EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114306662-56-01/F Helsinki, 30 July 2015

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

For acetalization products between glucose and c20-22(even numbered)- alcohol, EC No 923-835-0, 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 acetalization products between glucose and c20-22(even numbered)-alcohol, EC No 923-835-0, submitted by [redacted] (Registrant). The scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 9.1.5. and 9.1.6. relating to aquatic toxicity, of the REACH Regulation and related environmental hazard assessment. ECHA stresses that it has not checked the information provided by the Registrant for compliance with requirements regarding the identification of the substance (Section 2 of Annex VI).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of [redacted] per year. This decision does not take into account any updates after the deadline for updating (12 March 2015) communicated to the Registrant by ECHA on 3 February 2015.

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 09 May 2013.

On 15 July 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 07 August 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision that testing on long-term toxicity to invertebrates and fish was required. However, the Registrant had proposed a category approach and to test another substance: a member of the proposed category of substances considered to have similar properties instead of the registered substance.

The Registrant updated his registration dossier on 24 January 2014 with the submission number [redacted] and again on 27 October 2014 with submission number [redacted]

ECHA considered the Registrant's comments received. On basis of this information ECHA noted that the draft decision initially sent to the Registrant did not address the category justification which formed part of the registration dossier with submission number

[redacted]. ECHA considered that the provided category justification must be considered in its evaluation decision. Therefore, ECHA decided to consult the Registrant again in accordance with Article 50(1) of the REACH Regulation, on the amended draft decision that addresses the category justification in order to allow the Registrant to submit comments.

On 13 November 2014 ECHA sent the draft decision a second time 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 19 December 2014 ECHA received comments from the Registrant on the draft decision.

On 12 March 2015, the Registrant updated his registration dossier with the submission number [redacted].

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

On 11 June 2015 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. 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)(vi) and/or (vii), 12(1)(d), 13 and Annex IX of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

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

2. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210).

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. Deadline for submitting the required information

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **06 February 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

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. Grouping of substances and read-across approach

With respect to the information in the technical dossier derived from the sequential application of the Annexes VII to XI, the Registrant has used a read-across and grouping approach based on Annex XI, 1.5. of the REACH Regulation. ECHA notes that as the scope of this compliance check is limited to the standard information requirements of Annex IX, Sections 9.1.5. and 9.1.6. relating to long-term aquatic toxicity to invertebrates and fish of the REACH Regulation and related environmental hazard assessment, ECHA has also limited its assessment of the category approach as it relates to these endpoints only. Hereby ECHA has considered the documentation and the scientific validity of the proposed read-across and grouping approach, before assessing whether the information provided for these endpoints is compliant with the information requirements. ECHA has based its assessment on the plausibility of the proposed read-across for these two endpoints on the documentation submitted in the technical dossier and the information submitted by the Registrant in their comments to the initial draft decision (DD) notified to the Registrant on 15 July 2013 (communciation number CCH-D-0000002256-77-08/D; from hereon referred to as the initial DD). As mentioned above, 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.

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*". The Registrant has described a category of structurally related substances and uses information from members of this category to predict for the registered substance physico-chemical properties, ecotoxicity information for environmental hazards and toxicity information for human health hazards using read-across. Any technical dossier has to contain the information as codified in Annexes VII to X of the REACH Regulation either by providing (robust) study summaries of experimental studies or by presenting a documented and justified adaptation argument in order to meet the information requirements of REACH, *i.e.* to be compliant. As noted above, this decision concerns only the read-across and category approach in relation to the endpoints of Annex IX, Sections 9.1.5. and 9.1.6. relating to long-term aquatic toxicity.

ECHA considers that the grouping and read-across approach 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 other category members. 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, both in

relation to the documentation provided (see section 0.1) and the scientific rationale of the read-across approach (see section 0.2).

1. Documentation of the category and read-across approach

It is a requirement of Annex XI, 1.5., that "*adequate and reliable documentation of the applied method shall be provided.*"

As part of the chemical safety report the Registrant has submitted a justification for the category approach named "*Reporting format for substance obtained from Acetalization product between glucose and C20/22(even numbered)-alcohol*". The same category justification document has been uploaded under the category information section in the updated technical dossier (submission number [redacted]). In the catgeory justfication document the Registrant has followed the reporting format provided in ECHA Guidance on Information Requirements and Chemical Safety Assessment Chapter R6 QSARs and grouping of chemicals (May 2008). ECHA notes that no category justification document was submitted as part of the comments on the initial draft decision, however, reference is made to the report "Reporting format for substance obtained from Acetalization and distilled acetalization between glucose and C12/22(even numbered)-alcohol".

