25 - 26.10.2023 | DAY 1

Chemical Regulations and Sustainability Symposium 2023

100 YEARS 1923 - 2023 Chemical Business Association

REACHLAW COMPLIANCE. SUSTAINABILITY.

Risk management of chemicals in the UK

Authorisation process

Risk management of chemicals in the UK

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1. Racap UK REACH authorisation process
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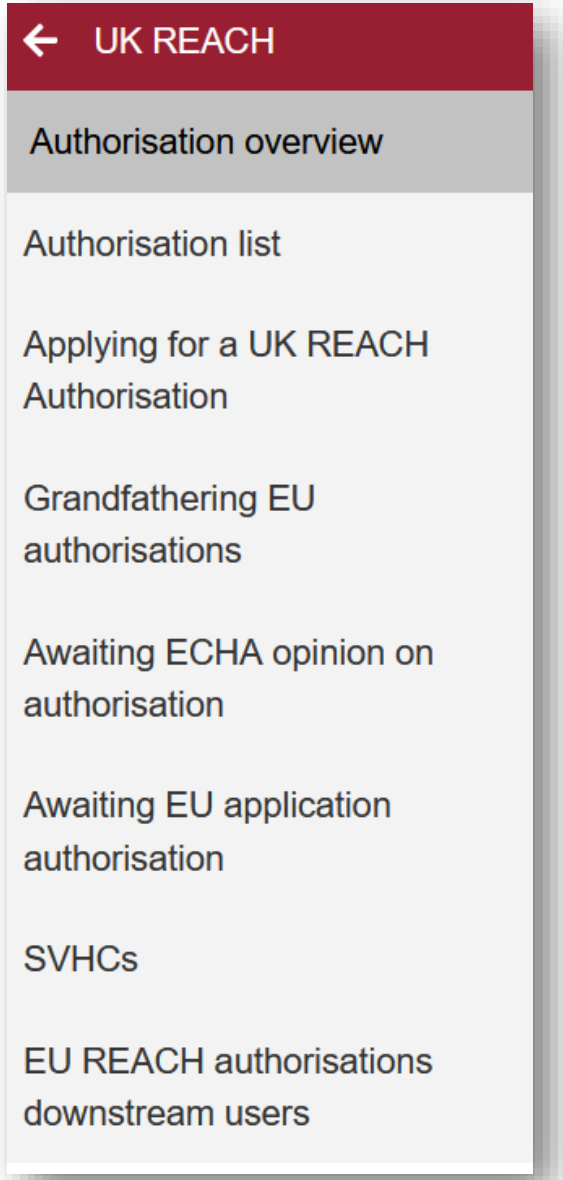
Duration: 20 mins

1. Racap UK REACH authorisation process
2. Case study – same applications submitted for both regulations
3. Looking to the future

UK REACH Authorisation recap
UK REACH Transition from EU

- On EU Exit, certain transitional provisions came into force
  - The **ECHA candidate list as at December 31 2020** was **transposed into UK REACH**
  - The EU REACH ***Authorisation list*** was **transposed into UK REACH.**
    - Existing *Latest Application Dates* (LAD) and *Sunset Dates* (SSD) did not change
    - Special cases for "in-flight" applications made in advance of an LAD, where the LAD was after 29 March 2017
  - Existing decided Authorisations were grandfathered in
  - "In-flight" applications were resubmitted to UK Authorities
  - Downstream users continued to be covered by upstream EU applications allowing continued use, subject to notification
- **Thereafter, UK REACH for GB entities operates independently of the EU**
  - EU Authorisation does not cover use in GB, candidate & authorisation lists are independent after entry 54



Decision making process
Key Decision Bodies - EU and UK REACH

	EU / EEA		UK	
	Opinion	**Decision**	**Opinion**	**Decision**
Authorisation	RAC / SEAC	REACH COM	HSE & Risep	Defra SoS

HSE Health and Safety Executive (case team & Secretariat)

RISEP UK REACH Independent Scientific Expert Pool

Defra Government Department of the Environment, Food and Rural Affairs

SoS Secretary of State for Environment, with the concurrence of the devolved administrations (Scotland and Wales)

UK REACH Authorisation

UK REACH Authorisation Decision Making and Granting

- The UK Agency within the HSE performs all functions of ECHA in the EU
  - Supported by the REACH independent scientific expert pool ("RISEP")

- These draft the UK Agency opinion which is then passed to central government
  - The **Secretary of State for DEFRA** makes final Authorisation decisions with consent of the devolved Wales and Scotland administrations.

HSE Health and Safety Executive

UK REACH Independent Scientific Expert Pool (RISEP)

HSE acts as the Agency for UK REACH. Independent experts advise on the safety of chemicals and support the Agency's scientific opinions.

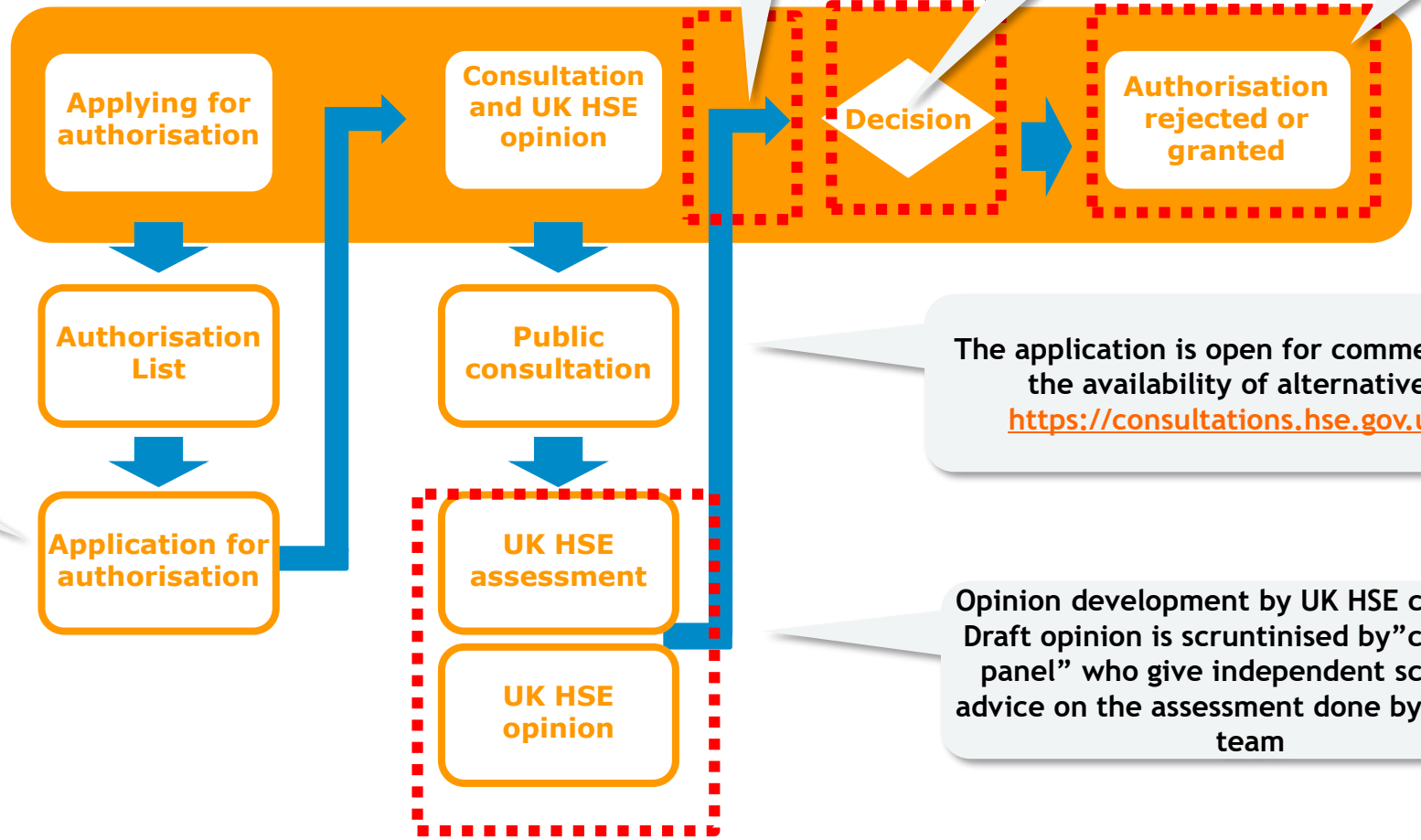
RISEP members are scientific experts in:

