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COMMISSION IMPLEMENTING DECISION

of 8.1.2016

**granting an authorisation for uses of hexabromocyclododecane (HBCDD) under
Regulation (EC) No 1907/2006 of the European Parliament and of the Council**

(Text with EEA relevance)

[ONLY THE ENGLISH TEXT IS AUTHENTIC]

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Hexabromocyclododecane (hereinafter referred to as "HBCDD") is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) An application for authorisation was jointly submitted by INEOS Styrenics Netherlands BV, INEOS Styrenics Ribecourt SAS, INEOS Styrenics Wingles SAS, Synthos Dwory 7 Spółka z ograniczoną odpowiedzialnością spółka komandytowo-akcyjna², Synthos Kralupy a.s., StyroChem Finland Oy³, Monotez SA, RP Compounds GmbH, Synbra Technology bv, Sunpor Kunststoff GmbH, Dunastyr Polystyrene Manufacturing C. Co Ltd, Versalis SpA and Unipol Holland bv (hereinafter referred to as "applicants") on 13 February 2014 for two uses (hereinafter referred to as "uses applied for") of HBCDD in accordance with Article 62 of Regulation (EC) No 1907/2006. The uses applied for are the formulation of flame retarded expanded polystyrene ("EPS") to solid unexpanded pellets using HBCDD as the flame retardant additive (for onward use in building applications) and the manufacture of flame retarded EPS articles for use in building applications. In order to align the wording of the latter use with the terminology of Regulation (EC) No 1907/2006, that use should be referred to as "the production of flame retarded EPS articles for use in building applications".

¹ OJ L 396, 30.12.2006, p. 1.

² This legal entity subsequently changed its name to Synthos Dwory 7 Spółka z ograniczoną odpowiedzialnością spółka jawna.

³ This legal entity subsequently changed its name to Bewi Styrochem Oy.

- (3) HBCDD is included in Annex A to the Stockholm Convention on Persistent Organic Pollutants as a chemical for which the parties to the Convention shall prohibit and/or take the legal and administrative measures necessary to eliminate its production, use, import and export with a specific exemption for the production and use of HBCDD in expanded polystyrene and extruded polystyrene in buildings. The uses applied for by the 13 applicants fall within the scope of that specific exemption. Part VII of Annex A to that Convention further requires that EPS containing HBCDD that are placed on the market can be easily identified throughout its life cycle by labelling or other means.
- (4) In order to implement this prohibition on production, use and import of HBCDD in the Union, that substance should be listed in Annex I to Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC⁴. The amendment of that Regulation in order to list HBCDD in Annex I thereto should impose, among others, identification requirements on EPS, in which HBCDD is used, throughout its life cycle.
- (5) The Committee for Risk Assessment (“RAC”) and the Committee for Socio-economic Analysis (“SEAC”) of the European Chemicals Agency adopted their opinions on the application on 8 January 2015⁵. The Commission received those opinions on 9 January 2015.
- (6) HBCDD is included in Annex XIV to Regulation (EC) No 1907/2006 because it meets the criteria in Article 57(d) of that Regulation. In accordance with Article 60(3)(b) of that Regulation, the provisions in Article 60(2) do not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.
- (7) In its opinions the RAC considered that, based on the information provided in the application, the uncertainties in the exposure assessment were too high to conclude on the risk of HBCDD from both uses applied for. The RAC considered that the emissions to the environment for these uses were not adequately described by the applicants. As a consequence, the RAC stated in its opinion that it was unable to evaluate the appropriateness and effectiveness of the operational conditions and the risk management measures described in the application in reducing the risks. Based on these uncertainties, the RAC recommended the implementation of best practices in emission reduction. According to the RAC, the exposure assessments provided in the application for the use of HBCDD in the formulation of flame retarded EPS to solid unexpanded pellets rely heavily on the documentation of the Voluntary Emissions Control Action Programme (VECAP) of the European and international flame retardant industry. The RAC acknowledged that the VECAP principles included in the chemical safety report (“CSR”) would become a mandatory condition once the authorisation for this use was granted, and recommended the implementation of the VECAP best practices, where possible. The Commission notes that the risk management measures and operational conditions contained in the CSR already include advice on implementation of the VECAP best practices.
- (8) Furthermore the RAC recommended imposing monitoring arrangements for both uses to quantify release factors and emissions of HBCDD to the environment.

⁴ OJ L 158, 30.4.2007, p. 7.

