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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For phenol, 4-nonyl-, branched, CAS No 84852-15-3 (EC No 284-325-5)

Addressees: Registrant(s)[1] of phenol, 4-nonyl-, branched, (Registrant(s))

This decision is addressed to the Registrant(s) of the above substance with active registration pursuant to Article 6 of the REACH Regulation on the date on which the draft for the decision was first sent for comments. If Registrant(s) ceased manufacture upon receipt of the draft decision pursuant to Article 50(3) of the REACH Regulation, they did not become addressee(s) of the decision. A list of all the relevant registration numbers of the Registrant(s) that are addressees of the present decision is provided as an Annex to this decision.

Based on an evaluation by the Health & Safety Executive as the Competent Authority of the United Kingdom (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision is based on the registration dossier(s) on 6 October 2015, i.e. the day until which the evaluating MSCA granted an extension for submitting dossier updates which it would take into consideration.

This decision does not imply that the information provided by the Registrant(s) in the registration(s) is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossier(s) of the Registrant(s) at a later stage, nor does it prevent a subsequent decision under the current substance evaluation or a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of the United Kingdom has initiated substance evaluation for phenol, 4-nonyl-, branched (trade name Nonylphenol) CAS No 84852-15-3 (EC No 284-325-5) based on registration(s) submitted by the Registrant(s) and other relevant and available information and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to Environment/Suspected PBT; Exposure/Wide dispersive use, consumer use, aggregated tonnage, phenol, 4-nonyl-, branched was included in the Community rolling action plan (CoRAP) for substance evaluation to be evaluated in 2014.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

The updated CoRAP was published on the ECHA website on 26 March 2014. The Competent Authority of the United Kingdom was appointed to carry out the evaluation.

In the course of the evaluation, the evaluating MSCA identified additional concerns as follows; For the environment - the level of protection against endocrine effects provided by the aquatic PNEC, the interpretation of environmental half-life data, aquatic risks from degradation of nonylphenol ethoxylate (NPEO), and apparent deficiencies in the data sets available for assessing wastewater treatment plant (WWTP) partitioning, bioaccumulation, sediment organism toxicity, soil organism toxicity and secondary poisoning. For human health - the DNEL derivation and exposure modelling.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 25 March 2015

On 7 May 2015 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

Registrant commenting phase

By 15 June 2015 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay. By 6 October 2015 Registrant(s) submitted update(s) of the registration dossier(s).

The evaluating MSCA considered the comments received from the Registrant(s) and the dossier update(s).

On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

Commenting by other MSCAs and ECHA

In accordance with Article 52(1) of the REACH Regulation, on 29 October 2015 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 4 December 2015 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and amended the draft decision.

Referral to Member State Committee

On 14 December 2015 ECHA referred the draft decision to the Member State Committee.

By 4 January 2016, the Registrant(s) provided comments on the proposals for amendment, in accordance to Article 51(5) and on the draft decision. The Member State Committee took the comments on the proposal(s) for amendment of the Registrant into account.

After discussion in the Member State Committee meeting on 2 – 4 February 2016, it was considered that no further information was required to clarify the concerns related to the interpretation of environmental half-life data, aquatic risks from degradation of nonylphenol ethoxylate (NPEO), and soil organism toxicity.

A unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 4 February 2016. ECHA took the decision pursuant to Article 52(2) and Article 51(6) of the REACH Regulation.

II. Information required

A. Information for PBT assessment

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision:

1. Analytical information to confirm the concentration of dinonylphenol (any isomer) present in the registered substance (typical and range), down to a level of 0.1% (w/w), as far as reasonably practicable.

B. Information for environmental exposure assessment

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information regarding the registered substance subject to the present decision:

2. Information on the annual tonnage of the registered substance manufactured and placed on the market by each Registrant for each of the Exposure Scenarios (ES) in the Chemical Safety Report (CSR), and also the annual supply tonnage of individual polymers (e.g. resins, nonylphenol ethoxylates (NPEOs)[2], etc.) (which can be grouped if justified) that are placed on the EU market by the Registrant(s) and their downstream users, broken down by use (estimated if necessary). This information can be provided separately by each Registrant or downstream user if it is commercially sensitive. If the Registrant(s) are unable to gather suitably representative data for any part of the life cycle, they shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification).

3. Information on the typical concentration of the registered substance as an unreacted impurity in polymers and the potential for its formation from the polymers during environmental degradation. This information can be provided separately by each Registrant or downstream user if it is commercially sensitive. Following an assessment of relevance, Exposure Scenarios (ES) shall be produced for significant sources. If the Registrant(s) are unable to gather suitably representative data for any part of the life cycle, they shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification).

4. Justification as to why Exposure Scenarios involving NPEO do not take account of the further degradation of NPEO released in Waste Water Treatment Plant (WWTP) effluent to the registered substance.

[2] 4-Nonylphenol, branched, ethoxylated [covering UVCB- and well-defined substances, polymers and homologues, which include any individual isomers and/or combinations thereof]

5. Justification as to why registration dossiers do not include ES15 (Service life of paints containing NPEO) as a relevant use when they include ES9 (Formulation of paints containing NPEO).

6. An update of all Exposure Scenarios (ES) to include the waste phase or justification as to why it is not relevant. This should include all lifecycle steps, including production/formulation/ processing and disposal of products containing the registered substance (or polymers) at the end of their service life.

C. Information for environmental fate

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions (in accordance with Article 13(3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

7. Surface tension of the registered substance (test method: EU A.5/OECD TG 115).

8. The observed variation in actual sewage treatment efficiency (including K_{OC}) to be included in the Chemical Safety Assessment (CSA) as part of a sensitivity analysis, in such a way that the conditions of safe use are clearly described in terms of the assumed level of wastewater treatment plant (WWTP) removal efficiency (affecting both releases to water and to land).

9. Update the robust study summaries (RSS) of all published fish bioconcentration factor (BCF), biota-sediment accumulation factor (BSAF), biomagnification factor (BMF) and trophic magnification factor (TMF) studies for the registered substance, including lipid normalisation where the data are available, and addressing invertebrates (not just fish). In particular, the RSS of the Ekelund *et al.* (1990) study[3] shall be updated to include mussels, and an RSS for the following study shall be provided:

   - Diehl J., Johnson S. E., Xia K., West A. and Tomanek L. (2012). The distribution of 4-nonylphenol in marine organisms of North American Pacific Coast estuaries. Chemosphere, 87(5), 490-497.

   A weight of evidence analysis shall be performed to compare the corrected data for all relevant bioaccumulation measures (fish and invertebrate) with the Annex XIII criteria and associated guidance.

D. Information for environmental PNECs

Unless the Registrant(s) conclude that the registered substance meets the PBT criteria, requests concerning the environmental PNECs (10-15) are required.

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions (in accordance with Article 13 (3) and (4) of the REACH Regulation) and the registered substance subject to the present decision:

10. Derivation of a long-term NOEC/EC_{10} for the registered substance with Rainbow Trout *Oncorhynchus mykiss*, taking account of transgenerational effects as described

[3] Ekelund R, Bergman Å, Granmo Å and Berggren M (1990). Bioaccumulation of 4-nonylphenol in marine animals - A re-evaluation. Environ. Pollut., 64, 107-120.

by Schwaiger *et al*. (2002)[4] and the Risk Assessment Committee opinion (ECHA, 2014c [5]).

11. An estimated chronic NOEC for Winter Flounder *Pleuronectes americanus* based on the reported 96-h LC_{50} of 17 µg/L from Lussier *et al*. (2000[6]) and the worst case acute:chronic ratio from other fish species in the aquatic toxicity data set.

12. Long-term toxicity testing of the registered substance on aquatic molluscs:

    a. A reproduction study with the freshwater gastropod *Potamopyrgus antipodarum* in accordance with the OECD mollusc reproduction test guideline approved in April 2016 (the latest protocol of the draft guideline can be found at this link: http://www.oecd.org/env/ehs/testing/Potamopyrgus%20for%202nd%20WNT%20comments_clean.pdf[7])
    b. A life cycle study with the marine bivalve *Crassostrea gigas* in accordance with the method of Nice *et al*. (2003)[8]. An oyster embryo-larval toxicity test[9] may be performed to help with range finding, in accordance with an appropriate standard method (e.g. ICES TIMES No 54[10] or US EPA OPTTS 850.1055[11]).

13. Long-term toxicity testing of the registered substance on echinoderms. In the absence of an EU standard method, the study shall be conducted in accordance with a suitable national standard method (e.g. Environment Canada Biological test method EPS 1/RM/27[12]). The Registrant(s) shall justify the choice of test species based on an assessment of the most sensitive species from studies reported in the scientific literature.

For tests 12 and 13, a study must be performed if a reliable chronic NOEC/EC_{10} for reproduction and growth for these species cannot be derived from published studies in the literature, as specified in section III.

14. Revision of the $PNEC_{water}$ for both fresh and marine surface waters (combined if relevant) once the Registrant(s) have provided the information for requests 10-13. This shall include specifying the end point and species choice (in terms of taxonomic coverage), a description of relevant summary statistics for the species sensitivity distribution (if derived) to justify the choice of model in accordance with ECHA

[4] Schwaiger J, Mallow U, Ferling H, Knoerr S, Braunbeck T, Kalbfus W and Negele RD (2002). How estrogenic is nonylphenol? A transgenerational study using rainbow trout (*Oncorhynchus mykiss*) as a test organism. *Aquatic Toxicology*, 59 (3-4), 177-189.

