Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Opinion

on an Application for Authorisation for

Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane

Use: Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications)

ECHA/RAC/SEAC: AFA-O-0000004949-56-11/D

Consolidated version

Date: 08 January 2015

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Consolidated version of the

Opinion of the Committee for Risk Assessment
and
Opinion of the Committee for Socio-economic Analysis

on an Application for Authorisation

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular Chapter 2 of Title VII thereof, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have adopted their opinions in accordance with Article 64(4)(a) and (b) respectively of the REACH Regulation with regard to an application for authorisation for:

Chemical name(s):	**Hexabromocyclododecane (HBCDD), alpha-hexabromocyclododecane, beta-hexabromocyclododecane, gamma-hexabromocyclododecane**
EC No.:	**221-695-9, 247-148-4**
CAS No.:	**3194-55-6, 25637-99-4, 134237-50-6, 134237-51-7, 134237-52-8**

Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications)

Intrinsic property referred to in Annex XIV:

Persistent, bioaccumulative and toxic (Article 57(d) of the REACH Regulation)

Applicants and reference numbers:

INEOS Styrenics Netherlands BV	**11-0000000360-88-0000**
INEOS Styrenics Ribecourt SAS	**11-0000000360-88-0002**
INEOS Styrenics Wingles SAS	**11-0000000360-88-0004**
Synthos Dwory 7 spółka z ograniczoną odpowiedzialnością spółka komandytowo-akcyjna.	**11-0000000360-88-0006**
Synthos Kralupy a.s.	**11-0000000360-88-0008**
StyroChem Finland Oy	**11-0000000360-88-0010**
Monotez SA	**11-0000000360-88-0012**
RP Compounds GmbH	**11-0000000360-88-0014**
Synbra Technology bv	**11-0000000360-88-0016**
Sunpor Kunststoff GmbH	**11-0000000360-88-0018**
Dunastyr Polystyrene Manufacturing C. Co. Ltd	**11-0000000360-88-0020**
Versalis SpA	**11-0000000360-88-0022**
Unipol Holland bv	**11-0000000360-88-0024**

Rapporteur, appointed by the RAC: **Hans-Christian Stolzenberg**
Co-rapporteur, appointed by the RAC: **Pietro Paris**

Rapporteur, appointed by the SEAC: **Åsa Thors**
Co-rapporteur, appointed by the SEAC: **Karen Thiele**

This document compiles the opinions adopted by RAC and SEAC.

PROCESS FOR ADOPTION OF THE OPINIONS

On 13 February 2014 the applicants submitted an application for authorisation including information as stipulated in Articles 62(4) and 62(5) of the REACH Regulation. On **29 April 2014** ECHA received the required fee in accordance with Fee Regulation (EC) No 340/2008. The broad information on uses of the application was made publicly available at http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/applications-for-authorisation on **14 May 2014**. Interested parties were invited to submit comments and contributions by **9 July 2014**.

The draft opinions of RAC and SEAC take into account the comments of interested parties provided in accordance with Article 64(2) of the REACH Regulation as well as the responses of the applicants.

The draft opinions of RAC and SEAC take into account the responses of the applicants to the requests that the SEAC made according to Article 64(3) on additional information on possible alternative substances or technologies.

The draft opinions of RAC and SEAC were sent to the applicants on **18 December 2014**.

On **07 January 2015** the applicants informed ECHA that they did not wish to comment on the opinions. The draft opinions of RAC and SEAC were therefore considered as final on **08 January 2015**.

ADOPTION OF THE OPINION OF RAC

The draft opinion of RAC

The draft opinion of RAC, which assesses the risk to human health and/or the environment arising from the use of the substance – including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives – was reached in accordance with Article 64(4)(a) of the REACH Regulation on **25 November 2014**.

The draft opinion of RAC was agreed by consensus.

The opinion of RAC

Based on the aforementioned draft opinion and in the absence of comments from the applicants, the opinion of RAC was adopted as final on **08 January 2015.**

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC, which assesses the socio economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as described in the application was reached in accordance with Article 64(4)(b) of the REACH Regulation on **27 November 2014**.

The draft opinion of SEAC was agreed by consensus.

The opinion of SEAC

Based on the aforementioned draft opinion and in the absence of comments from the applicants, the opinion of SEAC was adopted as final on **08 January 2015**.

THE OPINION OF RAC

RAC has formulated its opinion on the risks arising from the use applied for and the appropriateness and effectiveness of the described risk management measures, and on the assessment of the risks related to the alternatives as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

RAC confirmed that it is not possible to determine a PNEC or RCRs for the persistent, bioaccumulative and toxic properties of the substance in accordance with Annex I of the REACH Regulation.

RAC considers that, based on the information provided by the applicants, the uncertainties in the exposure assessment are too high to conclude on the remaining risk of the use applied for. RAC considers that the emissions to the environment for this use have not been adequately described in the application. As a consequence, RAC was unable to evaluate the appropriateness and effectiveness of implemented and proposed operational conditions and risk management measures in reducing the risks.

However, should an authorisation be granted, RAC recommends the additional conditions and monitoring arrangements described below.

The duration for the review period has been suggested below.

THE OPINION OF SEAC

SEAC has formulated its opinion on the socio-economic factors and the availability, suitability and technical and economic feasibility of alternatives associated with the use of the substance as documented in the application and on information submitted by interested third parties as well as other available information.

The application included the necessary information specified in Article 62 of the REACH Regulation that is relevant to the Committee's remit.

SEAC took note of RAC's confirmation that it is not possible to determine a PNEC or RCRs for the persistent, bioaccumulative and toxic properties of the substance in accordance with Annex I of the REACH Regulation.

SEAC confirmed that there do not appear to be suitable alternatives in terms of their technical and economic feasibility for the applicants at the time the application was submitted.

SEAC took into account RAC´s assessment on the emissions and the risk. Furthermore, SEAC evaluated the applicants´assessment of (a) the potential socio-economic benefits of the use, (b) the potential adverse effects to human health or the environment of use and (c) the assessment used to compare the two. SEAC considered that the large uncertainties in the socio-economic analysis make it difficult to use cost-effectiveness as the sole basis on which to conclude on if the benefits of an authorisation would outweigh the risks. However, based on the general consideration that this authorisation was requested to address a temporary shortage in the availability of a suitable alternative to HBCDD (i.e. a

bridging application), SEAC concludes that the benefits of granting the authorisation may outweigh the risks (approximated by the potential emissions to the environment).

Should an authorisation be granted, SEAC recommends the additional conditions described further below.

The duration for the review period has been suggested below.

Use

The authorisation is considered for the following use:

Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications) ("Use 1")

SUGGESTED CONDITIONS AND MONITORING ARRANGEMENTS

Conditions

The following conditions are recommended in case the authorisation is granted:

- In addition to the mandatory implementation of the operational conditions and risk management measures described in the application the applicants should implement where possible the best practices in emission reduction described in section 6 of the justifications.
- For the applicants to substitute to the polymeric flame retardant ("pFR") as soon as sufficient supply is available and testing has been conducted with a positive result and no later than 21/08/2017. During the review period the applicants should communicate the progress of the work on phasing in the alternative pFR in terms of production capacity, sufficient supply and test results to the Commission in relation to the requirements of Article 61(1) of the REACH Regulation.

Monitoring arrangements

The following monitoring arrangements are recommended in case the authorisation is granted:

- The applicants performing Use 1 (i.e. "formulators") should put in place a monitoring programme to quantify release factors and emissions of the substance to environmental compartments during all activities described in Use 1 for the period of the authorisation.
- The monitoring programme should consider emissions to air, water and land from all the formulation sites.
- Annually, applicants should prepare a report that contains the results obtained from the monitoring programme. The annual report should also include details of the methodology used to obtain the results e.g. sampling points and frequency (at least monthly) and details of any relevant analytical methodology.
- Upon request, applicants should provide national enforcement bodies with the annual reports. Any review report in terms of Article 61(1) of the REACH Regulation should include the results of the monitoring programme.