⁵ <http://echa.europa.eu/documents/10162/39f508ec-f0c8-47e7-9c89-d98efa1d64e5>
<http://echa.europa.eu/documents/10162/0144eda8-0377-4cc6-aa94-c0de9a5a9456>

- (9) In its opinion the RAC also recommended, with regard to the use of HBCDD in the production of flame retarded EPS articles for use in building applications, that industrial and professional actors in the authorisation holders' supply chain are provided with guidance on operational conditions and risk management measures and on best practices for using EPS articles containing HBCDD in order to minimise emissions for all exposure scenarios in the life-cycle stages, as foreseen in the CSR.
- (10) In order to be able to assist Member States in the obligations arising from the Stockholm Convention on Persistent Organic Pollutants and Regulation (EC) 850/2004 it should be possible to ascertain whether articles containing HBCDD are placed on the market in the territory of the Member States and in which quantities.
- (11) In its opinion the RAC did not assess the exposure of workers to HBCDD, as it was unclear whether worker exposure for a persistent, bioaccumulative and toxic ("PBT") substance needed to be addressed. At the time of the identification of HBCDD as a PBT substance, the assessment of the toxic properties was based on toxicity for the environment. Although the substance was subsequently classified as toxic for reproduction (category 2) in accordance with Regulation (EU) No 1272/2008 on classification, labelling and packaging of substances and mixtures⁶, such classification had not yet been enacted when the substance was identified as a substance of very high concern and included in the candidate list in accordance with Article 59(1) of Regulation (EC) No 1907/2006. Therefore an assessment of workers' exposure to this substance during the review period should be included in the review report.
- (12) In its opinions, the SEAC underlined the large uncertainties in the socio-economic analysis, both in terms of emissions to the environment and cost estimations, and noted the difficulties in concluding whether the benefits outweigh the risks solely based on cost-effectiveness assessment. However, considering the fact that the application was requested for a short period of time in order to address a temporary shortage in the availability of a suitable alternative to HBCDD the SEAC concluded that the socio-economic benefits arising from the use of HBCDD in the uses applied for may outweigh the risks to the environment arising from those uses. In the justification to its opinion, the SEAC indicated that it has been demonstrated that the benefits of continued use of HBCDD exceed the risks of continued use.
- (13) The SEAC confirmed that the alternative substance benzene, ethenyl-, polymer with 1,3-butadiene, brominated (brominated co-polymer of styrene and butadiene) (hereinafter referred to as "polymeric flame retardant" or "pFR") would be technically feasible for the applicants once successful testing and certification of flame retarded expanded polystyrene and articles thereof produced with that substance has been completed by the applicants and their downstream users. The SEAC took note of the fact that the applicants considered pFR as an economically feasible alternative. The SEAC also confirmed that pFR was not available in sufficient quantities to the applicants at the time of issuing its opinions, however the SEAC concluded that, according to the available information, it was expected that pFR would become available in sufficient quantities to meet the demand estimated in the application by 2017. Therefore, the SEAC confirmed that at the time of adoption of its opinions there are no suitable alternative substances or technologies available, in accordance with the provisions in Article 60(5) of Regulation (EC) No 1907/2006.
- (14) Based on the RAC and the SEAC opinions, it is appropriate to authorise the uses of HBCDD applied for, subject to conditions concerning the risk management measures

⁶ OJ L353, 31.12.2008, p.1.

and operational conditions to be applied and provided that the applicants regularly report to the Commission on the progress of the work on phasing in pFR in terms of capacity of supply and on test and certification progress. Furthermore, the RAC and the SEAC recommended the setting up of a monitoring programme to quantify release factors and emissions of HBCDD to the environment arising from all the activities described in the uses applied for, and to annually prepare a report on the results thereof, to be supplied to the national enforcement authorities upon request. Those results should also be included in the review report referred to in Article 61(1) of Regulation (EU) No 1907/2006. Since the monitoring programme should be set up by the holders of the authorisation as well as by their downstream users to whom the authorisation applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006, this obligation should be imposed as a condition of the authorisation.

