EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-2114293034-53-01/F Helsinki, 16 June 2015

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

For Fatty acids, tall-oil, reaction products with diethylenetriamine and maleic anhydride, CAS No 1419212-76-2 (EC No 800-430-6), 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 proposals submitted as part of the registration dossier in accordance with Articles 10(a)(ix) and 12(1)(d) thereof for Fatty acids, tall-oil, reaction products with diethylenetriamine and maleic anhydride, CAS No 1419212-76-2 (EC No 800-430-6), submitted by [redacted] (Registrant).

- 90-day oral toxicity study (OECD 408) oral route.
- Developmental toxicity / teratogenicity study (OECD 414).
- Long-term toxicity testing on aquatic invertebrates (OECD 211) using the analogue substance Fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CAS 1393571-43-1).

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 30 October 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 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.

The examination of the testing proposals was initiated upon the date when receipt of the complete registration dossier was confirmed on 10 February 2014.

ECHA held a third party consultation for the testing proposals from 5 June 2014 until 21 July 2014. ECHA received information from third parties (see section III below).

On 8 August 2014 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

By 15 September 2014 the Registrant did not provide any comments on the draft decision to ECHA.

On 30 October 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.

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 proposed tests pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26/OECD 408) in rats;
2. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31/OECD 414) in rats or rabbits, oral route.

The Registrant shall carry out the following proposed test pursuant to Article 40(3)(a) and 13(4) of the REACH Regulation using the indicated test method and the analogue substance: Fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CAS 1393571-43-1).

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

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, will 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 **23 June 2017** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance and scientific information submitted by a third party.

In relation to a testing proposal subject to the present decision, the Registrant has proposed to use a read-across and grouping approach, in accordance with Annex XI, 1.5, and to perform the long-term toxicity testing on aquatic invertebrates (section 3) with the analogue substance fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CAS no 1393571-43-1).

ECHA emphasises that any final determination on the validity of the read-across, including the grouping approach proposed by the Registrant, would be premature at this point in time. The eventual validity of the read-across hypothesis and grouping approach will be reassessed once the requested information is submitted. In the meantime, based on the information currently submitted, ECHA considers that the approach proposed by the Registrant is plausible.

ECHA has considered first the scientific validity of the proposed read-across and grouping approach (preliminary considerations; Section 0, below), before assessing the testing proposed (Section 3, below).

0. Grouping of substances and read-across approach (preliminary considerations)

a) Legal Background on ECHA's assessment of the grouping of substances and read-across hypothesis brought forward by the Registrant

The evaluation by ECHA of testing proposals submitted by registrants aims at ensuring that generation of information is tailored to real information needs. To this end, it is necessary to consider whether programmes of testing proposed by registrants are appropriate to fulfil the relevant information requirements and to guarantee the identification of health and environmental hazards of substances. In that respect, the REACH Regulation aims at promoting wherever possible the use of alternative means, where equivalent results to the prescribed test are provided on health and environmental hazards. In accordance with these objectives, ECHA shall assess whether a prediction of the relevant properties of the substance subject to this decision by using the results of the proposed tests is sufficiently plausible based on the information currently available.

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*".

According to Annex XI, 1.5 there needs to be structural similarity among the substances within a group or a category such that the relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation.

The Registrant has submitted a testing proposal, based on a grouping and read-across hypothesis, intended to fulfil information requirement for long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.). It is noteworthy that under the evaluation of the testing proposals. ECHA has not performed a compliance check on other endpoints such as mutagenicity, carcinogenicity and repeated dose toxicity and may do so at any time at its own discretion.

b) Information submitted by the Registrant to support the grouping approach and read-across hypothesis

In order to support its testing proposal, the Registrant has provided a grouping and read-across justification document in which data on the following substances has been provided:

- Fatty acids, tall-oil, reaction products with diethylenetriamine (DETA), maleic anhydride (MA), tetraethylenepentamine (TEPA) and triethylenetetramine (TETA) (CAS 68990-47-6). ECHA notes that the Registrant refers to this substance as the "source substance" although he proposes to test other substances. For the sake of clarity in the developments below, ECHA will refer to this substance as the so-called "source" substance.
- Fatty acids, tall-oil, reaction products with diethylenetriamine and maleic anhydride (CAS 1419212-76-2). This is the registered substance subject to this decision. For the sake of clarity in the developments below, ECHA will also refer to this substance as "the substance subject to the present decision".
- Fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and maleic anhydride (CAS 1419212-77-3). For the sake of clarity in the developments below, ECHA will refer to this substance as "the analogue substance B".
- Fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CA) (CAS 1393571-43-1). This substance is the analogue substance proposed to be used as test material for the environmental endpoint. For the sake of clarity in the developments below, ECHA will refer to this substance as "the analogue substance C".