[5] http://echa.europa.eu/documents/10162/3cd10d95-60c0-4b38-9c68-9922d3a8ff47

[6] Lussier, S.M., Champlin, D., LiVolsi, J., Poucher, S. and Pruell, R.J. (2000). Acute toxicity of para-nonylphenol to saltwater animals. Environmental Toxicology and Chemistry, 19 (3), 617-621.

[7] The guideline has been approved by the OECD in April 2016 and the adopted guideline will be published on the OECD website: http://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm

[8] Nice, H.E., Morritt, D., Crane, M. and Thorndyke, M. (2003). Long-term and transgenerational effects of nonylphenol exposure at a key stage in the development of *Crassostrea gigas*. Possible endocrine disruption? Mar. Ecol. Progr. Ser., 256, 293-300.

[9] Although the exposure time in the embryo-larval method is short (up to 48 hours), it encompasses a period of intense cellular activity during which the impairment of a number of critical physiological and biochemical processes may result in poor growth and development. The response measured is, therefore, similar to that used in other early life stage tests which record growth and development (such as fertilization assays for echinoderms), and it has the advantage that exogenous feeding is not required, thus eliminating this source of variation in the test results. Such tests have been performed as long-term toxicity studies for other substances subject to EU regulation (e.g. nickel: EC (2008). European Union Risk Assessment Report: Nickel and Nickel Compounds. European Chemicals Bureau, Institute for Health Protection and Consumer Protection. European Commission. Final Version 30 May 2008).

[10] http://www.ices.dk/sites/pub/Publication%20Reports/Techniques%20in%20Marine%20Environmental%20Sciences%20(TIMES)/times54/TIMES%2054%20web.pdf

[11] http://www.epa.gov/ocspp/pubs/frs/publications/OPPTS_Harmonized/850_Ecological_Effects_Test_Guidelines/Drafts/850-1055.pdf

[12] http://www.ec.gc.ca/Publications/047B08AB-530E-49EA-8EC8-8AB8E8D75DA4%5C1_BiologicalTestMethodFertilizationAsayUsingEchinoidsSeaUrchinsSandDollars2ndEdition.pdf

Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.10, May 2008), and choice of assessment factor to apply to the HC5, together with a discussion about the suitability of the approach for any apparently sensitive trophic groups or species.

15. Assessment of all available information to address avian toxicity of the registered substance using the Integrated Testing Strategy (ITS) provided in section 7.10.19 in ECHA Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7c, version 2, November 2014) and observations whether avian testing is needed to address any remaining risks.

E. Additional concerns relating to human health

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall also submit the following information regarding the registered substance subject to the present decision:

16. A justification for the choice of oral bioavailability value used in the DNEL derivation.

17. Further information on exposure, specifically:

a) A description of all the input parameters used to model exposure. Where additional modifiers, such as maximum exposure concentration according to Dalton's law, gloves, level of dustiness, have been used these should be fully explained and their use justified.

b) Where a need for gloves to be worn has been identified, information should be given on the types of glove materials that are suitable, the required thickness and breakthrough times

c) A qualitative assessment to clarify whether additional risk management measures (RMMs) are required to protect against corrosivity.

d) Inhalation exposure estimates for scenarios involving spray application using a suitable modelling tool.

e) Recalculate potential consumer exposure from the use of coatings, paints, thinners and paint removers in accordance with the ECHA Guidance on Consumer Exposure Estimation Chapter R.15, Version 2.1, October 2012[13]).

Deadline for submitting the required information

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **6 November 2017** an update of the registration(s) containing the information required by this decision[14], including robust study summaries and, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

The Regulatory framework and the identified concerns

13 http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf

14 The deadline set by the decision already takes into account the time that Registrant(s) may require to agree on who is to perform any required tests and the time that ECHA would require to designate a Registrant(s) to carry out the test(s) in the absence of the aforementioned agreement by the Registrant(s) (Article 53(1) of the REACH Regulation).

Phenol, 4-nonyl-, branched (nonylphenol, NP) is on the REACH Candidate List because of its environmental endocrine disrupting properties and is already subject to specific restrictions on its marketing and use under REACH Annex XVII. Further risk management measures under REACH are likely to come into force in the near future. A restriction of the related substance nonylphenol ethoxylates (NPEOs) in textiles will come into effect on 3 February 2021[15]; NPEO is a source of nonylphenol (NP) in the environment. In addition, the Member State Committee is considering whether to prioritise NPEOs for addition to Annex XIV for authorisation. The registered substance is also on the Annex X list of priority substances (Decision 2455/2001/EC) under the Water Framework Directive 2000/60/EC (WFD). Monitoring data (particularly from the UK) indicate that the registered substance continues to be widely emitted from industrial and domestic sources to waste water treatment plants (WWTPs) and consequently to rivers in the UK and other EU Member States. Some water bodies in the UK are at risk of non-compliance with the Environmental Quality Standard (EQS) for the registered substance. In addition, the WFD requires the cessation or phasing-out of discharges, emissions and losses of priority hazardous substances by 2026. This means that there is political agreement that NP is a high priority for ongoing aquatic emission reduction at EU level. However, aside from setting an EQS, the WFD legislation itself does not prescribe the means to achieve cessation of emissions. Member States are responsible for putting measures in place to achieve cessation of emissions. Member States may therefore fail to meet the WFD objectives if further risk management measures are not put in place.

In a REACH context, further risk management depends on:

a) the magnitude of current and future exposure, and
b) the threshold of concern.

The registered substance is mainly used as a chemical intermediate at high tonnage to make many other types of substances (in which it can be present as an impurity, or re-formed through environmental transformation processes). The fact that there are multiple sources (not all of which have been quantified) means that it is very difficult to be sure of the effectiveness of current plans for emission reduction. In addition, whilst authorisation should limit non-essential uses of NPEOs in due course, it may not reduce exposure at all if adequate control is demonstrated by individual applicants.

Another issue is that according to the previous assessment under the Existing Substances Regulation (ESR), the registered substance contains 2,4-dinonylphenol (EC no. 284-323-4) as an impurity. That substance screens as vPvB (PBT list no. 103), and it is likely that all dinonylphenol isomers will have similar properties.

These considerations formed the initial concerns. Additional concerns were identified during the Substance Evaluation about the level of protection against endocrine effects provided by the aquatic PNEC (as flagged by ECHA's Committee for Risk Assessment (RAC) opinion on the proposed textile restriction; ECHA, 2014c[16]), apparent deficiencies in the data sets available for assessing WWTP partitioning, bioaccumulation, sediment organism toxicity, and secondary poisoning.

Some of the data requests outlined in this decision relate to testing that could result in the establishment of a $PNEC_{water}$ significantly lower than that currently used by the Registrant(s) and regulatory authorities (and hence the overall level of aquatic risk will increase). The

[15] http://echa.europa.eu/documents/10162/7dcd73a4-e80d-47c5-ba0a-a5f4361bf4b1
[16] http://echa.europa.eu/documents/10162/3cd10d95-60c0-4b38-9c68-9922d3a8ff47

RAC opinion pointed out that risks *could still remain* following the implementation of the textile restriction as the assessment was based on "minimum risks" (ECHA, 2014c[16]). Improving confidence in the $PNEC_{water}$ is therefore important to facilitate regulatory authorities' decisions about the need for further restriction proposals for the registered substance based on threshold-based risks. In addition, ECHA notes that the reliability of the $PNEC_{water}$ for the registered substance is directly relevant to the authorisation process for NPEO, since the reason for inclusion of NPEO on Annex XIV was transformation to the registered substance NP. Furthermore, ECHA noted some shortcomings in the derivation of the $PNEC_{oral}$ for secondary poisoning.

If PBT concerns were confirmed for the dinonylphenol impurity (or the substance itself), there would be scope for further emission minimisation based on non-threshold risks (in line with Commission objectives under the WFD as well as the 2020 SVHC Roadmap).

In either case, there would be a need to prioritize additional uses of the registered substance for risk management. Given the uncertainty in the effectiveness of existing risk management plans in reducing emissions, ECHA considers it important to gather additional information on use pattern (i.e. life cycle, sources and use volumes) and emissions (particularly for consumer/professional uses) to ensure that further risk management measures (if needed) can be appropriately targeted by both Registrant(s) (in their own supply chain) and regulatory authorities (e.g. a restriction might be warranted if a risk is identified from multiple sources). Whilst worst case assumptions about releases and tonnages could be made by regulatory authorities, it is likely that there would still be a need to refine the information before deciding on the most appropriate risk management measure(s). Substance Evaluation is the primary tool available to regulatory authorities to gather this type of information, especially as information flow in supply chains is a key feature of REACH. It is important to use the best available information from the Chemical Safety Reports (CSRs) to form the baseline for emission estimates wherever possible.

Overall, ECHA's concern is that the available data in the registration dossiers are insufficient to be confident that the environmental risks from the registered substance are adequately managed. This is despite there already being some regulatory measures in place. Therefore further information is needed.

Justification for the information requested

A. Information for PBT assessment

1. Analytical information to confirm the concentration of dinonylphenol

Monitoring data show that the registered substance is a ubiquitous and widespread pollutant in WWTP influent and effluent in the UK and other EU Member States (e.g. ECHA, 2014c[16]). Dinonylphenol was an impurity of NP identified previously under the ESR (EC, 2002[17]) and is mentioned in some (but not all) registration dossiers. 2,4-Dinonylphenol (EC number 284-323-4) was identified as having potential vPvB properties (PBT list no. 103) by the PBT Working Group of the Technical Committee for New and Existing Substances because it was not considered to be readily biodegradable and has a predicted log K_{OW} value above 5. No measured data were available. It is likely that all dinonylphenol isomers will have similar vPvB properties.