- environmental risk assessment
- human health toxicology
- human health exposure and control
- chemistry/regulatory science
- economics/impact assessment

Department for Environment Food & Rural Affairs

UK REACH process steps

Actors involved



Applicant(s) prepare an application covering one or more uses of the listed chemical

The application is open for comments on the availability of alternatives https://consultations.hse.gov.uk/

Opinion development by UK HSE case team Draft opinion is scruntinised by"challenge panel" who give independent scientific advice on the assessment done by the case team

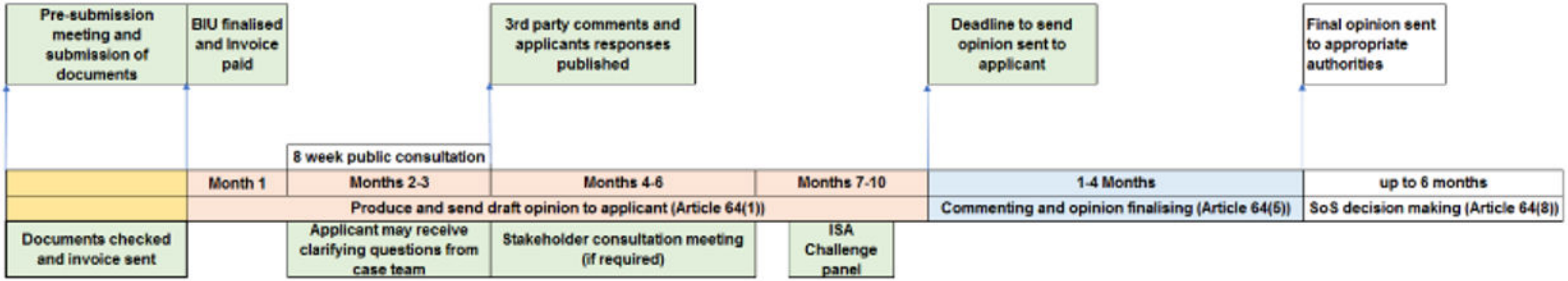
Opinion Adopted

Decision approved by the UK Secretary of State for DEFRA

Decision issued to the applicant and published on the HSE website

UK REACH Authorisation

Timeline for the UK application process



Key
Prior to 10 month deadline (deadline starts when invoice paid)
10 month period to produce and send opinion to applicant
Key steps applicant is involved in
Commenting and opinion finalising period

