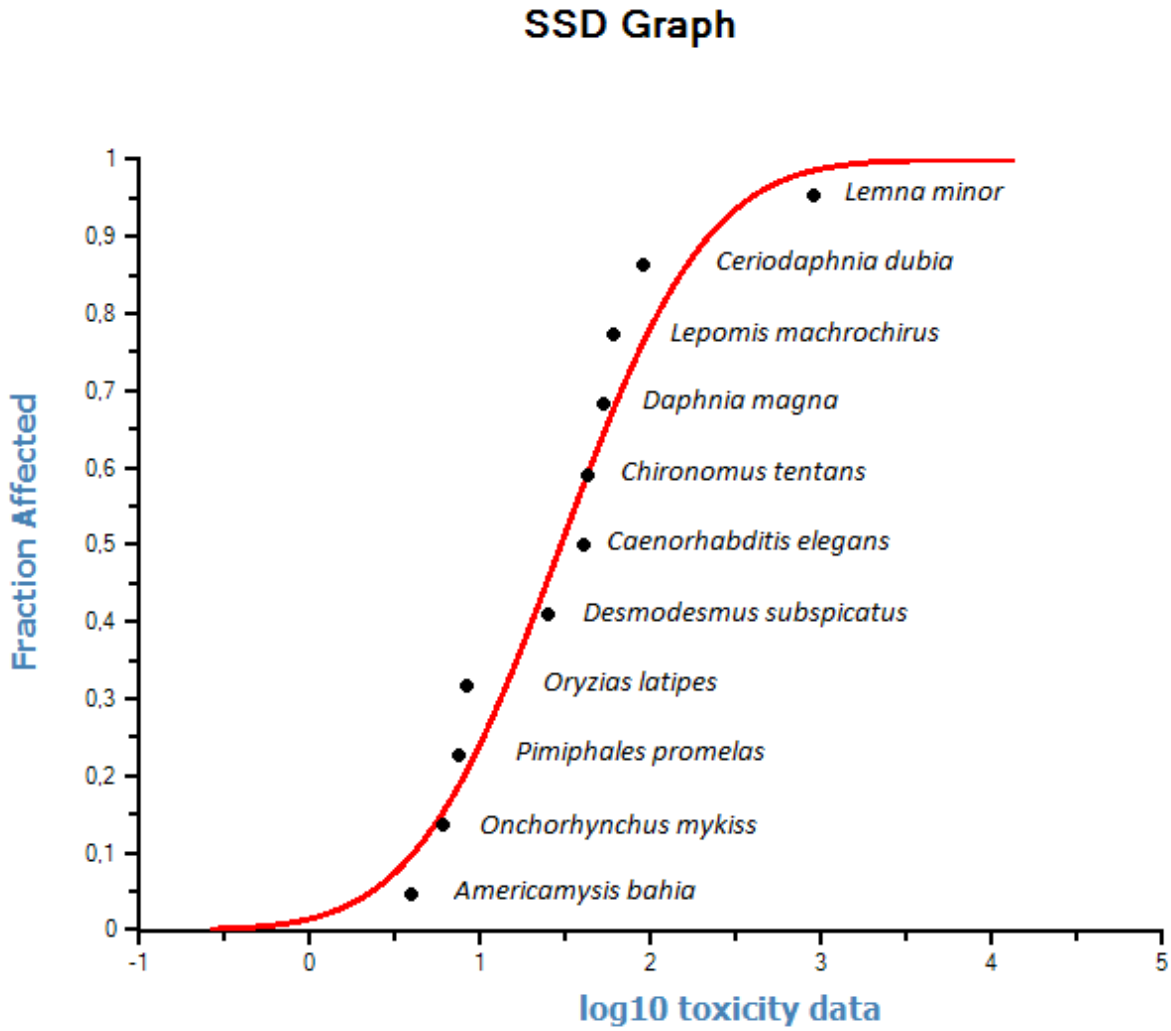


Figure 1: *Aquatic species sensitivity distribution for nonylphenol (log normal distribution) from the ETX 2.0-software with the names of the individual species inserted (BD Figure 6)*

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, as complexity of the endocrine system, risk for 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[1]. 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 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[2]; this is also a precautionary approach because less sensitive data (e.g. the putative result for marine algae) should also be included).

