

Applications for Authorisation for environmental endocrine disruptors (NPnEO and OPnEO)

Summary of the RAC evaluation and opinion on the proposal for a restriction on the use of NPnEO in textiles

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Peter SIMPSON

European Chemicals Agency, Helsinki

peter.simpson@echa.europa.eu

Background

- Sweden submitted a proposal (Annex XV report) for a REACH restriction on the use of NP and NPnEO in textiles
 - *Placing on the market of textile clothing, fabric accessories and interior textile articles containing NP or NPE that can be washed in water* (September 2013)
 - To address the risk from [imported] textiles that release NP or NPnEO during washing
- RAC / SEAC evaluated the proposal (developed an opinion)
 - Taking into account comments from public consultation
 - RAC opinion adopted, by consensus, in June 2014
 - Identified hazard and risk
 - Justification that action is required on an EU wide basis
 - Justification that suggested restriction is the most appropriate EU wide measure
 - Effectiveness in reducing the identified risks
 - Practicality, including enforceability
 - Monitorability

Identified hazard and risk

- Restriction based on following premise:
 - EU water bodies are at risk from NPEO degradation products, including effects arising from their combined toxicity and ED properties
 - NP, short chain nonylphenol ethoxylates (NPEOs) and nonylphenol ethoxycarboxylates (NPECs)
 - Significant source of these substances is textiles (particularly those imported from outside of the EU) as they can release NPEOs when they are washed in water, and these NPEOs can degrade to NP and short chain NPEOs/NPECs
 - Limiting NPEO content in textiles to 100 mg/kg (0.01 % w/w) will reduce risks significantly, whilst continuing to allowing the supply of textiles where NPEOs are only present unintentionally

Evaluation of hazard

- Dossier Submitter had derived NP PNECs for both the freshwater and marine compartments
 - Reasonably extensive dataset of studies reporting conventional, apical, endpoints
 - Deterministic
 - Freshwater: 0.06 to 0.60 µg/L; lower value based on additional AF (10) for ED
 - Marine: 0.006 to 0.039 µg/L; both with additional AF (10) for marine uncertainty
 - Probabilistic (SSD & HC5)
 - Freshwater: 0.59 µg/L
 - Freshwater and marine combined: 0.42 µg/L
- Observations of 'potentially endocrine-mediated effects' below most sensitive apical NOEC values
- Dossier Submitter considered that it was too difficult to derive threshold for ED properties

RAC observations on hazard

- Based on the available data for traditional, apical, endpoints, RAC questioned the need for separate $PNEC_{aqua}$ for freshwater and marine compartments
- In fish, indicators for endocrine-mediated effects tend to occur at concentrations an order of magnitude lower than traditional, apical, endpoints
 - RAC further evaluated additional fish studies reporting ED relevant endpoints (e.g. Schwaiger et al. 2002) – Annex 1
 - LOEC of 1 $\mu\text{g/L}$ for F1 larval mortality in rainbow trout
- In other taxonomic groups (molluscs & echinoderms), RAC noted observations of effects on non-traditional endpoints at concentrations in the range of 0.1 to 1.0 $\mu\text{g/L}$
 - However, effects not conclusively endocrine-related

RAC observations on hazard (2014)

- *'RAC agrees that the ED-related generic arguments justify ED substances coming under particular scrutiny. There is however ongoing scientific debate about how ED effects should be considered for hazard or risk-based regulatory actions'*
- *'RAC is aware that the Commission Services are considering the default assumption that a threshold cannot be determined experimentally'*
- *'Given this, RAC considers it premature in this specific case to give an opinion on whether or not it is possible to derive safe exposure level for the ED effects of NP'*

RAC conclusions on hazard

- For traditional, apical endpoints, a $PNEC_{\text{aqua}}$ of 0.4 $\mu\text{g/L}$ for NP could be derived (both freshwater and marine compartments)
- In terms of the ED properties of NP:
 - Appears difficult to precisely quantify threshold
 - $PNEC$ lowered by factor of 5 (0.08 $\mu\text{g/L}$) might be protective in fish (Annex 2)
 - Despite any specific indications [from literature], RAC cannot preclude that a lower threshold would be appropriate to protect other taxonomic groups (that currently lack adequate testing protocols)
- $PNEC_{\text{aqua}}$ of 0.4 $\mu\text{g/L}$ [therefore] used as a pragmatic means to evaluate the proposed restriction (is there an EU wide risk?)
 - If $RCR > 1$ in risk characterisation then overall risks from (i) ED properties of NP and (ii) combined hazard of NPEOs/NPECs will be greater.
 - **'Traditional' $PNEC$ insufficient to address all uncertainties**
 - **'RAC cannot offer any opinion about whether the proposed $PNEC$ is sufficiently protective of all relevant hazards posed by NP'**

RAC conclusions on other relevant NPEO degradation products

- RAC agrees that short chain NPEOs and NPECs contribute 'qualitatively' to overall toxic effects in the environment (including ED)
- The basis for quantification proposed by the Dossier Submitter (Toxicity Equivalent Factor [TEF] approach) has significant uncertainties
 - The approach clearly overestimates the contribution to toxicity of NPnEO (n = 3-8)
- TEF approach for NPEO and NPEC adds disproportionate uncertainty to quantitative hazard estimates

RAC conclusions on exposure and risk

- [Based on data reported under the WFD] NP is present in some European freshwaters at a concentration exceeding 0.4 µg/L.
 - The majority of waterbodies appear to be exposed to lower concentrations
- The approach to estimate the concentration of NPEO/NPEC based on NP concentrations in the environment should be considered as a useful screening tool, but is likely to result in significant overestimation of concentrations
- It can be assumed that at least a small proportion of freshwater bodies (and some marine bodies) in more than one Member State are at risk from NP
 - Other NPEO degradation products will add to this risk
 - Uncertainty in relation to the margin of safety afforded by the use of a 'traditional' PNEC
 - Only 'minimum risk' can be identified from risk characterisation using NP data

Summary

- RAC opinion on the restriction proposal for NPnEO in textiles gives a good basis for how RAC would approach an evaluation of a threshold for an ED substance in the future
- RAC opinion does not conclude on the threshold/non-threshold nature of the ED properties of NP
- Provides an indication of the uncertainties that need to be addressed to demonstrate that a PNEC would be protective of all relevant taxonomic groups [compartments]
- TEF approaches have been evaluated as uncertain

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Final adopted restriction – Entry 46a

- Nonylphenol ethoxylates (NPE) $(C_2H_4O)_n C_{15}H_{24}O$
- Conditions of restriction
 - Shall not be placed on the market after 3 February 2021 in textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0,01% by weight of that textile article or of each part of the textile article
 - Paragraph 1 shall not apply to the placing on the market of second-hand textile articles or of new textile articles produced, without the use of NPE, exclusively from recycled textiles.
 - For the purposes of paragraphs 1 and 2, 'textile article means and unfinished, semi-finished or finished product which is composed of at least 80% textile fibres by weight, or any other product that contains a part which is composed of at least 80% textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels'