Committee for Socio-economic Analysis (SEAC)

Opinion

on an Annex XV dossier proposing restrictions on

Nonylphenol and **Nonylphenol ethoxylates**

Draft

11 June 2014

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Opinion of the Committee for Socio-economic Analysis

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

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation 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 SEAC. The Background Document (BD), as a supportive document to both RAC and SEAC opinions, gives the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINION

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

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

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

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

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

OPINION

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

The proposed restriction is as follows:

Nonylphenol 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 SEAC

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

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

Effectiveness*:* the effectiveness of the restriction proposal is not expected to be significantly affected by including NP in the scope of the restriction. There is limited data available on NP concentrations in textiles. These data (studies from Klif 2011, Danish EPA 2013 and Greenpeace 2012a) show very low concentrations of NP in textiles, i.e. between 0.7 and 10 mg NP/kg textile with an average of 3.4 mg NP/kg textile. If NP is actually present in textile articles only in traces (such as the above mentioned studies indicate) the proposed limit value (0.01% by weight) would not contribute to the reduction of NP concentrations in textiles. Comments from two stakeholders received during public consultation indicate much higher NP concentrations (between 16.4 mg/kg and 660 mg/kg in 4% of the tested articles)[1] but these data are not conclusive and the respective stakeholders could not provide information on the sources of NP in textiles, i.e., intentional

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

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

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

Practicality (including implementability, manageability and enforceability) and monitorability: Nonylphenol could not be identified as being used intentionally in the textile manufacturing processes and it is unclear how NP ends up in the final textile product. As a result, the consequences of a restriction on NP for affected actors in the textile supply chain are unknown and it is unclear how actors could comply to the restriction if they do not know how NP enters the textile product. SEAC has no data at hand to draw any conclusion on potential impacts of the inclusion of NP in the scope in terms of practicality. Regarding testing, experts that have been contacted by the dossier submitter claimed that analyses for NP and NPE have to be performed separately. If NP was included in the scope of the restriction, both substances would need to be measured by enforcement authorities and by companies, who choose to test their products for compliance reasons. Currently there is a CEN standard test method under development (by the designated group TC248/Wg26)

which is expected to be available before the proposed restriction entry into force. However, this CEN standard is being developed for NPE only. Test methods for NP exist but are not standardised yet, which makes compliance control for both, enforcement authorities and industry difficult. Consequently, in SEAC's view, an inclusion of NP would make the restriction less practicable, less manageable and less enforceable. As regards the monitorability of the proposed restriction, SEAC could not identify any major differences between restricting both, NP and NPE, or restricting NPE only (for more information see section on Monitorability below).

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

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

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

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

SEAC agrees that such emissions should be avoided in the same manner as emissions from finished textile articles, which contributes to the benefits of the restriction. SEAC has no data at hand to conclude specifically on costs and benefits of restricting/not restricting R & SF articles. However, SEAC agrees with the dossier submitter's evaluation that there might be somewhat higher substitution costs since in principle, NPE used in R & SF articles should also be substituted as a result of the restriction if those articles are included into the scope (see Background document Appendix 13) but substitution costs are not considered to be a major negative factor in the evaluation of the proportionality of the restriction. Moreover, compliance control costs are not regarded to be significantly affected by including R & SF articles. The occurrence and the magnitude of compliance control costs are highly uncertain (see separate discussion in the section on costs) and the dossier submitter has accounted

for these uncertainties in the performed sensitivity analysis. Based on the argumentation given in the Background document and its Appendices, SEAC agrees with the dossier submitter's view that with the revised wording of the scope raw and semi-finished articles are indeed targeted by the proposed restriction (as it was already intended in the original wording of the restriction proposal) in order to avoid emissions of NPE during the processing of such textiles within the EU as well as to avoid NPE in the final textile articles placed on the EU market. SEAC emphasises that no specific cost-benefit assessment could have been performed by the dossier submitter on these types of articles. However, it can be assumed that the data on textiles which have been taken into consideration in the dossier submitter's cost analysis may already include to a certain proportion R & SF articles which are used to manufacture the final textile articles.