As part of the category hypothesis the Registrant states the following (section 1.1.a. of the report): "*The category is built with substances of Unknown or Variable composition, Complex reaction product or Biological material (UVCB substances). The substances in this particular category are consisting of fatty alcohols (even numbered) with mono and di-glucosides, called alkylpolyglucosides. Each category member is manufactured from fatty alcohol and glucose. All the members of this category are either mixture of fatty alcohols reacted with glucose or blends of alkyl glucosides of various chain lengths and degrees of polymerization. The alcohols are saturated linear compounds with a chain length of 12 to 22 carbons (even numbered), and the alkylpolyglucosides are formed of a hydrophobic carbon chain, with the same length, linked to one or two glucoses. The polymerization rate is close to one (1.2 to 1.5) The above mentioned UVCB substances can be considered as a category because the constituents are very closely related and thus can be treated similarly. Actually, the fatty alcohols results from natural sources (i.e. primarily edible food crops) or from reproducible synthetic source.*" Later on this section it is written that: " *All members are characterized by low water solubility (generally below 60 mg/L), a low vapor pressure, below 10-2 Pa and a high log Kow (> 5.8) based on the estimation of the alcohol. These fundamental properties that are confirmed by testing allow grouping of the chemicals in a category.*" As a conclusion (section 5 of the report) the Registrant states that the proposed category approach is justified based on weight-of-evidence including chemical, physico-chemical, ecotoxicological and toxicological similarity and the safety profile of the starting materials and metabolism pathway.

ECHA notes that as the hypothesis for the category the Registrant is stating that the starting material of the reaction products is similar, that the constituents of the category members appear to be very closely related, that physico-chemical properties (water solubility, vapour pressure, partitioning coefficient) are similar and that there is a lack of toxicity for human health. In support of this hypothesis, the Registrant provided a category approach justification and a data matrix, and conclusions per endpoint for classification and labelling, PBT/vPvB and dose descriptor.
In addition to the substance subject to the present decision the Registrant declares that the following six substances are members of the category: Acetalization product between glucose and C14 alcohol (APG C14; EC No 923-418-3), Distilled acetalization product between glucose and C12/18(even numbered)- alcohol (distilled APG C12-18; EC No 922-178-7), Acetalization product between glucose and C12/18(even numbered)-

Alcohol (APG C12-18; EC No 923-908-7), Distilled acetalization product between glucose and C12,14,18,20,22 alcohol (distilled APG C12-22; EC no 921-820-3), Acetalization product between glucose and C16/18(even numbered)-alcohol (APG C16-18; EC No 927-870-2) and Acetalization product between glucose and 12-hydroxystearyl alcohol (APG C12 hydroxy; EC No 700-891-2).

With regards to the endpoints related to this decision, in section 1.1.c. of the report the Registrant states that the category approach has been applied to endpoints of ready biodegradation, short-term toxicity testing on fish, algae growth inhibition, and acute daphnia study. ECHA notes that the long-term aquatic endpoints addressed in this decision are not included in this list of endpoints covered, nor is there a mentioning of these endpoints in the environmental assessment in section 2 of the category justification report.

With regards to the standard information requirements of Annex IX sections 9.1.5. and 9.1.6. in his comments to the initial draft decision the Registrant has provided the following justification: *"we consider that it is more relevant to perform the(se) test(s) on another member of the category:* [redacted] *("Acetalization product between glucose and C16/18 (even numbered) alcohols"). Indeed, as explained in the "reporting format for substance obtained from acetalization and distilled acetalization between glucose and C12/22 (even numbered)- alcohol", shorter are the C-chain more is water-soluble fraction and more is the toxicity on the aquatic species. This corroborates well with the results published from the short C-chain of alcohol in the literature. So the results of these aquatic chronic tests can be used for the other members of the category."* Regarding this statement ECHA notes that in terms of their potential for aquatic toxicity only long chain alcohols have been addressed by the Registrant in the Category justification document, but not the potential aquatic toxicity of glucosides. ECHA notes further that in his comments the Registrant has proposed to use "[redacted] *("Acetalization product between glucose and C16/18 (even numbered) alcohols")"* ((APG C16-18; EC No 927-870-2) as the source substance and to read-across the results to the registered substance and other substances in the proposed category. The scientific validity of the proposed category approach and read-across for long-term aquatic toxicity is discussed further in section 2 below.

In conclusion of the above, ECHA considers that due to the limited information provided regarding the read-across for the endpoints of long-term aquatic toxicity addressed in this decision the requirement of Annex XI section 1.5. of "adequate and reliable documentation of the applied method shall be provided" has not been met.

2. Scientific assessment of the proposed read-across approach to fulfil the standrad information requirements of Annex IX sections 9.1.5. and 9.1.6.