[1] 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).

[2] See Appendix 2 for details of additional tentative SSD approaches.

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[3] 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[4]. 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. 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

[3] 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.

[4] See Appendix 1 for further details of RAC's additional study evaluations, Appendix 2 for details of additional tentative SSD approaches.

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.

Conclusion 1: 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).

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 RE deviates from the corresponding TEF for NP1EC and NP2EC. This sheds further doubt on the conclusiveness of the selected 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.

Conclusion 2: 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[5] 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[6]), 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 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.

[5] http://cdr.eionet.europa.eu/
[6] 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.

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 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)).

Conclusion 3: 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)[7], 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
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.

[7] 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.

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[8] (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)[9], based on mean data for eight WWTP), approximately 1:3 (Sánchez-Avila *et al*., 2009[10]; based on sampling over two days only, for one WWTP), or 1:25 (Vega-Morales *et al*., 2010[11], 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.

[8] Geometric mean, where non-detects were assumed to represent concentrations at half the LoD.
[9] 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.
[10] 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.
[11] 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.

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.

Conclusion 4: 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 Characterisation of risk(s)

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 90^{th} 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 $PNEC_{aqua}$.

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 90^{th} 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.

Conclusion 5: 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 (cf. conclusion 1). 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.

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

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.

Conclusion 6: Action to reduce the risks arising from NP exposure needs to be taken on an EU-wide basis.

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

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.