However, the registration(s) do not consider any impurities in the PBT assessment.

[17] EC (2002). European Union Risk Assessment Report: 4-Nonylphenol (branched) and nonylphenol. European Chemicals Bureau, Institute for Health Protection and Consumer Protection. European Commission.

In light of the above mentioned concern relating to the possible presence in the registered substance of an impurity with vPvB properties at levels relevant for the PBT assessment, analytical information on the concentration of such dinonylphenol impurities contained in the registered substance is requested.

In their comments to the draft decision, the Registrant(s) stated that whilst dinonylphenol is often present in the commercial product below 0.1%, levels could be as high as 1% but did not provide any analytical evidence. In addition, the Registrant(s) stated that as the levels are very low, a PBT assessment is not warranted.

ECHA notes that it is established practice to consider PBT properties for any constituents, impurities and additives that are present in a registered substance above 0.1% w/w (Section R.11.4.1 of the ECHA Guidance on PBT/vPvB assessment (Chapter R.11, version 2, November 2014)).

The information requirement relating to dinonylphenol was amended following the response to the Registrant(s)' comments to make it clear that analytical information is required, along with both the typical concentration of dinonylphenol and the range.

Overall, based on current information, ECHA considers that the registered substance may contain an impurity above 0.1% w/w that screens as vPvB.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- Analytical information to confirm the concentration of dinonylphenol (any isomer) present in the registered substance (typical and range), down to a level of 0.1% (w/w), as far as reasonably practicable.

Note(s) for consideration by the Registrant(s)
The Registrant(s) are reminded of their obligation to perform a PBT assessment for all relevant impurities present in the registered substance at or above 0.1% w/w.

Although not the primary focus of the evaluation, comments made in a proposal for amendment to the draft decision during MSCA consultation have highlighted a possibility that the registered substance itself could potentially be identified meeting the Annex XIII PBT criteria on the basis of invertebrate data. Request 9 specifically addresses bioaccumulation in this context.

B. Information for Environmental exposure assessment

General introduction:
UK monitoring data[18] suggest that a significant proportion of the total load of the registered substance into WWTP is from domestic sources, but the registration data do not highlight any particular source(s) that could explain this. This could be due to: an under-estimate of releases from registered uses; additional unregistered uses that are not taken into account (e.g. polymers such as ether sulphates and phosphates, or because of assumed low tonnage - for example, lubricant additive packages are a use that appears relevant but does not appear in the CSRs); and/or an assumed level of removal by WWTP that is not a realistic worst case (as also suggested by monitoring data[18]). Overall, based on current information, ECHA considers that the exposure assessment may under-estimate environmental

[18] Comments and response to comments on Annex XV restriction report on Nonylphenol, branched and linear; Nonylphenol, branched and linear, ethoxylated UK CA comment, #313). http://echa.europa.eu/documents/10162/13641/rcom_NP_072014_en.rtf

emissions and concentrations arising from the whole life cycle of nonylphenol.

Future risk management, if necessary, will require information on the most relevant sources of exposure, which might be from high volume emissive uses of derivatives rather than direct uses of the substance itself. The registered substance is used as a chemical intermediate, and if the reactions are not 100% efficient, there will be an amount of residual unreacted substance present in such derivatives as an impurity. In addition, some of these derivatives may degrade in the environment to reform the registered substance (as is well known for NPEOs; indeed, this aspect of the life cycle formed the basis of the existing REACH restriction, SVHC identification for NPEO (ECHA, 2013[19]) and the restriction proposal for NPEO in textiles (ECHA, 2014a[20]). It may be relevant for other derivatives to be treated in a similar way.

In any case, the data on environmental exposure assessment in the present decision are required to inform risk management decisions by regulatory authorities, which could be implemented on the registered substance to prevent downstream emissions from substances manufactured from it. The data are also important for the individual Registrant's environmental exposure assessments as in a number of scenarios risk characterisation ratio (RCR) values are close to one, and even small changes in the predicted environmental concentration (PEC) or predicted no-effect concentration (PNEC) could cause the RCRs to exceed one, and consequently require the Registrant(s) to implement additional RMMs if they are not otherwise able to refine their assessment.

General comments of the Registrant(s) and proposals for amendments

In the initial draft decision information was requested in relation to the derivatives of the registered substance. In response to the original draft decision, the Registrant(s) questioned the proportionality of the requests, specifically highlighting their responsibility for providing information relating to the substance that they place on the market, and limitations in terms of delivering the requested information on polymers and other derivatives (especially as, according to the Registrant(s) these are not within the scope of the REACH registration). The Registrant(s) claimed that any information on the polymers in the current registration(s) was included voluntarily to reflect the conclusions of the previous EU risk assessment under the ESR, and could be removed without affecting the legal compliance of the registration. Whilst the Registrant(s) indicated that they are willing to gather available information using reasonable efforts via downstream user associations, they ask for the limitations in terms of delivering the requested information to be recognised in the information request.

ECHA supports the responsible approach of the Registrant(s) to include information on certain polymer uses from the previous EU risk assessment in the CSR(s), which is consistent with the REACH philosophy of addressing risks over the full life cycle of the substance.
ECHA further reminds the Registrant(s) that there is a high degree of concern associated with this substance (i.e. WFD Priority Hazardous Substance and Substance of Very High Concern under REACH). In terms of ensuring adequate (and proportionate) risk management, there is insufficient information in the CSR(s) to adequately assess the relative contribution of the various sources to the actual risks faced by the European environment.

[19] http://echa.europa.eu/documents/10162/13638/annex_xv_svhc_4nonylphenol_en.pdf

[20] http://echa.europa.eu/documents/10162/13641/final_background_doc_nonylphenol.pdf

In a proposal for amendment to the draft decision, ECHA recognized that the Registrant(s) have no formal responsibilities under REACH to consider risks arising from derivatives that are not polymers. In this respect, the present decision has been amended to remove all requests in relation to derivative substances that are not polymers.

In the same proposal for amendment ECHA however highlighted that information can be requested with respect to polymers formed by the registered monomer. Indeed, in ECHA's view, the Registrant(s) are responsible to cover in their Chemical Safety Report the whole life cycle of the monomer NP, and this includes the stage(s) of the polymer regarding exposure to the residual unreacted monomer and possible exposure to the monomer form following the possible degradation of the polymers. This view is supported by the European Court of Justice in its judgement in Case C-558/07 where it acknowledged that "*the obligation to register monomer substances, which are less numerous than polymers, makes information available not only on the risks specific to those substances but also on those monomers found as residues after polymerisation or in monomer form after the possible degradation of the polymer*" (paragraph 51).

Therefore, ECHA can request the Registrant(s) to provide information relevant to assess the risks arising from residual unreacted NP in polymers, or NP arising as a degradation product of polymers.

In response to ECHA's proposals for amendment the Registrant(s) disagreed with ECHA's interpretation of the European Court of Justice Judgement (hereafter referred to as the ECJ). The Registrant(s) considered that the judgement is specific to the dispute to which the case concerns (relating to challenges associated with registering polymers rather than the explicit objectives for registering monomers).

ECHA notes that the ECJ's judgment was about the scope and validity of the requirement under Article 6(3) REACH to register monomer substances of importers and manufacturers of polymers that have not been already registered up the supply chain. ECHA further notes that Article 6(2) REACH requires that a full registration is submitted for monomers that are used as isolated intermediates.

The reason for the registration requirements of monomers under Articles 6(2) and 6(3) is to fill the gap resulting from the exemption pursuant to Article 2(9) REACH for polymers to be registered. As the ECJ indicated this ensures that the main purpose of the REACH Regulation, which is to ensure a high level of protection of human health and the environment, is respected (see paragraphs 45 and 46).
As indicated in paragraph 51 of the ECJ's judgment, quoted above, the registration of monomer substances will provide more information on the polymer substances they are used to form. Furthermore, contrary to the Registrant(s)' view expressed in their comments, paragraphs 52 to 54 of the ECJ Judgment in fact justify why Registrant(s) of monomers need to provide further information on the polymers they are used to form. More specifically paragraph 52 of the judgment provides that "*where polymers are manufactured in the Community the advantages of registration of monomers is obvious, since monomer substances are used as unreacted monomers within the Community, with the result that it is necessary that the registration information be known there in order to address potential risks*". In a similar vein paragraph 53 explains that the benefit of registering monomers that are contained in imported polymers enables to obtain better knowledge of polymers. Finally, paragraph 54 mentions that the obligation to register monomers satisfies the precautionary principle as referred to in Article 1(3) of the REACH Regulation.

It is therefore apparent from the ECJ's judgment that the obligation under REACH to make a

full registration for monomers should enable ECHA to obtain more information on the risks associated with the polymers. This objective cannot be fulfilled were ECHA is precluded from requesting Registrant(s) of monomers to provide information in relation to the polymers which were manufactured by these monomers.

Therefore, ECHA maintains the requests of information related to polymers as indicated in the specific requests 2-6 in the current Decision, section B "Information for environmental exposure assessment".