REVIEW

Taking into account the information provided in the analysis of alternatives prepared by the applicants and the comments received on the broad information on use the duration of the review period for the use is recommended to be 2 (two) years.

JUSTIFICATIONS

Substance name: **Hexabromocyclododecane (HBCDD)**
alpha-hexabromocyclododecane,
beta-hexabromocyclododecane,
gamma-hexabromocyclododecane

Use name[1]: Formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using hexabromocyclododecane as the flame retardant additive (for onward use in building applications)

Applicants and reference numbers:

INEOS Styrenics Netherlands BV	11-0000000360-88-0000
INEOS Styrenics Ribecourt SAS	11-0000000360-88-0002
INEOS Styrenics Wingles SAS	11-0000000360-88-0004
Synthos Dwory 7 spółka z ograniczoną odpowiedzialnością spółka komandytowo-akcyjna.	11-0000000360-88-0006
Synthos Kralupy a.s.	11-0000000360-88-0008
StyroChem Finland Oy	11-0000000360-88-0010
Monotez SA	11-0000000360-88-0012
RP Compounds GmbH	11-0000000360-88-0014
Synbra Technology bv	11-0000000360-88-0016
Sunpor Kunststoff GmbH	11-0000000360-88-0018
Dunastyr Polystyrene Manufacturing C. Co. Ltd	11-0000000360-88-0020
Versalis SpA	11-0000000360-88-0022
Unipol Holland bv	11-0000000360-88-0024

The justifications for the opinion are as follows:

1. The substance was included in Annex XIV due to the following property / properties:

☐ Carcinogenic (Article 57(a))

☐ Mutagenic (Article 57(b))

☐ Toxic to reproduction (Article 57(c))

☒ Persistent, bioaccumulative and toxic (Article 57(d))

☐ Very persistent and very bioaccumulative (Article 57(e))

☐ Other properties in accordance with Article 57(f) [please specify]:

[1] Referred as “Use 1” in this document. “Use 2” in this document refers to the other use applied for an authorisation by the same applicants, i.e. “*Manufacture of flame retarded expanded polystyrene (EPS) articles for use in building applications*”

2. Is the substance a threshold substance?

☐ YES

☒ NO

Justification:

The substance HBCDD was included in Annex XIV of REACH because the inherent substance properties fulfil the criteria of Art. 57 (d) and of Annex XIII 1.1, 1.2 and 1.3. PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long time periods. Historical cases have shown that the effects of such accumulation are unpredictable in the long-term and that exposure is practically difficult to reverse, because an elimination of emissions will not necessarily result in a measurable reduction in chemical concentrations. The properties of the PBT and vPvB-substances lead to an increased uncertainty in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies. For PBT and vPvB substances a PNEC in the environment cannot be established using currently available methods and, accordingly, the quantification of risks is not foreseen in REACH. This means that, and as prescribed in section 4 of Annex I of REACH, a quantitative risk characterisation using a PNEC cannot be carried out with sufficient reliability.

3. Hazard assessment. Are the DNEL(s) appropriate?

Justification:

not applicable

4. Exposure assessment. Is the exposure from the use adequately described?

☐ YES

☒ NO

Justification:

Scope of the assessment and limitations

It is the task of RAC to evaluate the appropriateness and effectiveness of implemented and proposed OC[2] and RMM[3] and to evaluate if the emissions to the environment have been adequately described within the application for authorisation. This is of particular relevance for PBT/vPvB substances without a threshold (cf. section 2.) that are used in high volumes. RAC acknowledges that any exposure assessment comprises assumptions, estimations and approximations, including the effectiveness of, and compliance with, OC and RMM. Uncertainty is therefore inherent to any exposure assessment. Appropriate sensitivity analysis allows the significance of the uncertainty in an exposure assessment to be evaluated.

[2] OC: operational conditions
[3] RMM: risk management measures

RAC notes that the exposure assessment provided by the applicants focuses on the environment and that no worker exposure assessment has been provided. At the stage of drafting this opinion, due to the lack of clarity on the need to address worker exposure for a PBT substance and the scientific rationale and challenge of performing such an assessment, RAC only assessed the environmental exposure assessment provided by the applicants. The applicants claim that they implement the conditions and risk management measures detailed in the extended safety data sheets (eSDS) provided by their suppliers of HBCDD to ensure the safe use by workers.

Information provided by the applicants

A single generic "worst-case" exposure scenario, which covers the use by all applicants, is described in section 9.2 of the CSR[4] (p 66). Information on volumes used and releases to environmental compartments, including subsequent degradation and dissipation are reported.

The exposure assessment provided by the applicants relies heavily on information and documentation developed by VECAP (Voluntary Emissions Control Action Programme), a product-stewardship scheme developed by the European and International flame-retardant industry. VECAP has developed a Code of Good Practice and several BAT documents for the use of polymer additives that the applicants claim to adhere to (i.e. for appropriate handling and disposal of packaging[5] used to transport and store polymer additives). Members of VECAP also undertake self-audit and report information on potential or actual emissions to VECAP secretariat who publish information on emissions in a series of annual reports.

Emissions of HBCDD to the environment (air, land and water compartments) during the formulation of unexpanded flame-retardant EPS beads described in the application are based on the emission factors for HBCDD reported by VECAP in their 2012 annual report (VECAP 2012). Information on the methodology used to derive these emission factors was not included in the application, but was partially clarified during the Trialogue and via questions to applicants during opinion development and are described below.

Discussion

The emission factors for HBCDD presented in the 2012 VECAP annual progress report are aggregated, average emission factors for VECAP members[6] based on their responses to a questionnaire. Emissions of HBCDD from individual members are predicted, in the absence of measured emission data, based on the volume of HBCDD handled in combination with the use of various "default" emission factors associated with a member's specific use of HBCDD (i.e. plastic, textile, EPS, XPS)

[4] CSR: Chemical Safety Report

[5] Throughout this opinion justification the term "packaging" is used to refer to containers (e.g. sacks/bags) used to store and transport HBCDD and not to expanded polystyrene material that is used for packaging purposes.

[6] VECAP 2012 data represents 98 % of the volume of HBCDD sold by European Flame Retardant Association [EFRA] member companies in 2011

and the operational conditions and risk management measures present at a particular site e.g. size of HBCDD packaging used (i.e. 25 kg or 1000 kg) / use of local exhaust ventilation / waste disposal practice, etc.

The emissions factors for HBCDD in the 2012 report incorporate all uses of HBCDD by VECAP members (i.e. including uses in extruded polystyrene [XPS], plastics and minor uses in textiles). It is therefore uncertain, without additional information, to conclude that the aggregated emission factors are representative of either typical or reasonable worst-case emissions associated with the use of HBCDD in the production of unexpanded EPS beads. This is because (i) emissions from the other uses may be significantly different to those associated with unexpanded EPS bead production and (ii) the emissions from the different unexpanded EPS bead producing sites may be significantly different from each other.

In addition, and perhaps more significantly, information on the original methodology and data used to derive the "default" emission factors used by VECAP to estimate the site-specific emissions associated with different OC and RMM were not available to RAC and could therefore not be assessed. This includes the default emission factors associated with the OC and RMM that VECAP consider to represent best-practice for polymer additives.

RAC acknowledges that data on measured emissions can be used in questionnaire responses. However, data on measured emissions for this use supplied by applicants (at the request of RAC) is very limited (no measured data on emissions to air were available and three of 15 sites provided measured emissions data for water). Emissions estimates in the VECAP report are therefore likely to be predominantly based on the "default" VECAP emission factors, or measured data representative of other uses. RAC confirms that the upper range of emissions to water reported by applicants is in the same order of magnitude as the VECAP 2012 estimate. However, based on the limited number of sites for which data are available and the absence of accompanying metadata for most sites (e.g. number of samples and variability) RAC does not consider that these data are representative of the use or could be used to reliably estimate releases of HBCDD to water from the use.