1. Racap UK REACH authorisation process
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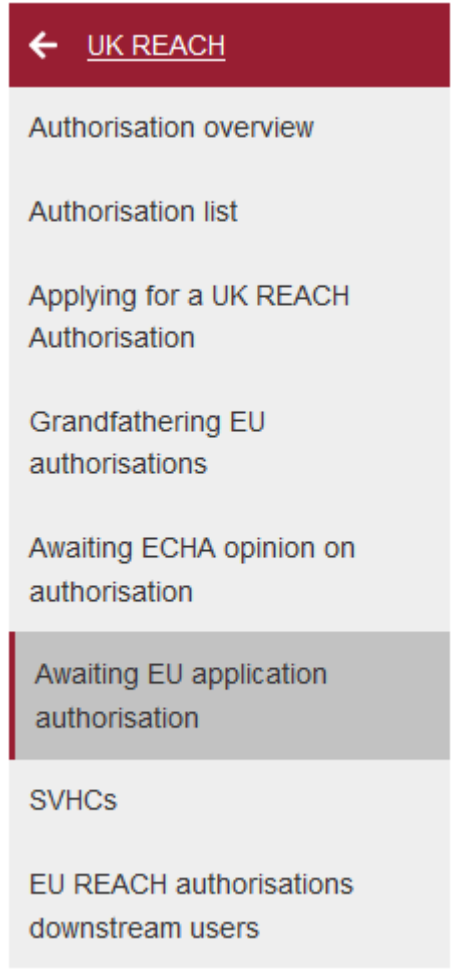
Same application – same assessment outcome?
Transitional arrangement application case studies

- Many EU applications with GB users were “in-flight” on the 1st January 2021
- Those that fulfilled the criteria for transitional arrangements submitted applications for GB uses during the 18 month period
  - This means that the same applications were submitted under both EU and UK REACH processes
  - Interesting to have a look at similarities and differences in the assessment and outcomes
- **Case study considered:**
  - Entries 42 & 43: Octlyphenol ethoxylates (OPnEO) & Nonylphenol ethoxylates (NPnEO))
    - Property of concern: endocrine disrupting chemicals
  - *Details taken from publicly available information from ECHA and UK websites*



Applying for UK REACH authorisation – getting started

Applying for a UK REACH Authorisation

The existing EU Authorisation list (Annex XIV) (as it stood at the end of the Transition Period) has been retaine under UK REACH. The same **latest application dates** (LADs) and **sunset dates** (SDs) apply except for entries 44 to 54 whose LADs are amended to 18 months after the end of the transition period (Article 127GA (7)&(8)). Additionally, in certain situations where an application was made before the EU LAD but was not granted by the end of the transition period special transitional provisions apply giving those applicants an extended LAD to submit an application under UK REACH.

The process for applying for an authorisation under UK REACH is very similar to the EU process and much of the ECHA guidance and templates can be used. There is information on the ECHA website on how to identify whether you need to apply for authorisation and how you can prepare.

If you think you will need to apply for UK REACH authorisation you should contact the Agency in the first instance to notify your intention at ukreach.authorisation@hse.gov.uk, using the subject "notification of intention to submit an application for authorisation".

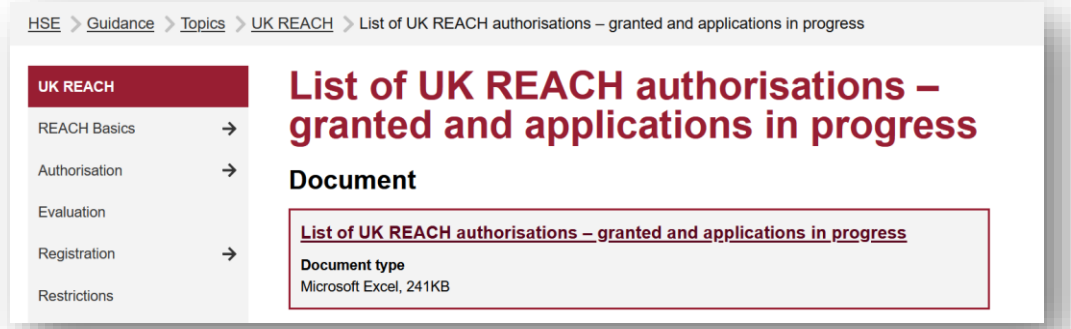
The following information should be provided:

- Foreseen submission date
- The Substance(s) and use(s)for which the application will be made
- The applicant(s) and role(s) in the supply chain
- Contact details

- No specific UK REACH Guidance or templates yet available
- Advice on the UK HSE site is to use the ECHA guidance and templates

- Approach taken
  - ✓ Update the existing application to refer solely to GB based downstream users
  - ✓ Take RAC & SEAC recommendations into account in preparing the reports