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

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

SEAC agrees that action is required on an EU-wide basis. The proposed restriction covers textile articles or textile parts of articles, where those articles comprise of textile clothing and accessories as well as interior textiles (for further information on the articles covered by the restriction see section A.1.2 of the Background Document as well as Appendix 13)[2]. Such products are extensively traded and used in all Members States. The use of Nonylphenol and Nonylphenol ethoxylates as substances or in mixtures, which are not used in closed systems, is already restricted in the EU within the textile sector since 2005 (REACH Annex XVII, Entry 46). However, the dossier submitter investigated that these substances are still used primarily outside the EU as detergents and auxiliaries in the manufacturing of textile articles. Furthermore, the major part of textiles consumed within the EU is imported from outside the Union. According to statistics from Eurostat the import of textiles was about 6 million tonnes in 2010 and the import share of EU consumption is assumed to be at least 75 % and probably close to 90 % (see sections B.9.3.4.1 and E.1.1.2.2 of the Background Document). This assumption is supported by data from the EUROSTAT PRODCOM database, which indicate that the textile import share of EU consumption was approximately 82% in 2010. SEAC agrees that an EU-wide restriction would remove potentially distorting effects that national restrictions or other national risk management measures may have on the free circulation of goods. Moreover, it would reduce the existing uncertainty for international suppliers regarding regulatory requirements, since it provides a clear statement of the requirements in the EU and can therefore easily be communicated to suppliers outside the EU (confirmed by stakeholders).

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

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

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

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

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

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

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

- **Stricter requirements on end-of-pipe measures in industrial facilities and WWTP** (Waste Water Treatment Plants) have been evaluated by the dossier submitter and have been found to be less cost effective than controlling emissions at the source.
    - According to the dossier submitter's research, end-of-pipe measures, in order to reduce NPE emissions, would imply large investment and on-going operational costs, which could be around € 70 billion per year. Costs may vary significantly among installations and according to technologies used. The literature shows a wide range of estimated costs for this type of measures (based on AMEC 2012 report, presented by the dossier submitter in section E.1.3 of the Background Document).
    - SEAC acknowledges that such measures - if implemented in order to reduce NPE emissions - may create substantial co-benefits as they would remove other pollutants than the substances of concern as well. But these co-benefits are difficult to estimate and would require site-specific assessment. It was not possible to perform such an assessment, neither by the dossier submitter, nor by SEAC.
    - The UK Environment Agency provided a large amount of data on NP and NPE during the public consultation (UK Environment Agency 2013c). In summary, the data show that releases of NP and NPE to waste water treatment works

(WWTW) is ubiquitous and widespread. The UK WWTW show good removal rates for NP (> 80%) but NP is still present in WWTW effluent in relatively high concentrations (see section E.1.3. of the Background Document). The UK Environment Agency stated that high percentages of the NP load to UK WWTW (up to ~ 75%) are believed to arise from domestic sources (it has to be noted that no similar analysis has been performed for NPE). Under the assumption that the UK findings are representative for other MS as well, many WWTPs across the EU would need to improve existing treatment processes or upgrade to additional treatment steps in order to achieve an overall emission reduction of NP/NPE. Based on the UK data on influent/effluent concentrations in WWTPs with different treatment processes, it may be difficult to predict the effectiveness of any additional treatment measures for NPE since there are other factors than the treatment technique itself that determine the amount of releases mitigated (see section E.1.3 of the Background document). The UK Water Industry Research Chemicals Investigation Programme[3] provides estimates on the cost-effectiveness of additional measures to achieve the EQS (Environmental Quality Standard) for NP in the UK[4]. Nonetheless, these studies are not directly comparable to the current case since the measures are assessed against the Water Framework Directive EQS which is lower than the PNEC identified in section B.10 of this restriction proposal. However, in SEACs view the results of these studies seem to support the conclusion that the implementation of end-of-pipe measures would imply significant investment costs and in addition, external damage costs due to increased CO_2 emissions associated with these investments. The CIP results indicate (for the UK) that additional treatment would have to be introduced at approximately 144 of the UK WWTPs in order to achieve NP concentrations of maximum 100% of the EQS. According to the report, the same result could be achieved if source control measures reduced influent by approximately 60%. The net present value of the investment in extra treatment (in the UK) would be in the region of £ 0.3 billion with an annual CO_2 emission of 22,000 tonnes. This cost estimate cannot be extrapolated to any reliable estimate for the EU level without extensive further investigations. Neither the dossier submitter, nor SEAC was able to perform such investigations. However, the dossier submitter still performed a simple illustrative calculation that gives an indication of the potential cost of such measures: the total annual cost in the EU would be estimated to € 214 million plus € 4 million external damage cost per year (for further information see section E.1.3, footnote 83 of the Background document). A further example on the cost-effectiveness of end-of-pipe measures is given in section E.1.3 of the Background document, dealing with the case of 17 alpha-ethinylestradiol (EE2). This evaluation indicates high costs of the measures (including external damage costs, increased energy production and an increase in sludge production that could imply additional costs of disposal) whilst being ineffective at reducing emissions from sources that are not connected to WWTP. Lastly, the implementation of end-of-pipe measures to reduce emissions of NPE from textile articles would not reflect the principles that environmental damage should – if possible - be rectified at source, according to the "polluter pays"-principle (which is one of the guiding

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

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

principles in EU policy – see European Parliament and the Council, 2013). Further information on the evaluation of end-of-pipe measures is provided in section E.1.3 of the Background Document and in Appendix 12.

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

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

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

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

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

- **The limit value:** As already mentioned above, it has to be noted that the limit value proposed by the dossier submitter targets NPE only and not NP (for further details, see the explanatory note in section A.3.3 of the Background Document). The dossier submitter proposes a limit value for NPE of 0.01% by weight textile. Additionally, two lower limit values (0.002% by weight for RMO2a and 0.005% by weight for RMO2b) are discussed in the restriction proposal. The level of the limit value primarily affects the risk reduction capacity, the technical feasibility and the costs of each restriction option. It was indicated by stakeholders that a limit value of 0.01% by weight textile is achievable and sufficiently stringent to deter any intentional use of NPE in the manufacturing of textile articles. Furthermore, it was indicated that the proposed value would not conflict with the current REACH Annex XVII entry 46 on NP/NPE, which applies to manufacturing of textiles in the EU. However, in SEAC's view consistency between existing and newly introduced restrictions is not a necessary condition for the choice of the limit value. Moreover, information provided by stakeholders further indicates that, even though NPE is substituted, there may still be NPE traces as impurities, by-products, or intentional components (at low concentrations) in some chemical formulations that are used in textile manufacturing. The use of such chemical formulations during the processing of textiles may thus result (unintentionally) in NPE being found in the final textile article. The issue of traces of NPE in chemical products could thus pose difficulties in terms of technical feasibility if the proposed limit value for NPE in textile articles is set too low (see section E.2.1.1.2.1 of the Background document, confirmed by Stakeholders during public consultation).

- The duration of the **transitional period:** the dossier submitter proposes a transitional period of 5 years. The dossier submitter has chosen the transitional period considering that it is manageable and practicable in terms of timing and costs (i.e. better manageable than, e.g., a 3 years transitional period) also for SMEs. The transitional period mainly affects the ability for industry to communicate the

restriction down the supply chain and the costs of each restriction option. This was confirmed by the stakeholders consulted (see section E.2.1.1.2.1 of the Background document).

- The dossier submitter presents several arguments in favour of a shorter transitional period and explains that the proposed restriction is not expected to incur any significant investments in new production equipment for textiles that are produced for exports to the EU market (confirmed during the public consultation). Hence, no considerable transition time is needed in this respect. Considering the relatively quick turnaround time of textile articles in the market, in particular for clothing textiles and accessories, it is likely that a transition time of one year would suffice to sell out existing stocks. Furthermore, the dossier submitter investigated that alternatives are available in sufficient amounts and their production has likely grown since 2002 worldwide, indicating that the market should be able to adapt in terms of supply within one year transition time and the impact on the market for chemicals is expected to be minor (see section E.2.1.1.2.1. of the Background Document). Two stakeholders argued during the public consultation (one NGO and one organisation representing manufacturers of auxiliaries and colorants used in textiles) that a three years transitional period would indeed be feasible or even too long. However, they based their argumentation mainly on the availability of alternatives and the time needed for shifting from NPE based detergents to alternative detergents. SEAC acknowledges that this shift is technically feasible and might be performed rather quickly.

- The above stated arguments seem to indicate the feasibility of a shorter than the proposed transition period of 5 years. However, the choice of 5 years is in line with comments received by almost all stakeholders during the different consultations that have been performed. It was indeed indicated by stakeholders that a 5 years transitional period is needed in order to have sufficient time to communicate the new legal requirement down the (global) supply chain. A period shorter than 5 years would be difficult to implement by actors in the supply chain and would therefore raise costs due to the need for more extensive communication strategies and possibly testing of products, which is stated by stakeholders to be likely not performed in case sufficient time for the implementation would be allowed. The dossier submitter qualitatively assessed the consequences of implementing a shorter transitional period (i.e. 3 years) and stated that it is not possible to make generalised statements about the form and magnitude of the involved compliance control costs (see section E.2.1.1.2.1 of the Background document). SEAC acknowledges that further quantitative assessment was not feasible, due to lack of relevant data. However, SEAC agrees that the issue of timing is closely related to the occurrence and magnitude of compliance control costs. Some stakeholder responses indicate that a shorter transitional period may imply significant extra efforts by textile importers and other actors in the textile supply chain. Section E.2.1.1.2.1 of the Background document stated there are indications that if sufficient time is not allowed for such supply chain communication to occur under normal business to business contacts, extraordinary measures by EU importers may be necessary in order to achieve compliance with the restriction in due time (further arguments are in detail listed in the relevant section under the heading “Timing”). Major concern about a shorter transition period raised by most of the respondents was not about technical issues, but about the communication of the legal requirement down the rather complex global supply chains connected with higher costs. The suggested time period of 5 years is expected to provide enough time for communication of the restriction and will allow actors outside the EU to react accordingly. Almost all stakeholders (except the two above mentioned) stated that the five-year period is considered to minimise

compliance control needs, and that costs of such controls are even considered unlikely to occur, which will positively affect the proportionality of the restriction.

SEAC acknowledges that it is difficult to conclude on the above discussed values as it is difficult to verify what is technically achievable and manageable for industry and how long it actually takes to communicate a new legal requirement down the respective supply chains. The limit value and duration period are mainly based on industry's declarations, received during the development of the restriction proposal, during a separately performed survey by ECHA[5] as well as during public consultation. From a technical point of view a lower limit value as well as a shorter transitional period might be achievable but SEAC has no information at hand that would support the choice of such values. In the public consultation the proposed setting was confirmed by almost all stakeholders to be the most appropriate. Stakeholders who claimed the feasibility of a lower limit value and/or a shorter transitional period during public consultations did not provide sufficient information (such as costs or other quantitative data) which substantiated their claim. Furthermore, from the perspective of proportionality (see separate discussion on proportionality below), without further or any contradictory information from stakeholders, SEAC does not have information to disagree with the dossier submitter that the proposed limit value and transitional period are the most appropriate ones.

Alternatives have been discussed within the restriction report and are considered to be available (see section C of the Background document). Although the dossier submitter acknowledges that it is difficult to replace NPE with one alternative formulation for all uses, a number of technically feasible alternative surfactants that have the same/similar performance characteristics as NPE are presented as being available on the market. The dossier submitter's investigation has shown that non-ionic surfactants are able to fulfil the properties needed: alcohol ethoxylates, glucose-based surfactants and alkyl phenol ethoxylates (when used as detergent) and sugar esters, alkanol fatty acid amides, quaternary ammonium compounds and again, alcohol ethoxylates and glucose-based surfactants (when used as emulsifier). Such alternatives have been in use by the textile industry for quite some time. Alcohol ethoxylates (AE) are the most investigated alternatives and also the most suitable alternatives in the textile process according to the dossier submitter. No concern is expected due to exposure of AE to health or the environment. Neither did RAC identify any concern associated with the alternatives evaluated in the restriction proposal (see RAC opinion for more details). Alternatives seem to be slightly more expensive than NPE (their prices indicated to be 0-10% higher) although it is difficult to determine the exact extra cost, as prices vary depending on demand and business relations between suppliers and customers. The replacement of NPE by suitable alternatives is considered to be applicable without any major changes in the textile production process as indicated during the public consultation. Furthermore, interested parties stated that alternatives are already used in the textile manufacturing process in- and outside the EU. As stated in section B.9.1.1 of the Background document, there already exist a number of company collaborations and voluntary commitments concerning the substitution of Nonylphenol and Nonylphenol ethoxylates in textiles, i.e. companies already voluntarily substitute NPE in the textile manufacturing process. SEAC agrees to the dossier submitter's assessment, which is backed up by feedback received in stakeholder consultation that suitable alternatives are available and are technically and economically feasible.

