EUROPEAN CHEMICALS AGENCY

Helsinki, 18 December 2017

Decision number: CCH-D-2114382035-53-01/F

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

For Poly[oxy(methyl-1,2-ethanediyl)], a-hydro-omega-hydroxy-, ether with 2,6 bis{[(2-hydroxyethyl)amino]methyl}-4-nonylphenol, EC No 614-668-1 (CAS No 68610-97-9), 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 Poly[oxy(methyl-1,2-ethanediyl)], a-hydro-omega-hydroxy-, ether with 2,6 bis{[(2-hydroxyethyl)amino]methyl}-4-nonylphenol, EC No 614-668-1 (CAS No 68610-97-9), submitted by [redacted] (Registrant).

This decision is based on the registration 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 the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage.

The compliance check was initiated on 14 October 2015.

On 14 December 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 03 February 2016 ECHA received comments from the Registrant on the draft decision.

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

On 07 September 2017 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, proposal(s) for amendment to the draft decision were submitted and ECHA modified the draft decision.

On 13 October 2017 ECHA notified the Registrant of the proposal(s) for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal(s) for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 23 October 2017 ECHA referred the draft decision to the Member State Committee.

By 13 November 2017 the Registrant did not provide any comments on the proposals for amendment.

A unanimous agreement of the Member State Committee on the draft decision was reached on 27 November 2017 in a written procedure launched on 16 November 2017.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Name or other identifier of the substance (Annex VI, Section 2.1.)
2. Composition of the substance (Annex VI, Section 2.3.)
3. Description of the analytical methods (Annex VI, Section 2.3.7.)

B. 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 Annexe 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. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD 309) at a temperature of 12 °C. The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.;
2. Identification of degradation products (Annex IX, Section 9.2.3.)

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.

C. 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 **25 June 2019** an update of the registration dossier containing the information required by this decision.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

A. Information in the technical dossier related to the identity of the substance

In order to ensure that potential hazardous properties of the substance are not underestimated, the information that is necessary to resolve the substance identification deficiencies below, must be available to the Registrant before identifying the test sample to be used for the testing requested in the present decision.

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Name or other identifier of the substance (Annex VI, Section 2.1.)

"Name or other identifier of the substance" is an information requirement as laid down in Annex VI, Section 2.1. of the REACH Regulation. The name and other identifiers are used to identify the substance in an unambiguous manner and are therefore fundamental for substance identification. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement

The Registrant has identified the registered substance as of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB). As indicated in chapter 4.3 of the "Guidance for identification and naming of substances under REACH and CLP" (May 2017,Version 2.1), referred thereinafter as "the SID Guidance" the naming of UVCB substances shall consist of two parts: (1) the chemical name and (2) a detailed description of the manufacturing process. ECHA observes that the Registrant did not provide sufficient information for correctly identifying the registered substance as explained below.

(i) Description of the manufacturing process

ECHA considers that the description of the manufacturing process provided in IUCLID section 3.1 is not sufficiently detailed to unambiguously identify the registered substance. In particular, the following information is missing:

- The identity and composition of the starting material "[redacted]". The identifier "[redacted]" is not specific and may refer to several isomers (linear and branched). A clear description of the identity and of the composition of this starting material is necessary to correctly identify the registered substance.

- The ratios of the starting materials and the relevant steps and process parameters (e.g. temperature and pressure) used for the manufacturing of the registered substance have not been specified. This information is relevant as variation on such parameters may lead to variation on the composition.

As the abovementioned missing elements of the manufacturing process are expected to affect the composition of the registered substance, and taking also into account the limited information on the composition of the registered substance in the current dossier, ECHA considers that these elements are necessary for the identification of the substance.

The Registrant is accordingly required to provide details of the manufacturing processing steps that are applied to the starting materials. The information submitted by the Registrant must at least include the following:

- Identity and composition of the starting material [redacted]
- Molar ratio of all the starting materials;
- Description of the manufacturing steps in the order they occur, including any preliminary step, the steps involving chemical transformation as well as the isolation and purification steps carried out for the synthesis. ECHA underlines that the Registrant shall provide a description of the relevant oligomerisation steps, including the parameters used to initiate, propagate and terminate the oligomerisation reactions.
- For each step, all relevant process parameters that affect the composition and therefore the identity of the substance must be provided.