- (15) In its opinions, the SEAC recommended the time-limited review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be established at two years. The recommended review period takes into account the likelihood that pFR would be available in sufficient quantities by August 2017 and the need for the applicants to carry out the required tests and certification with that substance. However in view of the probability that pFR becomes available on the market in sufficient quantities earlier than August 2017, the SEAC recommended to subject the authorisation to the condition that HBCDD is replaced by the pFR as soon as sufficient quantity of supply is available on the market and the necessary tests and certification have been conducted with a positive result, and that the applicants report on the progress in phasing out of HBCDD.
- (16) After the SEAC adopted its opinions, information has become available about the increased production capacities of the manufacturers of pFR, which would in principle suffice to meet the expected increased demand of that substance in substitution of HBCDD. However, after consultations have been carried out by the Commission with the applicants and with suppliers of pFR, uncertainties remain about the increased volumes available on the market at the time of adoption of this decision, since, according to the available information, not all the manufacturing facilities of pFR were operating at a capacity that would be able to meet the pFR demand indicated in the application. Furthermore, while the quantities of pFR are increasing, the applicants and their downstream users need to carry out the tests and certification of the alternative before substitution to pFR takes place.
- (17) It is therefore appropriate to follow SEAC's recommendation and set the review period referred to in Article 60(9)(e) of Regulation (EC) 1907/2006 to end at 21 August 2017, with the option for withdrawing the authorisation at an earlier stage, i.e. as soon as sufficient supply of pFR becomes available for the uses applied for. In order to ensure that substitution of HBCDD takes place as soon as sufficient quantities of pFR are available on the market, a report should be submitted by the applicants on a three-monthly basis to the Commission providing updated information on the available quantities of pFR on the market and on the progress in testing and certifying that substance for the uses applied for. Moreover, it is expected that pFR will be available in sufficient quantities on the market within the review period and consequently, it is foreseeable that authorisations will be withdrawn in accordance with Articles 61(2) and (3) of Regulation (EC) No 1907/2006 under the conditions set out in those articles, including when authorisation holders inform about successful replacement of HBCDD under their reporting obligations and in any case at the end of the review period if no review report is submitted within the applicable deadline.

- (18) In order to facilitate the enforcement of the decision, it is appropriate to include a monitoring arrangement requiring the holders of the authorisation to submit, upon request, to the competent authority of the Member State where the use takes place a succinct summary of the risk management measures and operational conditions of the relevant parts of the chemical safety report submitted as part of the application in an official language of that Member State.
- (19) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

1. An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of HBCDD (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), subject to the conditions in paragraph 3. The authorised use is identified by the following authorisation numbers:

[REACH/15/6/0]	INEOS Styrenics Netherlands BV	Use: formulation of flame retarded expanded polystyrene (EPS) to solid unexpanded pellets using HBCDD as the flame retardant additive (for onward use in building applications)
[REACH/15/6/2]	INEOS Styrenics Ribecourt SAS	
[REACH/15/6/4]	INEOS Styrenics Wingles SAS	
[REACH/15/6/6]	Synthos Dwory 7 Spółka z ograniczoną odpowiedzialnością spółka jawna	
[REACH/15/6/8]	Synthos Kralupy a.s.	
[REACH/15/6/10]	Bewi Styrochem Oy	
[REACH/15/6/12]	Monotez SA	
[REACH/15/6/14]	RP Compounds GmbH	
[REACH/15/6/16]	Synbra Technology bv	
[REACH/15/6/18]	Sunpor Kunststoff GmbH	
[REACH/15/6/20]	Dunastyr Polystyrene Manufacturing C. Co Ltd	

[REACH/15/6/22] Versalis SpA

[REACH/15/6/24] Unipol Holland bv

2. An authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following use of HBCDD (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), subject to the conditions in paragraphs 3 and 4. The authorised use is identified by the following authorisation numbers:

[REACH/15/6/1] INEOS Styrenics Netherlands BV Use: production of flame retarded expanded polystyrene (EPS) articles for use in building applications

[REACH/15/6/3] INEOS Styrenics Ribecourt SAS

[REACH/15/6/5] INEOS Styrenics Wingles SAS

[REACH/15/6/7] Synthos Dwory 7 Spółka z ograniczoną odpowiedzialnością spółka jawna

[REACH/15/6/9] Synthos Kralupy a.s.

