EUROPEAN CHEMICALS AGENCY

Helsinki, 22 May 2014

Decision/annotation number: Please refer to the REACH-IT message which delivered this communication (in format SEV-D-XXXXXXXXXX-XX-XX/F)

DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For 1,1'-(ethane-1,2-diyl)bis[pentabromobenzene], CAS No 84852-53-9 (EC No 284-366-9)

Addressees: Registrant(s)[1] of 1,1'-(ethane-1,2-diyl)bis[pentabromobenzene] (Registrant(s))

This decision is addressed to all Registrant(s) of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph. A list of all the relevant registration numbers subject to this decision is provided as an Annex to this decision.

Registrant(s) meeting the following criteria are *not* addressees of this decision: i) Registrant(s) who registered the above substance exclusively as an on-site isolated intermediate under strictly controlled conditions and ii) Registrant(s) who have ceased manufacture/import of the above substance in accordance with Article 50(3) of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by HSE as the Competent Authority of the United Kingdom (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

This decision does not take into account any updates of the registrations of the Registrant(s) after May 2013.

This decision does not imply that the information provided by the Registrant(s) in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the Registrant(s) at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of the United Kingdom has initiated substance evaluation for 1,1'-(ethane-1,2-

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

diyl)bis[pentabromobenzene] (EBP), CAS No 84852-53-9 (EC No 284-366-9) based on registration dossiers submitted by the Registrant(s) and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to unclear bioaccumulation potential and the possiblility of PBT/vPvB transformation products, EBP was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of the United Kingdom was appointed to carry out the evaluation.

EBP is likely to be a major substitute for the flame retardant decabromodiphenyl ether (decaBDE), for which the UK has submitted an Annex XV dossier for identification as a Substance of Very High Concern. A previous UK national assessment (Dungey & Akintoye, 2007[1]) also identified potential environmental risks based on default scenarios. The purpose of this evaluation is to assess any new data generated since the UK review, and identify specific studies to clarify these concerns based on recent experience with decaBDE.

In the course of the evaluation the following additional concerns were noted with respect to the environment: Information on vitellogenin formation was identified from the academic literature, raising uncertainty for endocrine disrupting effects in fish. Published studies were also identified that suggest effects in fish and aquatic invertebrates, raising some concern that the aquatic toxicity studies included in the registration dossiers might not be fully reliable. In addition a review of the compositional data provided by the Registrant(s) revealed the level of brominated diphenyl ethane congeners present as impurities (which, by analogy with polybromodiphenyl ethers, might have PBT properties) in some commercial products was higher than expected (i.e. above [redacted] % w/w), requiring further investigation. A possible concern for endocrine disruption in mammalian species (including humans) was not included within the scope of the present substance evaluation.

It was therefore considered that further information was required to clarify the abovementioned concerns and the evaluating MSCA prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 26 February 2013.

On 4 April 2013 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

The Registrant(s) provided comments to ECHA on the draft decision by the deadline of 6 May 2013.

On 10 May 2013 ECHA notified the evaluating MSCA of the comments received. The evaluating MSCA considered the comments received from the Registrant(s). The information contained therein was reflected in the Statement of Reasons (section III) and an amendment to the Information Required (Section II) was made.

In accordance with Article 52(1) of the REACH Regulation, on 31 October 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

[1] Dungey, S. and Akintoye, L., 2007. Environmental Risk Evaluation Report: 1,1'-(Ethane-1,2-diyl) bis[pentabromobenzene] (CAS No. 84852-53-9). Environment Agency, Bristol, UK. Science Report no.: SCHO0507BMOR-E-P. http://cdn.environment-agency.gov.uk/scho0507bmor-e-e.pdf

Subsequently, ECHA and two MSCAs submitted proposals for amendment to the draft decision.

On 5 December 2013 ECHA notified the Registrant(s) of the proposals for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the received proposals for amendment and amended Sections II and III of the draft decision.

On 16 December 2013 ECHA referred the draft decision to the Member State Committee.

By 7 January 2014, in accordance to Article 51(5), the Registrant(s) provided comments on the proposals for amendment. In addition, the Registrant(s) provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrants' comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 3 to 7 February 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 6 February 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions and the registered substance with composition as specified, subject to the present decision:

1. Analytical confirmation of the test concentrations used in the aquatic toxicity tests reported in the registration dossier. Test solutions shall be prepared in exactly the same way as was done for the acute aquatic toxicity tests and measurements of the dissolved EBP concentrations in relevant test vessels shall be made over 96 hours. The test substance should have the same composition as used in the original aquatic tests, but may be radio-labelled.

2. Long-term toxicity testing on aquatic invertebrates (test method: Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 4th ed. October 2002, US EPA 821/R-02-013 or Test of Reproduction and Survival Using the Cladoceran ('Ceriodaphnia dubia') EPS1/RM/21 or *Daphnia magna* Reproduction Test EU C.20/OECD TG 211). The study shall be performed with cladocerans, either *Ceriodaphnia dubia* or *Daphnia magna*, using suitable pre-conditioned, non-adsorbing vessels. Pending the results of the investigation of test solution stability, test solutions should be prepared in accordance with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances, using the least pure form of the registered substance with analytical verification of the exposure concentration (a limit test can be performed, with further test concentrations only required if effects are observed).

3. Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: Aqueous and Dietary Exposure test, OECD TG 305). Exposure should be via the diet. The test material shall be the least pure form of the registered substance, and it may be radio-labelled to overcome problems associated with analytical sensitivity. The study shall also include an assessment of vitellogenin formation in male fish. Sampling and determination of vitellogenin shall follow the guidance for this parameter in OECD TG 229. Vitellogenin induction and sex-determination shall be assessed in individual fish at termination of the uptake phase. At least 16 additional fish (as specified in OECD TG 234), consisting of at least 10 male fish, shall be sampled for this purpose from both the exposure and control groups. The test shall be conducted with one of the following fish species: Japanese medaka (*Oryzias latipes*), zebrafish (*Danio rerio*) or fathead minnow (*Pimephales promelas*). The vitellogenin measurement should be based upon a validated homologous Enzyme-Linked Immunosorbent Assay (ELISA) method, using homologous vitellogenin standard and homologous antibodies. A method capable of detecting vitellogenin levels in whole body homogenate as low as a few parts per billion is requested.

4. Soil simulation testing (test method; Aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307 with the following modifications; the study shall be run for at least six months, and include a plant treatment (under aerobic conditions), with the test duration, choice of plant species and growing conditions based on Huang et al. (2010)[2]. Modifications may include the volume of soil (since plants may require more soil for growth over a six-month period than allowed for in the OECD 307 guideline). The substance may be introduced adsorbed to sewage sludge at a relevant but sufficiently high concentration to enable the identification of any relevant transformation products. The Registrant(s) shall justify the choice of test concentration based on either modelling or monitoring. The homogeneity of dosing should be checked analytically. The soils should be free from contamination with potential transformation products, and not contain stones. Sufficient replicates should be used to allow appropriate statistical analysis. Suitable controls and precautions will be required to shield the test vessels from dust contamination. The influence of soil organic/inorganic carbon content, pH, clay content and microbial biomass/activity shall be assessed by repeating relevant parts of the test with three additional soils (depending on the results of the main study). The test material should be the purest form of the registered substance, and should be appropriately radiolabelled. The focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1%. The Registrant(s) shall justify the number of sampling intervals, and monitor for volatiles/mineralisation products if considered relevant.

5. Sediment simulation testing (test method; Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD TG 308). The study shall be performed in two different anaerobic sediment types reflecting different microbial activities and adsorption characteristics, and run for at least six months. The test material should be the purest form of the registered substance, appropriately radiolabelled, and may be introduced directly to the sediment using a suitable method (rather than dosed via water). The Registrant(s) shall justify the choice of test concentration based on either modelling or monitoring. The homogeneity of dosing should be checked analytically. The sediments should be free from contamination with potential transformation products, and not contain stones. Sufficient replicates should be used to allow appropriate statistical analysis. Suitable controls and precautions will be required to shield the test vessels

[2] Huang, H., Zhang, S., Christie, P., Wang, S. and Xie, M., 2010. Behavior of decabromodiphenyl ether (BDE-209) in the soil-plant system: uptake, translocation, and metabolism in plants and dissipation in soil. *Environmental Science and Technology*, 44 (2), 663-667.

from dust contamination. The focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1%. Monitoring for the formation of inorganic bromide should also be performed, and the presence of dehalogenating microbial species and microporous black carbon may also be established (at the start and end of the study, as relevant).

Furthermore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following;

6. A detailed exposure assessment (with sensitivity analysis) for the whole life cycle of EBP. This shall also include consideration of hazards and risks due to transformation products arising from high temperature processes such as plastic product manufacture and incineration of treated articles at the end of their service life.

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **29 November 2016** an update of the registration dossiers containing the information required by this decision.

At any time, the Registrant(s) shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrant(s).

III. Statement of reasons

Based on the evaluation of all relevant information submitted on EBP and other relevant and available information and taking into account the comments of the Registrant(s), proposals for amendment submitted by Member State Competent Authorities/ECHA and the deliberations of the Member State Committee, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

EBP is a very persistent, highly hydrophobic and poorly water soluble substance. It will therefore partition to sediments, sewage sludges and soils in the environment. There is no valid measure of bioaccumulation in fish (a study exists, but the test was performed above the limit of water solubility, using an inappropriate analytical method and too few fish), but environmental monitoring shows that it can be found in a variety of organisms at low concentrations (similar to those achieved by the analogue substance decaBDE). Aquatic toxicity testing is difficult due to the physico-chemical properties of the substance, and although it appears to cause little direct acute toxicity, there are conflicting results for invertebrates (involving a test of questionable reliability) as well as some indications of a possible oestrogenic response in fish from an *in vitro* screening test. No long-term toxicity data are available for pelagic organisms (there are data for sediment and soil-dwelling organisms). The analogue decaBDE has been studied intensively, and it has been found to debrominate under a variety of environmental conditions to form small amounts of lower molecular weight homologues that have PBT/vPvB properties.

The information requirements listed in section II therefore relate to:

- clarification of long-term toxicity in aquatic invertebrates (and confirmation of the concentrations that the organisms were likely exposed to in the available acute tests),
- confirmation of bioaccumulation potential in fish for relevant constituents of the commercial substance (with a check for an oestrogen biomarker), and
- studies investigating transformation potential in sediments and soils (involving microbes and plants, given that these were relevant for decaBDE).

Information provided in the registrations at the beginning of the evaluation process indicated that the commercial substance can be supplied at significantly different purity levels, depending on the Registrant. The substance identity description allows the main constituent to be present at a concentration of 80% w/w as a minimum. To ensure that relevant impurities were addressed in the information requirements, ECHA proposed that the tests should involve certain impurities that may be present in the commercial product of at least one Registrant.