ECHA notes that the grouping and read-across justification document provided by the Registrant seems to be intended to justify the read-across from the substance subject to the present decision, the analogue substance B and the analogue substance C to the so-called "source" substance. However, the Registrant has used the same document and justification to justify the read-across from the analogue substance C to the substance subject to the present decision.

According to the Registrant, the substance subject to the present decision can be grouped with other substances in a category for the purpose of read-across. The grouping is based on similar production processes and similarities between the chemical products formed, which are sufficiently similar to allow read-across.

More specifically, in ECHA's understanding the read-across hypothesis, as presented by the Registrant, is based on the fact that all substances within this category have similar physico-chemical properties and they can be assumed to have similar toxicokinetic and toxicodynamic properties, and no major differences in environmental behaviour will occur. In the grouping and read-across justification document, the Registrant has provided a description of the manufacturing processes and composition of the substances and an analysis of the chemical components of the starting materials. In addition, he has provided an assessment of the toxicokinetic properties of the different substances, a data matrix presenting the physico-chemical properties, environmental fate and ecotoxicity and mammalian toxicity of the substances.

The Registrant has provided short-term toxicity studies in *Daphnia,* growth inhibition studies in algae, and ready biodegradability conducted with all four substances. Short-term toxicity

in fish and activated sludge respiration inhibition tests have been conducted with the so-called "source" substance.

c) ECHA analysis of the grouping approach and the read-across hypothesis of the Registrant in light of the requirements of Annex XI, 1.5

ECHA understands that the grouping approach is based on a similar manufacturing processes and similarities in composition.

Based on the information on the manufacturing processes of the different substances used in this read-across approach provided by the Registrant, ECHA notes that the starting materials TOFA and DETA are the same for the substance subject to the present decision and the analogue substance C. Other starting materials are MA for the substance subject to the present decision, and Monomer and CA for the analogue substance C. The main (> [redacted] %) constituent of the substance subject to the present decision is amides, from MA, DETA and C18 fatty acids. ECHA further observes that, according to the information provided by the Registrant in the documentation of the read-across approach, the composition of the analogue substance C differs from the substance subject to the present decision since it consists of amides both from C18 fatty acids ([redacted]%) and from fatty acids, C16-C18, C18 unsaturated, linear and branched ([redacted]%). In addition, CA was used as a starting material instead of MA, which was used in the registered substance. However, ECHA considers, as suggested by the Registrant, that the differences in the starting materials MA and CA (initial concentrations are very low), and fatty acid composition are considered to have no/negligible effect on the toxicity profile of the substance subject to the present decision and the analogue substance C. This is further supported by the results of the short-term aquatic toxicity studies conducted with the substance subject to the present decision and the analogue substance C (see below).

The starting materials, TETA and TEPA, of the so-called "source" substance differ from the other substances. Due to different molecular weight of TETA (146 Da) and TEPA (189 Da) compared to DETA (103 Da), the molecular weight of the source chemical is higher, which is not expected to impact the toxicity of the substance.

The Registrant also hypothesises that these substances can be regarded as of low aquatic toxicity as consequence of the substances' high molecular weights (> 700) and high logKow's (> 6.5). This is confirmed in short-term toxicity studies in *Daphnia* and the other short-term aquatic toxicity studies conducted with all the substances included in this grouping and read-across approach and in which no toxicity was observed up to the maximum water soluble concentration.

Based on the data submitted and on the arguments developed by the Registrant, ECHA concludes that the starting materials and the composition of the substance subject to the present decision and the analogue substance C are sufficiently similar, physico-chemical and fate properties are similar, and no toxicity was observed in the short-term toxicity studies in *Daphnia* and the other short-term aquatic toxicity studies conducted with all four substances covered by the grouping hypothesis.

Accordingly, ECHA considers the read-across hypothesis plausible based on information on the starting materials and composition of the substances, and the supportive available physico-chemical and ecotoxicological information.

ECHA therefore concludes that the criteria of Annex XI, 1.5 are met, and the read-across approach, as presented by the Registrant, can be considered plausible to meet the information requirements in question.

A. Tests required pursuant to Article 40(3)

1. Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2.)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

A sub-chronic toxicity study (90 day) is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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 proposed testing on the registered substance, and ECHA considers this appropriate.

The Registrant has submitted a testing proposal for a sub-chronic toxicity study (90 day) via the oral route (EU B.26/OECD 408).

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

The Registrant proposed testing by the oral route. In light of the physico-chemical properties of the substance (paste with low vapour pressure), ECHA considers that testing by the oral route is most appropriate.

The Registrant did not specify the species to be used for testing. According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has proposed a weight of evidence approach: "The physicochemical properties of the chemicals (very low water solubility, high lipophilicity, molecular weight of the fatty acid amides > 700) imply that the UVCB substances are not bioavailable after oral ingestion. This assessment is consistent with findings of low acute oral toxicity (NOAEL of EC No. 806-510-7: > 2000 mg/kg bw/d) and the absence of systemic or reproductive adverse effects in OECD 422 screening studies with two structurally related fatty acid amides even at the maximum oral dose of 1000 mg/kg bw/d. Under these circumstances the proposed test is not expected to add toxicologically meaningful information and therefore may be waived in a weight-of-evidence approach which may supported by registration data of the residual starting material maleic anhydride and 2,2'-iminodi (ethylamine) with low molecular weights".

ECHA acknowledges that the third party has proposed a testing strategy including a weight of evidence approach for the Registrant to consider.

ECHA notes that it is the Registrant's responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.2. Therefore, the Registrant should assess whether he can justify weight of evidence as suggested by the third party. If the adaptation can be justified, he should include the adaptation argument with all necessary documentation in the registration dossier. Such update can only be taken into consideration in the decision-making if it is submitted before the draft decision is sent to the Member State Competent Authorities pursuant to Article 51(1) of the REACH Regulation.

ECHA notes that the information provided by the third party is insufficient for demonstrating that the conditions of Annex XI, Section 1.2. of the REACH Regulation are met.

ECHA observes that the third party has proposed a weight of evidence approach based on physicochemical properties implying lack of bioavailability, and studies conducted with structurally similar substances. ECHA considers that the Weight of Evidence adaptation, according to Annex XI, 1.2, does not have adequate and reliable documentation, as it does not set out the basis whereby the information from several independent sources together provide a sufficient weight of evidence leading to the assumption/conclusion that a substance has or has not a particular dangerous property, in this case for the parameters of sub-chronic repeated dose toxicity (a 90-day study). Moreover, relevant endpoint study records are not provided, and the read-across adaptations that are proposed do not have adequate and reliable documentation of the applied method, according to Annex XI, 1.5. Further ECHA considers that there is not sufficient weight of evidence from several independent sources of information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, in this case for the parameters of sub-chronic repeated dose toxicity (a 90-day study). Therefore, the information provided by the third party is not sufficient to adapt the standard information requirement.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408).

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

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

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 proposed testing on the registered substance, and ECHA considers this appropriate.

The Registrant has submitted a testing proposal for a pre-natal developmental toxicity study according to EU B.31/OECD 414.

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

The Registrant did not specify the species to be used for testing and did not specify the route for testing. 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.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has proposed a weight of evidence approach: "The physicochemical properties of the chemicals (very low water solubility, high lipophilicity, molecular weight of the fatty acid amides > 700) imply that the UVCB substances are not bioavailable after oral ingestion. This assessment is consistent with findings of low acute oral toxicity (NOAEL of EC No. 806-510-7: > 2000 mg/kg bw/d) and the absence of systemic or reproductive adverse effects in OECD 422 screening studies with two structurally related fatty acid amides even at the maximum oral dose of 1000 mg/kg bw/d. Under these circumstances the proposed test is not expected to add toxicologically meaningful information and therefore may be waived in a weight-of-evidence approach which may supported by registration data of the residual starting material maleic anhydride and 2,2'-iminodi (ethylamine) with low molecular weights".