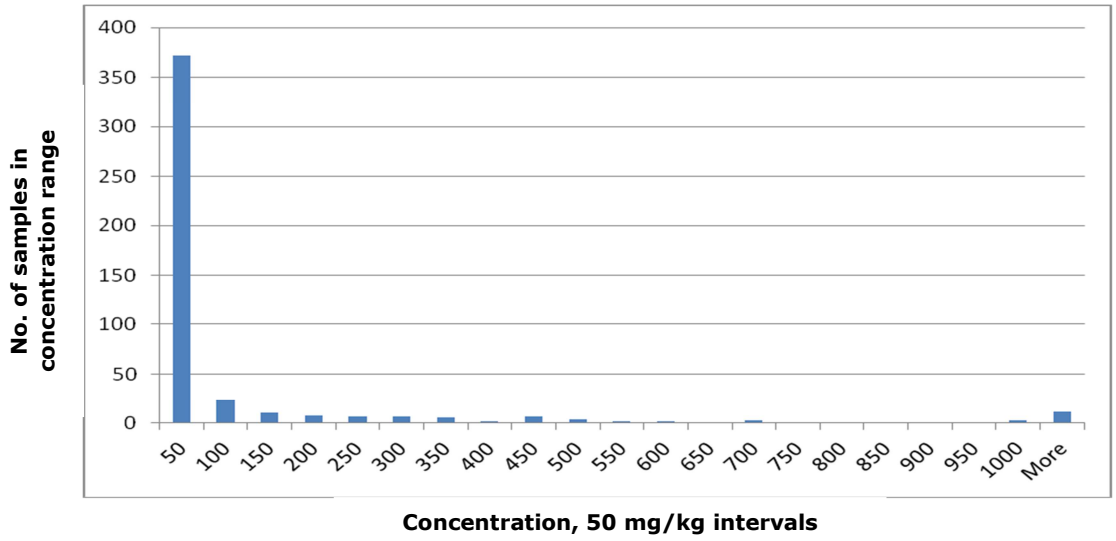


Figure 2: *Frequency of reported NPEO textile concentrations, n = 474*

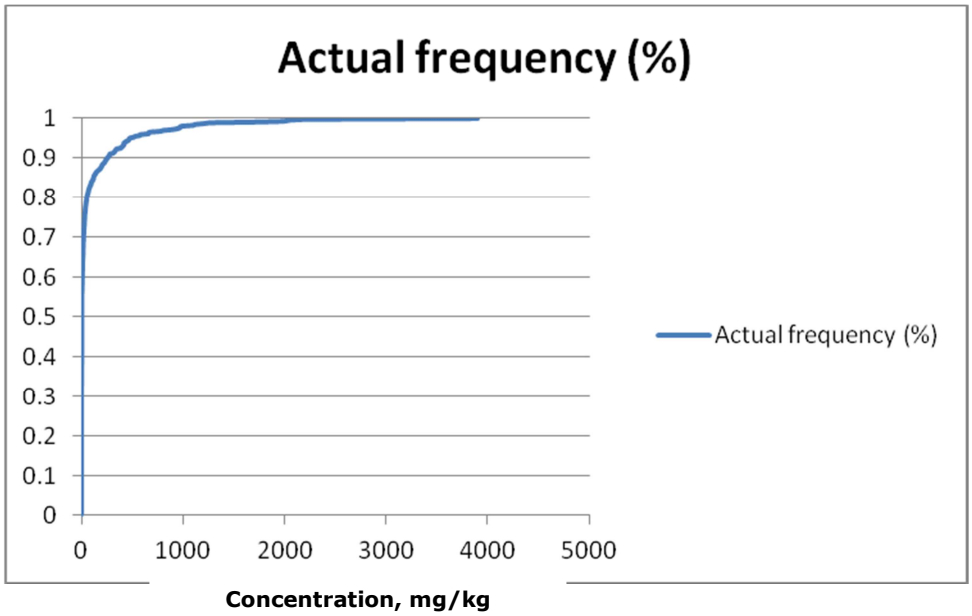


Figure 3: *Cumulative frequency of reported NPEO textile concentrations (three outliers removed)*

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[12], 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).

[12] 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.

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 (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.

Conclusion 7: 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 (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 NPconcentrations 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

Following discussion with Industry, the dossier submitter suggests that primarily *Clothing textiles (Clothtech)* and *Sports textiles (Sporttech)*[13] may be washed in water and hence contribute to NPEO releases to waste water. These article types are believed to represent approximately 10-15 per cent of global textile consumption. Although other textile types can be washed in water (e.g. *Protective textiles*), the vast majority of technical textiles are handled in such a way that releases from laundering are not expected to be significant.

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

[13] Classifications as specified by Techtextil, Messe Frankfurt Exhibition GmbH.

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 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 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.

Conclusion 8: 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 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[14]. 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.

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

- 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.

- 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[15] 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%[16]. 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

[15] 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).

[16] 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.

concentration. Clearly this estimate would change if the actual formation of NP from NPEO degradation was lower than 2.5%.

- 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.

Conclusion 9: 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

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 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.

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.

Conclusion 10: 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 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.

Practicality, incl. enforceability

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

Conclusion 11: Subject to some modifications of the wording of the restriction, RAC agrees that the proposal should be both practical and enforceable.

Monitorability

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 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.

Conclusion 12: 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.

BASIS FOR THE OPINION

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 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).

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.

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

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.

