EUROPEAN CHEMICALS AGENCY

Helsinki, 22 May 2014

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

For tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate, CAS No 3319-31-1 (EC No 222-020-0)

Addressees: Registrants)[1] of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate (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.

Registrant(s) meeting the following criteria are *not* addressees of this decision: i) Registrants 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 Umweltbundesamt GmbH on behalf of the Competent Authority of Austria (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 31 October 2013, the date upon which the draft decision was circulated to the other Competent Authorities of the Member States and ECHA pursuant to Article 52(1) of the REACH Regulation.

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 Austria has initiated substance evaluation for tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate, CAS No 3319-31-1 (EC No 222-020-0) based on registration dossiers submitted by the Registrant(s) and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

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

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to: Environment/Suspected PBT; Exposure/Wide dispersive use and high aggregated tonnage, tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate 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 Austria was appointed to carry out the evaluation.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information and submitted the draft decision to ECHA on 28 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.

By 6 May 2013 ECHA received comments from the Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the Registrants' comments received and did amend Section II of the draft decision. The comments were reflected in Section III of the draft decision (Statement of reasons).

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.

Subsequently, proposals for amendment to the draft decision were submitted.

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 proposals for amendment received and amended the draft decision accordingly.

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. The Member State Committee took the comments of the Registrant(s) on the proposal(s) for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 January 2014 in a written procedure launched on 10 January 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 and instructions, and the registered substance subject to the present decision:

Aerobic transformation in aquatic sediment systems according to Aerobic and anaerobic transformation in aquatic sediment systems (EU C.24 /OECD 308), at a temperature of 12°C, using radioactively ring-labelled test substance. The degradation half-life under environmentally relevant conditions and identification of the transformation products (metabolites) shall be determined in accordance with the test method. Carbon 14 labelling shall be used. If analytically possible, degradation products shall be identified below the level of 10% of the amount of the registered test substance added (as required according to the test method as a minimum) and preferably down to 1% and if feasible 0.1%. Furthermore, the degradation half-life/lives of relevant degradation products (metabolites) shall also be determined.

Furthermore, pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit robust study summaries for the information required in Section II.

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

III. Statement of reasons

Based on the evaluation of all relevant information submitted on tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate and other relevant and available information 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 regarding environment/suspected PBT, exposure/wide dispersive use and high aggregated tonnage. As tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate has been identified as a potential substitute for several phthalates (e.g. Annex XV reports for dibutylphthalate/benzylbutylphthalate), tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate tonnages and exposure are expected to increase in the near future.

Regarding PBT/vPvB assessment the Registrant(s) provided data on the P, B and T criteria which were assessed by the evaluating MSCA:

Persistence criterion (P)

Submitted biodegradation studies show that tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate is not readily and not inherently biodegradable ([redacted]2012[1], Anon 1977[2], [redacted]1986[3]) and respective half-life data according to Annex XIII of the REACH Regulation are not available for tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate. Hydrolysis is considered to be slow. It is expected to be a potential rate limiting step for the biodegradation of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate, which is impeded by the low water solubility of the assessed substance.

Four metabolites of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate were predicted by microbial catabolic reactions (Anon 2012[4]): Di-ester (CAS No. 58978-43-1), Mono-ester (CAS No. 68735-92-2), Trimellitic acid (CAS No. 528-44-9), and 2-ethylhexanol (CAS No.

1 [redacted] (2012). Assessment of biodegradability of Cereplas OTM using the Closed Bottle Test method. Testing laboratory: [redacted]. Report no.: [redacted]. Owner company: [redacted]. Report date: 2012-01-16.
2 Anon (1977). Report of degradation test results for Tris(2-ethylhexyl) benzenetricarboxylate. SIDS. Testing laboratory: [redacted] Owner company: [redacted] Report date: 1977-10-13.
3 [redacted] (1986). Shake flask biodegradation of 14C-Tris (2-ethylhexyl) trimellitate (TOTM). NTIS/OTS. Testing laboratory: [redacted] Owner company: [redacted] Report date: 1986-02-20.
4 Anon. (2012). UM-PPS Prediction

104-76-7). The prediction also indicates that there is a theoretical possibility that Mono(2-ethylhexyl)phthalate (MEHP) is formed. Whether these metabolites in fact occur in the respective environmental compartments is unknown.