In response to this proposal, the Registrant(s) objected to separate testing on several lower brominated diphenyl ethane congener groups that may be present as impurities in the commercial products. Instead, they argued that only testing on the commercial substance as supplied was legally permissible. Where the test substance was proposed to be "as pure as possible", the Registrant(s) also claimed that the lack of specification of an acceptable purity level would place a burden on them. To protect commercially sensitive information, they might also need to involve an independent third party, which would bring disproportionate costs. In response, ECHA considers that impurities (or constituents in the case of a substance of undefined or variable composition) are a legitimate subject for consideration under Substance Evaluation where those impurities (or constituents) are suspected of posing a greater hazard than the main component (or whole substance). Nevertheless, ECHA notes that the Registrant(s) organised an analysis of each of their commercial products at an independent laboratory and analytical information provided within 60 days of the receipt of the draft decision by the Registrant(s) suggests that the registered substances (as of April 2013) do not contain hepta-, hexa- or pentabromodiphenyl ethanes (at a limit of detection of 0.1% w/w). ECHA therefore recognises that the four Registrant(s) to whom the Decision is addressed now supply the substance at a high degree of purity. Assuming that this information is representative of variations in commercial batches of all suppliers and that the method is reliable, then testing on individual congener groups is no longer justified in terms of proportionality.

However, Registrant(s) who are part of the SIEF but did not have registrations when the Draft Decision was circulated for comment in April 2013 may still supply the substance at a different purity level. Although not bound by the final decision, ECHA believes it is in the interests of all Registrant(s) to support testing that can be applied to their individual registration of EBP. It is also important that risk management decisions are not delayed because of the submission of these additional registrations (which would thereby create uncertainty for the Registrant(s)). Therefore, in the interests of obtaining as much information as possible from the remaining tests, the decision has been amended to specify that some tests are required to use the least or most pure form of the commercial substance registered at the time the Decision is finalised (depending whether the focus of the test is on the transformation of the main constituent or bioaccumulation, respectively), rather than a specially prepared test substance. ECHA considers that this is justified to minimise interpretation problems in the former case (should small amounts of degradants be formed), and to obtain information on relevant impurities in the latter case. The Registrant(s) shall collectively decide on the most appropriate test substance composition in each case. If the Registrant(s) choose not to share relevant information directly, they will need to use a third party. However, ECHA does not consider this to be disproportionate given the concern, as the Registrant(s) would need to agree on the composition of the test substance in any case, and some Registrant(s) have already collaborated by performing analyses in an independent laboratory. Three tests, outlined in points 1-3 of section II, are needed to provide confirmatory data to allow clear conclusions to be drawn about aquatic toxicity and bioaccumulation potential, given the conflicting information currently available.

1. Analytical confirmation of the test concentrations used in the aquatic toxicity testing.

Information on acute aquatic toxicity is relevant for PNEC derivation, hazard classification and PBT assessment. No effects were observed in acute aquatic toxicity tests performed by the Registrant(s) ([redacted]), although there are uncertainties about the test concentrations that the organisms were exposed to since a water-accomodated fraction technique was used without any analytical monitoring (the substance is known to be poorly water soluble and adsorptive). During the evaluation, an independent test reported in the academic literature was identified[6] that suggests acute effects may occur in aquatic invertebrates. It is not fully reliable because it was carried out above the water solubility limit without analytical verification of exposure concentrations.

In response to the original draft decision, the Registrant(s) consider that the published study is of limited reliability, and therefore not sufficient to trigger further testing. However, a convincing explanation for the observations was not provided (the Registrant(s) suggest that excess toluene was the cause of the effects, but the ISO guideline specifies the maximum permitted solvent level, and there were no differences in response between solvent and plain medium controls). It may be concluded that the study is of unknown reliability but, since there is a conflict in the data, further reassurance about the reliability of the Registrant's studies is required to exclude the possibility of acute toxic effects. In recognition of potential analytical difficulties, the draft decision was amended to allow the use of radiolabelled test substance.

Confirmation of the likely exposure concentrations in the Registrants' studies is therefore needed to provide contextual information to re-assess their reliability. It should also provide useful information for the performance of a further study (see point 2 below).

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the registered substance (composition as for the original testing, although radio-labelling might be useful) subject to this decision: Test solutions shall be prepared in exactly the same way as was done for the acute aquatic tests and measurements of the dissolved EBP concentrations in relevant test vessels shall be made over 96 hours.

2. Long-term toxicity testing on aquatic invertebrates

Information on long-term aquatic toxicity is relevant for PNEC derivation, hazard classification and PBT assessment.

No acute effects were observed in tests with fish, *Daphnia* and algae performed by the

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[redacted]A 96-hour static acute toxicity test with the rainbow trout (*Oncorhynchus mykiss*).

[redacted]A 48-hour static actue toxicity test with the cladoceran (*Daphnia magna*)

[redacted]A 96-hour toxicity test with the freshwater alga (*Selenastrum capriconutum*)

[6] Nakari, T. and Huhtala, S., 2010. *In vivo* and *in vitro* toxicity of decabromodiphenyl ethane, a flame retardant. Environmental Toxicology, 25, 333–338.

Registrant(s), although the exposure concentrations were not verified. There are no long-term aquatic toxicity tests in the registrations, and the Registrant(s) claim that a study is not technically feasible due to the very low water solubility (around or below 1 µg/L). However, there is some evidence that the substance can accumulate in organisms (from monitoring studies) and effects have been observed in an independent acute aquatic invertebrate toxicity test reported in the academic literature (see point 1 above). By analogy with the polybromodiphenyl ethers, there are also concerns that congeners with fewer bromine atoms may be more bioaccumulative (and therefore toxic) than the fully brominated substance, but no measured toxicity data are available for them. Despite the low water solubility, reassurance about the lack of long-term aquatic toxicity is desirable for any constituent of the substance in this case.

In response to the original draft decision, the Registrant(s) objected to separate testing of several polybromodiphenyl ethane congeners, for the reasons given at the start of this section. This point has been accepted and the draft decision has been amended to require testing on the commercial substance only (using the least pure form of the registered substance to see if impurities make any contribution to toxicity). The Registrant(s) also raised objections to the use of a published study indicating acute effects (see point 1 above), provided quantitative-structure activity relationship (QSAR) estimates suggesting no toxicity, and pointed out that decaBDE is not considered to be toxic to aquatic organisms in long-term tests (based on testing on lower congeners). These arguments are not considered robust as the QSARs are unreliable and no formal read-across between the polybromodiphenyl ethers has been made in the registration dossiers (on the contrary, the Registrant(s) have emphasised the differences). However, it is recognised that aquatic testing for a substance with such low water solubility is highly unusual. The draft decision has therefore been amended to indicate that further work is needed to establish whether a stable test concentration can be maintained before carrying out the test (a limit test was already allowed).

To minimise vertebrate testing, a test to assess the long-term toxicity to pelagic invertebrates (cladocerans) is recommended. Due to practical issues arising from the low water solubility, further work is required to first establish whether stable test concentrations can be maintained over suitable time periods (see point 1 above). In addition, the cladoceran species *Ceriodaphnia dubia* may be selected instead of *Daphnia magna* because it completes its reproductive cycle over a significantly shorter time span which may reduce problems with test concentration maintenance.

The study shall use suitable pre-conditioned, non-adsorbing vessels. Test solutions should be prepared in accordance with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances, with analytical verification of the exposure concentration (a limit test can be performed, with further test concentrations only required if effects are observed).

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the least pure form of the registered substance (if technically feasible): Long-term toxicity testing on aquatic invertebrates (test method: Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, 4th ed. October 2002. EPA 821/R-02-013 **or** Test of Reproduction and Survival Using the Cladoceran ('Ceriodaphnia dubia') EPS1/RM/21 **or** *Daphnia magna* Reproduction Test EU C.20/OECD TG 211).

3. Bioaccumulation in fish (and oestrogenic effects screen)

One of the initial grounds for concern related to the unclear bioaccumulation potential of EBP. Information on aquatic bioaccumulation is relevant for the evaluation of hazard classification, PBT assessment and secondary poisoning risks.

The aquatic bioaccumulation study submitted in the registrations is invalid as the test was performed above the limit of water solubility, using an inappropriate analytical method and too few fish. There is some doubt about the relevance of the measured octanol-water partition coefficient (K_{ow}) to EBP's bioaccumulation potential. For example, decaBDE appears to bind to blood proteins, and the same may be true of EBP (making lipid partitioning less relevant). Environmental monitoring shows that EBP can be found in a variety of organisms at low concentrations (similar to those achieved by the analogue substance decaBDE). By analogy with the polybromodiphenyl ethers, there are also concerns that congeners with fewer bromine atoms may be more bioaccumulative than the fully brominated substance, but no measured bioaccumulation data are available for them. Therefore the registrations do not contain sufficient information to allow a conclusion to be drawn about the relevance of bioaccumulation for any constituent of the substance.

It is therefore proposed that due to its low water solubility, a fish dietary bioaccumulation study is necessary to clarify the bioaccumulation potential of EBP and all relevant constituents present above 0.1% w/w (the method permits exposure to multiple compounds at the same time).

Vitellogenin induction (a biomarker for oestrogenicity) has also been reported in freshly separated hepatocytes from males of two fish species by Nakari and Huhtala (2010). The *in vitro* assay found that vitellogenin was induced at an EBP concentration of around 6 µg/L (vitellogenin levels reached about 35 µg/mL for brown trout (*Salmo trutta m. lacustris*) and ~25 µg/mL for rainbow trout (*Oncorhynchus mykiss*); no information is given about the control response). At higher test concentrations the amount of vitellogenin in the culture medium started to fall. Induction of hepatocyte detoxification enzymes was also observed. This raises a new concern that was not identified at the time the substance was added to the CoRAP. There have been some doubts expressed about the reliability of the finding as pointed out by the Registrant(s) (see below), but a standard *in vitro* test method is not available. Since fish will be exposed to EBP for the purposes of bioaccumulation assessment, it provides an opportunity to examine the relevance of vitellogenin induction *in vivo* whilst avoiding a separate study involving vertebrates.

In response to this proposal, the Registrant(s) made four broad points:

- The proposal to test a specially synthesised mixture of penta-, hexa-, hepta-, octa-, nona- and decabromodiphenyl ethane congeners would not be representative of the commercial substance. ECHA accepts this point based on the evidence currently available and the decision has been amended to specify that the least pure form of the commercial substance is tested instead, and that radio-labelled substance may be used to overcome problems associated with analytical sensitivity.

- EBP has different molecular size, shape, electronic and lipid solubility properties to decaBDE, so that they are not identical. Whilst ECHA agrees that the substances are different, reassurance is required that their molecular and physico-chemical properties do in fact lead to different environmental behaviour. It is important to gather measured data where possible to provide further empirical evidence for the theoretical claims being made. No amendments have been made to the draft decision.

- No toxicity was observed in a 90-d rat study at doses up to 1000 mg/kg bw/d, a rat prenatal developmental study at doses up to 1250 mg/kg bw/d, and a rabbit prenatal developmental study at 1250 mg/kg bw/d. Two rat oral pharmacokinetic studies using ^{14}C-ring labelled test substance provided no evidence of uptake. Additional supporting information includes lack of effects in two aquatic sediment organisms up

to 5000 mg/kg dry sediment and birds exposed to dose levels of 1000 mg/kg diet/d. These points, which are relevant when considering the Annex XIII criteria, have been noted by ECHA but it is recognised that dosing of poorly soluble substances might be problematic (e.g. undissolved microcrystals could contribute to poor uptake), and that effects were observed in two soil organism toxicity tests, suggesting that uptake can occur. In particular, EBP has been detected in wild bird eggs at concentrations up to around 300 µg/kg ww. Since it cannot be excluded that the BCF is above 1,000 L/kg in the current fish bioaccumulation study (which might not have achieved steady state either), ECHA considers that there is a need to clarify such a significant level of bioaccumulation with a more reliable *in vivo* study. No amendments have been made to the draft decision.