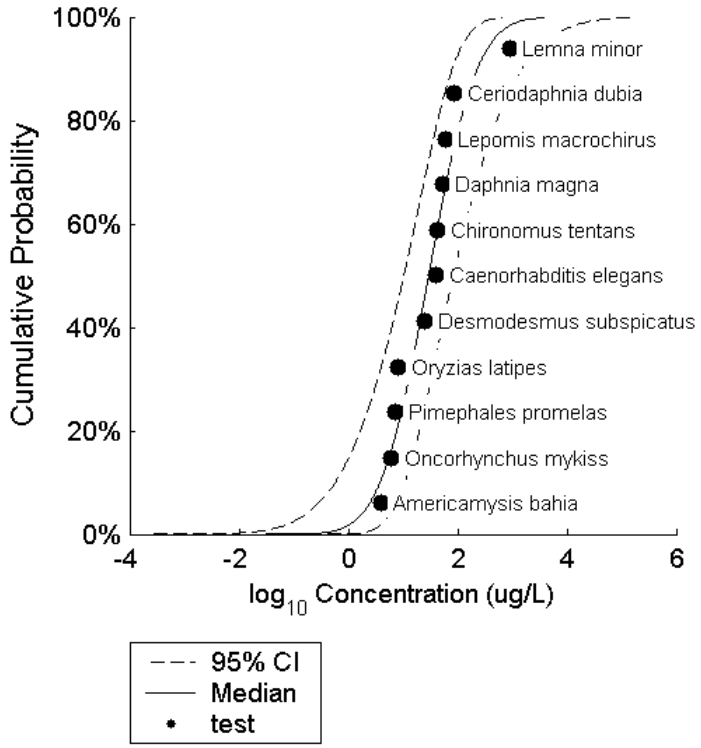
Appendix 2

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.

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

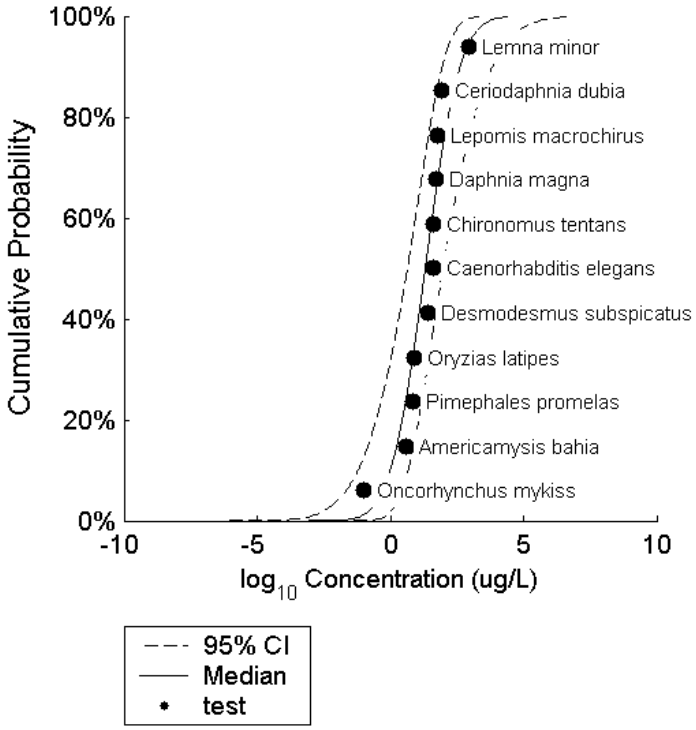
P-Values	Critical Values For Test Statistic	Accepted or Rejected
0.1	0.631	Accepted
0.05	0.752	Accepted
0.025	0.873	Accepted
0.01	1.035	Accepted

AD Stat: 0.4241
AD P-Val: 0.6819

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

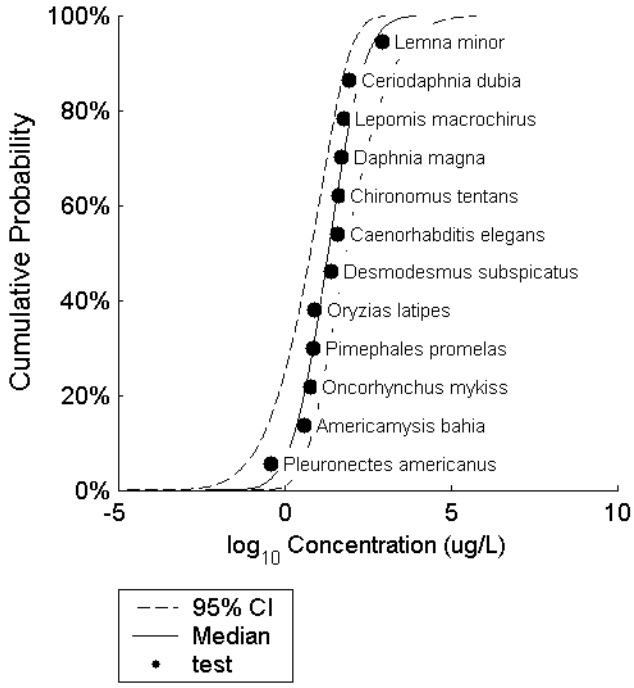
Anderson Darling

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.



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