ECHA acknowledges that the third party has proposed a testing strategy including a weight of evidence approach for the Registrant to consider.

ECHA notes that it is the Registrant's responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.2. Therefore, the Registrant should assess whether he can justify weight of evidence as suggested by the third party. If the adaptation can be justified, he should include the adaptation argument with all necessary documentation in the registration dossier. Such update can only be taken into consideration in the decision-making if it is submitted before the draft decision is sent to the Member State Competent Authorities pursuant to Article 51(1) of the REACH Regulation.

ECHA notes that the information provided by the third party is insufficient for demonstrating that the conditions of Annex XI, Section 1.2. of the REACH Regulation are met.

ECHA observes that the third party has proposed a weight of evidence approach based on physicochemical properties implying lack of bioavailability, and studies conducted with structurally similar substances. ECHA considers that the Weight of Evidence adaptation, according to Annex XI, 1.2, does not have adequate and reliable documentation, as it does not set out the basis whereby the information from several independent sources together provide a sufficient weight of evidence leading to the assumption/conclusion that a substance has or has not a particular dangerous property, in this case for the parameters of pre-natal developmental toxicity study. Moreover, relevant endpoint study records are not provided, and the read-across adaptations that are proposed do not have adequate and reliable documentation of the applied method, according to Annex XI, 1.5. Further ECHA considers that there is not sufficient weight of evidence from several independent sources of

information leading to the assumption/conclusion that a substance has or has not a particular dangerous property, in this case for the parameters of pre-natal developmental toxicity study. Therefore, the information provided by the third party is not sufficient to adapt the standard information requirement.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is requested to carry out the proposed 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).

3. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5)

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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 testing analogue substance Fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CAS 1393571-43-1) for long-term toxicity testing on aquatic invertebrates [*Daphnia magna* reproduction test, EU C.20/OECD 211/other] with the following justification: "In view of the outcome of the risk assessment a daphnia reproduction test is considered necessary to lower the RCR".

ECHA considers that the proposed study is appropriate to fulfil the information requirement of Annex IX, Section 9.1.5 of the REACH Regulation. ECHA has analysed the more detailed justification and data in light of the requirements of Annex XI, 1.5. ECHA considers the read-across approach plausible, as explained in section III.0., and testing shall be performed with the analogue substance fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CAS 1393571-43-1).

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. There were no indications in the dossier from the short-term toxicity studies on aquatic species that the fish would be substantially more sensitive than aquatic invertebrates.
In such a case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, long-term fish testing may need to be conducted.

b) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the Fatty acids, tall-oil, reaction products with fatty acids C16-C18 and C18-unsatd, branched and linear, diethylenetriamine and citric acid (CAS 1393571-43-1): Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211).

ECHA notes that in case where the results of the proposed long-term toxicity study on aquatic invertebrates performed in accordance with the present decision would not confirm the read-across hypothesis relied upon by the Registrant, this outcome shall not alter the obligation of the Registrant to meet the standard information requirements. Should the read-across approach be inadequate, it is the responsibility of the Registrant to ultimately submit reliable information or adaptations which is used in a way that does not underestimate hazards of the registered substance in relation to the relevant endpoint.

In any case, following the update of the dossier submitting the information required in the present decision, ECHA will determine whether the documentation provided is sufficient to satisfactorily address the information requirement of Annex IX for the substance subject to the present decision.

Notes for consideration by the Registrant

Once results of the proposed test on long-term toxicity to aquatic invertebrates are available, the Registrant shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation. If the revised chemical safety assessment indicates the need to investigate further the effects on aquatic organisms, the Registrant shall submit a testing proposal for a long-term toxicity test on fish in order to fulfil the standard information requirement of Annex IX, 9.1.6. If the Registrant comes to the conclusion that no further investigation of effects on aquatic organisms is required, he shall update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, 9.1.6.

Due to the substance properties, OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance, Chapter R7b, table R. 7.8-3 summarising aquatic toxicity testing of difficult substances should be consulted by the Registrant for choosing the design of the requested long-term ecotoxicity tests and for calculation and expression of the result of this test.

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 studies meet 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.

In addition, 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. If the registration of the substance covers different grades, the sample used for the new studies must be suitable to assess these.

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 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.

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