As no simulation degradation test in a relevant environmental compartment is available, no conclusion on the P/vP criteria can be drawn for the substance itself or as appropriate on its transformation products (metabolites) yet to be determined. Therefore, a sediment simulation test on the registered substance including assessment of relevant metabolites is required to determine, if the P/vP (persistent/very persistent) criteria are fulfilled.

Bioaccumulation criterion (B)

There exist several indications of the bioaccumulation potential of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate: the substance has a log Kow ≥ 3 (log Kow = 8.00, OECD TG 123), a molecular weight ≤ 700 g/mol (MW: 546 g/mol), is highly adsorptive (Log Koc= 22.96) and is considered to be immobile in soil and sediment.

From a study similar to OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish) very low BCF values of maximum 2.7 were obtained (Anon 1978[5]). This study is considered to be not reliable because the tested concentration is above the water solubility and the maintenance of the concentration is unknown. Plasma half-lives after oral exposure indicate some potential for bioaccumulation in rats (half live about 40 hours).

The Registrant(s) assume that the potential of bioaccumulation of metabolites is low. It is unknown which metabolites are formed in the relevant environmental compartments. Nevertheless, there are indications for the bioaccumulation potential of the di-ester (CAS No 58978-43-1): the di-ester has a log Kow ≥ 3 (estimated log Kow = 8.2, KOWWIN v 1.68; estimation provided by the evaluating member state).

Conclusion for the B criterion: Available data allow no final conclusion on the B/vB (bioaccumulative/very bioaccumulative) criterion. Due to animal welfare reasons the P criterion is evaluated before information requirements for the B criterion are considered.

Toxicity criterion (T)

No aquatic toxicity up to the level of water solubility of 3 µg/L (acute and chronic studies) has been observed. All tests have been performed at concentrations higher than the water solubility.

Four metabolites of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate were predicted by microbial catabolic reactions (Anon et al., 2012): di-ester (CAS No 58978-43-1), mono-ester (CAS No 68735-92-2), trimellitic acid (CAS No 528-44-9), and 2-ethylhexanol (CAS No 104-76-7). No information on the toxicity of these metabolites is available in the chemical safety report. Chronic fish toxicity was predicted by the evaluating Member State in a screening approach using the PBT profiler[6]. The predicted chronic fish toxicity of the mono-ester is 0.16 mg/L and the predicted toxicity of the di-ester is 0.00031 mg/L. The prediction also indicates that there is a theoretical possibility that MEHP is formed: MEHP is the major metabolite of bis(2-ethylhexyl)phthalate (DEHP), has proven to be toxic for mammals and may be responsible for many of the effects seen in toxicity studies with

5 Anon (1978). Report of the concentration test results for tris(2-ethylhexyl) benzenetricarboxylate. Testing laboratory: [redacted] Owner company: [redacted] Report date: 1978-03-25.
6 PBT profiler: a computational tool for predicting the P, B and T criteria of a substance based on its structure, see http://www.pbtprofiler.net/

DEHP. It is therefore likely that MEHP will be toxic also to other species like birds, fish, frogs, etc (European Union Risk Assessment Report on bis(2-ethylhexyl)phthalate (DEHP), 2008).

Repeated dose toxicity was tested in a recent 90 day rat feeding study with 50, 225 and 1000 mg/kg bw day. The test included additionally an analysis of spermatogenic cycling (histology of testis, staging according to Creasy 2003[7]) and oestrous cycle (last 2 weeks of treatment, vaginal smear). No adverse effects were observed on these parameters and on the histology of the reproductive organs. The critical effects were observed as clinical chemistry and histology effects related to liver and spleen. A no observed effect level (NOEL) / no observed adverse effect level (NOAEL) of 50/225 mg/kg bw day was proposed. Within a 28 day rat feeding study tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate effects were compared with DEHP effects. Tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate caused the same spectrum of organ weight and biochemical changes in the rat liver and slight peroxisome proliferation but was less potent than DEHP, with 2% tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate in diet producing less effect than 0.67% DEHP. Within a 28 day rat gavage study tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate affected the kidney and lung at the top dose of 1000 mg/kg bw day, which was however reported as NOAEL.

With regard to reproductive toxicity it is concluded that the dominant effects on the testis that were observed with DEHP and MEHP in repeated dose studies, developmental and reproductive studies (at dose levels ≥ 14 mg/kg bw day) were not observed in any of the respective studies with tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate with the exception of one reproduction/developmental screening test carried out with gavage at high doses of 1000 mg/kg bw day and to a minor extent at 300 mg/kg bw day. A mechanistic transcriptional profiling study further supports the evidence that tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate differs with regard to reproductive toxicity to phthalates DEHP and MEHP.

