ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114321175-60-01/F Helsinki, 11 March 2016

DECISION ON TESTING PROPOSAL(S) SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For benzyltoluene, EC No 248-654-8 (CAS No 27776-01-8), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposal submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for benzyltoluene, EC No 248-654-8 (CAS No 27776-01-8), submitted by [redacted] (Registrant).

- Developmental toxicity / teratogenicity study (OECD 414) with the analogue substance 1,1-Diphenylethane (1,1-DPE)

This decision is based on the registration dossier as submitted with submission number [redacted], for the tonnage band of 100 to 1000 tonnes per year. This decision does not take into account any updates after 21 January 2016, 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 decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration at a later stage.

ECHA received the registration dossier containing the above-mentioned testing proposal for further examination pursuant to Article 40(1) on 14 May 2013.

ECHA held a third party consultation for the testing proposal from 18 February 2014 until 04 April 2014. ECHA did not receive information from third parties.

On 11 August 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 37 days of the receipt of the draft decision.

On 11 September 2014 the Registrant updated the registration dossier. On 15 September 2014 ECHA received comments from the Registrant. On 29 October 2015 the Registrant updated the registration dossier.

The ECHA Secretariat considered the Registrant's comments and update. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 21 January 2016 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Testing required

A. Tests required pursuant to Article 40(3)

The Registrant shall carry out the following test pursuant to Article 40(3)(c) and 13(4) of the REACH Regulation using the indicated test method and the registered substance subject to the present decision benzyltoluene:

> Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route,

while the originally proposed test for a Pre-natal developmental toxicity study (OECD 414) proposed to be carried out using the analogue substance 1,1-Diphenylethane is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

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 request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, shall result in a notification to the Enforcement Authorities of the Member States.

B. Deadline for submitting the required information

Pursuant to Articles 40(4) and 22(2) of the REACH Regulation, the Registrant shall submit to ECHA by **20 March 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposal submitted by the Registrant for the registered substance.

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

With respect to the testing proposals subject to the present decision, the Registrant has used a read-across and grouping approach based on Annex XI, 1.5. of the REACH Regulation and proposed to perform the tests on the analogue substance 1,1-Diphenylethane (1,1-DPE) (EC No 254-179-7, CAS No 38888-98-1). To the extent that the proposed testing relies upon a read-across hypothesis ECHA has considered the documentation and the scientific validity of the proposed read-across and grouping approach (Section 0, below), before assessing the testing proposed (Section 1, below).

ECHA notes that the present decision concerns the read-across proposal from 1,1-Diphenylethane (EC No 254-179-7, CAS No 38888-98-1, source substance) to benzyltoluene (target substance), the substance subject to present decision, as submitted in the registration dossier for benzyltoluene for the prenatal developmental toxicity endpoint. ECHA did not evaluate the read-across used in any other endpoints for compliance with the REACH information requirements. Such evaluation may be carried out in a compliance check under Article 41 of the REACH Regulation at a later stage.

0. Grouping of substances and read-across approach

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "*provided that the conditions set out in Annex XI are met*". As far as the testing proposals addressed in this decision are concerned, the Registrant has described an analogue approach of a related substance and proposes to use information from this substance to predict the prenatal developmental toxicity for the registered substance using read-across.

ECHA considers that the analogue approach and the read-across proposed by the Registrant, does not convincingly show how the relevant properties of the registered substance can be predicted from the information on properties of the analogue substance. More specifically, Annex XI, 1.5. of the REACH Regulation sets out the conditions to be met by grouping and read-across so that information requirements will be considered met. At present, the read across proposed by the Registrant does not fulfil those conditions, in relation to the scientific rationale of the read-across approach.

Scientific assessment of the analogue approach

Section 1.5. of Annex XI states: *Substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances.*

The similarities may be based on:

(1) a common functional group;
(2) the common precursors and/or the likelihood of common breakdown products via physical and biological processes, which result in structurally similar chemicals; or
(3) a constant pattern in the changing of the potency of the properties across the category.