The dossier submitter also analyses the "extra washing" of textile articles as a possible consequence of the restriction proposed (see section E.2.1.1.1.2 of the Background Document). However, the dossier submitter considers that the proposed restriction is not

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

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

Overall, the proposed by RMO1 (limit value of 0.01% by weight and five-year transitional period) is considered as the most appropriate. During consultations performed by the dossier submitter, by ECHA[6] and during the public consultation on the restriction proposal no major concern was raised by industry about restricting NP and NPE in textiles under this setting. Moreover, the setting of the proposed restriction has been found to be effective in reducing NPE emissions, technically feasible and achievable to relatively low cost (see discussion below and section F.2.1 of the Background document). The proposed restriction effectively reduces the major part of NPE that is estimated to be emitted from imported textile articles (during the washing process) (for more details see RAC opinion). There are technically feasible alternatives available with similar effectiveness although at marginally higher prices compared to NPE. The proportionality of the restriction proposal is discussed in the section below.

Proportionality to the risks

Benefits: Imported textile articles are identified as a major source of NPE emissions to the aquatic compartment when such articles are washed in water. The restriction proposal will lead to a reduction of NPE concentrations in textiles (by approximately 69%, see section E.2.1.1.1.2 of the Background document as well as Appendix 11) and therefore to a reduction of emissions to the environment since the substances have been shown to be washed out during the usage phase. The proposed restriction is expected to reduce NPE emissions from textiles by 32% compared to the baseline scenario in the year 2021 (see section E.2.1.1.1.2 of the Background document as well as Appendix 11). Since contributions from other uses than textiles are also expected to be reduced (independently from the proposed restriction), along with more efficient waste water treatment, the total reduction in emissions to the water environment in the year 2021 may be around 55 % lower compared to emissions in 2010. Compared to the estimated total emission of NP/NPE to the environment (including all the assessed emission sources) in 2010, the proposed restriction alone would provide for an emission reduction by 21%. Different scenarios have been established by the dossier submitter in order to account for uncertainties regarding the concentration of NPE in textiles (see section B.2.3.1, B.9.3.4.1 and E.2.1 of the Background Document as well as Appendix 11). Back-calculations from monitored NPE concentrations in UK WWTP influents indicate that the dossier submitter's estimations can be considered reliable (see Appendix 12 of the Background document). Since the restriction would reduce emissions of NP/NPE, it would generate positive impacts (namely 'benefits') for the environment. The dossier submitter considers the benefits of the restriction to be substantial (however not quantitatively assessed) based on the fact that the negative impacts in the water environment (in particular on biodiversity and subsequent functions and services provided by water ecosystems) will be reduced (see section E.2.1.1.3 of the Background Document). However, SEAC notes that quantification of these benefits was not possible for the dossier submitter and therefore neither a direct comparison whether

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

benefits outweigh costs. A pure description of expected benefits without direct links to the substances of concern makes it very difficult for SEAC to draw an opinion on the magnitude of benefits and therefore, on the proportionality of the restriction proposal via a cost-benefit approach. Still, the dossier submitter included information on several evaluation studies (see section F.1.2.2 of the Background document) that give indications of the value that people place on improved water quality and biodiversity, based on the use and non-use values and the ecosystem functions and services approach. SEAC emphasizes that restricting NPE will lead to improvements of the quality of water bodies and will therefore contribute to achieving the Environmental Quality Standards. In the economic literature, there are studies available that link the increase in environmental quality standards of water bodies to improvements in human welfare. Therefore, SEAC concludes that there are benefits from the restriction.

Costs: Surfactants are used in the textile production process for certain functions (see Background document for any details, especially sections B and C). Alternatives to NPE are available and based on information provided by the dossier submitter and stakeholders (through different consultation processes carried out) SEAC considers them to be technically and economically feasible. Furthermore, there is no indication that the production process would be significantly altered when moving to alternative substances. It is not expected that EU producers of NPE face any significant costs due to a change in demand (decreasing) for NPE. This is because, according to stakeholder consultation, producers of NPE should be able to easily shift production to other substances such as alcohol ethoxylates or glucose-based substances without major changes in the production equipment. Costs that are further discussed and assessed by the dossier submitter are costs arising through substitution of NPE as detergent and emulsifier in the extra-EU[7] production of imported textiles (in the Background document and hereafter referred to as **substitution costs**), and costs for importers and retailers, e.g. for analytical testing of the NPE content in imported articles which are intended to be placed on the EU market (in the Background document and hereafter referred to as **compliance control costs**).

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

- Furthermore **compliance control costs** may be incurred for actors in the supply chain, e.g. for importers and retailers when testing for the NPE content in the imported textiles. The dossier submitter considers this type of cost very uncertain and dependent on how actors in the supply chain choose to implement any control measures to ensure compliance with the proposed restriction. During stakeholder consultations, it was indicated that importers primarily make use of contractual arrangements with their non-EU suppliers to ensure compliance with EU legislation, and provide information regarding these regulatory requirements to their non-EU

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

suppliers, who in turn test for restricted substances in products. Some costs might be expected to be borne by non-EU suppliers related to these tests. However, neither the dossier submitter nor SEAC has any indication that these costs would be passed on the importers. Moreover, only a few responses were received during consultations on this particular issue which makes an extrapolation to the whole EU difficult. Furthermore, when an EU regulation is in place (e.g. a restriction) the manufacturers outside the EU tend to know about it and comply with such legal requirements. No feedback from industry was received indicating any major concerns due to the restriction proposal, either during public consultation or during separately performed consultations regarding this type of costs. This could additionally be understood as an indication that the costs for EU textile industry could be regarded as an insignificant barrier to the implementability of the restriction. However, there was only limited feedback during consultation processes on this issue and it is not clear whether these findings and conclusions can be extrapolated to the whole EU. There are already existing information requirements for Nonylphenol ethoxylates as these substances have been identified as substances of very high concern and are included in the Candidate List for Annex XIV. However, these pieces of information remain uncertain and compliance control costs thus still may occur. The dossier submitter considered such costs as a worst case scenario for cost impacts and estimated them to be about €43 million per year from the year 2021 to 2031. As a whole, the total estimated costs of substitution and compliance control are estimated to approximately €46 million per year from the year 2021 to 2031 (see sections E.2.1.1.2 and F.2.1 of the Background document).

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

Proportionality:

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

  On one hand, the dossier submitter considers the benefits of the proposed restriction to be substantial, continuing in the long term since it avoids future negative impacts in the aquatic environment (see section F.1.2.2 of the Background Document). On

the other hand, the costs of the proposed restriction are regarded to be small, if only substitution costs are considered. If the potential costs of compliance control are taken into account as well, in particular if more pessimistic assumptions are made in the estimation of such costs (as shown by the sensitivity analysis), the dossier submitter acknowledges that it appears difficult to demonstrate that benefits outweigh costs and thus difficult to conclude about the proportionality of the restriction proposal (see section E.2.1.1.3 of the Background Document).

