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

Welcome and Introduction

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ECHA
EUROPEAN CHEMICALS AGENCY

2007-2017 10th Anniversary

Legislation

REACH,

CLP,

BPR,

PIC

ECHA Committee's

- Committee for Risk Assessment (RAC)
- Committee for Socio-Economic Analysis (SEAC)
- Member State Committee (MSC)
- Biocidal Products Committee (BPC)
- ECHA also hosts the Forum on Enforcement (Forum)

Programme

- 10:00 to 12:15 Morning session
  - Plenary presentations (15 mins + 5 mins for questions)
- 12:15 to 13:15 Lunch
  - No canteen available in the conference centre
  - Refer to page 3 of the programme for suggestions for lunch
  - Please return promptly and take account of the security
- 13:15 to 15:00 Afternoon session
  - World café style breakout discussions (4 groups)
  - Groups allocated by the colour on your name badge
- 15:00 to 15:20 coffee
- 15:20 to 16:00 feedback and summing up

Background

- On 13 July, NPnEO and OPnEO were added to Annex XIV of REACH on the basis of their *endocrine disrupting properties* (Article 57(f) - environment)
  - Entry 42: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [4-tert-octylphenol, ethoxylated; 4-tert-OPnEO]
  - Entry 43: 4-nonylphenol, branched and linear, ethoxylated [4-NPnEO]
- Latest application date: 04/07/2019
- Sunset date: 04/01/2021
- Authorisation (for a specific use) can be granted based on:
  - Adequate control – RCR values <1 (threshold substances)
  - Benefits outweigh the risks and no suitable alternatives (non-threshold or where adequate control not demonstrated)

Purpose

- Open exchange of views between stakeholders and ECHA on the available scientific evidence relating to the hazard and risk assessment of NPnEO and OPnEO.
- Consider whether it is possible to derive thresholds or dose-response relationships for these specific substances (and the necessary information)
- Raise awareness of key issues such as minimization of emissions in applying for authorisation of OP/NPnEO and thus assist applicants as they develop applications
- The workshop is not intended to:
  - Debate the identification of OPnEO and NPnEO as SVHC on the basis of ED properties or their inclusion on Annex XIV of REACH
  - Conclude on a 'recommended application approach' or identify 'reference values' for these substances
  - Consider socio-economic elements in any detail

Starting point for this workshop

- MSC (2012/13) identification as SVHC and subsequent recommendations for annex XIV

- RAC (2014) opinion on the restriction of NPEO in textiles – Restriction entry 46a (added in 2016):
  - Contains a quantitative PEC/PNEC risk assessment for NPEO based on NP but does not conclude on any safe threshold
  - Outlines the remaining uncertainties clearly

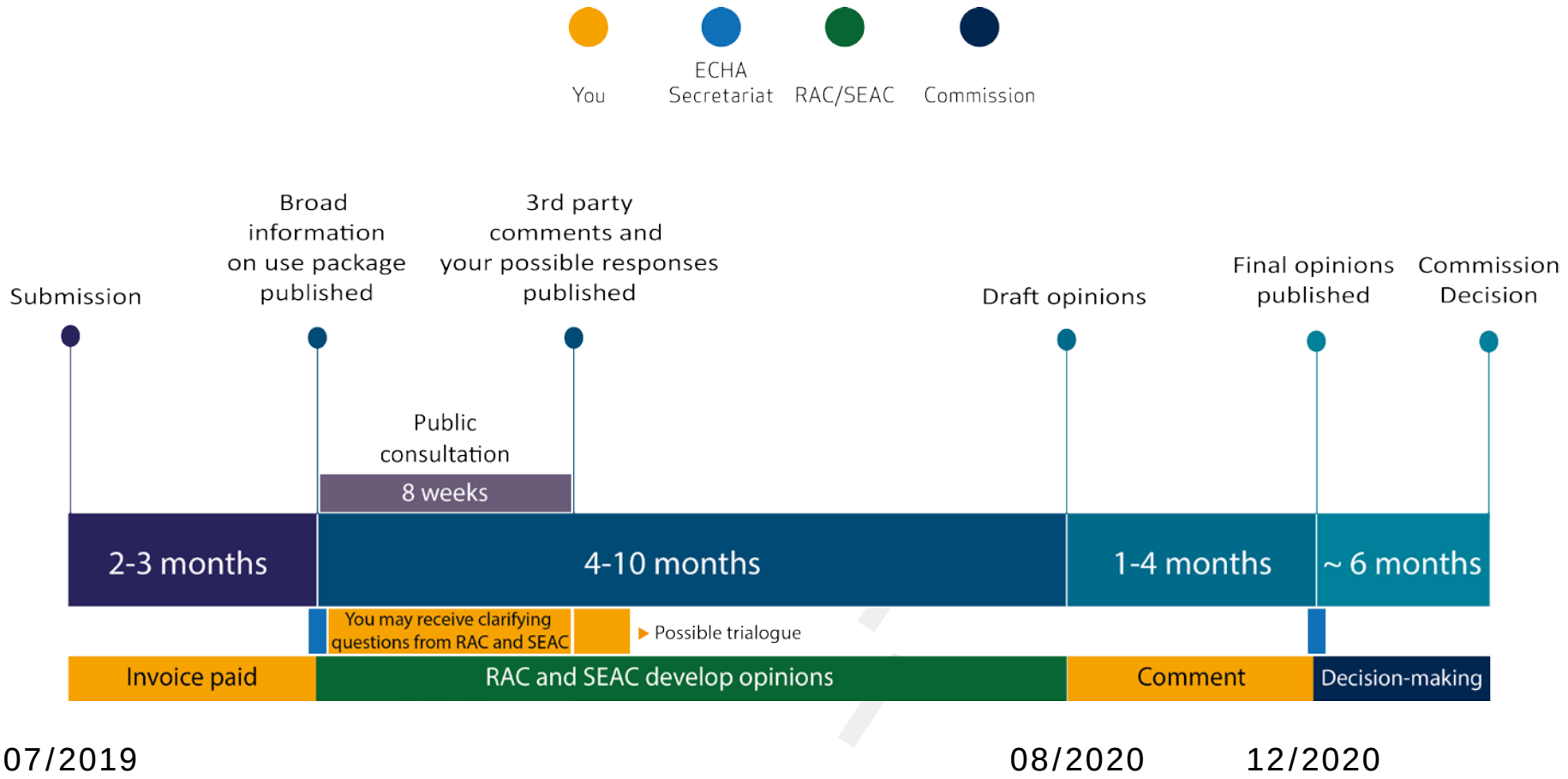
- COM (2016) communication to Council and Parliament on ED properties with specific reference to RAC
  - Industry is responsible for demonstrating any threshold

Under these circumstances, RAC is not in a position to provide reference values for entries 42 and 43

What is REACH Authorisation

- To ensure that the risks from Substances of Very High Concern (SVHC) are properly controlled and that these substances are **progressively** replaced by suitable alternatives while ensuring the good functioning of the EU internal market
- ECHA's Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) jointly evaluate and develop opinions on applications and provide a recommendation for the length of the **review period**.
- The final decision to grant an authorisation (with a specific review period) is taken by the European Commission (scrutiny by the REACH C'ttee)
- The duration of an authorisation can be extended (following review by RAC/SEAC and COM decision)

Application timeline: about 2 years



RAC opinions

RAC formulates its recommendations based on:

- The risks posed by the use (and the alternatives), including the hazard(s) and exposures
- 'Appropriateness and effectiveness' of risk management measures in limiting the risk [to the environment]
- Adequate control and/or minimisation of risks

RAC communicates its concerns to SEAC and the Commission on:

- Control of risk
- Uncertainties in the risk assessment

RAC may recommend

- That an authorisation should not be granted (not happened yet but there is less tolerance of poor applications)
- A short(er) review period for the authorisation (risk control concerns)
- Additional conditions and monitoring arrangements

What do RAC conditions look like?

For the authorisation (direct implementation)

- Introduce/continue/extend monitoring of emisions to the environment (frequency may vary)
- Review current RMMs to address emission control concerns
- Improve specific RMMs to reduce emissions to the environment
- Prepare and maintain records for inspection by enforcement agencies

For the review report (when reapplying for renewal at the end of the time limit)

- Summarise monitoring
- Other general conditions

SEAC opinions

SEAC evaluates and formulates its recommendation on the basis of:

- Whether the applicant's assessment of risk/benefit is plausible (when the risks are not adequately controlled)
- The technical and economic feasibility and availability of alternatives
- The comments from the Public Consultation (main purpose is to gather information on alternatives)
- The evidence presented for the length of the time-limited review period requested by the applicant
  - a long review period – max 12 years has to be properly justified)

Applications received and opinions adopted

Substance	Number of Applications received	Number of Uses (= opinions)
Phthalates	8	17
Lead chromate pigments	1	12
HBCDD	1	2
Diarsenic trioxide	4	5
Trichloroethylene	13	19
Lead chromate	1	1
EDC	15	15 + 3
16 Chromium VI substances	62	96 + 5
Diglyme	8	9
Arsenic acid	1	1
Technical MDA	1	2
MOCA	1	1
Total:	**116 from 200 applicants**	**180 + 8 more in opinion development**

Status on 5 September 2017, numbers subject to change

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Technical MDA	1	2
MOCA	1	1
Total: **T = threshold**	**116 from 200 applicants**	**180 + 8 more in opinion development**

Most substances processed by the Committees have been non-threshold, e.g. genotoxic carcinogens or PBT

Status on 5 September 2017, numbers subject to change

Scale of an application (definite Pro's an Con's)

Companies	Uses and sites
Single applicant One or more own uses on own site(s)	Typical, compact **downstream** applications submitted by companies (SME's to large multi-nationals) – should be clear and easy to evaluate
Consortium: single or multiple own uses on multiple (named) sites	Larger, more complex **downstream** applications – the representativeness of OC, RMM and exposure data comes into play – with sufficient detail, can be very efficient
Single applicant or consortium: single or multiple uses on multiple (mostly un-named) sites covering part of a supply chain	Very large **upstream** applications, where representative 'standards' on OC, RMM and exposure data are proposed: - scale of the exposure scenario can lack credibility – representativeness can become lost – clear OC and RMM's connected to convincing exposure data expected - Supply chain investigations problematic

NP / NPnEO restriction – Entry 46

Shall not be placed on the market, or used, as substances or in mixtures in concentrations equal to or greater than 0,1 % by weight for the following purposes:

1. industrial and institutional cleaning except:
   - controlled closed dry cleaning systems where the washing liquid is recycled or incinerated,
   - cleaning systems with special treatment where the washing liquid is recycled or incinerated.
2. domestic cleaning;
3. textiles and leather processing except:
   - processing with no release into waste water,
   - systems with special treatment where the process water is pre-treated to remove the organic fraction completely prior to biological waste water treatment (degreasing of sheepskin);
4. emulsifier in agricultural teat dips;
5. metal working except:
   - uses in controlled closed systems where the washing liquid is recycled or incinerated;
6. manufacturing of pulp and paper, cosmetics and PCPs, pesticides and biocides

REACH Article 60(10)
Granting an Authorisation

Notwithstanding any conditions of an authorisation, the holder shall ensure that the exposure is reduced to as low a level as is technically and practically possible

This applies regardless of whether the adequate control or socio-economic routes are followed

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