[REACH/15/6/11] Bewi Styrochem Oy

[REACH/15/6/13] Monotez SA

[REACH/15/6/15] RP Compounds GmbH

[REACH/15/6/17] Synbra Technology bv

[REACH/15/6/19] Sunpor Kunststoff GmbH

[REACH/15/6/21] Dunastyr Polystyrene Manufacturing C. Co Ltd

[REACH/15/6/23] Versalis SpA

[REACH/15/6/25] Unipol Holland bv

3. The authorisations referred to in paragraphs 1 and 2 shall be subject to the following conditions:

- (a) the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of Regulation (EC) No 1907/2006 corresponding to the respective uses⁷ shall be fully applied;

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<http://ec.europa.eu/DocsRoom/documents/8914/attachments/1/translations/en/renditions/native>
<http://ec.europa.eu/DocsRoom/documents/8915/attachments/1/translations/en/renditions/native>

- (b) the authorisation holders and the producers of EPS articles to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall set in place a monitoring programme in order to quantify release factors and emissions of HBCDD to air, water and land during all the activities in the uses referred to in Articles 1(1) and (2). The monitoring programme shall establish the methodology to be used to obtain the results, including sampling points and frequency (which shall be at least monthly), and the details of any relevant analytical methodology. Reports containing the details of the methodology used and the results of the monitoring programme shall be prepared. The first report shall be prepared by 31 December 2016 and a second one by 21 August 2017. These reports shall be submitted to the competent authorities of the Member State where the use takes place for enforcement purposes, in an official language of that Member State.
 - (c) the authorisation holders shall submit a report on a three-monthly basis to the Commission providing updated information on the available quantities of pFR on the market and on the progress in testing and certifying that substance with a view to its use in the uses referred to in paragraphs 1 and 2 in substitution of HBCDD. The first report is due by *[three months of the date of this Decision]*.
4. The authorisations referred to in paragraph 2 shall be subject to the following conditions:
- (a) guidance on operational conditions and risk management measures and on best practices for using EPS articles containing HBCDD in order to minimise emissions for all life-cycle stages of EPS articles, as foreseen in the CSR, is provided by the producers of EPS articles to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 to industrial and professional actors down his supply chain, in an official language of the Member State where the use takes place.
 - (b) producers of EPS articles to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 provide, upon request by the competent authority of a Member State, information on the quantities of EPS articles containing HBCDD supplied by them to industrial and professional actors in that Member State.

Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 for the authorisation granted by this Decision shall expire on 21 August 2017.

The present authorisation shall cease to be valid on 21 August 2017 with regard to the holders of an authorisation referred to in Article 1 who have not submitted the review report foreseen in Article 61(1) by 21 February 2016, unless a decision to withdraw the authorisation is adopted earlier in application of Article 61(2) and (3) of Regulation (EC) No 1907/2006.

Article 3

The following monitoring arrangements shall apply:

- (a) On request of the competent authority of the Member State where the authorised use takes place, the holder of the authorisation shall submit to that authority a succinct summary of the applicable risk management measures and

operational conditions referred to in Article 1(3)(a), in an official language of the Member State.

- (b) The review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 shall include the information referred to in Article 1(3)(b) as well as an assessment of worker exposure for the uses referred to in Articles 1(1) and (2) during the review period. The review report shall also include information on the implementation of the best practices that the applicants have put in place in order to reduce release of HBCDD from the use referred in Article 1(1), as indicated in the chemical safety report referred to in Article 1(3)(a).

Article 4

This Decision is addressed to:

- INEOS Styrenics Netherlands BV, Lijndonk 25, NL-4825 BG, Breda, Netherlands;
- INEOS Styrenics Ribecourt SAS, 704 rue Pierre et Marie Curie, 60170, Ribécourt, France;
- INEOS Styrenics Wingles SAS, Rue du Plat, F-62410, Wingles, France;
- Synthos Dwory 7 Spółka z ograniczoną odpowiedzialnością spółka jawna, ul. Chemików 1, 32-600, Oświęcim, Poland;
- Synthos Kralupy a.s., O.Wichterleho 810, 27801, Kralupy nad Vltavou, Czech Republic;
- Bewi Styrochem Oy, P.O. Box 360, 06101, Porvoo, Finland;
- Monotez SA, 111, Lefkis Street, 14568, Athens, Greece;
- RP Compounds GmbH, EPS building Plant I 119, 06258, Schkopau, Germany;
- Synbra Technology bv, Post Box 37, 4870AA, Etten-Leur, Netherlands;
- Sunpor Kunststoff GmbH, Tiroler Strasse 14, PF 414, 3105, St Polten, Austria;
- Dunastyr Polystyrene Manufacturing C. Co Ltd, Arpad Fejedelem utca 26-28, H-1023, Budapest, Hungary;
- Versalis SpA, P.zza Boldrini 1, 20097, San Donato Milanese, Milano, Italy;
- Unipol Holland BV, Rijnstraat 15°, P.O. Box 824, 5340AV, Oss, Netherlands.

Done at Brussels, 8.1.2016

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission

