EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-0000004336-75-05/F Helsinki, 19 August 2014

DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006

For 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol, CAS No 79-94-7 (EC No 201-236-9), registration number: [redacted]

Addressee: [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (also known as tetrabromobisphenol-A or TBBPA), CAS No 79-94-7 (EC No 201-236-9), submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Sections 3, 4, 5 and 6 of Annex I and Section 9.2.3 of Annex IX of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 6 March 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 5 March 2013.

On 22 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 19 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision.

The ECHA Secretariat considered the Registrant's comments.

On 6 March 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, a proposal for amendment to the draft decision was submitted.

On 10 April 2014 ECHA notified the Registrant of the proposal(s) for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal(s) for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

By 12 May 2014 the Registrant did not provide any comments on the proposal for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 26 May 2014 in a written procedure launched on 15 May 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Identification of degradation products as specified below in Section III.A.1. (Annex IX, Section 9.2.3.). More specifically, consideration of the results of the studies in the CSA (Annex I, 0.5 and 3.1.5 and Annex IX), as specified under section III.A.1 below.

- If the registrant can provide convincing evidence why the existing data from aerobic and anaerobic soil degradation studies are not considered reliable then a study on the Aerobic and Anaerobic Transformation in Soil (test method: EU C.23./OECD 307) shall be performed with the registered substance subject to the present decision with the purpose to identify and quantify degradation and/or transformation products (such as diethyl and dimethyl TBBPA derivatives).

- If the registrant can provide convincing evidence why the existing data from anaerobic digester sludge study are not considered reliable then a study on the Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (test method: EU C.24./OECD 308) shall be performed with the registered substance subject to the present decision with the purpose to quantify bisphenol A (BPA) formation in the environment.

- If the Registrant deems necessary, for the identification of degradation and/or transformation products he shall perform and submit the following information derived with the registered substance subject to the present decision: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (test method: EU C.25./OECD 309).

B. Information related to chemical safety assessment and chemical safety report

Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. a revised environmental hazard assessment (Annex I, Section 3.) as further specified in Section III.B.1. of the present decision;
2. a revised PBT and vPvB assessment including PBT and vPvB assessment for transformation and/or degradation products (Annex I, Section 4.) as further specified in Section III.B.2. of the present decision;
3. a revised environmental exposure assessment and risk characterisation including environmental exposure assessment and risk characterisation for transformation and/or degradation products (Annex I, Sections 5. and 6.) as further specified in Section III.B.3. of the present decision.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **26 February 2016.**

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier derived from the application of Annexes VII to XI

1. *Identification of degradation products*

Pursuant to Articles 10(a)(vii), 12(1)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII, VIII, IX, and X of the REACH Regulation. Pursuant to Annex IX, Section 9.2.3. of the REACH Regulation degradation products should be identified.

"Identification of degradation products" is a standard information requirement as laid down in Annex IX, Section 9.2.3 of the REACH Regulation. Pursuant to Annex I, Section 0.5. the chemical safety assessment (CSA) shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Available information from assessment carried out under other international and national programmes shall be included.

Pursuant to Sections 0.6.1. and 3 of Annex I of the REACH Regulation CSA performed by the Registrant shall include an environmental assessment. The hazard identification shall be based on all available information.

In the present case, ECHA observes that neither all available information was considered in the environmental hazard assessment nor justification for not considering available information is provided in the CSR.

More specifically, ECHA notes that there is EU Risk Assessment Report (RAR) for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA) available where it is concluded that the substance has several aerobic and anaerobic degradation products.

ECHA notes that in the EU RAR of TBBPA it is reported that dimethyl and diethyl TBBPA derivatives are formed in quantities exceeding the PBT criterion of 0.1% (results from the aerobic and anaerobic soil degradation studies by Fackler (1989c) and Fackler (1989b); referred in EU RAR to as Springborn Life Sciences, 1989e and as Springborn Life Sciences, 1989d, respectively; in tables 3.7 and 3.15 on pages 77 and 92). Additionally, the EU RAR reports that BPA is formed with the total yield being around 48% after 120 days (anaerobic digester sludge study by Schaefer and Stenzel (2006), referred in EU RAR to as Wildlife International, 2006a, in table 3.13 on page 89). Moreover, the EU RAR further concludes that bisphenol-A has been established as a degradation product of TBBPA under anaerobic conditions in freshwater sediments, estuarine (marine) sediments, contaminated sediments with high salt content and sewage sludge. The results of these tests are not taken into account in the CSA made by the Registrant, i.e. not reported and not discussed in the CSR.

ECHA also observes that in section 5.2.1 of the IUCLID registration dossier the Registrant has concluded that the substance "was not readily biodegradable under a MITI ready biodegradation test". Thus, ECHA concludes that specific rules for adaptation of the information requirement on identification of degradation products are not applicable for the registered substance. Furthermore, ECHA observes that in sections 5.2.2 and 5.2.3 of the IUCLID registration dossier the Registrant has provided results of a number of biodegradation simulation tests in water/sediment/soil. In some tests, the registrant made an attempt to identify degradation products, but has not fully identified them. In section 5.2.2 of the IUCLID registration dossier the Registrant concluded: "Metabolites of TBBPA were observed in anaerobic sediment and anaerobic sludge, but not identified definitively. In the anaerobic sludge, bisphenol A, monobromobisphenol A, dimethyl-TBBPA and monomethyl-TBBPA were not identified as metabolites based on comparison of the unknowns' retention times and ion ratios with those of authentic reference standards. In contrast, bisphenol A was reported as a degradant of TBBPA in estuarine sediments under conditions promoting either methanogenesis or sulfate reduction." In section 5.2.3 of the IUCLID registration dossier the Registrant concluded that "transformation of TBBPA to dimethyl- or diethyl-derivatives was not observed in the two separate aerobic and anaerobic studies." In section III.B.2. below, ECHA notes that there is publically available information on the degradation of the substance under specific conditions and on various stable degradation products which may be formed as referenced above. ECHA encourages the Registrant to examine such available information with a view to fulfilling the information gap.

Thus, ECHA concludes that degradation products are not identified by the Registrant.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to consider the results of the above mentioned existing studies in the CSA and submit the following information for the registered substance subject to the present decision: identification of degradation products. In case the Registrant considers that the results of above mentioned studies cannot be used in the CSA it shall be explained and justified in the CSR.

If the registrant can provide convincing evidence why the data from the above referenced aerobic and anaerobic soil degradation studies are not considered reliable then a study on the Aerobic and Anaerobic Transformation in Soil (test method: EU C.23./OECD 307) shall be performed with the registered substance subject to the present decision with the purpose to identify and quantify degradation and/or transformation products (such as diethyl and dimethyl TBBPA derivatives).

If the registrant can provide convincing evidence why the above referenced data from an anaerobic digester sludge study are not considered reliable then a study on the Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (test method: EU C.24./OECD 308) shall be performed with the registered substance subject to the present decision with the purpose to quantify bisphenol A (BPA) formation in the environment.
If the Registrant deems it necessary for the identification of degradation products he shall perform and submit the following information derived with the registered substance subject to the present decision: Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (test method: EU C.25./OECD 309).

ECHA notes that the Guidance on information requirements and chemical safety assessment Chapter R.7b: Endpoint specific guidance (ECHA, November 2012, version 1.2) indicates the following for the identification of degradation products in the context of assessment of potential persistency of metabolites:
"- *Based on the structure of the parent molecule, predictions of the structures of the breakdown products/metabolites may be made. These can be based on QSAR models/ expert systems e.g. CATABOL or Multicase and by employment of expert judgement, supported by appropriate documentation.*
- At higher tonnages (>100 t/y) there is a requirement to identify breakdown products/metabolites. The registrant shall provide sufficient evidence that either the approach above is sufficient or conduct specific analytical identification."

This Guidance also notes that "*when a substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis. The methods will have to be substance specific and consequently no guidance on choice of method can be given. For some substances, radio-labelled chemicals and specific chemical analyses may allow reasonable fate assessment by measuring subsequent metabolite formation and decay.*"
ECHA notes that the results of biotic degradation simulation tests (Aerobic and Anaerobic Transformation in Soil (OECD 307); Aerobic and Anaerobic Transformation in Aquatic Sediment Systems (OECD 308); and Aerobic Mineralisation in Surface Water – Simulation Biodegradation Test (OECD 309)) may include identification and concentration of major transformation products. Furthermore, ECHA notes that the fate and behaviour of the substance in the environment enables identification of the most appropriate degradation test.

Note for consideration by the Registrant:

The results of the studies requested under section II.A. shall be taken into account when revising the PBT and vPvB assessment (as requested under section II.B.2 and explained further under section III.B.2) and environmental exposure assessment and risk characterisation (as requested under section II.B.3 and explained further under section III.B.3.).

B. Information related to the chemical safety assessment and chemical safety report

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. Revision of the environmental hazard assessment

Pursuant to Sections 0.6.1. and 3 of Annex I of the REACH Regulation a chemical safety assessment (CSA) performed by a Registrant shall include the environmental hazard assessment. Pursuant to Annex I, Section 0.5 the CSA shall be based on the information on the substance contained in the technical dossier and on other available and relevant information. Available information from assessments carried out under other international and national programmes shall be included. Where available and appropriate, an assessment carried out under Community legislation (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the development of, and reflected in, the CSR. Deviations from such assessments shall be justified. Pursuant to Annex I, Section 3.1.1 the hazard identification shall be based on all available information. Based on the available information, the PNEC for each environmental sphere shall be established (Annex I, Section 3.3.1.).

The Registrant has summarised the environmental hazard assessment in his CSR. ECHA, however, observes that neither all available information was considered in the environmental hazard assessment nor justification for deviations from international assessments (including one carried out under Community legislation) has been provided.

ECHA notes that there are OECD SIDS Initial Assessment Profile (SIAM 20, 19-21 April 2005) and European Union draft risk assessment reports available for the registered substance. Both these documents refer to a published toxicity study with marine copepod *Acartia tonsa* where the lowest effect concentration to aquatic organisms was determined (reference: Wollenberger L., Dinan L. and Breitholtz M. (2005). Brominated flame retardants: Activities in a crustacean development test and in an ecdysteroid screening assay. Environ. Toxicol. Chem., 24, 400-407), which was further used in the PNEC for surface water derivation. Results of this test are not taken into account in the CSA, i.e. not reported and not discussed in the CSR. The results of the toxicity study with *Acartia tonsa* are giving rise to the highest concern, i.e. higher concern than studies used by the Registrant for the derivation of PNECs for surface waters (freshwater and marine water).

Therefore, pursuant to Article 41(1)(c) and (3) of the REACH Regulation, the Registrant is requested to take into consideration the results of above mentioned toxicity test with *Acartia tonsa* in the CSA and to revise the environmental hazard assessment in the CSR accordingly.

Note for consideration by the Registrant:

ECHA notes that according to Section 3.1.5 of Annex I of the REACH Regulation where there is more than one study addressing the same effect, then the study or studies giving rise to the highest concern shall be used to draw a conclusion and a robust study summary shall be prepared for that study or studies, and included as part of the technical dossier.

2. Consideration of degradation products of the registered substance in the PBT and vPvB assessment

Pursuant to Sections 0.6.1. and 4 of Annex I of the REACH Regulation a chemical safety assessment (CSA) performed by a Registrant shall include the PBT and vPvB assessment. Section 4.0.1. of Annex I notes that the objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. Annex XIII of the REACH Regulation lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as

well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance. Pursuant to the fifth introductory paragraph of Annex XIII, the identification shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and relevant transformation and/or degradation products.[1]

ECHA notes that the Registrant has summarised the outcome of the PBT and vPvB assessment of the substance in the CSRattached to the technical registration dossier as it is required by the REACH Regulation as well as in the "Endpoint Summary: Ecotoxicological Information" section in the technical registration dossier. The Registrant concluded that the "*substance is not considered as PBT / vPvB*". ECHA observes, however, that in the PBT and vPvB assessment only information on the registered substance has been evaluated against PBT/vPvB criteria. There is no indication in the CSR or technical registration dossier that PBT/vPvB properties of any relevant transformation and/or degradation products were considered in the PBT and vPvB assessment. ECHA concludes that the consideration of transformation and/or degradation products of the registered substance in the PBT and vPvB assessment is missing for this registration.

As already explained in Section III.A.1 above, ECHA further notes that in the EU RAR of TBBPA (results from the aerobic and anaerobic soil degradation studies by Fackler (1989c) and Fackler (1989b), respectively, in tables 3.7 and 3.15 on pages 77 and 92) it is reported that dimethyl and diethyl TBBPA derivatives are formed in quantities exceeding the PBT criterion of 0.1%.

Consequently, a PBT/ vPvB assessment should be performed for the dimethyl and diethyl TBBPA derivatives and any other transformation and/or degradation products exceeding the PBT criterion of 0.1%.

Therefore, pursuant to Sections 0.6.1. and 4.0.1. of Annex I and Annex XIII of the REACH Regulation the Registrant shall take account of the PBT/vPvB-properties of transformation and/or degradation products of the substance in the PBT and vPvB assessment, and update his CSA/CSR accordingly. If some transformation and/or degradation products of the substance are considered to be not relevant for the PBT and vPvB assessment of the substance, this should be explained and justified in the CSR.

In this context, ECHA notes that publically available information indicates that there is some evidence that tetrabromobisphenol-A can degrade to give bisphenol-A under certain anaerobic conditions, and that bisphenol-A is stable under these same conditions (see Appendix E in the European Union Risk Assessment Report for 2,2′,6,6′-tetrabromo-4,4′-isopropylidenediphenol (tetrabromobisphenol-A or TBBPA) Part II – human health, European Chemicals Bureau, 2006; see information referred to in the Draft risk assessment report for 2,2′, 6,6′-Tetrabromo-4,4′-isopropylidenediphenol (Tetrabromobisphenol-A), report R402_0706_env., European Chemicals Bureau, 2007; and see European Union Risk Assessment Report for 4,4'- isopropylidenediphenol, February 2010). Furthermore, the following is stated in the Draft Risk assessment Report for 2,2′, 6,6′-Tetrabromo-4,4′-isopropylidenediphenol (available at http://esis.jrc.ec.europa.eu/doc/risk_assessment/DRAFT/R402_0706_env_hh.pdf):

"*A number of degradation products (or metabolites) of tetrabromobisphenol-A have been postulated (and in some cases identified experimentally). These include the formation of bisphenol-A by the sequential debromination of tetrabromobisphenol-A under certain anaerobic conditions and the possible formation of the dimethylated derivative of*

[1] Annex XIII as amended by Commission Regulation (EU) No 253/2011 of 15 March 2011. Pursuant to Article 2 of Commission Regulation (EU) No 253/2011, registrations were to be updated in order to comply with that amendment no later than 19 March 2013.

tetrabromobisphenol-A (tetrabromobisphenol-A bis(methyl ether), a substance that has been found to occur in the environment) via O-methylation of tetrabromobisphenol-A. [...] On this basis tetrabromobisphenol-A bis(methyl ether) potentially meets the screening vPvB criteria."

In updating the dossier, the Registrant shall take this publically available or publically referred information into account pursuant to Section 0.5. of Annex I.

Therefore, pursuant to Article 41(1)(c) and (3) of the REACH Regulation, the Registrant is requested to revise the PBT and vPvB assessment including PBT and vPvB assessment for transformation and/or degradation products (Annex I, Section 4.), by taking into account information on dimethyl and diethyl TBBPA derivatives and any other degradation and/or transformation products, including publically available or publically referred information (Annex I, Section 0.5.).

3. Revised environmental exposure assessment and risk characterisation

Pursuant to Sections 0.6.2. and 5 of Annex I of the REACH Regulation CSA performed by a Registrant shall include the exposure assessment provided that the registered substance fulfils any of the cases of Section 0.6.3. of Annex I. ECHA notes that the substance has harmonized classification according to the Regulation (EC) No 1272/2008as Aquatic Chronic Category 1 and Aquatic Acute Category 1 and thus, fulfilling the criteria set out in Article 14(4) of the REACH Regulation to require an exposure assessment and a risk characterisation in the CSA.

The exposure assessment consists of two steps, firstly the development of exposure scenarios and secondly the exposure estimation. Pursuant to the Annex I, Section 5.2.1. of the REACH Regulation the second step (the exposure estimation) entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the respective exposure scenario (ES) have been implemented.

ECHA notes that in the CSR the Registrant has provided an environmental exposure assessment. It, however, has noted incompliances in the environmental exposure assessment and therefore pursuant to Article 41(1)(c) and (3) requires a revision of the assessment (Annex I, Section 5) and the risk characterisation (Annex I, Section 6.) which takes into account the following:

a) Justification of release factors used in exposure estimation

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information about operational conditions (OCs) and risk management measures (RMMs) based on which the assumed release factors and daily use rates can be justified. ECHA notes that the clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) of other than default environmental release category (ERC) release factors used in exposure estimation is not provided in the CSR, i.e., for example, relevant purification techniques with efficiencies of those to be used are not specified. Therefore, it is concluded that justification of release factors used in exposure estimation is missing in relevant ESs.

Thus, the Registrant is requested to either

- apply the default release factors, as recommended for the corresponding ERCs in Guidance Chapter R.16, in the exposure estimation for relevant ESs; or
- provide in the relevant ESs clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) of the use of non-default ERC release factors in the exposure estimation.

The CSR shall be amended accordingly.

b) Scope of the exposure estimation

ECHA notes that for most of the ESs provided in the CSR submitted on behalf of all Registrants, the exposure assessment is based on the Voluntary Emission Control Action Programme (VECAP) release factors. The Registrant has indicated in the CSR that "*VECAP currently covers* [redacted] *of TBBPA's total volume on the EU market*" and that "[redacted] *of the volume surveyed is handled with best practices*". It is therefore acknowledged by the Registrant that the VECAP initiative does not cover all companies handling the substance and that the "best practices" referred to are not in place in the whole market. Thus, ECHA presumes that exposure estimation (for the ESs where VECAP release factors are used) provided by the Registrant is based on the data from the companies handling the substance with the 'best practices'. ECHA concludes that the provided exposure estimation does not cover the worst case scenario where the substance is not handled with the "best practices" and/or is handled by companies not participating in the VECAP initiative.

Therefore, the Registrant is requested to

- either revise the exposure assessment to reflect on the whole market; or
- provide in the CSR justification why the VECAP release factors are applicable for the provided ESs and how they cover possible worst case scenario (e.g. where the substance is not handled with the 'best practices' and/or is handled by companies not participating in VECAP initiative).

The CSR shall be amended accordingly.

c) Exposure estimation of transformation and/or degradation products

In addition, in section III.A.1, ECHA noted that the substance degrades under specific conditions and various stable degradation products may be formed. ECHA observes that the consideration of transformation and/or degradation products (such as demethyl and diethyl TBBPA derivatives and BPA) of the registered substance in the exposure estimation is missing for this registration. Therefore, pursuant to Section 5.2.4. of Annex I of the REACH Regulation, the Registrant is requested to take account of the transformation and/or degradation products in the exposure estimation and risk characterisation and update his CSA and CSR accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation

In relation to the information required by the present decision, the sample of substance used for the new studies (if deemed necessary by the Registrant) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the

specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 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 ECHA's internet page at http://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
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