A read across justification is provided in the registration dossier. In essence the hypothesis is that the substances that comprise the diphenylmethane category all have similar molecular structures and do therefore possess a similar functionality. Additionally, the Registrant compares similarity of physico-chemical properties and human health effects within a group of analogues, and concludes "*It is therefore a valid assumption that the substances of this category will behave in a reasonably predictable manner, and with*

respect to physico-chemical, ecotoxicological/environmental and toxicological properties application of the read-across methodology is a valid assumption". Although it is not clearly stated, ECHA considers that the implicit basis whereby the Registrant makes predictions about the properties of the registered substance is the hypothesis that the substances have similar human-health properties, and so the properties of one substance may be used to predict the properties of another substance within the group. This basis for making predictions is justified by the underlying structural similarity and similar properties of the substances.

ECHA considers that this basis for predicting the developmental toxicity properties of the registered substance is inadequate, for three reasons. Firstly, ECHA considers that there is not sufficient toxicological information to justify the assumption that the developmental toxicity properties of one substance can be predicted from another substance in this category, given an underlying hypothesis that structural similarity is responsible for the similar human health effects of these chemicals. Secondly, some category members show a distinct spectrum and potency of toxicological effects, with for example two of the compared analogues, 1,1'-DPE and PTE having markedly different potencies in OECD 421 and 422 studies, respectively. Given that these chemicals have markedly different effects, the hypothesis of similarity, which is required to enable prediction of the properties of the registered substance, is falsified, and it is not possible to predict the properties of one substance from another. Thirdly, the proposed category has no information on developmental toxicity with adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3), i.e. a pre-natal developmental toxicity study according to test method: EU B.31/OECD 414. Specifically, the "DOSE-RANGE FINDING FOR A PRENATAL DEVELOPMENTAL TOXICITY STUDY" had insufficient animals per group (n=6), and the reproductive screening studies (similar to OECD 421/ 422) lack examination of the foetuses (paras. 28-32 of OECD 414). This is a requirement of Annex XI, 1.5. In any event, without such information on developmental toxicity, ECHA considers it is not possible to demonstrate that the developmental toxicity properties may be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach).

In addition, the data available on repeated dose toxicity shows that that the proposed read across does not seem to be a reasonable worst case scenario either. The substance 1,1`-DPE is the least toxic (NOAEL 500 mg/kg bw/d) in the repeated dose tests whereas benzyltoluene, "SAS 40" and "SAS 296" seem to be of similar toxicity (NOAELs of 50 mg/kg bw/d, 50 mg/kg bw/d and 50 mg/kg bw/d (female)/LOAEL 12.5 mg/kg bw/d respectively). These levels are more similar to the repeated dose toxicity of PTE (NOAEL 30 mg/kg bw/d).

In the official comments on the draft decision the Registrant disagrees with ECHA's decision. The Registrant responds to the three main lines of argument set out in ECHA's read-across assessment (see above).

In respect of the first argument, the Registrant argues that the read-across is also justified by structural similarity, similar/ regular pattern of physico-chemical properties, similar fate/ecotoxicity properties as well as similar toxicological effects, and that the data matrix is well-stocked with consistent data. ECHA notes that while structural similarity is a prerequisite for applying the grouping and read-across approach, ECHA does not accept in general or in this specific case that structural similarity per se is sufficient to enable the prediction of human health properties of a substance, since structural similarity does not always lead to predictable or similar human health properties. While similar/ a regular pattern of physico-chemical properties may in some instances be a prerequisite to make a reliable prediction of the human health properties of a substance, ECHA does not accept in general or in this specific case that physico-chemical properties are sufficient to enable the prediction of the prenatal developmental toxicity properties of a substance, since similar

physico-chemical properties do not always lead to predictable or similar prenatal developmental toxicity properties. ECHA does not accept in general or in this specific case that similar fate/ eco-toxicity properties are sufficient to enable the prediction of human health properties of a substance, since similar fate/ eco-toxicity properties do not always lead to similar human health properties. In respect of similar toxicological properties, ECHA addressed that in the second argument (see above and below). ECHA maintains that there is insufficient toxicological information to justify the assumption that the developmental toxicity properties of the substance can be predicted. For example, it is difficult to undertake a reliable comparison of the repeated-dose toxicity properties of 1,1'-DPE, the registered substance and PTE, with respectively (1) an OECD 421 study and a dose-range finding study for a prenatal developmental toxicity study (i.e. minimal investigation of visceral organs/ histopathology), (2) no study in the dossier (but reference to a 90-day study), and (3) an OECD 422 study. It would be necessary to have sufficient information about toxicological properties so as to identify a reliable basis for prediction of the toxicity of the registered substance in a prenatal developemental toxicity assay. ECHA considers that the arguments provided by the Registrant, alone and in combination, do not provide a reliable basis for prediction of the properties of the registered substance in a prenatal developmental toxicity assay. Further elements are needed to explain why different compounds have the same type of effect(s), with an explanation at the mechanistic level why the same type of effect(s) are seen in spite of structural differences.