- The Nakari and Huhtala (2010) study indicating the formation of vitellogenin in fish hepatocytes exposed to EBP did not take into consideration that low solubility compounds are not properly assayed by many *in vitro* systems due to their precipitation and/or adherence to walls of the vessel, which eliminates interaction with microsomal enzymes. In the Registrants' opinion, effects in this *in vitro* study attributed to EBP appear improbable, and the reported "dose response" is meaningless, because hepatocytes at all treatment concentrations would be exposed to the same effective dose. The Registrant(s) consider that the reported effects are more likely associated with the toluene component of the analytical standard used as the test substance or DMSO co-solvent than with the EBP molecule. If a further study were to be carried out, the Registrant(s) consider that it would be better to perform this independently from the fish bioaccumulation study.

ECHA recognises that the *in vitro* test system may have limitations for this poorly soluble substance. However, a response was detected. The reasons are unclear – the Registrant(s) provide a plausible explanation about the role of organic solvent (particularly the apparent oestrogenic effects of DMSO reported in the scientific literature), but on the other hand, it is not known how the test solutions were prepared in detail, the solubility of the substance in the test medium or whether suitable solvent controls were run. More soluble impurities may have been involved. ECHA therefore considers the findings to be of sufficient concern to trigger need for confirmation. Given the lack of validated *in vitro* assays and the low solubility of EBP, ECHA considers that a repeat *in vitro* study would not be appropriate. However, including a screen for vitellogenin in the fish dietary bioaccumulation study will make best use of that study to investigate the oestrogenicity issue while minimising the number of fish required. An important element is that the actual dose of the substance provided to the fish will be known. An additional reason is that this method of exposure is relevant for this hydrophobic substance in respect of the administration route. A separate test would need to have additional measurements to provide reassurance about the level of uptake, as well as controls. In contrast, the current proposal would involve a small number of additional fish in the control and treatment groups (which can be randomly selected for vitellogenin measurement). This would save fish (and costs) compared to a separate study. No amendments were made to the draft decision on this point.

During Member State commenting, a proposal for amendment (PfA) was submitted asking to combine the bioaccumulation study with, if feasible in the view of the Registrant(s), the essential elements of OECD TG 230 (21-day Fish Assay: A Short-Term Screening for Oestrogenic and Androgenic Activity, and Aromatase Inhibition); if this is not possible the PfA recommended that the two studies should be performed independently. The PfA asked that the minimum number of fish selected for the additional vitellogenin measurements should be the number specified in OECD TG 230. Some minor editorial changes were also suggested, and they asked for a summary of the current evidence for endocrine disruption potential of the registered substance, and clarity regarding the main points made by the

Registrant(s) and the responses/considerations of the eMSCA. The reasons provided in the PfA are that (in the Member State's opinion) the minimum acceptable oestrogenicity check in fish should be consistent with OECD TG 230, and two separate studies may be selected by the Registrant(s) instead of a single merged study to minimize the possibility of compromising essential parts of either study due to the increased complexity.

In response, ECHA notes that the *in vitro* evidence suggesting an oestrogenic effect includes uncertainty, as the solvent may have influenced the results. ECHA therefore concludes *That the test shall be conducted with one of the following fish species: Japanese medaka (*Oryzias latipes*), zebrafish (*Danio rerio*) or fathead minnow (*Pimephales promelas*)."* The reasons are that a procedure for measurements of vitellogenin induction in fish is described in the following test guidelines: OECD TG 229, OECD TG 230 and OECD TG 234. The three species that are validated for OECD TG 229 are also validated for the OECD bioaccumulation test (OECD TG 305). Phenotypic sex-determination of adult fish should be possible for all three species (although at varying complexity). The requested test only contains one exposure group and a dose-response relationship for vitellogenin induction can therefore not be derived. To achieve an adequate statistical power of the test the sampling shall include at least 16 fish from each replicate and control. This is identical to the minimum number of fish to be sampled for vitellogenin analysis in OECD TG 234. Since vitellogenin is naturally produced in female fish, interpretation of test results is more straightforward in male fish. For this reason, the 16 sampled fish from each replicate and control shall contain at least 10 male fish (by phenotypic determination).

ECHA notes the suggestion that two tests could be conducted separately to avoid complications (and this is in fact the preference of the Registrant(s)). However, it was not clear from the PfA whether the test if conducted separately should be a dietary study or a test with aqueous exposure. In the latter case, ECHA does not think this is particularly relevant for EBP in view of its very low water solubility (~1 µg/L), which will pose technical difficulties which could limit the usefulness of the test (and so represent an unnecessary use of vertebrates). If it is intended to expose the fish in the OECD TG 230 test via the diet, sufficient analytical measurements (and controls) would be needed to ensure that the fish are adequately exposed, which would introduce additional costs. ECHA therefore believes that the best course of action is to conduct this investigation in a single study combining bioaccumulation (the main purpose) with a screen for an oestrogenicity biomarker (vitellogenin). The inclusion of a small number of additional fish would not seem to add much more complexity in ECHA's opinion. Therefore, no amendment was made to the decision.

If the results of this study indicate that vitellogenin is induced by the substance, the evaluating MSCA will consider further testing in response (which may require dietary exposure).