ECHA notes that as far as the present decision is concerned, the scientific assessment of the read-across concerns only the category approach proposed for the endpoints of Annex IX sections 9.1.5. and 9.1.6. ECHA notes that in the category justification document these endpoints are not listed as being covered by the proposed category approach, this has only been identified in the Registrants comments to the initial draft decision.

Annex XI Section 1.5. of the REACH Regulation 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.*

Furthermore, for the grouping and category approach Annex XI, 1.5. provides: *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.

Ad (1): The group members share the same functional groups, the constituents are structurally similar. However, the ratio between long chain alcohols, mono-,di- and tri-glucosides varies. This may potentially lead to different toxicity among the group members.

Ad (2): The source substance (APG C16/18) is reported to be readily biodegradable, while the registered substance (APG C20/22) is reported to be readily biodegradable, but failing the 10-day window. This is also the case for the other members in the category. However, in the category justification document the Registrant states that for hydrophilic emulsifiers the criterion of 10-day window is not sufficient to change the conclusion on the ready biodegradability studies. ECHA notes that according to the Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3 (OECD 2006) 10-day window may not apply to complex mixtures where sequential biodegradation may take place. Therefore, ECHA notes that based on the ready biodegradation data the fate of the chemicals in the environment may be similar.

Ad (3): With regards to the physico-chemical properties influencing aquatic toxicity, all members have low water solubility (below 1mg/l) and all but APG C14 have high LogKow values. Acute toxicity has been observed only for APG C14 which the Registrant refers to in the category justification document. ECHA notes that within the proposed category there is currently no data on long-term aquatic toxicity. As discussed further in the paragraphs below, it is hence not possible to conclude on the requirement of (3) above.

ECHA understands that in the case of long-term aquatic toxicity, the proposed read-across within category relies on similar physico-chemical and environment fate properties. Furthermore in the category justification document the Registrant states that "*Acute toxicity is predicted well by category-specific (Q)SARs. Their success in predicting toxicity for category members suggests that the members do not possess any particularly unique features. In addition, no effects up to the limit of water solubility for these UVCB are observed.*" Based on the acute ecotoxicity data available the Registrant hence considers that the substances in the category "*do not constitute an environmental risk even under unrealistic worst case conditions*".

Even if based on acute aquatic toxicity the toxicities of the group members may show a similar pattern, ECHA considers that the Annex XI, section 1.5 requirement of constant pattern in the toxicity potency of the category in relation to the endpoints assessed here is not reliably demonstrated for the following reasons. Firstly, all substances have low water solubility and acute aquatic toxicity was only observed for APG C14 which the Registrant referred to in his category justification document. The ECHA Guidance on information requirements and chemical safety assessment (Version 1.2, November 2012), Chapter R7b, page 32, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with a substance having low water solubility can, therefore, not be considered to adequately address the toxicity potential of such substances. Secondly, no long-term aquatic data is provided for any of the members in the category and also the Environment assessment section of the Category justification refers to acute aquatic toxicity only.
Furthermore, ECHA notes that under the current process, a compliance check, ECHAs role according to Article 41 of REACH is "to verify ... that the information in the technical dossier ... complies with the requirements of Article 10". Hence under the compliance check only the quality of the current dossier is assessed. As no data for this endpoint is yet available in the

technical dossier there is a data gap and it is necessary to provide the information for the registered substance. As no data on the proposed read-across source substance (Acetalization product between glucose and C16/18(even numbered)-alcohol (APG C16-18; EC No 927-870-2)) is yet available ECHA considers that the conditions of Annex XI, 1.5 are not met.

In conclusion, ECHA considers that the conditions of adaptation by way of read across have not been fulfilled. There is currently significant uncertainty within the category in relation to the predicted properties in relation to aquatic toxicity. Therefore, the adaptation of the information requirements suggested by the Registrant is not accepted.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of [redacted] per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation. The scope of the present decision covers Annex IX, 9.1.5. and 9.1.6. as well as related environmental hazard assessment.

1. and 2. Long-term aquatic toxicity testing on invertebrates and fish

According to column 1 of Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, long-term toxicity testing on invertebrates and on fish is required to fulfil the standard information requirements.