In response to the second argument, the Registrant claims in his comments that PTE is an outlier for reproductive effects, that this argument was already in an attached expert statement in the dossier, and that the conclusions of the read-across justification remain. However, ECHA notes that the chemical category definition and justification document present in the dossier includes PTE (3.1a, 3.1b), that the list of endpoints which is covered by the read-across justification includes reproduction (3.1c, Sections 5 and 6). ECHA has evaluated the Registrant's read-across justification in the chemical category definition and justification document. ECHA also evaluated the attached expert statement, but considers that this is not the Registrant's read-across justification. Firstly, it principally sets out the case that PTE is an outlier for reproductive toxicity, and this does not form a basis for a read-across justification for a category. Secondly, it is in contradiction to the Registrant's chemical category definition and justification document present in the dossier, wherein PTE is a part of the read-across and reproductive toxicity is covered by the read-across. Thirdly, there is no coherent basis set out for the nature of the category without PTE, and the consequences for category membership and justification, in the attached expert statement. ECHA points out that the Registrant's expert claims that the PTE is an outlier. However, ECHA notes from the conclusion sections that the Registrant's expert had a pre-existing hypothesis that, for the diphenylmethane category, the human health effects of the covered members are likely to be similar, whereas the results from the OECD 422 screening study with PTE seem to overthrow this concept. On the basis of the results from the reproductive toxicity data set (the Registrant has three reproductive screening studies (OECD 421/ 422) and no prenatal developmental toxicity studies for the eight category members), ECHA considers that there is no reliable basis for concluding that PTE is an outlier. Indeed the finding that one out of three chemicals tested causes severe reproductive effects shows that the read-across hypothesis is not an adequate basis for predicting the human health properties of the registered substance.

In the initial draft decision, ECHA gave the example of 1,1'-DPE and PTE as having markedly different toxicological properties. Additional examples of different toxicity are presented in the expert statement referred to by the Registrant in his comments :

- "Decreased body weight (1,1'-DPE, BT, "SAS-40", "SAS-296")
- Changes in various haematological and clinical chemical parameters
- Decrease in hemopoetic foci in spleen (PTE)
- Kidney weight increase ("SAS-305")

- Adrenal weight increase (BT)
- Adrenal weight decrease ("SAS-296")
- Testes weight increase (1,1'-DPE)
- Thyroid weight increase (PTE)

After analysing these effects, the expert states "*Taken together a consistent mode of action with regard to the observed effects cannot be derived from this data the fact of which may be explained by the observation that the vehicles used were (partly) quite different from their physico-chemical properties such that the resulting systemic "burden" may have been very different.*" Thus the different toxicological properties to which ECHA referred in the initial draft decision are acknowledged in the expert's statement, although he makes an explanation for these differences. ECHA agrees that there are differences in toxicological properties, and considers the explanation of the expert to be speculative and improbable. ECHA considers that these markedly different properties falsify the prediction that the chemicals in the category will have similar human health properties.

In respect of the third argument, the Registrant argues that "ECHA's argument that the diphenylmethane category is devoid of relevant information on developmental toxicity is invalid", on the basis that there are two studies in another registration dossier for this substance. However, ECHA notes that these two studies were not performed using the registered substance, but using an analogue substance, and furthermore, the read-across substance used in these two studies is not included in the category proposed by [redacted] and there is no other read-across justification provided to include this other analogue substance. The existence of read-across data in another joint submission does not fulfil the information requirement for this registration. A test with the registered substance is thus not available in another registration.

For the reasons given above, ECHA considers that, on the basis of the Registrant's adaptation, the developmental toxicity properties cannot be predicted from data for reference substance(s) within the group by interpolation to other substances in the group (read-across approach). The read-across adaptation fails to satisfy the requirements of Annex XI, 1.5, and is rejected.