RAC acknowledges that VECAP annual reports are not intended to be used for risk assessment. However, RAC is concerned that the VECAP information used in the application does not adequately describe emissions of HBCDD associated with its use in the production of unexpanded EPS beads. In addition, RAC notes that there is also no obligation to monitor emissions or achieve certification as a requirement of VECAP membership. However, adherence to certain VECAP principles to reduce release of HBCDD is assumed as a technical condition in the exposure scenario. RAC notes that the principles described in the exposure scenarios would become a mandatory condition of use should an authorisation be granted for this use.

The application contains a mass balance estimate for the amount of HBCDD that would be contained in products and released to various environmental compartments associated with the uses applied for and tonnage (Use 1 and Use 2

combined). This mass balance is based on standard default partitioning and fate assumptions used in EUSES and it assumes that a proportion of the release to water is subsequently removed by wastewater treatment. However, in response to a question from RAC, the applicants clarified that the removal efficiency of on-site waste water treatment is already incorporated into the VECAP emissions factors used for estimating the release to water. Therefore, as it is not known if each site is also connected to a municipal wastewater treatment facility, emissions reduction resulting from the additional wastewater treatment described in the mass balance may not be appropriate for all sites. Similarly, whilst applicants confirm that sludge from on-site wastewater treatment was not disposed of via land, it is unclear if similar provisions are in place for any connected municipal wastewater treatment facility. It would therefore seem reasonable for RAC to consider emissions to the aquatic environment and land without the additional municipal wastewater treatment described in the mass balance. RAC notes that the applicant assumes that all of the HBCDD emitted to the aquatic environment accumulates in freshwater sediments.

Some of the exposure scenarios rely on assumptions that differ significantly from the EU Risk Assessment Report for HBCDD (RAR, EC 2008), which is considered by RAC as a relevant reference. These deviations between the RAR and the CSR are not considered by RAC to have been adequately justified and documented by the applicants. The assumptions of the applicant lead to emissions that are significantly lower than those that are described in the RAR (EC 2008).

Based on the considerations above, RAC considers that the exposure from the use is not adequately described by the 2012 VECAP emission factors. This is primarily because the methodology used to derive the default emission factors, including those of the OC and RMM associated with best practice, were not available for assessment / verification by RAC and that the aggregated emission factors for VECAP are also based on emissions from other uses (e.g. XPS and textile uses).

Sensitivity analysis

In order to provide an appropriate estimate of the potential range of emissions associated with this use for SEAC, and in the absence of appropriate measured data on emissions, RAC requested the applicants to undertake a sensitivity analysis of total emissions for both Use 1 and Use 2 that compared the applicants' assumptions with reasonable worst-case assumptions suggested by RAC. Reasonable worst-case assumptions for Use 1 were based on emission factors from a previous VECAP annual report (2008) whilst those for Use 2 used selected factors from the RAR for HBCDD (EC 2008). The sensitivity analysis was based on the applicants' mass balance calculations (supplied to RAC as an excel template). In addition RAC decided that the sensitivity analysis should include the emissions related to article end of life (building demolition and incineration). RAC highlights that the methodological issues and information gaps identified in earlier parts of this opinion are not addressed by this sensitivity analysis. However, the results

provide a relevant potential range of emissions that could be associated with the use[7].

Table 1: Modified emission factors for reasonable worst case exposure assessment relevant to Use 1:

Emission factor	Applicants' assumptions (2012 VECAP)	Reasonable worst-case (2008 VECAP)	% reduction in emission compared to 2008
Land[8]	1 g/t	170 g/t	94,4%
Water	2 g/t	7 g/t	72%
Air	16 g/t	35 g/t	54%

These emission reductions occur, according to VECAP, because of the progressive implementation of the VECAP Code of Practice from 2008 to 2012 at formulation sites. The greatest reduction between 2008 and 2012 relates to emissions to land, which was the result of a change in the practice used to dispose/recycle used packaging material or wastewater treatment sludge that contained residual HBCDD. According to VECAP best practice, used packaging should not be disposed of to uncontrolled landfill or recycled and should instead either be disposed of in a chemically secure landfill or in an approved chemical waste incinerator. Wastewater treatment sludge should not be applied to agricultural land. The VECAP 2012 annual report describes that 96% of packaging waste was handled in accordance with VECAP best practices. RAC notes that emissions to the environment from incineration and landfill are assumed to be negligible under the VECAP scheme but in the application a small proportion of HBCDD is assumed to be released from incineration and landfill.

Based on the use of 32,000 metric tonnes of HBCDD (8,000 t/a during four years from 2015) and the release factor assumptions from the applicants (with minor adjustments for correction), the total releases to the environment are calculated as 5.17 tonnes HBCDD[9], of which 3.2 tonnes are to be released, delayed by decades, from demolition and disposal. The total release equates to a release factor of 0.016%. This release factor would also apply to greater or lower use tonnages.

RAC contrasts this estimate with a conceivable realistic worst case based on the release factor assumptions for formulation taken from the 2008 VECAP annual report (Use 1) and, from RAR, the release factor for cutting during professional

[7] RAC requested that the applicants incorporate potential emissions from all life-cycle stages (including at the end of service life) in the sensitivity analysis of their mass balance. However, the applicants chose not include end of service life emissions in their sensitivity analysis. Therefore, RAC incorporated these end of service life emissions in the mass balance. In addition, the applicants incorrectly applied the worst-case emission factor suggested by RAC for ES2b to ES2a. RAC corrected this error in the mass balance calculations presented in this opinion.

[8] Emissions to land result from disposal of HBCDD packaging via uncontrolled landfill or disposal of wastewater sludge or recycling wastes to agricultural land.

[9] Errors in the original mass balance figures presented by the applicant that were corrected in the mass balance information subsequently supplied to RAC lead to minor differences between the estimates presented here and the original CSR.

use and proportion of manual deconstruction (Use 2). Under this scenario, the total release resulting from the use of 32,000 tonnes of HBCDD equates to 29.17 tonnes, of which 23.6 tonnes are expected from delayed demolition and disposal. The resulting total release factor is 0.091%, i.e. almost 6 times greater. The main driver for this difference are deviating assumptions for how demolition at end of life will take place (the applicants assume 100% manual deconstruction, whilst the RAR assumes 30% manual deconstruction). It should be noted that in the reasonable worst case scenario RAC still assumed that all recovered EPS is disposed of via incineration (described by the applicants as a mandatory condition).

The differences between the total release estimates without demolition and disposal, i.e. 1.97 tonnes according to the applicants' assumptions *versus* 5.59 tonnes in the realistic worst-case assumption, are driven by the reduction in emissions from 2008 to 2012 as reported by VECAP (see table above) for Use 1 and release factor assumptions for EPS boards cutting at construction sites (Use 2). As these reductions are not verified by adequate measurements, and based on assuming adherence to the VECAP BAT scheme without fail, RAC considers the ca. 2.8-fold higher estimate is a reasonable indicator for the range of some quantified uncertainties in the applicants' exposure assessment.

Table 2: summary of key release estimates:

	Assumptions in the application for authorisation		**Reasonable worst-case assumptions**	
	Tonnes (if 32,000 tonnes HBCDD are used)	Release factor [%]	Tonnes (if 32,000 tonnes HBCDD are used)	Release factor [%]
Total release	**5.17**	**0.016**	**29.17**	**0.091** (5.6-fold)
Release – excluding demolition and disposal	1.97	0.006	5.59	0.017 (2.8-fold)
Delayed release from demolition and disposal	3.20	0.01	23.58	0.074 (7.4-fold)

Conclusion

RAC considers that the emissions to the environment for this use have not been adequately described in the application. As a consequence, RAC was unable to evaluate the appropriateness and effectiveness of implemented and proposed OC and RMM in reducing the risks.

5. If considered a threshold substance, has adequate control been demonstrated?

☐ YES

☐ NO

Justification:

not applicable

6. If adequate control is not demonstrated, is the remaining risk reduced to as low a level as is technically and practically possible?

Justification and concluding on the remaining risk:

Description of the methodology and the related issues

The remaining "risk" is in the case of PBT-/vPvB-substances referred to as impact to the environment. However, for RAC, it is important to note that in general the amount of emission or the resulting environmental concentrations are not scientifically equivalent with impacts. As outlined in SEAC's evaluation framework for PBT and vPvB substances[10], the potential to cause impacts depends moreover on the specific combination of intrinsic hazard potential ("PBT-ness", above all), on characteristics, size, dynamics of the substance stock, and its flow in society and the environment as caused by the specific environmental fate and distribution of the considered emission amount.

As a consequence, using estimates of the amount of emission or environmental concentrations alone does not allow RAC to assess the severity of these emissions and concentrations.

It is the task of RAC to give an opinion on the appropriateness of the manner in which the impact on the environment has been estimated. The applicants decided to model environmental concentrations of HBCDD in sediment and soil for a period of 10 years, assuming constant emissions of HBCDD in years 1 to 4. They apply a stock pollution approach, where the stock (i.e. the environmental concentration after a certain period) is assumed to depend on the initial concentration of HBCDD in soil and sediment, the corresponding emissions and on subsequent degradation/dissipation rates of the substance in the environment. Other environmental compartments are assessed by standard EUSES modelling.

In Appendix 2 of CSR (Appendix F of SEA) the applicants state that if the initial "concentration is large, the relative impact of continuing manufacture and use of EPS for a limited period is small". Whilst RAC acknowledges that the applicants attempted to identify an appropriately low starting concentration in their analysis we consider argumentation based on relative impact as inappropriate. When comparing the expected impacts with the expected benefits the relative impact does not matter. RAC considers that opinion-making on applications for authorisation should preferably be based on marginal impacts / benefits), irrespective of other sources of contamination. Addressing the relative impacts

[10] "SEAC/24/2014/04 - Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC"

would imply that a continued use of a chemical would matter less if initial pollution stocks are already high. Also, the conclusion that relative impacts are higher if initial concentrations are low is scientifically only justified if a linear relationship between environmental concentrations and impacts can be assumed (i.e. impacts increase proportionally with environmental concentrations). Neither does the applicant provide nor is RAC aware of any scientific evidence supporting this hypothesis for HBCDD, and for PBT substances in general.

The application for authorisation provides some sensitivity analysis for emissions and modelled environmental concentrations. The applicants themselves emphasise that many parameters, including some OC and RMM described, the initial environmental concentrations and subsequent rates of degradation and dissipation are highly uncertain. RAC is not able to evaluate the likelihood and range of expected emissions and concentrations in the environment without being able to compare best case scenarios with worst case scenarios. The applicants only present model results for selected key values and do not present model results for reasonable worst case values.

The application assesses concentrations in the environment on the continental, regional and local scale. However, when addressing dissipation / degradation of HBCDD in specific compartments, the applicants do not adequately account for transfer of HBCDD between environmental compartments, including accumulation in biota. The application also lacks a comparison of the modelling results with the findings of environmental monitoring. Despite the availability of evidence in the literature that the concentrations of HBCDD in some compartments can decrease should emissions cease (Law et al. 2008[11]), RAC has strong and well-founded doubts that the rapid decline in the environmental concentrations of HBCDD predicted by modelling would be demonstrated across environmental compartments.

The long range transport (LRT) potential of HBCDD (confirmed by the Stockholm Convention) is not addressed in the application. However, RAC recognises that an assessment of the LRT potential is not a requirement under REACH.

Furthermore, RAC sees no reason to assume that impacts at the local scale, as reported by the applicant, are likely to be less severe than impacts observed at the regional or continental scale. For RAC it seems inappropriate to assess impacts at different spatial scales separately while the task is to assess the sum of all impacts on all spatial scales and compare this to the overall benefit of an authorised use.

RAC notes that HBCDD is a confirmed POP and PBT substance with well-known properties of particular concern for the environment. RAC fully acknowledges the importance of compartment-specific considerations of existing stocks of the substance, of the emissions distribution, and of the incremental effects of additional emissions.

In section 4 above, RAC provides a table with key release estimates which could support SEAC in its assessment of risk and benefits of a granted authorisation. However, as mentioned above, estimates of amount of emissions or

[11] Law et al. (2008). A significant downturn in levels of hexabromocyclododecane in the blubber of Harbor Porpoises (*Phocoena phocoena*) stranded or bycaught in the UK: an update to 2006. Environ. Sci. Technol., 42(24), 9104–9109

environmental concentrations alone does not allow RAC to assess the impacts of these emissions and concentrations, and their severity.

Best practices in emission reduction

According to RAC's evaluation of the information provided by the applicants, the following measures can contribute significantly to reducing the emissions from Use 1. In the event an authorisation is granted for this use, the applicants should implement these measures, where possible:

- Use of large bags of HBCDD (1000kg bags supposed to reduce releases from residues by a factor of 10, compared to 25kg bags)
- Use of low dust granules of HBCDD (supposed to reduce releases by factors from 2 to 8, increasing with decreasing bag sizes)
- Air emissions can be reduced both by using low dust granules of HBCDD (supposed to reduce releases by a factor of 10) and by air filter exhaust/ventilation systems (supposed to reduce releases by a factor of 4 without, and by 25 with proper maintenance)
- Full adherence to VECAP BAT for HBCDD packaging waste disposal (e.g. use of complete bags, requiring suppliers to deliver fully closed bags on clean pallets, storing emptied bags in closed containers, incinerating the emptied bags in approved chemical waste incinerator)
- Full adherence to all other elements of VECAP BAT

Summary of issues related to the risk assessment

In summary, the following major issues seriously limit RAC's ability to conclude on the remaining risk from the two HBCDD uses applied for:

- The PBT nature of HBCDD prevents using concentration increments in the environment or additional time needed for degradation to prior-to-use concentration levels, as adequate indicators for assessing the remaining risk and impacts.
- Similarly, the PBT nature of HBCDD prevents the use of total release estimates as adequate indicator for the remaining risk.
- The high uncertainties related to the release estimates impede concluding on the level of these releases. The sensitivity analysis - performed in an attempt to take into account some of these uncertainties - contrasts the applicants' total release estimate with an almost 6-fold higher estimate as plausible worst case.
- These uncertainties are lower for Use 1 (plausible quantified range spans a factor of less than 3).
- Particular uncertainties are related to the major release estimates for Use 2, namely from demolition and disposal (plausible quantified range spans a factor of more than 7), which in addition are delayed by several decades of service life, and would be particularly widespread but not

implicitly with even distribution.

- Even though explicitly excluded by this application, RAC has reliable information about well-established and considerable recycling practice for EPS scrap from conversion, construction, and demolition. If not effectively prevented in the future, these activities would lead to further releases of HBCDD to the environment that are not quantified by the current application.

Conclusion

Because of the lack of relevant information provided by the applicant on the one hand and the challenges of developing an adequate impact assessment for a PBT on the other, RAC is unable to confirm that the remaining risk is reduced to as low a level as is technically and practically possible.

7. Justification of the suitability and availability of alternatives

7.1 Are the alternatives technically and economically feasible?

☒ YES

☐ NO

Justification:

In the analysis of alternatives the applicants consider seven different alternative substances in detail, which all are brominated organic substances. One of the brominated organic substances assessed in the analysis of alternatives is considered to be technically and economically feasible by the applicants once available in sufficient quantities and testing and certification of FR[12] EPS with the alternative has been completed. This is a brominated co-polymer of styrene and butadiene ("pFR": alternative 1 in the analysis of alternatives).

According to the conclusion of the applicants, other flame retardant types are not technically feasible, because they do not provide adequate fire protection at concentrations that do not affect the EPS properties and/or are compatible with the EPS manufacturing process employed in the EU.

Technical feasibility of pFR

The applicants conclude that pFR is a technically feasible alternative to HBCDD in the manufacture of FR EPS to be used in building applications. This conclusion is confirmed by the contribution of third parties in the public consultation, who are already producing FR EPS with pFR. Accordingly, pFR does not affect the properties of the EPS or its manufacturing process. The quality of FR EPS produced with pFR is the same as FR EPS produced with HBCDD.

The applicants have already started testing pFR in their operations. Hence, the

[12] FR: flame retardant

process of substituting HBCDD with pFR could be performed in a short period of time once sufficient pFR will be available to be used in their operations. However, it is not guaranteed that pFR will be available in sufficient quantities in 2015 from all suppliers (see point 7.3) to perform the necessary testing and certification of the pFR-EPS. Therefore, this testing and certification might not be completed by the sunset date (21/8/2015). According to the Guidance on Application for Authorisation this would mean that pFR is not "technically feasible" for the applicants.

SEAC concludes that pFR in general will be a technically feasible alternative as stated in the application for authorisation once successful testing and certification of FR EPS produced with pFR has been completed.

Economic feasibility of pFR

The applicants also consider pFR as being economically feasible to them. They base their consideration on the fact that they are planning to switch to pFR and that they need a bridging authorisation because of the current lack of availability of pFR to them.

However, the applicants acknowledge that the use of pFR will entail higher costs to them compared to using HBCDD, even though they did not provide an explicit cost assessment. This cost increase was supported by providing data on the price of pFR for the applicants. The higher costs of pFR compared to HBCDD was confirmed by third parties in the public consultation and the trialogue. It was indicated by users of pFR that the final product (FR EPS) costs 1 to 5% more using pFR (on this basis SEAC estimated an additional price of 1.48 to 7.38 €/kg pFR compared to HBCDD, see Table B in Annex 1).

SEAC takes note that the applicants consider pFR as an economically feasible alternative. Based on information provided by the applicants and third parties SEAC concludes that pFR is more costly than using HBCDD. The applicants have stated that they are prepared to pay these increased costs.

Technical and economic feasibility of other alternatives

The analysis of alternatives also identifies other alternative substances that could be used to manufacture FR EPS including TBBPA derivates. However, the applicants conclude that these are not likely to be suitable due to their potential hazards, especially compared to pFR. Information received by third parties in the public consultation as well as in a recent report of the US EPA[13] confirms that certain TBBPA compounds are already used as flame retardants in XPS and are likely to be feasible alternatives to HBCDD in EPS as well. However, even if TBBPA compounds turn out to be suitable alternatives for the applicants, the time period needed for the applicants to switch to these compounds is expected to be significantly longer than to switch to pFR (see section 7.3). Hence, SEAC

[13] US EPA "Flame retardant alternatives for hexabromocyclododecane (HBCD) Final report" - June 2014

concludes that TBBPA based alternatives are less relevant for the assessment of SEAC at this time.

In the analysis of alternatives the applicants mention that in some EU/EEA countries (for example in Belgium, Norway, Finland, Iceland and Sweden) non-flame retarded EPS is used in building applications. SEAC notes that this is another suitable alternative to the use of HBCDD. The fire standards in these countries focus on more general requirements for fire protection rather than on the use of flame retardants. Some EU/EEA countries use FR EPS but this is not necessarily mandatory in all applications. However, SEAC also takes note of the information provided in the analysis of alternatives that non-flame retarded EPS will not comply with the existing fire safety standards in many EU Member States.

7.1.1 Are the technical and economic feasibility of alternatives adequately described and compared with the Annex XIV substance?

☒ YES

☐ NO

Justification:

Technical feasibility

The analysis of alternatives gives an overview on the technical requirements the alternative substances need to fulfil to replace HBCDD in FR EPS. Because the applicants consider pFR as the most suitable alternative, the analysis of alternatives provides comprehensive information on the selection/development process of pFR.

Economic feasibility

With regard to economic feasibility, the analysis of alternatives does not include an analysis of the additional costs that the applicants expect to incur by using pFR. Hence, it is not possible for SEAC to assess the economic feasibility compared to HBCDD based on the information presented in the analysis of alternatives. In the public consultation further information on the cost increase by using pFR in FR EPS was provided by third parties (see section 7.1). Further information on the costs of using pFR was also provided by the applicants on request by ECHA after the application was sent in.

SEAC has considered the further information provided during the public consultation including the further information provided by the applicant later on in the opinion-making process. **With this additional information SEAC finds the economic feasibility of pFR as the main alternative to be adequately described.**

7.2 Would the alternatives lead to overall reduction of risk?

☐ YES

☐ NO

☒ NOT APPLICABLE

Justification:

See answers to questions 7.1 and 7.3

7.2.1 Are the risks of alternatives adequately described and compared with the Annex XIV substance?

☐ YES

☒ NO

☐ NOT APPLICABLE

Justification:

In the analysis of alternatives, the applicant provides information on seven alternative flame retarding substances with varying, and in no case conclusive, data on their hazard profile and resulting risks. Only one of these alternatives, a brominated co-polymer of styrene and butadiene (pFR), is concluded to meet the basic technical requirements. Based on the available data (including the probable absence of PBT concern), the applicants consider pFR to have a low hazard. The applicants intend to use pFR as drop-in replacement for HBCDD after sufficient amounts become available.

7.3 If alternatives are suitable, are they available?

☐ YES

☒ NO

☐ NO SUITABLE ALTERNATIVES EXIST

Justification:

Demand and supply of pFR

In their socio-economic analysis the applicants provided estimates of the global supply and demand of pFR from 2015 – 2019. Based on these estimates the applicants conclude that there will not be sufficient pFR available to them before 2019.

The actual ratio of supply and demand of pFR at the sunset date (the 21st of August 2015) depends on different variables such as:

- the progress of commercialising pFR and the capacities reached by the companies that are currently building up production of pFR (i.e. ICL-IP and Albemarle)
- the non-EU demand of pFR
- the amount of pFR that will be used in the production of XPS (compared to

other alternatives)
- the demand of FR EPS and XPS
- the amount of pFR to be used in FR EPS and XPS (compared to HBCDD)

These variables are partly highly uncertain, e.g. the non-EU demand for pFR. They have been estimated on the basis of assumptions provided in the application and provided by third parties in the public consultation. Hence, the results very much depend on the sets of assumptions used and can only be considered as illustrative values.

In the original estimates of the applicants there was a calculation error resulting in an overestimation of the global demand of pFR. The applicants have therefore on request by ECHA revised their estimates of global demand and supply of pFR correcting this error (See table A below).

Table A: Applicants' best estimates for global, EU and non-EU, pFR supply and demand (tonnes)

Total supply and demand of pFR	2015	2016	2017	2018	2019
Total global supply of pFR	22,333	25,667	28,500	28,500	28,500
Total non-EU demand for pFR	5,699	6,334	6,995	7,682	17,245
Remaining supply for the EU (once non-EU demand met)	16,634	19,332	21,505	20,818	11,255
EU demand for pFR	16,639	17,005	16,019	16,372	16,732
EU Surplus/deficit	-5	2,327	5,486	4,446	-5,477

The revised estimates indicate that no significant shortage of pFR can be expected at the sunset date of HBCDD (August 2015), if both supply and demand develop as foreseen. The shortage in 2019 is due to the assumption that China would at that time switch 50% of its FR demand from HBCDD to pFR. SEAC considers the time when China will switch away from using HBCDD to be highly uncertain as also indicated by several parties during the public consultation on alternatives. In addition to the timing, it is unknown to what extent China will switch to using pFR compared to other possible alternatives (e.g. TBBPA derivates). Hence, the estimated deficit of pFR indicated for 2019 is not considered to be sufficiently robust for SEAC to be taken into account in the assessment of the availability of pFR. In addition, a shortage of pFR from 2019 onwards for EU EPS producers is unlikely to occur in practice, because they are expected to switch to pFR before Chinese producers meaning that they will have contractually secured supply. Moreover, it can be expected (based on the economic concept for 'supply and demand') that such a long-term high demand for pFR would trigger additional supply capacities to be provided by the pFR manufacturers. This has also been confirmed by third parties during the public consultation on alternatives. It should also be noted that the applicants, in their replies to comments received during the public consultation, revised their assessment and requested a review period shorter than the 4 years initially described (see below). Therefore, in addition to the fact that the supply/demand estimates are highly uncertain, the assessment of the availability of pFR from 2019 onwards is of little relevance.

In the event of a one-year delay in the development of ICL's production capacity in Israel, the applicants calculated a deficit of 7130 tonnes of pFR in 2015 (based on the new information collected during the public consultation, see Table B below).

Table B: Applicants' estimates for EU availability of pFR (tonnes) in the event of a one-year delay in production of the ICL Israel plant.

EU availability of pFR	2015	2016	2017	2018	2019
EU Surplus/deficit	-7,130	2,327	5,486	4,446	-5,477

Information received from the producers of pFR in the public consultation and in the trialogue indicates that production capacities are expected to progress to amount about 22,400 t of pFR in 2015. Even though the non-EU demand is uncertain, SEAC considers it to be likely that that no shortage in the supply of pFR is to be expected to cover EU demand at the sunset date. Despite the reassurances from the pFR suppliers, the applicants have highlighted the uncertainties related to the near future supply and demand of pFR (as illustrated in Table B) and the impacts this would have on their business. This is the reason for them applying for an authorisation with a short review period. The applicants commit to switch to pFR as soon as possible and – in response to the information received in the public consultation -have changed their request for an authorisation of four years to a shorter period (i.e. depending on the point in time when ICL-IP/Albemarle will have reached full and stable capacity in their plans to increase the production of pFR). According to the applicants, this time period is needed for testing and certification of FR EPS produced with pFR.

In conclusion, the date at which the applicants will be able to switch to pFR depends on the development of pFR supply (availability of pFR) as well as on completed testing and certification of FR EPS produced with pFR by the applicants and their downstream users. Based on the information provided in the application, the public consultation and the trialogue, **SEAC concludes that the substitution of HBCDD with pFR can be expected to be feasible and that suitable alternatives will be available for the applicants between 2015** (i.e. at the sunset date) **and 2017.**

Alternative materials (e.g. PUR/PIR or mineral wool) or alternative methods (e.g. not flame retarded EPS) are available and commonly used on the market.

8. For non-threshold substances, or in case adequate control cannot be demonstrated, have the benefits of continued use been adequately demonstrated to exceed the risks of continued use?

☒ YES

☐ NO

☐ NOT RELEVANT

Justification:

General considerations

On the whole, SEAC considers that there are large uncertainties related to the magnitude of the costs and benefits (in terms of emissions avoided) of the non-use scenario making it difficult to evaluate the cost-effectiveness of not granting the authorisation to facilitate a conclusion on benefits compared to risks of the authorisation.

SEAC recognises that the applicants are seeking a bridging authorisation for minimising the impacts on their business during a time period where it is uncertain if there will be sufficient pFR supply available in order to meet the demand for production of EPS.

The overall assessment of the market development for the alternatives and ongoing work and measures taken in order to phase in the use of pFR indicate that pFR is a cost-effective alternative. Actors on the market are prepared to pay the substitution cost for HBCDD leading to a price increase in the range of 1 to 5 % of the final product (pFR EPS, see Table B in annex 1). The applicants also stated this in their communication to ECHA after submitting the application. The actors on the EU market implicitly show by their behaviour that the phasing out of HBCDD is manageable to industry.

Non-use scenario: cost assessment

In their socio-economic analysis the applicants assume that as a response to the refusal of the authorisation it is likely that they will have to cease (or at least reduce) production of FR EPS due to a shortfall in the supply of pFR. Accordingly, the costs of the non-use scenario have been assessed on the basis of lost sales to the applicants related to Use 1 as well as on lost value added to EPS converters and the costs of consumers to switch to other insulation materials (Use 2).

SEAC considers that a reduction in production of the applicants due to a lack in supply with pFR is a likely impact if the authorisation was not granted. However, the use of lost sales is inadequate and will overestimate the cost of the non-use scenario to FR EPS formulators, because they do not reflect the net economic impact of the production loss. Instead, lost value added should be used.

In terms of costs incurred down the supply chain, SEAC considers that the information presented in the application does not provide sufficient and reliable evidence to quantify the costs to EPS converters as well as to consumers (= end

users of insulation material) in case the authorisation will not be granted. If consumers will switch to other insulation materials as a response of not granting the authorisation, also the extra value added of the producers of these materials will have to be taken into account when assessing the total net economic impact of the non-use scenario. However, the actual response of EPS converters and consumers depends on the possibility to import FR EPS pellets not containing HBCDD from outside the EU, which is likely to influence the extent to which consumers will switch to using other insulation materials, which is uncertain. Hence, SEAC has not been able to evaluate the cost estimates given by the applicants for impacts on EPS converters and consumers.

Overall, SEAC considers the loss in unexpanded FR EPS production (lost value added to EPS formulators) to be the most reliable impact to assess the costs of the non-use scenario.

Taking into account the revised estimates of supply and demand of pFR indicating that pFR will become available to the applicants much earlier than 2019, SEAC considers that this scenario (i.e. shutdown of total FR EPS formulation and conversion until 2019) also leads to an overestimation of the costs of the non-use scenario. It is very unlikely that the total production of FR EPS from 2015 until 2019 will stop in case the authorisation will not be granted, because the applicants are prepared to switch and incur the increased costs of pFR as soon as it will be available to them in sufficient quantities.

Hence, the overall cost of the non-use scenario depends on the point in time when pFR will become available to the applicants. SEAC has no clear indication when exactly this point in time will be, but considers it to be likely between 2015 and 2017. SEAC considers that the relevant time period of the non-use scenario (= impacts of not granting the authorisation) to assess is the period when there will be insufficient supply of pFR. According to the estimates provided by the applicants (see 7.3) this can only be expected for 2015.

Therefore, SEAC considers 2015 as a reference year to assess the costs (as well as the benefits in terms of emissions) of not granting the authorisation. Even though some time might be needed for the applicants to test and certify the pFR from the new producers and that a full switch of the applicants to the pFR might only happen in the course of 2016, SEAC considers the year 2015 as an appropriate reference for the purpose of the cost assessment.

In this respect, the best case cost scenario would be that the applicants could switch to pFR at the sunset date, i.e. there is sufficient supply of pFR and completed testing and certification is completed. For the reasons elaborated in 7.1 and 7.3, SEAC considers this scenario to be uncertain. A more realistic scenario is that the applicants will be able to switch to pFR at some stage after 2015. Based on the estimates of the applicants on the supply and demand of pFR

(see 7.3), SEAC has considered two scenarios for 2015 to assess the cost of not granting the authorisation[14]:

- Scenario A "realistic case" (Table A in 7.3): There is a deficit of 5 t of pFR (equivalent to 3.85 t of HBCDD) meaning the applicants are already mainly using pFR.
- Scenario B "realistic worst case" (Table B in 7.3): There is a deficit of 5,200 t of pFR (equivalent to 4,000 t of HBCDD) meaning the applicants are not able to use any pFR yet.

The costs of these two scenarios have been assessed taking into account information received from the applicants as well as from third parties during the public consultation on lost production value added[15] (see Table A in Annex 1).
On this basis SEAC concludes that it is likely that the total cost to the applicants related to Use 1 for the non-use of HBCDD in terms of lost added value will be within the range of:

- Scenario A: 0.018 million € (lost value added related to a deficit of 3.85 t HBCDD) and
- Scenario B: 20 million € (lost value added related to a deficit of 4,000 t HBCDD).

In both scenarios it is likely that there will be additional costs to downstream users/article consumers for not using FR EPS containing HBCDD, reflected by a price increase in the range of 1 to 5% of the final product (pFR EPS). However, as stated above SEAC has been presented too limited information to conclude on the magnitude of these costs.

In case the authorisation will be granted, SEAC notes that the use of HBCDD by the applicants will contribute to the general problem of HBCDD in the recycling of EPS, which may have significant economic consequences to the recycling and waste management industry.

Non-use scenario: Benefits assessment

Baseline scenario: Mass balance of HBCDD in case of continued use 2015-2019

In the socio-economic analysis (based on a modelling study in appendix F) the applicants provide an estimate of 1.97 t of HBCDD emitted over the originally requested four year authorisation period. According to RAC the estimates of emissions provided by the applicants are highly uncertain, because they are based on very limited information and not all relevant release sources of the different life-cycle steps (e.g. demolition and disposal) have been adequately

[14] Based on an average annual use of 8000 t of HBCDD. 4000 t is considered in this assessment, representing a probable amount used in 2015 after the sunset date (21/08/2015).
[15] Taking 12.5% of sales as an estimate of value added for Use 1, as indicated by the applicants and third parties.

considered by the applicants. As a result, RAC agreed that it was not possible to conclude on the remaining risk reduced (related to emissions avoided) in case the authorisation was not granted.
Nevertheless, a sensitivity analysis was performed under RAC's initiative on a set of specific data to estimate the potential releases in a reasonable worst case scenario in addition to the emission estimates provided by the applicants. This analysis results in an upper bound estimate of total emissions of 29.17 t taking into account also delayed releases from the demolition of HBCDD EPS articles produced during a 4 year authorisation with use of 32,000 tonnes of HBCDD, as initially applied for by the applicants. Emissions from disposal other than incineration (e.g. landfill) or potential recycling of FR EPS has not been assessed by RAC. The assessment of RAC highlights that demolition can have a major influence on emissions, depending how these activities are performed. At the same time, the size of emissions from the end of life of FR EPS are very uncertain, also because demolition and disposal practices of FR EPS containing HBCDD are likely to change substantially within the next decades.

Overall, SEAC notes the considerable uncertainties related to this analysis provided by RAC. However, SEAC still considers that the results are valuable to provide SEAC with information on the cost-effectiveness of the non-use scenario.

Cost-effectiveness of HBCDD emissions reduced
Taking into account the assessment of RAC on emissions as well as the conclusion on the costs of the non-use scenario, SEAC has assessed the cost-effectiveness of HBCDD emissions reduced by not granting the authorisation based on the potential cost and emission scenarios for 2015 described earlier.

Emission estimates:

- Scenario A: Use of 3.85 t of HBCDD resulting in emissions between 0.6 kg (applicants' release factor: 0.016%) and 3.5 kg (reasonable worst case: 0.091%) if authorisation is granted
- Scenario B: Use of 4,000 t[16] of HBCDD resulting in emissions between 640 kg (applicants' release factor) and 3,646 kg (reasonable worst case)

Cost-effectiveness estimates:

- Scenario A:
  - high: 0.018 Mio€/3.5kg = 5,143 €/kg
    low: 0.018 Mio€/0.6kg = 30,000 €/kg
- Scenario B:
  - high: 20 Mio€/3,646kg= 5,486 €/kg.
  - low: 20 Mio€/640kg= 31,250 €/kg

Despite the limitations related to these cost-effectiveness estimates, SEAC considers that they can support the assessment of the proportionality of the authorisation being granted (in addition to the general considerations on this

[16] Based on an average annual use of 8000 t of HBCDD. 4000 t is considered in this assessment, representing the probable amount used in 2015 after the sunset date (21/08/2015).

application as a bridging authorisation) in the absence of other means to evaluate the impacts of HBCDD on the environment. This assessment is in line with the agreed approach of SEAC to evaluate impacts of PBT/vPvB-substances. Nevertheless, SEAC takes note of the conclusion of RAC that emission volumes do not adequately reflect the environmental impacts of HBCDD and that the emissions and release factors, in particular those used by the applicants, are highly uncertain. Furthermore, SEAC considers that the cost figures derived are conservative estimates as potential impacts to downstream users/consumers of FR EPS are not included.

Based on the assessment of costs to the applicants and potential emissions of HBCDD in 2015, SEAC estimates that the cost-effectiveness of not granting the authorisation is likely to be within the range of 5,000 and 30,000 € per kg HBCDD emissions avoided. This broad range reflects the uncertainties related to the emissions estimated under the non-use scenario. Therefore, SEAC was not able to derive a central estimate of the cost-effectiveness of reducing HBCDD emissions by not granting the authorisation. SEAC notes that the mean cost-effectiveness values that have been estimated for regulating the marketing and use of other PBT(-like) substances (mercury and phenyl-mercury) under REACH[17] are lower than the range of cost-effectiveness values estimated for HBCDD here. Therefore, whilst acknowledging the remaining uncertainty, SEAC considers that the cost-effectiveness of not granting the authorisation is likely to be rather low (i.e. relatively high costs per emission unit abated) and less cost-effective than previous restrictions for PBT-like substances.
SEAC recognises that the risks posed by different PBT(-like) substances (on a unit mass basis) may not be directly comparable, which complicates the direct comparison to mercury and phenyl-mercury outlined above[18]. However, overall, SEAC considers that the cost-effectiveness estimates tend to support a conclusion that granting the authorisation would be proportionate.

Hence, based on the fact that this authorisation was requested to address a short-term potential shortage in the availability of an alternative (i.e. a bridging application), SEAC concludes that the benefits of granting the authorisation may outweigh the risks (approximated by the potential emissions to the environment). This conclusion tends to be supported by the cost-effectiveness considerations outlined above. However, SEAC highlights the major uncertainties that remain in the cost-effectiveness assessment, both in terms of the emissions and cost-estimates that were used to underpin the calculations.

9. Do you propose additional conditions or monitoring arrangements

☒ YES

☐ NO

[17] Mercury in measuring devices: 4,100 (0 – 19,200) € per kg; Phenyl-Mercury: 649 €/kg

[18] As indicated in SEAC paper SEAC/24/2014/04 on "Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC", available information did not allow SEAC to set benchmarks for acceptable cost-effectiveness for PBT/vPvB substances.

Detailed description for additional conditions and monitoring arrangements:

RAC recommends the following additional conditions and monitoring arrangements:

- The applicants performing Use 1 (i.e. “formulators”) should put in place a monitoring programme to quantify release factors and emissions of the substance to environmental compartments during all activities described in Use 1 for the period of the authorisation.
- The monitoring programme should consider emissions to air, water and land from all the formulation sites.
- Annually, applicants should prepare a report that contains the results obtained from the monitoring programme. The annual report should also include details of the methodology used to obtain the results e.g. sampling points and frequency (at least monthly) and details of any relevant analytical methodology.
- Upon request, applicants should provide national enforcement bodies with the annual reports. Any review report in terms of Article 61(1) of the REACH Regulation should include the results of the monitoring programme.
- In addition to the mandatory implementation of the operational conditions and risk management measures described in the application the applicants should implement where possible the best practices in emission reduction described in section 6 of this opinion justification.