ECHA notes that the Registrant has sought to adapt the long-term testing on fish using the following justification: "*Considering REACH Annex IX, 9.1. criteria, long term toxicity to fish may be proposed to be investigated. This test is not proposed to be performed as the substance is readily biodegradable, poorly water soluble and non-toxic in available aquatic toxicity tests.*" ECHA further notes that the Registrant has waived the long-term toxicity on aquatic invertebrates using the following justification: "*Considering REACH Annex IX, 9.1. criteria, long term toxicity to invertebrates may be proposed to be investigated. This test is not proposed to be performed as the substance is poorly water soluble and non-toxic in available aquatic toxicity tests.*"

ECHA points out that these justifications for omission of information requirements provided by the Registrant do not meet the criteria of the general adaptation rules as provided for in Annex XI to the REACH Regulation. ECHA notes that the adaptation proposed by the Registrant for these endpoints have not been modified in the updated dossier (submission number [redacted]). The Registrant has only referred to the proposed category and read-across approach in the comments to the initial draft decision communicated to the Registrant on 15 July 2013. As outlined in section A above, ECHA does not accept the category and read-across approach as proposed.

The ECHA Guidance on information requirements and chemical safety assessment (Version 1.2, November 2012), Chapter R7b, page 32, indicates that the need to conduct further testing according to column 2 of Annex IX, section 9.1., may be triggered e.g. when due to low water solubility of a substance, short term toxicity tests do not reveal any toxicity. The absence of toxicity observed in the short-term tests with the registered substance having low water solubility can, therefore, not be used as an argument for adaptation of long-term tests.

In addition to the substance being non-toxic in available aquatic toxicity tests and poor water solubility, the Registrant has used the claim of substance being readily biodegradable

as a further justification for not proposing to conduct the long-term toxicity testing on fish. ECHA notes that the ready biodegradation of a substance is not a valid adaptation according to Column 2 of Annex IX, section 9.1.6. It does not fulfil either any of the adaptation possibilities given in Annex XI.

Therefore, the adaptation proposed by the Registrant cannot be accepted.

In the updated dossier submission number [redacted] (12 March 2015), the Registrant presented a weight-of-evidence approach to justify his conclusion that no further aquatic testing is needed for the registered substance. The comments concerning low water solubility, biodegradation and absence of aquatic toxicity have been raised in section III., A. above. Furthermore, the Registrant refers to the Log K_{OC} value of 4.49 and 5.05, indicating that the compartments of most concern are soil and sediment and to technical difficulties (low water solubility, UVCB structure and frequent renewal due to ready biodegradability leading to expensive costs).

Concerning adsorption, ECHA notes that the substance is used as a cosmetic ingredient (surface active agent) with wide dispersive uses, which indicates that exposure to the aquatic compartment by the registered substance cannot be ruled out and is likely, especially in the absence of a quantitative risk assessment and characterisation.

Concerning the technical difficulties, with the information currently available in the dossier, ECHA considers that it has not been sufficiently shown why aquatic toxicity testing is not relevant or why it is not possible to modify some conditions of the test design according to the guidelines to enable the performance of valid tests. In particular, the Registrant has not adequately considered the OECD Guidance document on aquatic toxicity testing of difficult substances and mixtures (Environmental health and safety publications, Series on testing and assessment No. 23; ENV/JM/MONO(2000)6).

ECHA acknowledges that, if the registrant's assumption of technical difficulties materialise during the study, the test may prove unfeasible to continue because of the physicochemical properties of the substance. In such a case, the registrant may decide, based on preliminary test results or laboratory assessment, that the test is technically not possible and then stop testing. The information as to why the tests were stopped and the reasons for not being technically possible then need to be explicitly included in the registration dossier.

As a result of the Registrants comments and update (submission number [redacted]) ECHA considers that the submitted information does not fulfil the above information requirements, neither as individual elements nor as a combined weight-of-evidence argumentation pursuant to REACH Annex IX, Section 1.2. Thus, there are information gaps and it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with the relevant information requirements. The requested study is tailored to real information needs and suitable to achieve the objective of compliance for this endpoint requirement.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1., ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 26). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 1.2., November 2012, p. 26). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

As for the test method for the long-term toxicity testing on aquatic invertebrates, ECHA considers the standard recommended test method EU C.20./OECD 211 to be the most appropriate and suitable.

The Registrant is reminded that this decision does not take into account any updates submitted after 12 March 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

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:

- Daphnia magna reproduction test (test method: EU C.20./OECD 211); and
- Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

Once the results of the above long-term aquatic studies are available to the Registrant, he shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation, including an updated derivation of the aquatic PNECs.

Notes for consideration by the Registrant

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), 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. In such 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, the long-term fish study needs to be conducted.

Due to the low solubility of the substance in water 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

ECHA stresses that the information submitted 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. The Registrant is reminded of his responsibility to ensure that his registration covers one substance only and that the substance is correctly identified in accordance with Annex VI, Section 2 of the REACH Regulation.

In carrying out the studies required by the present decision it is important to ensure that the particular sample of substance tested 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.

Furthermore, 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://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 Guilhem De Seze, Head of Unit, Evaluation E1

[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.