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the least pure form of the registered substance (radio-labelled test substance may be used to overcome problems associated with analytical sensitivity): Bioaccumulation in aquatic species (test method: Bioaccumulation in fish: Aqueous and Dietary Exposure test, OECD TG 305). Exposure should be via the diet. The test shall include the following modification: measurement of vitellogenin in male fish. Sampling and determination of vitellogenin shall follow the guidance for this parameter in OECD TG 229. Vitellogenin induction and sex-determination shall be assessed in individual fish at termination of the uptake phase. At least 16 additional fish (as specified in OECD TG 234), consisting of at least 10 male fish, shall be sampled for this purpose from both the exposure and control groups. The test shall be conducted with one of the following fish species: Japanese medaka (*Oryzias latipes*), zebrafish (*Danio rerio*) or fathead minnow

(*Pimephales promelas*). The vitellogenin measurement should be based upon a validated homologous Enzyme-Linked Immunosorbent Assay (ELISA) method, using homologous vitellogenin standard and homologous antibodies. A method capable of detecting vitellogenin levels in whole body homogenate as low as a few parts per billion is requested.

Notes for consideration by the Registrant(s):

In relation to the abovementioned considerations concerning the potential endocrine disruptive properties of the substance no conclusion is currently drawn in relation to mammalian species and human health. ECHA notes in this context that currently the Registrant(s) have sought to adapt the standard information requirement of Annex IX and X, 8.7.3. Hence results of the corresponding test method referred to in Article 13(3) are not currently available. ECHA stresses that the evaluation of this specific standard information requirement for Annex IX and X was not within the scope of the present decision and may therefore still be evaluated pursuant to Title VI of the REACH Regulation (dossier or substance evaluation).

4. Soil simulation testing

EBP is a very persistent, highly hydrophobic and poorly water soluble substance and will therefore partition to sediments, sewage sludges and soils in the environment. Information on transformation potential in soils is required to first determine whether the registered substance degrades under the conditions of the test and secondly identify any transformation products. The initial concern relates to whether EBP behaves like decaBDE, transforming to substances that may have PBT/vPvB properties.

No soil simulation test is currently available for EBP although the Registrant(s) have been planning to conduct a standard soil simulation test using ^{14}C-EBP. It is agreed that this study is necessary, but should be modified to take account of data for the analogue decaBDE, which was seen to degrade to more hazardous substances when plants were introduced to dosed soil[7].

In response to the original draft decision, the Registrant(s) do not consider the Huang et al. (2010) study reliable as it was not performed according to an international guideline or Good Laboratory Practice, the raw data are not available for review, the supplemental data provided with the publication is limited, the study has not been replicated by another laboratory, and the findings are inconsistent with previous work. They therefore question the appropriateness of including plants in any investigations required as a result of the substance evaluation process as they consider this to be basic research in need of substantial method validation and development (they did however suggest a further test with decaBDE).

Whilst it is conceded that this study was not performed in accordance with any test guideline, full study details are not available and the study has not been replicated exactly by another laboratory (although the same research group has performed some follow up work that seems to support the findings), these points do not necessarily make the results invalid. It is known from work with other substances that plants can enhance biodegradation potential. Given that EBP is likely to partition significantly to sewage sludge and therefore be present in agricultural soil, it is very important to assess the relevance of plants to its degradation behaviour, based on this evidence for a similar substance. If plants

[7] Huang, H., Zhang, S., Christie, P., Wang, S. and Xie, M., 2010. Behavior of decabromodiphenyl ether (BDE-209) in the soil-plant system: uptake, translocation, and metabolism in plants and dissipation in soil. *Environmental Science and Technology*, 44 (2), 663-667.

are shown to enhance degradation, the Registrant(s) will need to assess the relevance of the findings (as well as the properties of any metabolites formed in relevant amounts). The inclusion of an appropriate number of plant treatments in a study of EBP degradation in soil does not seem to present insurmountable obstacles or require laborious method development work. Therefore, no amendments have been made to the draft decision.

It is therefore relevant to include an additional plant treatment group to the soil simulation study, to provide information about the relevance of transformation in soils in the presence and absence of plants over the time period of the test. The focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1% (analytical sensitivity permitting).

The plant treatment shall use the same test duration and growing conditions as the decaBDE study (whilst the choice of plant species is left to the Registrant, they should justify the selection based on the evidence from the decaBDE study). One fresh EU soil type should be used and extreme characteristics should be avoided for this part of the test.

The influence of soil organic/inorganic carbon content, pH, clay content and microbial biomass/activity shall be assessed by repeating relevant parts of the test with three additional soils (depending on the results of the main study).

The test material should be the purest form of the registered substance, to minimise interpretation problems for the Registrant(s) should small amounts of degradants be observed. In addition, it should be appropriately radiolabelled, and introduced to fresh soil adsorbed to sewage sludge at a relevant but sufficiently high concentration to enable the identification of any relevant transformation products. The Registrant(s) shall justify the choice of test concentration based on either modelling or monitoring. Care should be taken to dose the test substance in as homogeneous a way as possible, and this should be checked analytically. Test chambers should be shielded from dust deposition. Sufficient replicates should be used to allow appropriate statistical analysis, and the soil should be free from contamination with potential transformation products, and not contain stones.

Although the test guideline indicates that the test should not exceed 120 days (4 months), it is recommended that the test is allowed to run for at least six months (longer if possible), to give sufficient time for any transformation products to appear.