From this assessment, SEAC's view is that there are no data at hand that would allow a conclusion on the magnitude of benefits. An attempt was made to better define the benefits of the proposed restriction in connecting them to improvements in meeting the Environmental Quality Standards applicable to surface water. However, the monitoring data set is not sufficient for such an assessment and the actual degree of improvement will depend on several factors currently being considered by individual Member States. Nonetheless, NP is a Priority Hazardous Substance under the Water Framework Directive, so the current restriction proposal will contribute to achieving a phase out of NP emissions, released to the environment due to the degradation of NPE. SEAC agrees that costs are relatively small compared to the total import value for clothing in the EU in 2010 (the respective figures are stated above) if only substitution costs are considered. The situation is more difficult to judge if compliance control costs are considered as well, especially if more pessimistic assumptions (e.g. low NPE concentrations in textiles, high test frequencies) are made. SEAC thus concludes that for the current restriction proposal it is not possible to decide on the proportionality of the restriction proposal based on a cost-benefit comparison, although it is acknowledged that benefits indeed will occur.

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

(€7.3 million) for the proposed restriction compared to the least cost-effective measure (metals). In this case, the proposed restriction does not appear cost-effective compared to the previous measure. However, SEAC would like to emphasise that in the evaluation of the previous measure on NP/NPE no quantified costs of compliance control or monitoring are reported. This may induce some bias in the comparison with the cost-effectiveness of the restriction proposed for the 'worst case' situation.

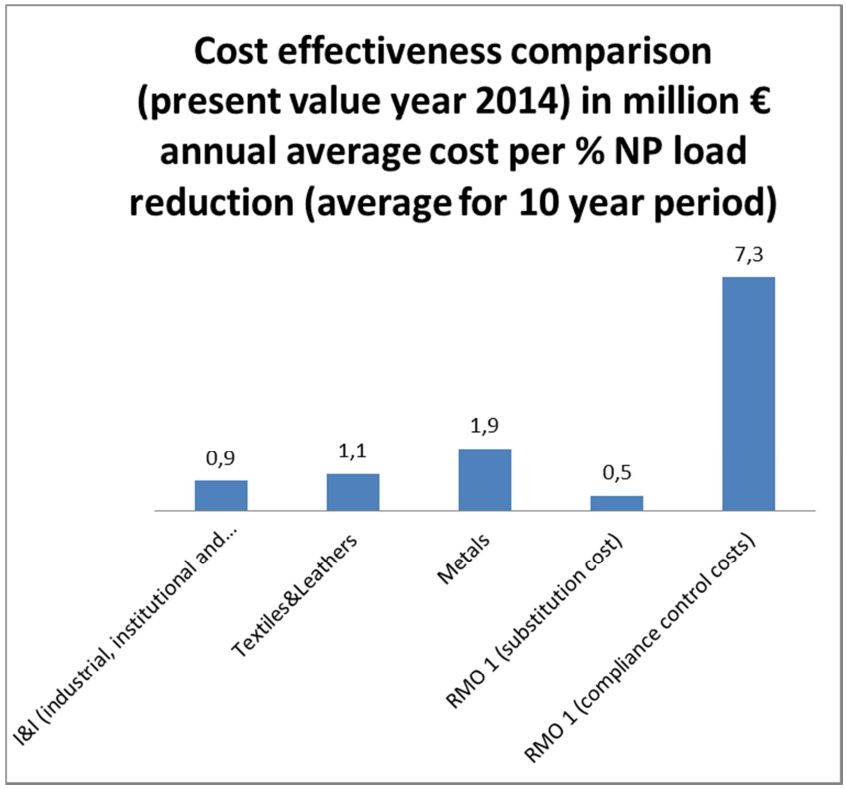

Figure 1 Cost-effectiveness of previous measures to reduce NP/NPE emissions compared to the proposed restriction[8]

The cost-effectiveness comparison has been subject to sensitivity analysis (see section E.2.1.1.3 and Appendix 11 of the Background document), where a number of input parameters were altered in order to identify the most sensitive ones. It appears that the results are mostly sensitive to the following parameters: the NPE concentration in textiles and the inclusion/exclusion of compliance control costs as well as the test frequencies applied. The sensitivity analysis shows that the conclusion on cost-effectiveness as regards substitution costs is robust except where very low NPE concentrations (in textiles) are used as input parameters. If compliance control costs are additionally considered, the analysis indicates that the proposed restriction is relatively cost effective – compared to the existing restriction – only in scenarios where very high NPE concentrations in textiles are used as input parameters. Thus the result of the cost-effectiveness comparison is highly sensitive to the assumptions made about concentrations of NPE in textile articles. Experimentation in sensitivity analysis additionally shows that the test frequencies used in estimation of compliance control

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

costs greatly outweigh other uncertainties in the cost estimates. The result does not change substantially if any of the other input parameters are altered.