UK REACH Authorisation
Case study



UK application

Reference	Annex 14 entry number	Application Type	Applicant	Use applied for	Status	Public Consultation Documents (non-confidential parts of the application & Broad information on use(BIU))	Comments received in Public Consultation (Y/N) & responses to comments if received	Any additional relevant non-confidential information	Agency Opinion	Challenge panel summary or justification for not using ISA	Authorisation Decision & Reason for decision	UK Authorisation number	Expiry date	Deadline for review report
AFA007-01	42 43	Initial	IDEXX Laboratories Limited	Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and use of 4-Nonylphenol, branched and linear, ethoxylated in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions	Opinion adopted	Link to public consultation and associated documents - AFA007 - 4-tert-OPnEO/4-NPnEO	N		Agency Opinion (public) - AFA007-01	Challenge panel summary - AFA007-01	AFA007-01 Decision	UKREACH/23/02/0	30.6.2034	30.12.2032

EU application

0185-03	Initial	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated	-	-	IDEXX B.V. [name of the applicant in the original application: "IDEXX EUROPE B.V." updated due to a notified corporate name change] IDEXX Montpellier SAS	Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions	Commission decided	Details

https://www.hse.gov.uk/reach/applications-for-authorisation.htm
https://echa.europa.eu/fi/applications-for-authorisation-previous-consultations

Case study: Applications for uses of OPnEO & NpEO
EU REACH assessment

- RAC opinion on risk related considerations
  - Non-threshold substances (endocrine disrupting chemicals)
  - No “predicted no effect concentration level” (PNEC) derived
  - Exposure assessment will consider the appropriateness and effectiveness of the operating conditions and risk management measures in place to minimise releases to the environment
- ECHA committee assessment of applications received
  - RAC: releases to the environment (kg released to aquatic compartment)
  - SEAC: cost benefit analysis based on the cost of avoided emissions

https://echa.europa.eu/documents/10162/17229/npneo_and_opneo_for_agreement_final_en.pdf/026cbafc-6580-1726-27f3-476d05fbeef0

Applications for uses of OPnEO & NpEO
EU REACH assessment & outcome

- Commission decisions
  - Review periods requested generally granted
  - Conditions of use imposed on the authorisation holders and downstream users to collect all detergent containing waste for adequate treatment

Article 3

The authorisation bearing numbers REACH [redacted] shall be subject to the following condition: the authorisation holders and their downstream users shall collect all solid waste and wastewater contaminated with 4-tert-OPnEO or 4-NPnEO for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release into the sewer system or to surface waters does not constitute adequate treatment.

Article 5

Where the authorisation holders submit a review report, it shall include the following:

(b) as regards the authorisation bearing numbers REACH/22/43/2 to REACH/22/43/5, a representative survey concerning the downstream users' methods of collection and treatment in accordance with the condition referred to in Article 3.

List of all EU applications available on the Commission website: https://ec.europa.eu/docsroom/documents/51878

Applications for uses of OPnEO & NpNEO
UK REACH assessment

- No specific information available from the UK HSE on how to derive risk
- Application reports submitted following the same approach as for EU REACH taking the conditions of use recommended by the ECHA committees into account
  - SEA route – cost of avoided emissions
  - Exposure scenario: no emissions to the environment
- However the UK HSE assessment approach for risk was quite different
  - The Agency compared PECs with **Environmental Quality Standards (EQSs)** proposed for **ethinylestradiol (EE2),** an endocrine disruptor with the same estrogenic mode of action
  - Conclusion: residual emissions coming from the use (ca. 100 kg) would not result in discernible environmental impacts on wildlife in the receiving surface waters

PROPOSED CONDITIONS, MONITORING ARRANGEMENTS AND RECOMMENDATIONS

No additional conditions for the authorisation are proposed.

No monitoring arrangements for the authorisation are proposed.

No recommendations for the review report are made.

EU application - ECHA committee opinion
Extracts with the rationale

In this application, the applicants did not derive PNEC(s). Therefore, RAC concluded, in accordance with Annex I of the REACH Regulation, that for the purposes of the assessment of this application it was not possible to determine PNEC(s) for the endocrine disrupting properties for the environment of the substance.

RAC did not evaluate the predicted environmental concentrations (PECs) provided by the applicants since 4-tert-OPnEO are treated as a non-threshold substance with regard to its endocrine disrupting properties for the environment and therefore no appropriate PNECs are available for comparison, nor is the Water Framework Directive EQS value considered to be suitable for this purpose.

3.3. Conclusions on risk characterisation

RAC is of the view that the applicants **have not** demonstrated that releases to environment have been minimised as far as technically and practically possible.

RAC

Proposed additional conditions

All solid and liquid waste shall be collected for adequate treatment. The treatment shall minimise releases to environmental compartments as far as technically and practically possible. Release to the sewer system or to surface waters is not considered as adequate treatment.

UK application – UK HSE opinion
Extracts with the conclusions

THE OPINION OF THE UK AGENCY

Summary: The Agency has assessed the application and has concluded that the OCs and RMMs have been shown to be appropriate and effective at limiting the risks. There are currently no technically or economically feasible alternatives and the socioeconomic benefits from the use of the substance are significant and positive. If authorisation is granted, the Agency recommends a review period of 12 years.

The Agency concluded that the operational conditions and risk management measures described in the application **are** appropriate and effective in limiting the risk.

The use applied for may result in up to 100kg per year releases of the substances to the environment.

The Agency has estimated that the use applied for may result in approximately 130kg of emissions of 4-tert-OPnEO and 4-NPnEO over 12 years to the environment. Given that the impact of these emissions cannot be quantified using the threshold approach for the SVHC, the Agency assessed environmental risk by reference to a well-characterised endocrine disruptor with the same mode of action; ethinylestradiol. Taking into account differences in potency, the Agency concluded that the use applied for will have no discernible environmental impacts in relation to endocrine disruption. Consequently, the socio-economic benefits are higher than the associated risks.

https://www.hse.gov.uk/reach/applications-for-authorisation/ra-aahz-0408.pdf

UK HSE opinion
Extracts with the rationale

The applicant has treated 4-tert-OPnEO & 4-NPnEO as non-threshold substances and did not attempt to derive PNECs or RCRs. This approach is in line with the EU REACH guidance paper "Risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO" and the Committee for Risk Assessment's (RAC) conclusion at its 50th meeting (November 2019) that a reliable threshold for endocrine disrupting effects could not be determined based on currently available data.

The applicant has chosen the SEA route for the application, and the case for authorisation has been considered on that basis, in terms of the benefits and costs (risks). Our evaluation of the environmental risks uses an indirect threshold type approach (i.e. via comparison of the PECs to ethinylestradiol (EE2) as discussed below in 4.4). However, we have used our findings to weigh up the benefits and costs of authorisation, rather than to draw any conclusions about adequate control.

https://www.hse.gov.uk/reach/applications-for-authorisation/ra-aahz-0408.pdf

UK HSE opinion
EQS – something new

Environmental quality standards (EQS)
Value for chemical (EE2) with same mode of action was taken as a proxy for PNEC

The Agency did not directly evaluate the predicted environmental concentrations (PECs) provided by the applicant since they treat 4-tert-OPnEO & 4-NPnEO as non-threshold substances for their endocrine disrupting properties for the environment and therefore no appropriate PNECs or other benchmark values such as Environmental Quality Standards (EQSs) are available for comparison. However, the Agency has compared the surface water PECs with EQSs[12] proposed for ethinylestradiol (EE2), an endocrine disruptor with the same estrogenic mode of action[13]:

- The recommended chronic (annual average) EQS for freshwater was 0.0032 ng/L; and
- The recommended chronic (annual average) EQS for saltwater was 0.0016 ng/L.

The comparison made by the Agency between EE2 and 4-tert-OPn is based on the available ED data where apical effects were measured as sourced from Parrott *et al.,* 2016 [14], and the SVHC dossier. 4-tert-OPn was concluded to be an SVHC[9] due to adverse effects in fish that were considered to be estrogen mediated. Therefore, we consider the comparison to EE2, a highly potent estrogen, to be reasonable. The same approach is also considered to be reasonable for the comparison with 4-NPn[10] and EE2.

Although there are uncertainties in the comparison, given the much greater potency of EE2 (100 - 1000 times more potent), the Agency has been able to conclude that the environmental exposure would not cause adverse impacts on aquatic species through endocrine disruption. It has not been

The use applied for may result in some emissions of 4-tert-OPnEO and 4-NPnEO to the environment which could potentially be transformed to 4-tert-OPn and 4-NPn respectively. Based on comparisons of the applicants PECs for 4-tert-OPnEO and 4-NPnEO with the EQS for endocrine disruptor ethinylestradiol, which has the same mode of action but is more potent, the Agency considers that these residual emissions would not result in discernible environmental impacts on wildlife in the receiving surface waters, should any inadequate disposal of waste occur. The overall risks to wildlife in surface water from the wide-dispersive environmental emissions of 4-tert-OPnEO and 4-NPnEO are not considered significant when compared to EE2.

https://www.hse.gov.uk/reach/applications-for-authorisation/ra-aahz-0408.pdf

Challenge panel
Review of opinion

11. Challenge Panel's Recommendation on the Draft Opinion?

At the Challenge Panel meeting held on 13 September 2022, the Panel agreed with the Agency's recommendation that an authorisation should be granted and made the following consensus recommendations to the Agency:

4	Agency to consider including conditions proposed by the CP (in written comments and at the meeting) i. Good product stewardship to propagate best practices with customers – IDEXX to ensure customers are following the information on the SDS and minimising emissions e.g., providing product training for customers (including disposal) ii. IDEXX to provide updates to the Agency on their progress against the substitution plan (every 3 years) iii. IDEXX to get information from DUs on a regular basis regarding volumes of liquid waste and how the waste is disposed of. This information should be collated and provided to the Agency.	The Agency does not believe it would be beneficial to include these conditions for the reasons outlined below.

i & ii. Whilst we understand the reason for this suggestion, we feel it is unlikely to add value and will not carry it forward. A significant proportion of the use covered by this application is in the SNAP tests and a SDS is not legally required for these. We understand that advice on disposal is already provided and many used tests will be disposed of as clinical waste (due to use testing biological samples). For the ELISA test use, the users are lab technicians and training is the responsibility of their employers, not their suppliers. Although this is a good suggestion, we feel it is unlikely to add value. Any regular updates during the review period would be 'for information only'. If the applicant were to successfully substitute, then the use of OPnEO/NPnEO would cease and any time remaining in the review period would be redundant. If the applicant was not successful in their substitution efforts, any progress made would be documented in a review report (should the applicant wish to continue use of OPnEO/NPnEO). It is at this point that an update on their progress would add value as this information would be assessed by the Agency during the opinion-forming process.

iii. Although this is a good suggestion, we feel it is unlikely to add value. We've already modelled and made the assessment on a worst-case basis were all of the substances are released to the environment and they all degrade into their respective phenols. Further information on actual waste volumes could only show that wastes were lower than our worse-case assumption.