A PfA was submitted asking to perform the study at 12 °C, since this is a representative temperature for EU soils and will avoid problems with selecting a suitable correction factor if the test is run at a higher temperature. However, ECHA notes that the purpose of this study is to investigate the possibility of transformation to other substances (rather than measuring the half-life, as EBP is already considered to be 'very persistent' within the meaning of the Annex XIII criteria). A test at 20 °C will provide a worst case scenario for this investigation, especially as the influence of plant growth is also being investigated, which might be restricted at a lower temperature. Nevertheless, ECHA agrees that due to the purpose of this test for EBP, the temperature used is different to the normal approach for persistence determination where the environmentally relevant temperature of 12 °C is used to assess parent half-life.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the the purest form of the registered substance: Soil simulation testing (test method; Aerobic and anaerobic transformation in soil, EU C.23/OECD TG 307 with the following modifications; the study shall be run for at least six months, and include a plant treatment (under aerobic conditions), with the test duration,

choice of plant species and growing conditions based on those used by Huang et al. (2010)[8]. Modifications may include the volume of soil (since plants may require more soil for growth over a six-month period than allowed for in the OECD 307 guideline). The substance may be introduced adsorbed to sewage sludge at a relevant but sufficiently high concentration to enable the identification of any relevant transformation products. The Registrant(s) shall justify the number of sampling intervals, and monitor for volatiles/mineralisation products if considered relevant.

5. Sediment simulation testing

EBP is a very persistent, highly hydrophobic and poorly water soluble substance and will therefore partition to sediments, sewage sludges and soils in the environment. Information on the transformation potential in sediments is required to first determine whether the registered substance degrades under the conditions of the test and secondly identify any transformation products. The initial concern relates to whether EBP behaves like decaBDE, transforming to substances that may have PBT/vPvB properties.

No standard sediment simulation test is currently available for EBP although the Registrant(s) have been planning to conduct a sediment simulation test using ^{14}C-EBP. It is agreed that this study is necessary, taking account of information on a sediment simulation test published in the academic literature, as well as data for the analogue decaBDE, which was seen to degrade to more hazardous substances when it was introduced to a lake sediment mesocosm (and when tested with known dehalogenating microbial species). However, the study is needed to establish the relevance of transformation in sediments over the time period of the test rather than to generate a half-life.

In response to the original proposal, the Registrant(s) commented that the rationale for requiring measurement of dehalogenating microbial species and black carbon was unclear and beyond the requirements of the OECD 308 Test Guideline. Standardized methods are not available, and it is not known if laboratories that may be capable of such measurements could do so under Good Laboratory Practice, or if these parameters might change over the duration of the study. However, it is noted that these parameters have been shown to affect the degradation of other recalcitrant (brominated) substances, as shown by a search of the academic literature. So, for example, if the chosen sediment has black carbon present, it is likely that the test substance will have a lower bioavailability than would otherwise be the case. Similarly, presence of dehalogenating microbial species would provide reassurance that a lack of debromination was not due to the species composition of the sediment. This would need to be taken into account in the choice of sediment (characterisation would presumably take place before the main test, and perhaps is already known for some sites). It is in the Registrants' interests to attempt their measurement to avoid future criticism of the results, but since these parameters are not part of the formal test guideline, the draft decision was amended to indicate that their measurement is a suggestion rather than a requirement, and that inorganic bromide should be measured (however, see also the first Member State PfA below).

A standard sediment simulation study is therefore required, using two different anaerobic sediment types reflecting different microbial activities and adsorption characteristics. (Anaerobic conditions are emphasised since this is more likely to stimulate debromination reactions; steps should be taken to ensure that the test chambers remain anaerobic throughout the course of the test.) Microbial biomass, chemical composition of the sediment

[8] Huang, H., Zhang, S., Christie, P., Wang, S. and Xie, M., 2010. Behavior of decabromodiphenyl ether (BDE-209) in the soil-plant system: uptake, translocation, and metabolism in plants and dissipation in soil. *Environmental Science and Technology*, 44 (2), 663-667.

(e.g. in terms of metals, electron donors and acceptors), mineralogy, particle size distribution and pH values should be determined. Extreme characteristics should be avoided. Presence of dehalogenating microbial species and microporous black carbon are known to be important in the degradation behaviour of other persistent halogenated substances, so it would be helpful if these were also measured (at the start and end of the study, as relevant) to provide additional context for the interpretation of the results. The sediments should be free from contamination with potential transformation products, and not contain stones. Test chambers should be shielded from dust deposition. Sufficient replicates should be used to allow appropriate statistical analysis.

The test material should be the purest form of the registered substance, to minimize interpretation problems for the Registrant(s) should small amounts of degradants be observed. In addition, it should be appropriately radiolabelled, and introduced directly to the sediment using a suitable method (rather than dosed via water). The Registrant(s) shall justify the choice of test concentration based on either modelling or monitoring (taking account of experience with decaBDE but avoiding exceedance of solubility in the matrix). The homogeneity of dosing should be checked analytically.

Although the test guideline indicates that the test should not exceed 100 days (~3 months), it is recommended that the test is allowed to run for at least six months (longer if possible), to give sufficient time for any transformation products to appear. The focus should be the identification of transformation products formed at levels of 1% or more of the amount of test substance added, with reasonable attempts made to quantify these down to 0.1% (analytical sensitivity permitting). Monitoring for the formation of inorganic bromide should be performed.

A PfA was submitted asking that the measurements of presence of dehalogenating microbial species and microporous black carbon should be an explicit requirement, rather than an option. ECHA notes that the Registrant(s) objected to any requirement for measurements that are not included in the OECD test guideline, pointing out the lack of standardised techniques and questioning its proportionality. ECHA acknowledged these points and so changed the explicit requirement to say it "would be helpful if these were also measured". ECHA has already stated that this information would be useful.

In addition, a second PfA was submitted asking to perform the study at 12 °C, since this is a representative temperature for EU sediments and will avoid problems with selecting a suitable correction factor if the test is run at a higher temperature. However, ECHA emphasises that the purpose of this study is to investigate the possibility of transformation to other substances (rather than measuring the half-life, as EBP is already considered to be 'very persistent' within the meaning of the Annex XIII criteria). A test at 20 °C will provide a worst case scenario for this investigation. Nevertheless, ECHA agrees that due to the purpose of this test for EBP, the temperature used is different to the normal approach for persistence determination where the environmentally relevant temperature of 12 °C is used to assess parent half-life.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the purest form of the registered substance: Sediment simulation testing (test method; Aerobic and anaerobic transformation in aquatic sediment systems, EU C.24/OECD TG 308), run for at least six months.

6. Environmental exposure assessment

The initial concern related to bioaccumulation potential and PBT assessment as well as potential risks based on default scenarios identified in a previous UK review[9].

An exposure assessment has not been performed by the Registrant(s) because the substance is not classified as hazardous. Nevertheless, the Registrant(s) have derived PNECs for various environmental compartments (e.g. soil, for which classification criteria are not available) and it is possible that hazardous substances may be formed during high temperature processes (by analogy with decaBDE). In the absence of an exposure assessment, it is not possible to conclude on the risks.

In response to the original proposal, the Registrant(s) argued that an exposure assessment can only be requested in case a substance is classified as dangerous or assessed to be PBT/vPvB, and that in the absence of classification, the PNEC cannot form a lawful basis for requesting an exposure assessment. However, Article 46 (1) of the REACH Regulation clearly indicates that requests for further information may go beyond the standard information requirements of Annex VII to X, if the competent authority considers that further information for clarifying the concern is necessary.

The Registrant(s) also claimed that it is unclear what is meant by transformation products from high temperature processes, and that this request was disproportionate as REACH is related to the evaluation of a substance for its identified uses and reaction products are not an inherent property of the substance. ECHA observes that the substance is used in high temperature processes such as plastic product manufacture, and treated articles may also be disposed of via incineration at the end of their service life. The Registrant(s) seem to interpret Article 47(1) as limiting the evaluation to the registered substance and structurally related substances and that no information on transformation products could be requested. In this respect it is however noted that the evaluation of a substance does not only cover the intrinsic properties of the substance, but also transformation products (see for example the standard information requirement of Annex X, 9.3.4. and Annex I, 4. in conjunction with Annex XIII of the REACH Regulation). It is therefore appropriate that the Registrant(s) consider the potential hazards and risks arising from substances formed during these processes, such as octabromodiphenyl ethane congeners, brominated toluenes (including pentabromotoluene), brominated phenanthrenes, and potentially dioxins and furans (as suggested by studies reported in the open literature[10]). An exhaustive assessment of every possible transformation product is not required, but there is a precedent for decaBDE under the Existing Substances Regulation. The draft decision was amended to make this clear.

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[9] Dungey, S. and Akintoye, L., 2007. Environmental Risk Evaluation Report: 1,1'-(Ethane-1,2-diyl) bis[pentabromobenzene] (CAS No. 84852-53-9). Environment Agency, Bristol, UK. Science Report no.: SCHO0507BMOR-E-P. Available using the following link (checked October 2012). http://cdn.environment-agency.gov.uk/scho0507bmor-e-e.pdf

[10] For example:
Grause, G., Karakita, D., Ishibashi, J., Kameda, T., Bhaskar, T. and Yoshioka, T., 2011. TG–MS investigation of brominated products from the degradation of brominated flame retardants in high-impact polystyrene. Chemosphere, 85 (3), 368–373.
He, M.-J., Luo, X.-J., Chen, M.-Y., Sun, Y.-X., Chen, S.-J. and Mai, B.-X., 2012. Bioaccumulation of polybrominated diphenyl ethers and decabromodiphenyl ethane in fish from a river system in a highly industrialized area, South China. Science of the Total Environment, 419, 109–115
Jakab, E., Uddin, Md. A., Bhaskar, T. and Sakata, Y., 2003. Thermal decomposition of flame-retarded high-impact polystyrene. Journal of Analytical and Applied Pyrolysis, 68-69, 83-99.
Puype, F. and Samsonek, J., 2008. Identification of decabromodiphenylethane in plastics by thermal desorption GC-MS. Organohalogen Compounds, 70, 914-917.

Consequently, an environmental exposure assessment is required in addition to the generation of the requirements outlined in points 1 to 5, to establish conditions of safe use. The Registrant(s) should assess the need to perform additional tests if the output is sensitive to the input parameters (e.g. organic carbon-water partition coefficient, earthworm bioaccumulation, etc.).

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to provide the following information subject to this decision: A detailed exposure assessment (with sensitivity analysis) for the whole life cycle of EBP. This shall also include consideration of hazards and risks due to transformation products arising from high temperature processes such as plastic product manufacture and incineration of treated articles at the end of their service life (for consistency with the European risk assessment of decaBDE performed under the Existing Substances Regulation, EC no. 793/93[11]).

IV. Avoidance of unnecessary testing by data- and cost- sharing

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between Registrant(s). Since several Registrant(s) of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the Registrant(s) to perform the tests on behalf of all of them. If a Registrant performs a test on behalf of other Registrant(s), they shall share the cost of that study equally and the Registrant performing the test shall provide each of the others with copies of the full study reports.

This information should be submitted to ECHA using the following form stating the decision number above at:

https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

V. General requirements regarding Good Laboratory Practice

ECHA always reminds Registrant(s) of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

VI. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under

[11] EC, 2002. European Union Risk Assessment Report: Bis(pentabromophenyl ether). 1st Priority List, Volume 17. EUR 20402 EN. European Chemicals Bureau, Institute of Health and Consumer Protection, European Commission. http://echa.europa.eu/documents/10162/da9bc4c4-8e5b-4562-964c-5b4cf59d2432

Articles 52(2) and 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on the ECHA's internet page at http://echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Jukka Malm
Deputy Executive Director

Annex: List of registration numbers – This annex is confidential and not included in the public version of this decision