Decision number: CCH-D-2114289316-41-01/F Helsinki, 16 December 2014

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

For 2-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate, CAS No 15625-89-5 (EC No 239-701-3), 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-ethyl-2-[[(1-oxoallyl)oxy]methyl]-1,3-propanediyl diacrylate, CAS No 15625-89-5 (EC No 239-701-3), submitted by [redacted] (Registrant).

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 12 June 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 2 August 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. That draft decision was based on submission number [redacted].

On 20 December 2013 ECHA received comments from the Registrant on the draft decision. On 6 May 2014 the Registrant updated his registration dossier with the submission number [redacted]

The ECHA Secretariat considered the Registrant's comments and update. On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 12 June 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, proposals for amendment to the draft decision were submitted.

On 18 July 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 proposals 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 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

The present decision relates solely to a compliance check requesting information in form of pre-natal developmental toxicity study, revised DNELs for workers, revised predicted no effects levels (PNECs) for sediment and soil, revised environmental exposure assessment and risk characterisation and documentation for the recommended personal protective equipment. The other compliance check requirement of two-generation reproductive toxicity study, is addressed in a separate decision although all information requirements were initially addressed together in the same draft decision.

After discussion in the Member State Committee meeting on 16-18 September 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 16 September 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 X of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route.

Note for consideration by the Registrant:

The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.

Failure to comply with the requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.

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

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

1. Revised DNELs for workers and the general population (Annex I, Section 1.4.1.), as specified under section III.B.1. below;
2. Revised predicted no effects levels (PNECs) for sediment and soil (Annex I, 3.3.1.), as specified under section III.B.2. below;
3. Revised environmental exposure assessment and risk characterisation (Annex I, sections 5 and 6), as specified under section III.B.3 below;
4. Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b)), as specified under section III.B.4. below.

C. Deadline for providing the required information

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 **23 December 2015**.

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

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 IX and X of the REACH Regulation.

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, oral route.

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

The technical dossier contains information on a pre-natal developmental toxicity study in rats by the oral route using the registered substance as test material. However, there is no information available for a pre-natal developmental toxicity study in a second species.

In addition, the technical dossier does not contain an adaptation in accordance with column 2 of Annex X, Section 8.7. or with the general rules of Annex XI for this standard information requirement. Consequently, there is an information gap for Annex X, Section 8.7.2. and it is necessary to provide information for this endpoint.

The test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rabbit as a second species to be used.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his agreement to perform the test requested.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the oral route.

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 (CSR) which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

According to Article 14(3) and Annex I Section 0.6.1., the chemical safety assessment shall include human health, physicochemical and environmental hazard assessments.

Further, according to Article 14(4) and Annex I Section 0.6.2, if the substance fulfils the criteria for any of the hazard classes or categories referred to in Article 14(4) and Annex I Section 0.6.3. of the REACH Regulation, the chemical safety assessment shall also include exposure assessment including the generation of exposure scenarios (or the identification of relevant use and exposure categories if appropriate) and exposure estimation, as well as risk characterisation.

1. Revised DNELs for workers and the general population (Annex I, Section 1.4.1.)

Annex I, 1.4.1 of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The ECHA *Guidance on information requirements and chemical safety assessment*, R.8. (Version 2.1, November 2012) provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1.

ECHA notes that when deriving a systemic long term DNEL for the inhalation route for workers and the general population the Registrant has used an intraspecies Assessment Factor (AF) of 3 for workers and 5 for the general population and an AF of 1 for the remaining interspecies difference while the above-mentioned ECHA guidance default AFs are intraspecies AF of 5 for workers and 10 for the general population and 2.5 for the remaining interspecies difference. The Registrant has not provided any substance specific justification for deviating from these default AFs.

ECHA also notes that the Registrant has used hazard data from another substance than the registered substance as starting point for the DNEL derivation. However, the Registrant has not provided and documented a read-across justification assessing the structural similarity and systematic comparison of toxicological properties that would allow predicting properties from the analogue substance to the registered substance subject to the present decision and thus, the requirements in Annex XI, Section 1.5. have not been fulfilled. Therefore, the Registrant should use hazard data obtained with the registered substance for the DNEL derivation.

As explained above, the information provided on DNEL for the registered substance in the CSR does not meet the general provisions for preparing a CSR as described in Annex I, 1.4.1. because (1) without read-across justification it cannot rely on data for another than the registered substance and (2) the assessment factors used are neither in accordance with ECHA Guidance on information requirements and chemical safety assessment Volume 8, Chapter R.8. nor are they fully justified. Consequently it is necessary to revise the DNELs or to provide a full justification.

As the read-across argument has not been justified, the Registrant shall base the DNELs exclusively on data on the registered substance.

For deriving such revised DNELs, the Registrant is given two options: The Registrant shall revise the DNELs for workers by applying the assessment factors recommended by ECHA that are appropriate in this case. Subsequently, the Registrant shall re-assess related risks. In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1, provide a full justification for the DNELs derived for workers provided in the chemical safety report by specifying how the following has been taken into account:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;
c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report the following information: Revised DNELs for workers and the general population using data obtained with the registered substance as starting point and

- using the assessment factors recommended by ECHA and re-assessment of related risks or providing a full justification for not using the recommended assessment factors in DNEL derivation.

2. Revised predicted no effects levels (PNECs) for sediment and soil (Annex I, 3.3.1.)

Annex I, Section 3.3.1. of the REACH Regulation requires to establish a PNEC for each environmental sphere based on the available information and to use an appropriate assessment factor to the effect values.

The Registrant has applied the Equilibrium Partitioning Approach for deriving PNECs for sediment and soil: i.e. 0.0062 mg/kg and 0.0043 mg/kg respectively. The Registrant indicates that those PNECs are expressed as concentrations in dry sediment or in dry soil respectively (i.e. in mg per kg of dry weight sediment or soil respectively).

However, ECHA notes that considering the data provided by the Registrant, those units are not correct. The values of 0.0062 mg/kg and 0.0043 mg/kg correspond to concentrations expressed for wet weight of sediment or soil respectively.

The Registrant shall either correct the units for the PNECs for sediment and soil or calculate PNECs that are actually corresponding to concentrations in dry sediment or soil.

The ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.10 (Version May 2008) provides further details on the Equilibrium Partitioning Method.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his intention to revise the PNECs for sediment and soil considering the deficiencies pointed out by ECHA. However, ECHA notes that the Registrant has not revised that information.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit revised PNECs for sediment and soil considering the deficiencies pointed out above and re-assessment of related risks.

3. Revised environmental exposure assessment and risk characterization (Annex I, Sections 5 and 6)

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I Section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario and shall consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

ECHA's Guidance on information requirements and chemical safety assessment, Part B: Hazard Assessment (Version 2.1, December 2011), Section B.8.4. (pages 47 to 48) states that "if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed".

In the CSR provided by the Registrant the exposure assessment for the environment is missing. The Registrant claims that no exposure assessment is necessary for the environment by stating that *"as the substance is not classified and labelled according to DSD (67/548/EEC) as amended with regard to the risk to the environment there is no need exposure assessment and hence no quantitative risk assessment necessary. Nevertheless the substance is classified with regard to human health, hence the potential for indirect exposure to humans via the environment will be calculated at the regional scale"*.

ECHA notes that the Registrant has classified the substance as Skin Irrit.2, Eye Irrit. 2 and Skin Sens. 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 chemical safety assessment.

Additionally, ECHA notes that adverse effects were observed in some environmental toxicity studies. In particular, in the short-term toxicity studies to fish a 96h-LC50 of 1.47 mg/L, in the short-term toxicity studies to Daphnia a 48h-EC50 of 19.9 mg/L and in the toxicity studies to algae a 96h-EC50 of 4.9 mg/L were obtained.

In the comments to the draft decision, the Registrant argued that an exposure assessment for environment has to be performed only if environmental hazards leading to classification have been identified. With regard to these comments ECHA points out the following:

Generally, two of the main purposes of both the REACH and CLP Regulation are to ensure a high level of protection of human health and the environment (Article 1(1) of the REACH and CLP Regulation respectively). The additional steps in a chemical safety assessment of exposure assessment and risk characterization serve this objective as they allow estimating and characterizing any risk to mankind or the environment. The arguments of the Registrant that this shall be done only for hazards that have been classified in accordance with the CLP Regulation and not for other identified hazards ignore this overall context. These arguments remain on a formal level leaving aside the rationale of the legislation.

The REACH Regulation obliges manufacturer and importer to ensure the safe use of their substances in general while the CLP Regulation sets up an obligation to conclude on concrete risk management measures by classification for certain hazards and to communicate this via labelling in the supply chain. The REACH and CLP Regulations can be interpreted in a coherent and consistent way without reducing unnecessarily the scope of both pieces of legislation. Whereas in line with recital 12 of the CLP Regulation terms and definitions of REACH and CLP should be interpreted consistently, 'hazard' or 'identified hazard' is not defined in either of the Regulations. More explicitly, ECHA points out firstly that both REACH and CLP Regulations make a difference between the terms 'hazard' and 'hazardous' and 'hazard classes'. This becomes clear from:

- Article 3 of the CLP Regulation referring to fulfilling the criteria relating to 'physical hazards', 'health hazards' or 'environmental hazards';
- Article 14(4) and Annex I, Section 0.6.3. to the REACH Regulation referring to 'hazard classes';
- Annex I, section 5 to the REACH Regulation referring to the term 'hazard' (and not hazard class) when defining the scope of the exposure assessment.

Hence, both in the REACH and CLP Regulation the term 'hazard' is independent from the term 'hazardous' and consequently from the classification of the substance in 'hazard classes'. Thus, the term 'hazard' in Annex I, Section 5 does not refer solely to 'hazard classes'. The legislation contains both clearly distinct terms and the legislator would have used the more specific term 'hazard classes' instead of the term 'hazard' if that was his intention.

Pursuant to Annex I, Section 3.0.2. of the REACH Regulation five environmental spheres shall be assessed for hazards (aquatic including sediment, terrestrial, atmospheric compartments, including the potential effects via food-chain accumulation, microbiological activity of sewage treatment systems). Annex I, Sections 5 and 6 require an exposure assessment and risk characterization for the "environmental spheres for which exposure to the substance is known or reasonably foreseeable". ECHA points out that following the Registrant's argumentation, the environmental exposure assessment and risk characterization would only be possible for the aquatic environmental sphere (and excluding sediment) since the results for a number of standard data requirements for the other environmental spheres (e.g. information on soil/sediment toxicity, activated sludge respiration inhibition testing etc.) do not lead to the classification of substances as hazardous, as no hazard classes or classification criteria based on the results of these tests are codified in the CLP Regulation. As this would result in a situation where a large part of standard data requirements set out in the REACH Annexes would become irrelevant in the hazard and exposure assessment and risk characterization of a substance, such an approach cannot be correct.

Instead it is self-evident that the legislator has a clear intention to use the standard information required in Annexes VII to X of the REACH Regulation for the hazard assessment. I.e. hazards might be determined from any of standard information required in Annexes VII to X and not only from information leading to classification of the substance as hazardous, and use it for the risk characterization of the substance.

Second, from a scientific point of view, if a hazard is identified as a consequence of assessing all the available information, and levels of exposure to the substance above which humans or the environment should not be exposed are derived then, the consequence should be to assess whether those levels are exceeded during the lifecycle of the substance. However, for reasons of proportionality, the REACH Regulation limits the requirement of this assessment only to those substances that fulfil the criteria for classification in any of the hazard classes or categories set out in Article 14(4) to the REACH Regulation and Annex I to the CLP Regulation. In that regard the request by ECHA to understand exposure and risk of the substance subject to the present decision is not exceeding what is appropriate and necessary to attain the objectives of the legislation. As outlined above, knowledge of properties and possible exposure to mankind or environment is crucial in chemicals regulation. The additional administrative to gain this knowledge has to be balanced against the safe use of the substance as one of the core REACH objectives. The identified hazard, even though not classified, in this case has been demonstrated by the short-term toxicity studies to fish with a 96h-LC50 of 1.47 mg/L, in the short-term toxicity studies to Daphnia with a 48h-EC50 of 19.9 mg/L and in the toxicity studies to algae with a 96h-EC50 of 4.9 mg/L. On that basis ECHA's request for environmental exposure assessment and risk characterization does not exceed what is necessary to address the concern.

In his update (Submission No. [redacted]), the Registrant has only provided an exposure assessment and risk characterization for man via the environment.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation of the REACH Regulation, the Registrant is requested to generate an exposure assessment and risk characterisation for the environment. The chemical safety report shall be amended accordingly.

Notes for consideration by the Registrant

In the context of the evaluation of compliance of the registration dossier with Annex I, ECHA has noted that currently the registration neither contains data for the endpoints of Annex IX, 9.1.5., 9.1.6., Annex X, 9.4. and Annex X, 9.5.1. nor a justified adaptation thereof. However, as the Registrant has not had a chance to comment on ECHA's finding regarding these interrelated endpoints, ECHA holds it in this case appropriate to follow a step-wise approach by not requiring the fulfilment of these information gaps at this stage. The Registrant is reminded to reassess these endpoints once he has revised the CSR in accordance with the present decision. He should first assess whether the endpoints can be adapted (further information can be obtained in ECHA Guidance on information requirements and chemical safety assessment (version 1.2., November 2012), Chapter R7b, Sections R.7.8.5. and R.7.8.12. for the aquatic and sediment compartments and Chapter R7c, Section R.7.11.6. for the terrestrial compartment). If he concludes that the endpoints can be adapted he should fully justify such adaptation in the registration dossier. Otherwise, the Registrant should submit testing proposals for the endpoints in question taking into account the testing strategy recommended by ECHA in the above-mentioned guidance documents.

4. Documentation for the recommended personal protective equipment (Annex I, 5.1.1. in conjunction with Annex II, 0.1.2. and 8.2.2.2(b))

Article 14(6) as well as Annex I, 0.1, 5.1.1, 5.2.4 and 6.2 of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented.

Pursuant to Annex II, Section 0.1.2. of the REACH Regulation the information provided in the Safety Data Sheet shall be consistent with that in the CSR. The requirements of Safety Data Sheets are specified in Annex II (amended by Commission Regulation (EU) No 453/2010).

Annex II, Section 8.2.2.2(a) and (b) of the REACH Regulation provides that the type of eye/face protection equipment, the type of gloves to be worn when handling the substance or mixture and, if necessary, the type and quality of protection equipment required to protect a part of the body other than the hands shall be clearly specified based on the hazard of the substance or mixture and potential for contact

The Registrant has indicated the following in the CSR: "*working with this substance requires a stringent use of appropriate chemical resistant gloves, protective clothing and suitable eye protection if any skin/eye contact is foreseen*".

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated: "*Hand protection: Camatril Velours / nitrile / 0.4 mm / Level 6 > 480 min. In case of full contact. Dermatril / nitrile / 0.11 mm / Level 1 > 10 min. In case of spray contact. Eye protection: Goggles which can be tightly sealed.*"

ECHA notes that the substance is classified as a skin sensitizer. To ensure the safe use of a substance it is essential to have detailed guidance on risk management measures, e.g. personal protective equipment. Although gloves and protective clothing are reported in the CSR as required personal protective equipment to prevent dermal exposure to the substance, only the material type of gloves to be worn, its thickness and typical or minimum breakthrough time are further specified. However, the type and quality of protective clothing, such as gauntlets, boots or bodysuits are missing from the information provided by the

Registrant. No further skin protection measures and/or specific hygiene measures have been indicated in the CSR.

In his comments, following the procedure set out in Article 50(1) of the REACH Regulation, the Registrant indicated his intention to provide the information requested. However, ECHA notes that the Registrant only states that "*protective clothing should cover the skin completely (long sleeves, closed shoes)*". The Registrant has not specified the type and quality of the protective clothing in the form of a European standard. In this case, ECHA notes that, as a minimum, it should be required a type 6 protective clothing.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide documentation for the recommended type and quality of protective clothing with regard to the amount and duration of dermal exposure in the CSR.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also addressed another study (two-generation reproductive toxicity study, Annex X, Section 8.7.3). As this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 12 months from the date of the adoption of the decision. The decision was therefore modified 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 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]
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