In addition to the conditions and monitoring arrangements recommended by RAC, SEAC recommends the following conditions for the applicants to commit to in order to be granted an authorisation:

- For the applicants to substitute to pFR as soon as sufficient supply is available and testing has been conducted with a positive result and no later than 21/08/2017. During the review period the applicants should communicate the progress of the work on phasing in the alternative pFR in terms of production capacity, sufficient supply and test results to the Commission in relation to the requirements of Article 61(1) of the REACH Regulation.

Justification for additional conditions and monitoring arrangements:

An authorisation for a high-volume use of a PBT-/vPvB-substance should be based on a robust and well justified exposure and emissions assessment. In the present case, the recommended monitoring arrangements would address many of the uncertainties in the emission and exposure assessment and would verify that the claimed RMM are implemented and effective. RAC considers that these conditions would contribute to further reducing emissions to as low a level as is technically and practically possible.

The suggested additional conditions by SEAC in terms of reporting the progress of the substitution and testing activities are justified by the requirements set in article 61 of the REACH Regulation.

The applicants have already committed to substitute to pFR as soon as sufficient supply is available and testing and certification has been conducted. Therefore this condition is justified to add to the decision of granting this application. This condition would also handle the uncertainty of setting a realistic and efficient length of the review period and would ensure that a substitution is carried out when possible, perhaps even sooner than the set date for the review period.

SEAC finds this condition to be in line with the intention and incentives of the REACH regulation as well as with the commitment already given by the applicants to substitute to pFR.

SEAC also finds this additional condition to contribute to the further work needed in order to carry out substitution to pFR.

10. Proposed review period:

☐ Normal (7 years)

☐ Long (12 years)

☐ Short (4 years)

☒ Other: 2 years

Justification for the suggested review period:

For the reasons described in the previous sections (especially section 4 and 6) and reminding the unknown (but potentially severe) impacts any additional releases of HBCDD could have, RAC recommends that (in the event an authorisation would be granted for this use):

1. the additional conditions and monitoring arrangements described in section 9 are included in the authorisation decision;
2. the authorisation should not exceed four years (period suggested by the applicants in their original application) in order to limit the amounts released in the environment.

SEAC notes that the applicants have, after the application was sent in to ECHA, provided further information that states that the originally 4 years review period requested is no longer valid. The applicants are now communicating that a shorter period than 4 years will be enough in order for pFR to be a fully suitable and available alternative in terms of testing and sufficient supply. If production capacities by flame retardant manufacturers develop as foreseen sufficient supply is likely to be available in 2015. Then there will be additional time needed for testing and certification by the applicants before a substitution to pFR can be carried out. SEAC has no clear indication on how long testing and certification could take, one indication presented by the applicants is 6 month after the supply has been made available to them.

SEAC also takes into account that RAC concluded that a short review of a maximum of 4 years period would be recommended in case an authorisation would be granted. However they did not assess the further information communicated by the applicants stating that they would no longer need a 4 year review period as was stated in the application.

SEAC finds the criteria for the short review period to be fulfilled. The analysis of alternatives and the information presented by the applicants show that suitable alternatives will be available within a short review period. The remaining question is how short? The applicants are seeking a "bridging" authorisation to enable a transition to pFR which will become available over the shorter term. In order to propose a review period different short term periods have been assessed and considered by SEAC. Therefore the following review periods have been considered: 18 months, 24 months, 36 months and 48 months.

Review period (set from the sunset date, 21/8/2015)	**End of review period**	**Review report to be submitted to ECHA by**
18 months	02/2017	08/2015
24 months	08/2017	02/2016
36 months	08/2018	02/2017
48 months	08/2019	02/2018

When considering the different drivers for the availability of the alternatives and the information presented by the applicants SEAC finds that a 2 year review period could to be justified as this is a bridging application for an authorisation.

However, the availability of alternatives depends on the progress of commercialising pFR, the capacities reached by the companies building up a production of pFR, the demand of pFR outside of the EU, the amount of pFR that will be used in the production and the demand of FR EPS and XPS. The length of alternative review periods within the shorter time frame is therefore further discussed below.

18 months: Despite the reassurances from the pFR suppliers, the applicants have highlighted the uncertainties related to the near future supply and demand of pFR (as illustrated in Table B) and the impacts this might have on their business. This is the reason for them applying for an authorisation.
Based on the information and assessment at hand SEAC finds that it is uncertain whether the alternatives will be available at amounts that meet the demand during an 18 months review period and also tested and certified in order to be used in the production of pFR and FR EPS. **Based on these uncertainties SEAC does not find it justified to recommend an 18 month review period.** The proposed conditions for the applicants to commit to substitute to pFR as soon as sufficient supply is available and testing has been conducted could result in a situation where the companies end up using less time than granted for the authorisation and that the actual timeframe of using HBCDD could still end up being 18 months after the sunset date.

24 months: The information provided by the applicant's state that alternatives will likely be available after 24 months. As stated earlier in the justification in

paragraph 7.3 the information received from the producers of pFR in the public consultation and in the trialogue indicates that production capacities are expected to progress as foreseen as presented in Table A above and is in support of the conclusion that no shortage in the supply of pFR is to be expected at the sunset date. The applicants are committed to switch to pFR as soon as possible but according to them this time is probably needed for testing and certification of FR EPS produced with pFR. **SEAC therefore finds that this review period would be sufficient in order for the applicants to carry out the required tests and certification of the alternative.** The capacities of the companies building up production capacity of pFR will probably meet the demand by that time.

36 months: After 36 months the alternative will most likely be available for the applicant and the progress of commercialising pFR will most probably have reached sufficient amount of supply in order to meet the demands. **SEAC concludes that the substitution of HBCDD with pFR can be expected to be feasible and that suitable alternatives will be available for the applicants between 2015 (i.e. at the sunset date) and 2017. Therefore this length of review period is not justified.**

48 months: In the original application the applicant applied for 4 years. It can therefore be expected that the alternative will be available for the applicant and that the progress of commercialising pFR will have reached sufficient amount of supply in order to meet the demands after 48 months. **SEAC concludes that the substitution of HBCDD with pFR can be expected to be feasible and that suitable alternatives will be available for the applicants between 2015 (i.e. at the sunset date) and 2017.Therefore this length of review period is not justified.**

Annex 1: Non-use scenario: Cost assessment

Table A: lost value added (of HBCDD EPS) in case of a shortage of pFR in 2015 (pro rata of initial assumptions in the application, taking 12.5% of sales as an estimate of value added for Use 1, as indicated by the applicants and third parties.)

Scenario	shortage of pFR (T)	equivalent to HBCDD (tonnes) (considering that 30% more pFR is needed compared to HBCDD)	Lost sales Use 1 (NPV) (Mio€)	**Lost value added Use 1 (Mio€)**
Original application	n/a	32000	1175.00	**146.88**
A	5	3.85	0.14	**0.018**
B	5200	4000	146.88	**18.36**

Table B: calculation of additional price of pFR based on assumptions of 1 to 5% price increase of pFR EPS (compared to HBCDD EPS)

	Using HBCDD	**Using pFR: 1% price increase in end product**	**Using pFR: 5% price increase in end product**
Price of EPS end article (compared to HBCDD=100)	100	101	105
Average price of EPS end article (/ton)	1 800 USD	1 818 USD	1 890 USD
Concentration of HBCDD in the end product	0.70%	0.70%	0.70%
Concentration of pFR in the end product	0.91%	0.91%	0.91%
Kilos of HBCDD avoided (if alternative is used) per tonne of end product	7	7	7
Kilos of pFR per 1000kg of pFR-EPS	n/a	9.1	9.1
Additional price of pFR EPS (per ton of EPS)	n/a	18 USD	90 USD
Additional price of pFR EPS (per ton of EPS)	n/a	13.43 EUR	67.16 EUR
Additional price of pFR EPS/kg HBCDD	n/a	1.92 EUR	9.59 EUR
Additional price of pFR EPS/kg pFR	**n/a**	**1.48 EUR**	**7.38 EUR**