Additionally, the Registrant(s) claimed in their comments that there are difficulties to gather the required information from the downstream users as there are often several levels in "the value chain". Since the industry was able to provide such data for the previous EU risk assessment under the ESR, ECHA does not consider that there are major obstacles to prevent Registrant(s) from describing conditions under which they believe that emissions of NP can be adequately controlled. ECHA considers that the Registrant(s) and their supply chain are best placed to provide suitable data and make reasonable assumptions about the relative contribution of these multiple sources to the risk. The ECHA Guidance on environmental exposure assessment (Chapter R.16, version 3, February 2016) suggests various ways in which this information can be shared (e.g. by downstream user sectors, the Registrant's own customers and from an analysis of the markets), and indicates that if it is not possible to gather the required information, the assessment should be based on conservative assumptions. ECHA has amended the draft decision to clearly express that alternative.

The Registrant(s) also claimed that another difficulty is that information regarding product supply is considered confidential business information. ECHA acknowledges that some information might be confidential. Therefore, ECHA has amended the draft decision to indicate that the information can be provided separately by the Registrants if it is confidential.

Specific requests and justifications:

2. Information on the annual tonnage for each Exposure Scenarios (ES)

Information on the amounts of the registered substance actually manufactured and placed on the EU market by the individual Registrant(s) is necessary for a thorough assessment of releases from the whole life cycle of the substance (as well as further information about its typical concentration in derivatives (polymers) as an impurity, and formation from them through degradation processes). The large number of registrations makes it necessary to ensure that the relevant information on tonnages is sufficiently accurate, since a risk assessment by regulatory authorities requires the summation of the separate tonnages for each ES. The evaluation of risks based only on tonnages supplied by an individual Registrant will therefore underestimate the actual risks to the European environment from this substance.

At present it is unclear what the aggregate tonnage is for each ES. This is important for understanding which uses of NP, including polymer uses, are the most significant, and whether the aggregate tonnage results in an environmental risk when the Predicted Environmental Concentration (PEC) for that ES is compared to the PNEC. Together with other information requested in the Decision, this will help identify which, if any, uses require further risk management. It also ensures that any RMM decisions are based on accurate supply data.

In response to the original draft decision, the Registrant(s) indicated that they are willing to

gather available information using reasonable efforts, but they asked for the limitations in terms of delivering the requested information to be recognised in the information request. The request in the draft decision has been modified accordingly, as explained in the part "General comments of the Registrant(s) and proposals for amendments" above.

3. Information on the typical concentration of the registered substance as an unreacted impurity in polymers and the potential for its formation from the polymers during environmental degradation.

Polymers are widely recognised to be potentially significant sources of NP in the environment (as indicated by the Candidate Listing and restriction of NPEOs). Information on the amounts of the registered substance as an unreacted impurity in polymers and its potential formation during environmental degradation of the polymer is necessary for a thorough assessment of releases from the whole life cycle of the substance. Since polymers can contain NP as an impurity, and be degraded to NP in the environment, risks should be assessed as part of the formulation and use life-cycle stages.

Release of the registered substance from polymer products has not been considered in the CSRs as the Registrant(s) claim that "it is not expected". Further justification should be provided to substantiate this claim (e.g. the amount of residual registered substance in the polymers, the use of the polymers, and overall tonnage and potential for release). In addition, the Registrant(s) shall assess the relevance of impurities/degradation for each main polymer group, and produce an exposure assessment for any that is likely to be a significant source. It is recognised that the Registrant(s) may not be in possession of all relevant information, especially if they do not make the polymers themselves, and that some data may be confidential. However, it should be possible to provide estimates based on market data from trade associations (as was done under the ESR, for example).

It is important to quantify the likely NP emissions for the individual polymer uses, as these may be different for each polymer type. Together with the aggregate tonnage for each ES (request 2 of the present decision), it will be possible to understand which polymer uses give rise to the most significant releases of NP, based on quantification of that release. These data can be aggregated across the registrations by the regulatory authority to determine whether there is an environmental risk when the PEC is compared to the PNEC for each relevant ES. Together with other information requested in the Decision, this will help identify which, if any, uses require further risk management.

In response to the original draft decision, the Registrant(s) indicated that they are willing to gather available information using reasonable efforts, but they asked for the limitations in terms of delivering the requested information to be recognised in the information request. The request in the draft decision has been modified accordingly, as explained in the part "General comments of the Registrant(s) and proposals for amendments" above.

4. Justification as to why Exposure Scenarios involving NPEO do not take account of the further degradation of NPEO released in WWTP effluent to the registered substance.

The CSR(s) take some account of the potential degradation of NPEO emitted to WWTP, but do not explain why this is the only relevant polymer in this respect, nor address further formation of the registered substance following release of partially degraded NPEOs in WWTP effluent. For example, EC (2002)[17] states that 25% of the NPEO in WWTP influent can be released as NP1EO/NP2EO/NPnEC in the effluent, and these substances should also

be assumed to degrade to the registered substance at a level of 2.5% (i.e. the total release of the registered substance will be 3.125% of the NPEO influent concentration). The Registrant(s) therefore appear to have overlooked this additional source and needs to provide a scientifically robust justification for this.

In response to the draft decision, the Registrant(s) claimed that the assumed conversion rate of NPEO to NP released in effluent from WWTPs was consistent with the ESR assessment and has been accepted by the RAC (ECHA, 2014c). They therefore asked for the deletion of the request to justify why ESs involving NPEO do not take account of its further degradation following release from a WWTP.

ECHA disagrees that the assumption applied by the Registrant(s) is consistent with the previous ESR assessment, since an additional conversion factor *was* used to take account of further degradation of released long chain NPEOs from WWTP. The Registrant(s) are simply being asked to align their CSRs with what was done previously, or explain why this is not necessary (data to be used are available in the public domain). Reference to the RAC Opinion on the restrictions on NP and NPEOs (ECHA (2014c) is not relevant in this context, since that opinion only needed to identify whether a) there was a risk, and b) the proposed risk reduction measure was appropriate. Accounting for further degradation in this scenario would have indicated an even higher risk.

The request in the draft decision has therefore not been modified.

5. Justification as to why registration dossiers do not include ES15 (Service life of paints containing NPEO) as a relevant use when they include ES9 (Formulation of paints containing NPEO).

In terms of NPEO use, fourteen Registrants have provided an ES for the formulation of paint (ES9), but only one has considered the service life of the paint (ES15). Since NPEO can be released by washing painting equipment, etc., this is a relevant scenario for all Registrant(s) that have paint formulation as a scenario, and they therefore need to justify why it is omitted.

In the comments to the draft decision, the Registrant(s) stated that their CSR is consistent with the ESR risk assessment report, and that the release of NP over the service life of paints containing NPEO was considered "*de minimus*" compared to other stages of the life cycle. They therefore asked for the deletion of the request.

ECHA notes that the ESR assessment had to prioritise the assessment of releases of NPEOs because the supply tonnage was high and use pattern diverse. Following the partial restriction introduced following the ESR assessment, and carried across to REACH Annex XVII (e.g. for use in domestic cleaning products, and plant protection products, etc.), it is possible that releases from coatings could be relatively more important now. Some Registrants do include the service life of paints in their CSR, and both SpERCs and OECD emission scenarios exist for this life cycle stage. In accordance with Annex I (section 5.0) of the REACH Regulation, the exposure assessment which contains the generation of exposure scenarios shall consider all stages of the life cycle of the substance resulting from manufacture and identified uses. Furthermore, the ECHA Guidance on environmental exposure assessment (Chapter R.16, version 3, February 2016) also discusses service life as a life cycle step for the purposes of an environmental exposure assessment. Since the Registrant(s) have not provided a sufficient justification to show that service life of paints is not a significant source of NP in the environment, the request has not been modified.

6. An update of all Exposure Scenarios (ES) to include the waste phase or justification as to why it is not relevant.

Another aspect of the Exposure Scenarios is that none of them adequately consider the potential emissions of the registered substance associated with the disposal of process wastes and products at the end of their useful life. Landfill sites and waste facilities are known to be a potential source of substances in the environment so adequate control should not be assumed without further justification.

In response to the original request in the draft decision, the Registrant(s) stated that their CSR is consistent with the ESR risk assessment report, and that they are not in a position to make recommendations for derivatives. They therefore asked for the deletion of the request.

ECHA notes that the ESR assessment was produced at a time when emissions from waste were not routinely considered. In accordance with Annex 1 (section 5.2.2) of the REACH Regulation, the life-cycle stages resulting from the manufacture of the substance and from identified uses cover, where relevant, the waste stage. The ECHA Guidance on environmental exposure assessment (Chapter R.16, version 3, February 2016) further clarifies that all life cycle stages should be considered, including waste handling and treatment. If this life cycle stage is not considered a significant source, a relevant justification should be provided in the CSR. The fact that this stage was not included in the ESR assessment is therefore not relevant. The extent to which recommendations can be made for downstream products (such as polymers) will depend on the amount of information available. This request has been maintained, but the scope of the request has been adjusted to include polymers and not other derivatives, as explained in the part "General comments of the Registrant(s) and proposals for amendments" above.

Conclusion:

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- Information on the annual tonnage of the registered substance manufactured or placed on the market by each Registrant for each of the ESs in the CSR, and also the annual supply tonnage of individual polymers (e.g. resins, nonylphenol ethoxylates (NPEOs)[2], etc.) (which can be grouped if justified) that are placed on the EU market, broken down by use (estimated if necessary). If the Registrant(s) are unable to gather suitably representative data for any part of the life cycle, they shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification).

- Information on the typical concentration of the registered substance as an unreacted impurity in polymers and the potential for its formation from the polymers during environmental degradation. Following an assessment of relevance, ESs shall be produced for significant sources. If the Registrant(s) are unable to gather suitably representative data for any part of the life cycle, they shall base their assessment of that life cycle stage on reasonable worst case assumptions (with justification).

- Justification as to why ESs involving NPEO do not take account of the further degradation of NPEO released in WWTP effluent to the registered substance.

- Justification as to why registration dossiers do not include ES15 (Service life of

paints containing NPEO) as a relevant use when they include ES9 (Formulation of paints containing NPEO).

- An update of all ESs to include the waste phase or justification as to why it is not relevant. This should include all lifecycle steps, including production/formulation/processing and disposal of products containing the registered substance (or polymers) at the end of their service life.

In all cases where a justification has been requested, the response must be scientifically robust, or alternatively the Registrant(s) shall remedy the situation by providing a relevant assessment to take the missing information into account.

Depending on the outcome of the assessment of the information provided in response to requests 2-6 of the present decision, in accordance with Article 46(3) of the REACH Regulation the evaluating Member State may in the follow-up evaluation consider requesting the generation of new monitoring data on the registered substance.

C. Information for Environmental fate

These are additional concerns identified during the substance evaluation.

7. Surface tension of the registered substance

A reliable surface tension value is required because it is relevant for the consideration of K_{OW} data derived using the shake flask method. The waiving argument provided by the Registrant(s) is inadequate as the substance's water solubility is above 1 mg/L and it has structural features (a hydrophobic alkyl chain and hydrophilic hydroxyl group) that may affect surface tension.

In response to the original draft decision, the Registrant(s) agreed to this request.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance subject to this decision:

- Surface tension (test method: EU A.5/OECD TG 115).

8. Sewage treatment removal efficiency

The organic carbon-water partition coefficient (K_{OC}) value is an important property for the environmental exposure assessment. The Registrant(s) derive an estimated K_{OC} value of 14,390 L/kg, based on a measured log K_{OW} value of 5.4.

ECHA considers that this K_{OC} value is not adequately justified. Firstly, the choice of QSAR is not explained in the CSRs. If the non-hydrophobics QSAR is used (as was done in EC, 2002), a log K_{OW} value of 5.4 is equivalent to a K_{OC} of 6,730 l/kg, which is significantly lower than the value used in the CSRs. Secondly, the Registrant(s) do not justify the use of their chosen K_{OW} value, which is significantly higher than that used in EC (2002) and ignore publicly available data.

The K_{OC} is used to estimate WWTP removal efficiency. The CSRs assume that the overall removal efficiency is 77.5% (22.5% release to wastewater). Monitoring evidence from the UK indicates that some WWTPs have removal efficiencies considerably lower than 80% (down to 66%, which is consistent with the reasonable worst case estimate included in the ESR assessment). If the removal efficiency assumed in EC (2002) (65%) is substituted for the figure in the modelling for the CSRs, some local RCRs become greater than 1. The assumptions in the registration dossiers therefore do not represent a reasonable worst case

scenario for the aquatic environment.

The original draft decision contained a request for organic carbon-water partition coefficient (K_{OC}) in sewage sludge on the registered substance according to OECD TG 106, modified to test sewage sludge. In response to the original draft decision, the Registrant(s) performed an updated literature search and added additional K_{OC} studies to the registration dossier. Further justification for the QSAR estimate was also provided. They did not agree to conduct a new study using sewage sludge, but indicated that they may, as appropriate, provide a sensitivity analysis on WWTP removal efficiency based on the arithmetic and geometric mean of reliable reported K_{OC} values.

ECHA acknowledges the registration update, which still indicates a wide range of K_{OC} values. The Registrant(s) have not (yet) amended their choice of K_{OC} nor provided an updated Chemical Safety Assessment (CSA). As a lower WWTP removal efficiency value could imply an aquatic risk in some scenarios, the Registrant(s) should take the variability of Koc values into consideration to demonstrate the safe use of the substance in the CSA. In view of the amount of information already available, ECHA agrees to delete the requirement for a test, but still requires the observed variation in actual sewage treatment efficiency (including K_{OC}) to be taken into account as part of a sensitivity analysis, such that the conditions of safe use are clearly described in terms of the assumed level of WWTP removal efficiency (affecting both releases to water and to land). The requirement has therefore been modified accordingly.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information on the registered substance subject to this decision:

- The observed variation in actual sewage treatment efficiency (including K_{OC}) to be included in the CSA as part of a sensitivity analysis, in such a way that the conditions of safe use are clearly described in terms of the assumed level of WWTP removal efficiency (affecting both releases to water and to land).

9. Robust study summaries for BCF, BSAF, BMF and TMF studies

Since the substance could be concluded to meet the Annex XIII P criteria and is certainly "T", it is important to perform a comprehensive assessment of bioaccumulation potential.

With regard to the P criterion, the corrected half-life data provided by the Registrant(s) in response to the draft decision indicate that the sediment half-life is variable, with some studies suggesting half-lives significantly above the Annex XIII P criterion of 120/180 days under both oxic and anoxic conditions when normalised to 12 °C. Whilst the Registrant(s) still conclude that the substance is not P or vP, ECHA notes that a case could be made for P. ECHA concludes that there is no need to ask for further information to support the persistence assessment, and so the request for derivation of environmental half-life data in the original draft decision has been deleted.

However, before concluding on the B assessment, a properly corrected data set is needed, including information on food chain transfer from the public literature that is not currently in the CSRs. The Registrant(s) originally selected a fish BCF of 740 L/kg ww and BMF of 1 based on information available in the late 1990s. However, further information has become available in the meantime, especially regarding the potential for food chain transfer (e.g. Diehl *et al*., 2012[21]). The Registrant(s) were therefore asked to justify their selection of

[21] Diehl J., Johnson S. E., Xia K., West A. and Tomanek L. (2012). The distribution of 4-nonylphenol in marine organisms of North American Pacific Coast estuaries. Chemosphere, 87(5), 490-497.

BCF, BMF and TMF values, based on an updated review of the scientific literature (specifying the search terms, date range and databases used) and taking account of growth dilution and lipid normalisation to a 5% lipid content, if relevant, for the interpretation of laboratory studies. This may include scientifically justified read across from studies with other relevant 4-alkylphenols.

In response to the original draft decision, the Registrant(s) agreed to this request, and performed a further literature search for data published since 2010, subsequently included in the registration dossier update with lipid correction. This resulted in an amended maximum BCF of 860 L/kg (Brooke, 1993)[22], which is well below the B criterion. However, normalisation to 5% lipid content does not seem to have been applied to all fish studies, and they did not include all available data (e.g. omitting the study of Diehl *et al*. (2012) on food chain transfer).

Additionally, in the Ekelund *et al*. (1990)[3] steady-state was not achieved for mussels, and analysis after 16 days' exposure showed that >80% of the radioactivity present co-chromatographed with NP (suggesting a parent substance BCF of 2,190-3,300 L/kg ww). Whilst elimination from fish was rapid, a significant proportion of the NP in mussel tissue remained after the 30-day elimination period.

While the standard information requirement for aquatic bioaccumulation in REACH Annex IX states "Bioaccumulation in aquatic species, preferably fish", Annex XIII states only that B/vB is assessed from "bioconcentration factor in aquatic species", so invertebrate data are not excluded from this assessment and are in fact of relevance. It is therefore necessary to use the available mussel bioaccumulation (including BSAF) data with lipid normalization in the B assessment for comparison with the B criteria which could potentially lead to identification of NP as meeting the B criterion. Although the study Ekelund et al (1990) is included in the registration dossiers, the mussel data are missing from the robust study summary.

Therefore whilst ECHA agrees that the lipid normalised data provided in the updated dossier suggest that fish BCFs are below the Annex XIII B criterion, there are studies available which demonstrate high BAF/BSAF values for invertebrates (e.g. bivalves) as well as available information on trophic transfer (as explained above), which has not been considered by the Registrant(s). As NP appears to meet both the P and T criteria, a comprehensive and clearly argued weight of evidence analysis is still required to draw a clear conclusion about bioaccumulation potential. The requirement has therefore been retained with the addition of a request for the presentation of a weight of evidence analysis for all relevant bioaccumulation measures in the CSA.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- Update the robust study summaries (RSS) of all published fish bioconcentration factor (BCF), biota-sediment accumulation factor (BSAF), biomagnification factor (BMF) and trophic magnification factor (TMF) studies for the registered substance, including lipid normalisation where the data are available, and addressing invertebrates (not just fish). In particular, the RSS of the Ekelund *et al.* (1990) study[3] shall be updated to include mussels, and an RSS for the following study shall be provided:

  Diehl J., Johnson S. E., Xia K., West A. and Tomanek L. (2012). The distribution of 4-

[22] Brooke, L. (1993). Nonylphenol Toxicity: Accumulation and Lethality for Two Freshwater Fishes (Fathead Minnow and Bluegill) to Nonylphenol. USEPA Report. Testing laboratory: University of Wisconsin-Superior. Report no.: EPA Contract No. 68-C1-0034.

nonylphenol in marine organisms of North American Pacific Coast estuaries. Chemosphere, 87(5), 490-497.

A weight of evidence analysis shall be performed to compare the corrected data for all relevant bioaccumulation measures (fish and invertebrate) with the Annex XIII criteria and associated guidance.

Note(s) for consideration by the Registrant(s)
The Registrant(s) are reminded of their obligation to revise the CSR and PBT assessment once new information is available. If a risk is identified, the Registrant(s) shall either propose risk management measures, or identify further information needs to refine the assessment.

D. Information for Environmental PNECs

These are additional concerns identified during the substance evaluation, relating to the possibility that several taxonomic groups might be more sensitive to NP than assumed by the Registrant(s), which could lower one or more aquatic PNECs significantly (and therefore lead to an environmental risk in some existing registration scenarios, or when considering all sources). The $PNEC_{water}$ could be lowered as a result of each information requirement, even if the new NOEC value is within the range of the data used in the current Species Sensitivity Distribution (SSD) used by the Registrant(s). This is because the data could affect the tail of the distribution (which influences the HC5 value derived), as well as the resulting consistency with the assumption of normality and therefore the statistics used to derive the HC5). Furthermore, ECHA noted some shortcomings in the derivation of the $PNEC_{oral}$ for secondary poisoning.

Unless the Registrant(s) concludes that the registered substance meets the PBT criteria, requests concerning the environmental PNECs (10-15) are required.

10. Long-term NOEC/EC10 with Rainbow Trout *Oncorhynchus mykiss*

Discussions by ECHA's Risk Assessment Committee (ECHA, 2014c[16]) highlighted that the $PNEC_{water}$ derived by the Registrant(s) may not be sufficiently protective of endocrine hazards. In particular, the available ecotoxicity data for Rainbow Trout *Oncorhynchus mykiss* were considered. This highlighted that a study by Schwaiger *et al*. (2002)[4] suggests transgenerational effects on egg mortality at concentrations lower than the Rainbow Trout NOEC selected by the REACH Registrant(s) (6 µg/L). 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 the 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 $PNEC_{water}$ based on a species sensitivity distribution by a factor of about 5. The Registrant(s) are therefore required to perform a detailed review of all available Rainbow Trout studies to select an appropriate long-term $NOEC/EC_{10}$ for this species that encompasses the sensitivity of early life stages. This information will allow a more robust assessment of an apparently sensitive apical end point for this species, which is expected to reduce the $PNEC_{water}$.

In response to the original draft decision, the Registrant(s) did not agree to this request. They stated that the $PNEC_{water}$ derived using a species sensitivity distribution (SSD) in the CSRs is robust and protective of adverse endocrine effects, including the Schwaiger *et al*. (2002) study. Only two test concentrations were used in that study, so an EC_{10}/NOEC is not reported in the paper. They claim that the RAC opinion is consistent with the PNEC derivation in the REACH registration dossier but is ambivalent on the evaluation of

endocrine effects. Specifically, they quote that RAC notes *"that it still appears difficult to precisely quantify the threshold for adverse endocrine 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)".* To address the concern, instead of deriving a long term NOEC/EC10 for Rainbow Trout *Oncorhynchus mykiss,* the Registrant(s) proposed to carry out an updated literature search for aquatic toxicity data, and recalculate the $PNEC_{water}$ using an SSD approach (taking account of the RAC opinion).

ECHA agrees that an updated literature search would be useful, but it is not sufficient by itself. The RAC opinion points out that trans-generational effects in fish (as well as effects in non-tested taxonomic groups) could be more sensitive than the existing data included in the SSD. In addition, the level of analysis by RAC was limited, as once an EU-level risk was confirmed, nothing more needed to be done. However, the RAC opinion does highlight that the risks based on a $PNEC_{water}$ derived from an SSD using "traditional" apical effects may be under-estimated when considering endocrine-related data.

Whilst an adequate dose-response is not available for the Rainbow Trout studies, ECHA believes that reasonable assumptions could be made based on the existing information (e.g. by dividing the lowest effect concentration by a suitable factor to obtain a long-term NOEC/EC10). Therefore, the information requirement has not been changed. An alternative might be to perform a new study with more concentrations. However, in the interests of animal welfare and to minimise the testing burden on the Registrant(s), ECHA will evaluate the need for any further fish studies once the data currently requested are provided and evaluated by the evaluating MSCA.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- Derivation of a long-term NOEC/EC_{10} for Rainbow Trout *Oncorhynchus mykiss*, taking account of transgenerational effects as described by Schwaiger *et al*. (2002)[4] and the Risk Assessment Committee opinion (ECHA, 2014c[16]).

11. Estimated chronic NOEC for Winter Flounder *Pleuronectes americanus*

Winter Flounder *Pleuronectes americanus* is a sensitive fish species in acute tests, with a reported 96-h LC_{50} of 17 µg/L (Lussier *et al*., 2000[6]). No long-term toxicity data are available in the phenol, 4-nonyl-, branched data set for this or other marine fish species. As described in the RAC opinion (ECHA, 2014c[16]), the long-term NOEC for Winter Flounder might be around 0.4 or 0.8 µg/L, based on the acute:chronic ratio for Rainbow Trout or Fathead Minnow, respectively. This is an order of magnitude lower than the current lowest fish NOEC in the data set used by the Registrant(s) (6 µg/L) and suggests that the $PNEC_{water}$ derived by the Registrant(s) may not be sufficiently protective. It is therefore important to obtain a reliable measure of chronic toxicity for Winter Flounder.

In the original draft decision, a long-term toxicity study according to OECD TG 210, modified using Winter Flounder *Pleuronectes americanus* (or a closely related flat fish species), was requested.

In response to the original draft decision, the Registrant(s) did not agree to this request. They state that test laboratories have confirmed that a long-term test on Winter Flounder is not technically possible. Whilst another saltwater species (Silverside) is recommended for the OECD 210 study, the extremely high rate of control mortality makes it difficult to complete a valid study. The preferred species would be Sheepshead Minnow based on the

feedback. To address the concern, the Registrant(s) proposed instead to carry out an updated literature search for aquatic toxicity data, and recalculate the $PNEC_{water}$ using an SSD approach (taking account of the RAC opinion).

ECHA acknowledges that the originally proposed test may not be technically feasible. The concern arose because of the apparently high acute sensitivity of Winter Flounder, and the implication that a chronic NOEC may be close to the PNEC value. A chronic test with another saltwater species from a different taxonomic group would not necessarily address this concern. ECHA has therefore modified the request to clarify that the Registrant(s) shall predict a chronic NOEC for Winter Flounder for inclusion in the SSD, based on the existing acute data for this species and a worst case acute:chronic ratio from other fish species.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- An estimated chronic NOEC for Winter Flounder *Pleuronectes americanus* based on the reported 96-h LC_{50} of 17 µg/L from Lussier *et al*. (2000[6]) and the worst case acute:chronic ratio from other fish species in the aquatic toxicity data set.

12 - 13. Long-term toxicity testing on aquatic molluscs and echinoderms

The Registrant(s) have not taken account of studies available in the academic literature that describe the toxicity of the substance towards molluscs and echinoderms. ECHA (2014c[16]) highlighted that this contributed to significant uncertainty in the $PNEC_{water}$ derivation. The RAC opinion notes that "*in tests with other taxonomic groups other than fish, notably various invertebrates (e.g. echinoderms and molluscs), RAC notes a few observations for non-traditional endpoints at concentrations down to the range of 0.1 – 1.0 µg/l*". More specifically, several studies suggest NOECs for species of mollusc and sea urchin that are very close to (or below) the $PNEC_{water}$ of 0.53-0.61 µg/L derived by the Registrant(s). For example, a LOEC of 5 µg/L was reported for the analogue 4-*tert*-octylphenol with *Potamopyrgus antipodarum* (Jobling *et al*., 2004[23]); the NOEC was below 1 µg/L in a life cycle study with the Pacific oyster (*Crassostrea gigas*) (Nice *et al*., 2003[8]); the estimated 72-h NOEC was 0.47 µg/L in an embryotoxicity study with the sea urchin *Paracentrotus lividus* (Arslan *et al*., 2007[24]). Information is therefore required to extend the chronic database coverage with two important additional invertebrate taxonomic groups (i.e. echinoderms and molluscs), which will provide more confidence that the $PNEC_{water}$ for the marine compartment is sufficiently protective, as well as further information on species that may be susceptible to endocrine-mediated effects. For freshwater gastropods, *Potamopyrgus antipodarum* is the preferred species because existing data (e.g. Duft *et al*., 2003b[25] and Jobling *et al*., 2004[23]) for both the registered substance and the analogue 4-*tert*-octylphenol suggest that it is sensitive to alkylphenols. The $NOEC/EC_{10}$ for echinoderms shall be derived as an indication of long-term toxicity, following precedents set for the use of echinoderm toxicity data with other substances subject to EU regulation (e.g. Nickel).

In response to the original draft decision, the Registrant(s) agreed that available published studies on molluscs and echinoderms can be used to elaborate the effects of the registered substance, but did not consider that they should be used in the SSD. In addition, they did

[23] Jobling, S., Casey, D., Rodgers-Gray, T., Oehlmann, J., Schulte-Oehlmann, U., Pawlowski, S., Braunbeck, T., Turner, A.P. and Tyler, C.R. (2004). Comparative responses of molluscs and fish to environmental estrogens and an estrogenic effluent. *Aquat. Toxicol*., 66, 207-222.

[24] Arslan, O.C., Parlak, H., Oral, R. and Katalay, S. (2007). The effects of nonylphenol and octylphenol on embryonic development of sea urchin (*Paracentrotus lividus*). Arch. Environ. Contam. Toxicol., 53, 214-219.

[25] Duft, M., Schulte-Oehlmann, U., Weltje, L., Tillmann, M. and Oehlmann, J. (2003b). Stimulated embryo production as a parameter of estrogenic exposure via sediments in the freshwater mudsnail *Potamopyrgus antipodarum*. Aquat. Toxicol., 64, 437–449.

not agree to conduct long-term toxicity testing on aquatic molluscs or echinoderms because this is not a "*Registration end point*", and a well-established test guideline does not exist. They also referred to the RAC opinion which suggested that "*chronic tests with these species ... would not reveal significantly lower adverse effect concentrations for the traditional, apical endpoints than those in the current data set*". To address the concern, the Registrant(s) proposed instead to carry out an updated literature search for aquatic toxicity data, and recalculate the $PNEC_{water}$ using an SSD approach (taking account of the RAC opinion). The Registrant(s) indicated that they will further elaborate the basis and strength of the SSD, the adequacy of existing data and the potential value of any new marine study to that dataset.

ECHA agrees that an updated literature search would be useful, and possibly sufficient, if it leads to derivation of reliable $NOEC/EC_{10}$ for reproduction and growth for aquatic molluscs and echinoderms. The REACH Annexes make it clear that all relevant available information should be included in the registration dossier.

In response to the Registrant(s) reference to the RAC opinion, ECHA highlights that the quotation by the Registrant(s) is made out of context, which leads to a misinterpretation of the RAC opinion. The point of discussion was whether there was evidence from the available data that marine species were more sensitive than freshwater species. In the following paragraph of the RAC opinion it states: "*For the specific case of NP, RAC considers it is therefore adequate to derive a common $PNEC_{aquatic}$, 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 R10.3.2 of ECHA's guidance on IR and CSA for the marine compartment*".

In addition, ECHA highlights that the purpose of the RAC opinion was different to the aim of this Decision requiring further information in the remit of Substance Evaluation. RAC provided an opinion within a specific context, namely whether an environmental risk arises from the use of NP in textile applications, and therefore whether a Restriction was justified. Instead, the requirements of this section of the Decision are to provide information to address the concern that the aquatic PNEC may be lower than the one currently derived by the Registrant(s) leading to risks at a Registrant or aggregate tonnage level. Therefore, ECHA considers that the need for a refinement of the aquatic PNEC is still relevant in the context of Substance Evaluation.

ECHA agrees with the Registrant(s) that toxicity data on molluscs and echinoderms are not standard information requirements. However, Article 46(1) of the REACH Regulation states that "*If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission.*" Therefore, the information requests under Substance Evaluation are not limited to standard information requirements, and ECHA can require non-standard data if there is the need to address a concern. In this instance, some of the available data suggest a high degree of sensitivity for these taxonomic groups, and there are indications in the scientific literature that molluscs at least might have oestrogen-like receptors. ECHA considers that it is important for molluscs and echinoderms to be represented by reliable data in the SSD. In response to the Registrant(s)'s comment about "*the absence of well established test guidelines*" ECHA notes that mollusc studies have been requested previously under the ESR (e.g. for tetrabromobisphenol-A and bisphenol-A) and there is now a well developed OECD test guideline for prosobranch molluscs, which has been approved by the OECD in April 2016. Several other standardised guidelines have been extensively used in North America. The two other requested studies are using national guidelines, which is a possibility offered in the REACH Endpoint guidance 7B (R.7.8.3.1 -

Data on aquatic pelagic toxicity) specifically where acceptable alternatives to OECD test guidelines are discussed. Chronic mollusc and echinoderm data have also been used in the SSDs for several metals.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following studies for the registered substance subject to this decision:

- Long-term toxicity testing on aquatic molluscs:
    a. A reproduction study with the freshwater gastropod *Potamopyrgus antipodarum* in accordance with the OECD mollusc reproduction test guideline approved in April 2016 (the latest protocol of the draft guideline can be found at this link: http://www.oecd.org/env/ehs/testing/Potamopyrgus%20for%202nd%20WNT%20comments_clean.pdf[7])
    b. A life cycle study with the marine bivalve *Crassostrea gigas* in accordance with the method of Nice *et al*. (2003)[8]. An oyster embryo-larval toxicity test[9] may be performed to help with range finding, in accordance with an appropriate standard method (e.g. ICES TIMES No 54[10] or US EPA OPTTS 850.1055[11]).

Long-term toxicity testing on echinoderms. In the absence of an EU standard method, the study shall be conducted in accordance with a suitable national standard method (e.g. Environment Canada Biological test method EPS 1/RM/27[12]). The Registrants shall justify the choice of test species based on an assessment of the most sensitive species from studies reported in the scientific literature. The maintenance of test concentrations shall be confirmed by analytical measurements.

One or more of these three tests may be waived if the Registrant(s) can justify the derivation of reliable long-term reproduction and growth NOEC/EC_{10} values for gastropod mollusc, bivalve mollusc and/or echinoderm species based on an updated review of the scientific literature (specifying the search terms, date range and databases used) (which may include scientifically justified read across from studies with other relevant 4-alkylphenols if appropriate). These data, which may form the basis for NOEC/EC10 values, should be equivalent to data generated by the corresponding requested test.

14. Revision of $PNEC_{water}$ for both fresh and marine surface waters

The Registrant(s) have derived a $PNEC_{water}$ using statistical extrapolation techniques that have not been adequately documented, and fail to take account of potentially sensitive species as indicated by recent EU reviews (e.g. ECHA, 2012a,c). The Registrant(s) are required to justify the derivation of the $PNEC_{water}$ for both fresh and marine surface waters (combined if appropriate, as suggested by RAC (ECHA, 2014c)), including end point and species choice (in terms of taxonomic coverage), a description of relevant summary statistics for the species sensitivity distribution (if derived) to justify the choice of model in accordance with the REACH Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.10, May 2008), and choice of assessment factor to apply to the HC5, together with a discussion about the suitability of the approach for any apparently sensitive trophic groups or species. This is necessary to provide reassurance that the $PNEC_{water}$ is sufficiently protective and takes account of all relevant data. This information is particularly important as it may form the basis for future risk management decisions.

In response to the original draft decision, the Registrant(s) agreed to this request.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- Revise their $PNEC_{water}$ for both fresh and marine surface waters (combined if relevant) once they have provided the information for requests 10-13. This shall include specifying the end point and species choice (in terms of taxonomic coverage), a description of relevant summary statistics for the species sensitivity distribution (if derived) to justify the choice of model in accordance with the REACH Guidance on information requirements and chemical safety assessment (Chapter R.10), and choice of assessment factor to apply to the HC5, together with a discussion about the suitability of the approach for any apparently sensitive trophic groups or species.

15. Information on avian toxicity

The bioaccumulation assessment remains to be completed by the Registrant(s) as explained in request 9 of the present Decision, but within the available dataset high bioaccumulation is shown in mussels which constitute food for marine predators such as birds. As environmental concentrations of NP may even be underestimated, ECHA is concerned about the possibility of a secondary poisoning risk for NP. Therefore, ECHA has reviewed the registration data for reproductive toxicity to birds.

The Registrant(s) have read across to a study that investigated the effects of 4-*tert*-octylphenol (source substance) on a non-standard bird species (Millam *et al*., 2001)[26], and used it for deriving the $PNEC_{oral}$ for secondary poisoning. Although the Registrant(s) considers that this study is valid with restriction, ECHA considers that there are several shortcomings to this test which make it inadequate for regulatory purposes. The single dose selected was the lowest oral dose required to induce maximum masculinisation of song nuclei in female finches in an earlier study, but the relevance of this is not discussed in the registration dossiers, and it is not stated whether behaviour was affected. In addition, the birds were kept either in communal cages or force paired in individual breeding cages. The communal cages included both control and treated birds, and females were often observed in more than one nest box (this species is prone to brood parasitism), so the analysis was restricted to the top five producing nest boxes (the number of possible monogamous pairs) and to the first clutches only. Top-producing nest boxes were identified on the basis of the presence and number of eggs, candled fertility and hatching success. The reliability of the findings is therefore compromised by the study design. In addition, the proposed read across between the registered substance and the source substance is inadequate because there is no actual comparison of physico-chemical properties or aquatic toxicity data, and the proposed approach does not consider any differences in potency between the two substances in mammalian studies. Therefore, there is no reliable basis to predict the relevant property of the registered substance from the data obtained with the source substance.

Given the high aggregated tonnage, persistence and bioaccumulation potential, and the known endocrine disruptive properties of this substance, it is therefore important to establish a more reliable measure of toxicity to birds to ensure that risks for food chains are adequately controlled.

The Registrant(s) are therefore required to apply the Integrated Testing Strategy (ITS) at paragraph 7.10.19 in the REACH Guidance on Information Requirements and Chemical

[26] Millam J R, Craig-Viet C B, Quaglino A E, Erichsen A L, Famula T R and Fry D M (2001). Posthatch oral estrogen exposure impairs adult reproductive performance of zebrafinch in a sex-specific manner. Hormones and Behaviour, 40, 542-549.

Safety Assessment (Chapter R.7c, version 2, November 2014). This requires a $PNEC_{oral}$ for secondary poisoning to be derived based on mammalian data, as well as a screening $PNEC_{oral}$ for birds. If a risk to avian predators is subsequently indicated for either the aquatic or terrestrial environment, the Registrant(s) shall follow the ITS for avian toxicity described in the Guidance for this end point. The Registrant shall provide its observations whether avian testing is needed to address any remaining risks. The possible need for further testing will be considered by the evaluating MSCA in the follow up evaluation

The original draft decision sent to the Registrant(s) contained a request for Reproductive toxicity testing on birds (test method: OECD TG 206) unless the Registrant(s) could show such testing was unnecessary by applying the ITS. In their comments the Registrant(s) agreed to update their literature search, re-evaluate existing avian data and prepare an ITS according to guidance. The draft decision was therefore amended to reflect that a reproductive toxicity test on birds was not requested at this stage, but instead an assessment of available information on avian toxicity of NP. However, following the submission of the currently requested information, further testing to address this endpoint may be required in a follow-up evaluation.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information for the registered substance subject to this decision:

- Assessment of all available information to address avian toxicity of the registered substance using the Integrated Testing Strategy (ITS) provided in section 7.10.19 in REACH Guidance on Information Requirements and Chemical Safety Assessment (Chapter R.7c, version 2, November 2014) and observations whether avian testing is needed to address any remaining risks.

E. Additional concerns relating to human health

These are additional concerns identified during the substance evaluation related to human health.

16. Justification for the choice of oral bioavailability value used in the DNEL derivation

In their CSR the Registrant(s) have derived long-term systemic, dermal and inhalation DNELs from oral data using route-to-route extrapolation.
Orally administered NP is well absorbed and rapidly metabolised, such that post-hepatic bioavailability of unchanged NP is very limited. The ESR RAR concluded that post-hepatic bioavailability is around 10-20%; "*Absorption from the gastrointestinal tract is initially rapid and probably extensive. The major metabolic pathways are likely to involve glucuronide and sulphate conjugation, and there is evidence of extensive first-pass metabolism of NP absorbed through the gastrointestinal tract. Because of first-pass metabolism of unconjugated NP, the bioavailability of unconjugated NP is probably limited following oral exposure at no more than 10-20%.*"

In contrast, the Registrant(s) have used a value of 50% for oral absorption. This value appears to be based on a study in bile-duct cannulated rats (Green et al 2003)[27] in which 50-80% of the administered NP was eliminated in the bile as a glucuronide following oral dosing. Another toxicokinetic study ([redacted])[28], also reported in the CSR, compared

[27] Green T, Swain C, Van Miller JP, Joiner RL. Absorption, bioavailability, and metabolism of para-nonylphenol in the rat. Regul Toxicol Pharmacol. 2003;38:43–51.
[28] [redacted]

blood levels following oral and i.v. dosing and found bioavailability to be around 25-29%.

The oral absorption value of 50% used by the Registrant(s) implies that NP glucuronide in the bile is deconjugated in the gastro-intestinal tract and all the free NP reabsorbed. The discrepancy between the oral absorption and bioavailability data indicates that not all the glucuronide eliminated in the bile was available for enterohepatic recirculation. This is supported by the Green et al 2003 study which found mostly free NP in faecal extracts, suggesting that NP probably transits the gut bound to diet.

Overall the use of 50% for oral absorption has not currently been justified. As a consequence, the Registrant(s) are overestimating the amount of substance needed to be taken up via the dermal and inhalation routes to cause an adverse effect and therefore the derived DNELs may not be sufficiently protective. Therefore, further information to support the DNEL derivation is needed.

In response to the original draft decision, the Registrant(s) agreed to this request.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information:

- A justification for the choice of oral bioavailability value used in the DNEL derivation.

17. Further information on exposure

(a)
For each ES the Registrant(s) provided limited information to support their choice of input parameters used for modelling exposure. Using the same information and modelling tool (ECETOC TRA tool v. 2), as claimed by the Registrant(s), it has not been possible to reproduce all of the values, particularly for inhalation exposure. Given that many of the exposure values generated by the evaluating MSCA using modelling tool lead to RCRs>1 for many exposure scenarios when using not only the lower DNEL derived by the evaluating MSCA but also the DNEL derived by the Registrant(s), it is important to understand why these differences have arisen and establish whether the RMMs in place are sufficient.

It is necessary to clearly identify all input parameters used by the Registrant(s) particularly where additional modifiers, such as the use of a "maximal expected concentration in air", have been applied. Therefore the Registrant(s) are required to provide full details and justification for the input parameters they have used and any modifiers that they have applied.

It is also noted that in the Registrant(s)' risk characterisation a transcription error has resulted in RCRs >1 not being reported for two ESs; *use as an intermediate* and *use as a monomer in polymer production* for the task *sampling of raw materials* [PROC 9]. In these cases the modeled long term systemic inhalation exposure value has been reported as the RCR. The Registrant(s) will need to further consider these scenarios in order to demonstrate safe use.

(b)
Where gloves are identified as a necessary risk management measure (RMM) it is important that the barrier properties of the gloves ensure the substance does not migrate through the glove during the proposed use. Annex II of REACH specifies that information on suitable glove materials and minimum breakthrough times for different materials shall be communicated in safety data sheets. To provide assurance that this is being done effectively, this information should also be presented in the IUCLID dossier and CSR and

currently, this information is not visible therein. Further advice is available in the draft version 3.0 of Chapter R14 of the Information Requirements and Chemicals Safety Assessment Guidance currently being updated[29].
(c)
NP is classified for corrosivity, but the Registrant(s) have not provided any qualitative assessment to consider whether the proposed risk management measures (RMMs) are sufficient to protect against this hazard. The control measures have been identified based on the long term DNELs for systemic effects and an assessment should be made whether these are adequate to minimise adverse local effects to the skin, eyes and respiratory tract.

(d)
For low volatility substances such as NP the estimation of inhalation exposures to liquid aerosols is outside the applicability domain of the ECETOC TRA model (ECETOC Technical Report 114, section 2.2.7). The ECETOC TRA model may underestimate exposures for aerosol forming processes and potentially any risk management measures that have been identified on the basis of these exposure assessments may not be sufficient. For those scenarios involving spray application (i.e. using PROC 7 and PROC 11) the Registrant(s) should re-calculate the exposures using an alternative tool that includes aerosol forming processes within its applicability domain. Alternatively measured data for the substance itself or an analogous substance could be provided. If analogous data is used, the Registrant(s) should include a justification to demonstrate why the substance and/or process is representative for the contributing scenarios to which it is being applied.

(e)
The Registrant(s) have used the ECETOC consumer TRA modelling tool to estimate the exposure from the use of coatings and paints, thinners and paint removers. Using the input parameters and information provided in the CSR the exposure value can be reproduced by the evaluating MSCA. However the Registrant(s) have further modified the value that has been taken forward to risk characterisation based on the assumption of 5 events a year and averaging this total exposure across a one year period.

According to section 15.2.5 of ECHA Guidance on Consumer Exposure Estimation Chapter R15, version 2.1, October 2012)) for products used infrequently, use frequency should not be used to average out exposure over a longer time period. In the first instance exposure should be calculated for the actual duration of an event (event exposure) and then expressed as that exposure per day. Therefore the Registrant(s) should recalculate the exposures and justify the parameters for use that are used.

In response to the original draft decision, the Registrant(s) agreed to the request for further information on exposure in general. However, they indicated that they may consider revising to CSR to exclude ESs relating to the use of derivatives and polymers therefore, in such a case items (d) and (e) would not be included in a revised CSR. However, ECHA considers that, based on the information provided in the current CSR, the ESs indicated under requests (d) and (e) above are related to the exposure to the registered substance and not to NP derivatives. Anyway, the exposure to polymers, for the reasons explained in section III, B, "General comments of the Registrant(s) and proposals for amendments", should be accounted for. Specifically, ECHA understood that in the current CSR for some ESs human exposure had not been considered because exposure was only to the NP derivatives. The Registrant(s) made the statement that exposure to NP as a result of degradation is not expected to be significant, which is a reasonable assumption. On that basis it is assumed that where human exposure has been considered in the CSR then NP, rather than a derivative, is being used. Currently the CSR indicates that NP is used in

[29] http://echa.europa.eu/documents/10162/13564/r14_draft_for_peg_en.pdf

spraying applications and is present in coatings, paints, thinners and paint removers available for consumer use. If this is not the case the Registrant(s) should provide a statement to this effect and update the CSR accordingly.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide further information on exposure, specifically:

a) a description of all the input parameters used to model exposure. Where additional modifiers, such as maximum exposure concentration according to Dalton's law, gloves, level of dustiness, have been used these should be fully explained and their use justified.

b) Where a need for gloves to be worn has been identified, information should be given on the types of glove materials that are suitable, the required thickness and breakthrough times

c) a qualitative assessment to clarify whether additional risk management measures (RMMs) are required to protect against corrosivity.

d) Inhalation exposure estimates for scenarios involving spray application using a suitable modelling tool.

e) Recalculate potential consumer exposure from the use of coatings, paints, thinners and paint removers in accordance with the ECHA Guidance on Consumer Exposure Estimation Chapter R.15, Version 2.1, October 2012)

IV. Adequate identification of the composition of the tested material

In relation to the required experimental studies, the sample of the substance to be used shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested material to be subjected to the tests subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the tests must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost-sharing

In relation to the experimental studies the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). Registrant(s) are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at: https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the studies on behalf of all of them.

VI. Deadline

In the original draft decision the time indicated to provide the requested information was 24 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a monitoring programme. As this request is not addressed in the present decision, ECHA considers that a reasonable time period for providing the currently required information in the form of an updated registration is 18 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[30] by Leena Ylä-Mononen, Director of Evaluation

Annex: List of registration numbers for the addressees of this decision. This annex is confidential and not included in the public version of this decision.

[30] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.