Furthermore from the kinetic and metabolism studies it is supported that tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate is more stable in the gastrointestinal tract (GIT) compared to DEHP. Mainly hydrolysis products are absorbed via the GIT and therefore the overall oral absorption rate is lower. This may also substantially contribute to the difference in toxicology results in spite of structural similarity.

Due to the overall negative results for reproductive toxicity: 1/ in a 90 day study extended with an analysis of spermatogenic cycling and oestrous cycling, 2/ in a developmental study extended with an analysis of post-natal development till 15 weeks (male offspring) and 6 weeks (female offspring) including endocrine and developmental parameters as well as histology of reproductive organs, and 3/ in developmental/reproductive tests according to OECD TG 421 and 422 with full histology, no further testing appears necessary.

No genotoxicity was observed in the standard in vitro tests (bacterial gene mutation, mammalian gene mutation, mammalian chromosomal aberration, unscheduled DNA synthesis tests) nor in the additional in vivo dominant lethal test.

No carcinogenicity study is available. However no genotoxicity was observed in the standard in vitro tests nor in the additional in vivo dominant lethal test and no hyperplasia or other indications of potential carcinogenic effects relevant for humans were observed in the available repeated dose studies.

Conclusion on T criterion: Based on the available (eco)toxicity data the T criterion is not

7 Creasy (2003) Evaluation of Testicular Toxicology: A Synopsis And Discussion Of The Recommendations Proposed by the Society of Toxicologic Pathology. Birth Defects Research (Part B) 68:408-415

fulfilled. Nevertheless ecotoxicity data on metabolites might lead to the fulfilment of the T criterion for a metabolite.

As a general conclusion of the PBT/vPvB assessment, simulation testing is required to assess the persistence of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate and to gain necessary information on metabolites and transformation products (see section on P criterion).

Tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate has high aggregated tonnage and has wide dispersive uses. Distribution modeling using Level III Fugacity Model revealed that the substance tends to end-up in sediment and soil. The predicted half-life for all 4 metabolites is higher in sediment than in soil. Sediment revealed the highest half-life (140 days). In addition, Predicted environmental concentrations (PECs) were calculated by the evaluating member state using EUSES 2.1. In the scenario "Production" and "Formulation" PECs were higher for the sediment than for the soil compartment.

In the light of the reasons given above a sediment simulation test of the registered substance and its relevant degradation products (metabolites) is required for assessing aerobic transformation in aquatic sediment systems according to test Guideline "**Aerobic and anaerobic transformation in aquatic sediment systems" (EU C.24/OECD 308), at a temperature of 12°C, using radioactively ring-labelled test substance** to assess whether the registered substance fulfils the P/vP criteria according to the criteria set out in Annex XIII of the REACH Regulation and/or whether metabolites/transformation products are formed, which are potentially PBT or vPvB substances according to Annex XIII of the REACH Regulation.

According to Annex XIII of the REACH Regulation, the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions. The substance subject to the present decision is used and released within the context of the REACH Regulation in the EU. Therefore, the Registrant(s) are requested to perform the study at 12°C (285K) as this temperature is indicated in the Guidance on information requirements and chemical safety assessment Chapter R.16., Table R.16-9 (version 2.1 October 2012) as the average environmental temperature for the EU to be used in the chemical safety assessment. In their comments, the Registrant(s) accepted that this temperature may be more representative of conditions in Northern Europe, however they also expressed their concerns regarding the possibility to find laboratories which could perform the test at 12°C and the acceptability of a simulation test performed at 12°C for other regulatory regimes. The Registrant(s) pointed out that simulation tests are commonly performed at 20°C and that the degradation rates can be corrected to a given temperature by using the Arrhenius equation.

However, ECHA considers that performing the test at the temperature of 12°C is within the applicable test conditions of the OECD Test Guideline 308 and represents relevant environmental conditions in the EU. Paragraph 33 of the OECD Test Guideline 308 indeed specifies that "w*here appropriate, an additional lower temperature (e.g. 10°C) may be considered on a case-by-case basis, depending on the information required from the test".* Chapter R.7b of the ECHA Guidance on information requirements and chemical safety assessment further specifies that simulation tests "*attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment*". When only existing results for tests performed at 20°C are available, then ECHA Guidance R.7b. indicates that a temperature correction based on the Arrhenius equation is permitted. The Arrhenius equation reflects the fact that the temperature dependence of a chemical reaction depends on the intrinsic activation energy of that reaction. The higher the activation energy, the