Case study 1: differences and similarities
EU and UK REACH assessment & outcome

- Key outcome the same
  - Authorisation granted for 12 years
- Methodology used in the assessment quite different
  - EU: SEA route with costs of avoided emissions; do not derive PECs!
  - UK: combination approach – SEA and semi-adequate control; derive PECs!
- Opinion making
  - EU: RAC note on approach available before application – no surprises in the opinion making
  - UK: no info available – assessment approach only apparent in the Challenge Panel meeting
- Conditions of use recommended
  - EU: collect all waste!
  - UK: level of emission to the environment coming from the use will not have a discernible environmental impact
- Cross-talk between applications?
  - Absolutely none – no reference at all to the EU application, opinion or decision in the UK assessment and opinion

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UK REACH Authorisation
Our experience

- Our experience so far with applications grandfathered into UK REACH & applications submitted under transitional arrangements
  - UK HSE very helpful to the applicants
  - Process runs well with few delays (volume of applications received so far low)
  - IT system for submissions and communication not yet in place but has not hindered the process
  - Qs from case team much more targeted to national legislation (COSHH)
    - Recent chrome plating applications – UK HSE team asked the applicant to complete a questionnaire specifically relating to COSHH compliance
  - No UK specific guidance available – ok to use EU guidance
  - No UK specific templates – ok to use EU templates
  - UK process has far fewer actors involved in the assessment and decision making – more agile?

UK/EU REACH Authorisation process in practice

Heavy versus lean decision making?

Process steps	EU actors	UK actors
Assessment of the application and preparing draft opinion	2 sets of rapporteurs appointed from 2 standing committees with experts nominated by the 27 EU member states (RAC & SEAC)	Case team from 1 agency
Review of draft opinion	RAC and SEAC	Group of independent experts (RISEP) appointed to a challenge panel
Decision making	Comitology procedure REACH Committee with representatives nominated by each EU member state	UK government minister Secretary of State for DEFRA

3 committees feed into the EU process – consensus/qualified majority can be a challenge due to number of committee members
UK process – more agile?

UK Authorisation process state of play
Up and running – looking at challenges ahead

- Process up and running – no delays
- Low numbers of applications submitted to date but numbers expected to increase significantly with the expiry of review periods
- Some interesting challenges for them ahead
  - Will they develop their own guidance?
  - How will they process upstream applications – will these unloved applications have a harder/easier time to getting through the process?
    - Review reports from upstream authorisation holders now under assessment (ADCR applications)
    - Same applications are also under review under EU REACH
  - Will the UK HSE be more willing to refuse authorisation (the EU process has refused only a handful out of the 200+ processed so far)
  - Will longer review periods be granted?
  - What about EU REACH 2.0 (and the very recently proposed restriction for CrVI substances!)

Divergence in authorisation lists post 2021
Already divergence and more to come

- UK REACH and EU REACH are separate regulations since 1st January 2021
  - there is already divergence
- Currently UK and EU Authorisation Lists have 54 & 59 entries respectively
  - 5 entries added to EU List in April 2022, no new entries added to UK list to date
- Any chemical with SVHC status is a candidate for future inclusion on the Authorisation List
  - e.g. 26 additional entries added to the EU SVHC list since January 2021 but not to the UK list
  - 8 additional entries recommended by ECHA for inclusion on the EU Authorisation list but only 2 (dicyclohexylphthalate and disodium octaborate) were recommended by the UK HSE for inclusion on the UK Authorisation list
- Commission and UK Secretrary of State may not include the same entries on the EU and UK Authorisation Lists
  - UK Candidate List: https://www.hse.gov.uk/reach/candidate-list.htm
  - UK recommendation list: https://www.hse.gov.uk/reach/recommendations.htm

Divegence in EU and UK applications processes
Looking to the future

- **Today:** A lot of similarities between EU and UK REACH authorisation process
  - 54 entries in common, application process follows the same logic (submission, assessment, opinion making, decision taking, granting/refusal)
- **Next 1-2 years:** some more divergence likely in the coming years in terms of entries
  - Different entries recommended for inclusion on the Authorisation Lists
  - Different entries ultimately included
- **Next 2-5 years:** potentially massive divergence
  - Oct 2023 proposal to delist of chromium trioxide and chromic acid from the EU list
  - The ongoing reform of the EU Authorisation process under the EU Chemicals Strategy for Sustainability
    - the process will be changed and there will be a period of transition between old and new
  - No indication to date on how the UK government will react

Thank You for Your Attention!

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