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414 with the analogue substance 1,1-Diphenylethane (1,1-DPE).

However on 11 September 2014, following receipt of the draft decision, the Registrant updated the registration dossier (submission number [redacted]) and removed the testing proposal from the endpoint study record and instead selected "study scientifically unjustified". In their updated registration dossier submitted on 29 October 2015 (submission number [redacted]), the following waiving statement is included.

"*According to annex XI of the REACH Regulation testing for developmental toxicity does not appear scientifically necessary.*
The OECD Guideline 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test with "SAS-296" revealed no evidence

of substance related effects on reproduction/developmental parameters even though body weight gain was decreased also for females by 5-8 %. No substance related effects on the number, sex ratio, body weight, or viability were found in pups. Furthermore no external or internal malformations were found in pups at any dose.

In the OECD Guideline 421 Reproduction/Developmental Toxicity Screening Test with 1,1`-DPE (1,1-Diphenylethane ((phenylethyl)benzene), CAS 38888-98-1) after oral gavage in the vehicle cotton seed oil (which should allow for appropriate dissolution of the test substance) clear maternal toxicity (mortality and significantly reduced body weights) was evident at the highest tested dose of 1000 mg/kg bw/d. Therefore it may be argued that the reduced pup weights at 1000 mg/kg bw/d are related to the toxic effect of 1,1`-DPE on the maternal organism such that the observed effects are probably of an indirect (secondary) nature.

Even though for PTE developmental effects have been observed in a reproduction/ developmental screening test, there is not enough substantial evidence for classification of Benzyltoluene as developmental toxicant since data from screening assays with 1,1`-DPE and SAS-296 does not support the assumption for any developmental potency (see section 13 "statement developmental toxicity") and does not substantiate a classification of the substance as developmental toxicant.

Furthermore, testing according to OECD Guideline 414 Prenatal Development Toxicity Study for the substance 1,1-DPE which is used also for read-across purposes as the parent substances for Benzyltoluene is ongoing. Data on the already executed dose range finding (DRF) study are already available and have clearly shown no indication of any prenatal development toxicity for this substance (see endpoint study record in section 7.8.2). The (maternal) no-observed-adverse-effect level (NOAEL) was 100 mg 1,1-Diphenylethane/kg b.w./day for the dams. The no-observed-adverse-effect level (NOAEL) for the fetal organism was 400 mg 1,1-Diphenylethane/kg b.w./day.
A slightly but statistically significant reduced fetal body weight was noted at the materno-toxic dose level of 800 mg 1,1-Diphenylethane/kg b.w./day. No dead fetuses, no malformations and no test item-related variations were noted at any of the tested dose levels.

In conclusion, based on the already existing study results for developmental toxicity for the substance Benzyltoluene and the new data already generated for the substance 1,1-DPE, testing of Benzyltoluene is not justified to gain a validated assessment for this endpoint for two reasons:

- *The specifically elaborated read-across seem to be applicable not only from a theoretical point of view but also practically from the outcome of the DRF with 1,1-DPE.*
- *In order not to breach Article 25 of the REACH Regulation ("In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.") testing of the substance Benzyltoluene for developmental toxicity is scientifically unjustified and unethical since (preliminary) data indicate that the substance Benzyltoluene is devoid of any developmental toxicity.*

The dossier for Benyltoluene will therefore be updated accordingly when the results of the main study with 1,1-DPE will become available.

Higher-tier fertility study (two-generation study) is not required at this tonnage band, since there were no adverse effects observed in the repeated dose toxicity studies in reproductive organs or tissues or any adverse effects in the screening studies for reproductive toxicity (OECD 421/422). Therefore, there is no data gap in fertility. There is no reason to believe that results of the screening study would not be relevant for fertility in humans and, therefore, for risk assessment."

ECHA firstly notes that there is no Pre-Natal Developmental toxicity (PNDT) study on substance benzyltoluene, CAS No 27776-01-8 (EC No 248-654-8) available in any submitted registration dossier.

Secondly, ECHA notes that the Registrant, both in its dossier update and his comments has expressed an intention of testing an analogue substance (1,1-Diphenylethane) to meet the information requirements for the presently registered substance. Once a formal Testing Proposal is submitted, ECHA will examine in the context of that testing proposal examination any intention of testing, including testing of an analogue substance, to determine whether the proposed strategy of generation of data is tailored to the relevant information needs for the endpoint and the dossier under the assessment. In view of the above, ECHA concludes that there is still an intention to conduct a test, and therefore ECHA has continued with the Testing Proposal Examination. The Registrant also referred to ongoing testing according to OECD Guideline 414 Prenatal Development Toxicity Study for the substance 1,1-DPE for read-across purposes. However, the results of this study are not yet available and, therefore, the ongoing study is insufficient to waive the standard information requirement for the registered substance.

Thirdly, ECHA notes that the Registrant has for this endpoint provided three studies, in addition to the justification above. These are (1) a key study, an OECD 422 study on Phenyl Tolyl Ethane (PTE: CAS # 40766-30-1) (2) a key study, a dose-range finding for a prenatal developmental toxicity study of 1,1-diphenylethane (1,1'-DPE; CAS # 38888-98-1) (3) a weight of evidence study equivalent to OECD 422 on 1,4-dimethyl-2-(phenylethyl)benzene (CAS # 6165-51-1, a constituent of SAS-296). In view of the failure of the read-across adaptation, for the reasons as set out in section III.0, ECHA considers that none of these studies fulfils the information requirement for the registered substance. Additionally, ECHA considers that these studies also do not meet the requirement of Annex XI, 1.5 for "adequate and reliable coverage of the key parameters addressed in the corresponding test method referred to in Article 13(3)", i.e. a prenatal developmental toxicity study according to OECD 414, as set out in Section III.0, and for this reason also the studies are insufficient to meet the information requirement. ECHA considers that the Registrant's argumentation for addressing the information requirement are fully addressed under Section III.0 according to Annex XI, 1.5, i.e. including the weight of evidence of all the read-across argument and data, and that there is no formally separate adaptation according to Annex XI, 1.2 (Weight of Evidence).

In the Registrant's comments to the draft decision, and in their updated dossier of 11 September 2014, the Registrant made reference to an additional registration dossier for the substance Benzyltoluene. The studies referred to by the Registrant in their comment and in their updated registration dossier of 11 September 2014 as present in another registration dossier are PNDT studies done on an analogue substance Dibenzyltoluene. ECHA notes that benzyltoluene and dibenzyltoluene are structurally different, which could result in different toxicological properties, but such difference was not discussed by the Registrant. Moreover, as already mentioned above, the category proposed by [redacted], and the justification thereof, does not contain the analogue substance Dibenzyltoluene, and so the Registrant has not proposed any basis on which the tests on Dibenzyltoluene could meet the requirements of Annex XI, 1.5. The existence of read across data in another joint submission does not fulfil the information requirement for this registration, including Article 10 (obligation to provide the respective study summaries in the registration dossier with the permission to refer to the full study reports) and requirements of Annex XI, section 1.5. of the REACH Regulation.

On 3 June 2015 ECHA sent a letter to the Registrant to provide an opportunity for the launch of a data sharing dispute, if Registrant considered the data relevant, before

proceeding with referral to the Competent Authorities of the Member States (MSCAs). By the deadline given of 15 July no data sharing dispute was launched and no dossier update received.

Consequently, the decision making process was continued with referral of the draft decision to MSCAs.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation. However ECHA requests that testing is performed on the registered substance, Benzyltoluene.

As elaborated above in section III. 0 the proposed read-across does not meet the requirements of Annex XI section 1.5. and is therefore rejected together with the respective testing proposal as non-compliant with the REACH Regulation (Article 40(3)(d) of the REACH Regulation).

The Registrant proposed testing in rats by the oral route. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit 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 rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is requested to carry out the following study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in rats or rabbits, oral route (test method: EU B.31/OECD 414).

IV. Adequate identification of the composition of the tested material

The process of examination of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the new study meets real information needs. Within this context, the Registrant's dossier was sufficient to confirm the identity of the substance to the extent necessary for examination of the testing proposal. The Registrant must note, however, that this information has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

It is important to ensure that the particular sample of substance tested in the new study 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. If the registration of the substance covers different grades, the sample used for the new study must be suitable to assess these.

Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study 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 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://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.