SEAC's conclusion on proportionality:

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

Practicality, incl. enforceability

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

transitional period above).

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

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

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

  Comments were received during stakeholder consultation suggesting that the definition of non-washable articles should be based on accepted EU-wide or global definitions to provide a robust framework for business. It has been suggested that the applicability of the restriction should be aligned with voluntary European/international standards like ISO 3758 and DIN EN 23758 which apply to care symbols. This issue is identified as a possible improvement of the clarity of the proposed restriction, however SEAC agrees with the dossier submitter's view that it is inappropriate to link the proposed restriction to a voluntary standard, both because the latter is not mandatory for all actors in the market and also because the standards mentioned above might change – which could in turn change the scope of the restriction. A possible solution to the issue could be to include standards concerning care symbols in the REGULATION (EU) No 1007/2011 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products, since that would harmonize the use of care symbols in textile articles placed on the EU market. According to Article 24 in the abovementioned directive, the Commission is to submit a report to the European Parliament and the Council regarding possible new labelling requirements to be introduced at the Union level. It is explicitly stated in Article 24 p.3 (b) that the report will examine the option of a harmonised care labelling system. Depending on the outcome of the review, the enforceability (and manageability) of the proposed restriction could thus possibly be enhanced further.

- SEAC agrees that the restriction defines to the extent possible what is meant by "textile articles" or "textile parts of articles" (it refers to already existing definitions[9]) as well as other phrases used such as "washed in water".

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

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

derogation on used articles placed on the market.

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

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

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

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

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

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

- The clarity in the formulation of the restriction (in terms of scope and timing) is expected to facilitate communication of the requirement for actors in the textile supply chain
- The limit value set for NPE (0.01% by weight textile) has been balanced against the actors' ability to comply, taking into account the possibility of unintentional NPE contamination of textiles due to e.g. traces of NPE in chemical formulations
- Furthermore, NPE is included in the Candidate list and there are already specific restrictions at the EU level for azocolourants (REACH Regulation 1907/2006/EC) and pentachlorophenol (PCP) (Directive 94/783/EC) in textiles, procedures in the supply chain should already exist for providing and requesting information on compliance to chemical legislation. Therefore, there should be no significant additional effort of training, capacity building, development of systems for compliance control, etc. because of the proposed restriction

- The types of textile clothing, fabric accessories and interior textiles that are of concern have been specified to the extent possible (see also section on Enforceability above as well as section A.1.2 of the Background document), and the whole group of NPE substances are covered, the communication of the restriction should be manageable.

Monitorability

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

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

- Monitoring of the concentrations and/or amounts of NPE in effluent water from WWTP within the European Union: the dossier submitter indicates that there is currently a reporting requirement for NP/NPE for large industrial facilities (including WWTP) in the EU according to the Regulation EC 166/2006, whereby information on releases of NP/NPE to the environment is updated on an annual basis presented in the European pollutant release and transfer register (E-PRTR) which is made publicly available by the European Environment Agency. However the information does only provide a rough estimation on total releases of NP/NPE and the releases of NP and NPE are reported separately which makes it a less useful tool for monitoring the effect of the proposed restriction. Additionally, there have been several monitoring programs for NP in municipal WWTP, but there is no full EU coverage expected in this respect.

- Monitoring of the environmental concentrations of NP within the EU: the dossier submitter reminds that the WFD requires the Member States to monitor the progressive reduction in the concentrations of priority substances (PS) and the phasing out of priority hazardous substances (PHS) (European Commission 2009), such as NP concentrations in the water environment. Even though SEAC does not have sufficient evidence to support a restriction on NP, a restriction on NPE only will also contribute to a reduction of NP concentrations in the environment due to the degradation of NPE to NP. However, no detailed assessment has been made of any on-going or planned monitoring activities within the WFD concerning NP, i.e. it is not clear to what extent Member States will actually carry out monitoring of NP.

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

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 the same as described in the RAC opinion.

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