slower the reaction rate at reduced temperature. In practice, temperature dependence of the activation energy is specific for each chemical and reaction. High extrapolation uncertainties can be best avoided by selecting appropriate testing temperatures. Furthermore, this equation was derived originally to illustrate the temperature dependence of chemical reaction rates, not of biological activity. The scientific basis for using the Arrhenius equation for complex biological processes like biodegradation is therefore weak. In order to avoid these extrapolation uncertainties, a new simulation test shall be performed directly at a temperature that represents best the real environmental conditions in the EU, which is 12°C. ECHA acknowledges that most of the existing simulation tests were performed at 20°C or more, and that performing such tests at 12°C will require some technical adaptations from the testing laboratories. However ECHA considers that performing the test at 12°C will be still technically feasible.

The degradation half-life under environmentally relevant conditions and identification of the transformation products (metabolites) shall be determined in accordance with the test method. Carbon 14 labelling shall be used. If analytically possible, degradation products shall be identified below the level of 10% of the amount of the registered test substance added (as required according to the test method as a minimum) and preferably down to 1% and if feasible 0.1%. Furthermore the degradation half-life/lives of relevant degradation products (metabolites) shall also be determined.

If this is not possible with sufficient certainty in the study with the registered substance, independent simulation degradation study/studies with relevant degradation products which may fulfil the PBT/vPvB criteria shall be conducted.

Depending of the result of this/these studies further studies concerning bioaccumulation and long-term toxicity may be required on the registered substance and/or relevant degradation products. This will later be decided by the evaluating MSCA.

In their comments, the Registrants were mentioning that the identification of degradation products below 10% was disproportionate. Nevertheless, as the substance is a potential PBT/vPvB substance this procedure is considered necessary and appropriate if it is analytically feasible because concentrations below 10% are relevant for this assessment.

The Registrant(s) also made the remark that poorly water-soluble substances were a challenge in biodegradability testing and that the specific activity of the labelled substance in the OECD Test Guideline 308 might be too low to work below the water solubility limit of the substance. They proposed to firstly examine the biodegradability of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate using the enhanced/modified tests outline in REACH Guidance on information requirements and chemical safety assessment Chapter R.7b regarding testing the substance at around the limit of water solubility. This would have the advantage that the analysis would be more straightforward than in the OECD 308 test where extraction methods and sample clean-up procedures will need to be developed prior to the analysis of the transformation products. Initial pre-work is suggested by the registrant(s) also to assess means of improving the bioavailability prior to testing. According to the Registrant(s), if the substance can be shown to mineralise within a defined period (up to 60 days) to >60%, consideration could be given that no further testing would be required. As an alternative to the OECD Test Guideline 308 the Registrant(s) mentioned the OECD Test Guideline 309 (with added sediment) as it simulates the water column with some suspended sediment possibly leading to less sorption.

Nevertheless, OECD Test Guideline 308 is deemed applicable to poorly soluble substances, as stated in the Guideline itself. This Test Guideline does not foresee the improvement of the bioavailability for tested substances. The simulation test (OECD Test Guideline 308) can

be used directly to identify and quantify the metabolites and determine the biodegradation rate using high concentration for the identification and low concentration ^{14}C-labelled tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate for the biodegradation rate. A main reason to choose OECD Test Guideline 308 were predictions indicating that soil and sediment are the compartments which are likely to be exposed to tris(2-ethylhexyl) benzene-1,2,4-tricarboxylate and its predicted metabolites.

The performance of another "enhanced/modified tests" in a row of already existing tests is deemed not to bring further clarification on the persistence of tris(2-ethylhexyl) benzene-1,2,4- tricarboxylate and its transformation products.

In conclusion, the objections made above by the Registrant(s) were not deemed sufficient to amend the present decision.

Without the requested information it will not be possible to clarify the suspected concern and whether there remains an uncontrolled risk with the substance that shall be subject to further risk management measures.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers 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 required test, the sample of substance used for the new study shall have a composition that is within the specifications of the substance composition that are given by all Registrant(s). It is the responsibility of all the Registrant(s) to agree on the tested materials to be subjected to the test subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the study must be shared by the Registrant(s).

V. 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 Registrants. Since several Registrants 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 Registrants, 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 shall 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.

VI. General requirements regarding Good Laboratory Practice

ECHA 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).

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the registrant(s) shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under 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/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Deputy Executive Director

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