Regarding how to report the description of the manufacturing process of the UVCB substance, the information shall be included in the "Description of composition" field relative to the legal entity composition record in IUCLID section 1.2.

In your comments to the draft decision according to Article 50(1) of the REACH Regulation you have expressed your concerns for possible disclosure of confidenatial information relative to the description of the manufacturing process.
Please notice that legal entity's description of the manufacturing process is a confidential information which is not disclosed/disseminated. A more general (non confidential) description of the manufacturing process that is relative to the registration (i.e. joint submission) can be provided in the "Description of composition" field relative to the boundary composition record, that the lead registrant needs to provide in IUCLID section 1.2.

(ii) Chemical name and CAS name

The Registrant reported the CAS number 68610-97-9 as CAS information for the registered substance. The CAS name for this entry is "Polypropoxylated p-nonylphenol-formaldehyde-diethanolamine Mannich Base". In addition, the substance was identified with list number 614-668-1 (Formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide) and chemical name: Poly[oxy(methyl-1,2-ethanediyl)], a-hydro-omega-hydroxy-, ether with 2,6 bis{[(2-hydroxyethyl)amino]methyl}-4-nonylphenol

ECHA is of the opinion that the identifiers used are not describing the registered substance correctly, as they all refer to a polymeric substance. However, according to the information provided in the dossier, and especially the analytical data provided in IUCLID section 1.4, the substance does not seem to meet the definition of polymer within the meaning of Article 3(5) of the REACH Regulation.

Accordingly, the Registrant shall delete the CAS number currently specified under the "CAS information" header of the reference substance in IUCLID section 1.1 and report a CAS number specifically corresponding to the registered substance (if available). If the Registrant deems it appropriate, he may specify the current CAS entry 68610-97-9 under the "Other identifiers" section in IUCLID section 1.1 for the registered substance.

In addition, as the current list number does not correctly identify the registered substance, it will need to be revised. However, the Registrant is requested not to remove or modify the EC entry currently assigned to this registration when updating the dossier. As this registration is linked to this EC entry in REACH-IT, the IT system will not accept the updated dossier as an update when the EC entry has changed.
The Registrant is instead requested to include in the "Remarks field" of the reference substance the following: "The EC entry currently assigned does not specifically correspond to the registered substance. This identifier cannot be modified in the present registration at this stage for technical reasons".

Finally, the Registrant should provide a chemical name which is representative of the registered substance. More information on how to name a UVCB substance can be found in the SID Guidance.

The Registrant shall ensure that representative identifiers are used throughout the dossier, and are consistent with the information on the composition in section 1.2 and the analytical data in section 1.4 of the IUCLID dossier.

Regarding how to report the chemical name, it shall be included in the "IUPAC name" field in section 1.1of the IUCLID dossier.

In your comments you clarified that the term "poly" in the name is used to reflect the use of [redacted] of reactant in the manufaturing process, and that the substance is not a polymer. In addition, you mentioned that the CAS name for entry 68610-97-9 is "Polypropoxylated p-nonylphenol-formaldehyde-diethanolamine Mannich Base". Please note, the CAS name is "Formaldehyde, polymer with nonylphenol, reaction products with diethanolamine and propylene oxide", and this refers to a polymer, and therefore it is not appropriate for the identification of the substance. Therfore the requests above relative to the identifiers (CAS, EC/list entry, and chemical name) are not amended.

The Registrant should note that ECHA has established a process, subject to certain conditions, enabling registrants to adapt the EC identifier of an existing registration, while maintaining the regulatory rights already conferred to the substance concerned.

However, pending the resolution of all the incompliances highlighted in the present decision, the adaptation of the identifier can only be effective once ECHA is at least in a position to establish unambiguously the identity of the substance intended to be covered by the Registrant with this registration. Should the information submitted by the Registrant as a result of the present decision enable ECHA to identify the substance unambiguously, the process of adapting the identifier will be considered relevant. In that case, ECHA will inform the Registrant in due time as to when the identifier adaptation process shall be initiated.

In any case, the Registrant should note that the application of the process of adapting the identifier does not affect his obligation to fulfil the requirements specified in this decision.

Further information on how to report the substance identity in IUCLID can be found in the manual "How to prepare registration and PPORD dossiers" available on ECHA webpage (https://echa.europa.eu/manuals).

2. Composition of the substance (Annex VI, Section 2.3.)

The substance composition corresponds to the chemical representation of what the substance consists of and is therefore an essential part of substance identification and the cornerstone of all the REACH obligations.

Annex VI, Section 2.3. of the REACH Regulation requires that each registration dossier contains sufficient information for establishing the composition of the registered substance and therefore its identity.

In that respect, according to chapter 4.3 of the SID Guidance, the Registrant shall note that for UVCB substances presenting a large number of constituents, such as the registered substance, the following applies:

- All constituents present in the substance with a concentration of ≥ 10 % shall be identified and reported individually,
- All known constituents and constituents relevant for the classification and/or PBT assessment of the registered substance shall be identified and reported individually; and
- Unknown constituents shall be identified as far as possible by a generic description of their chemical nature.
- For each constituent or group of constituent, the typical, minimum and maximum concentrations shall be specified.

ECHA notes that the Registrant did not provide any information on the identity and concentration levels of the constituents or groups of constituents present in the composition of the registered substance. The Registrant instead reported the composition as consisting of [redacted]% of the substance itself, i.e. of the [redacted].
ECHA underlines that the report from the gel permeation chromatography (GPC) analysis attached in section 1.4 includes information indicating the presence of predominant constituents in the analysed sample and that a resolution of the composition can thus be achieved.

Therefore ECHA concludes that the information provided on the composition has not been provided to the required level of detail.

The Registrant is accordingly requested to specify the identity and typical, upper and lower concentration level of the constituents and groups of constituents required to be reported. Concerning the reporting of the unknown constituents, the Registrant shall note that, for substances such as the registered substance, a subdivision of these unknown constituents according to the degree of oligomerisation is necessary for this purpose as a baseline. For each group of unknown oligomeric constituents, information on the relative content of Mannich base and propylene oxide units shall be specified.

ECHA notes that in the event the Registrant covers different grades of the registered substance in the present registration dossier, he shall report separately the compositional information of each grade. This means that if the substance covered by the present registration has two (or more) different compositions, then these must be presented separately. ECHA highlights that failure to report separately the compositional information of each grade of a substance may result in one or more grades not being covered by this registration.

Regarding how to report the composition in IUCLID, the following applies:

The Registrant shall indicate each composition of the registered substance in IUCLID section 1.2.

For each constituent required to be reported individually, the IUPAC name, CAS name and CAS number (if available), molecular and structural formula, as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

For the other constituents to be reported under a generic description, a generic chemical name describing the group of constituents, generic molecular and structural information (if applicable), as well as the minimum, maximum and typical concentration, shall be reported in the appropriate fields in IUCLID.

The Registrant shall ensure that the reported composition is consistent with the description of the process used for the manufacturing of the registered substance, including the identity of the starting materials used. The Registrant shall also ensure that the composition is verifiable and therefore supported by a description of the analytical methods for the identification and quantification of the constituents required to be reported, as required under Annex VI, Section 2.3.7.

Further information on how to report the compositional information in IUCLID can be found in the manual "How to prepare registration and PPORD dossiers" available on ECHA webpage (https://echa.europa.eu/manuals).

3. Description of the analytical methods (Annex VI, Section 2.3.7.)

ECHA observes that the Registrant did not provide sufficient and appropriate description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance, as requested according to Annex VI section 2.3.7.

The Registrant provided a description of a gel permeation chromatographic (GPC) analysis. Three peaks that are not well resolved are visible in the chromatogram. This information however does not provide any indication on the identity of the actual constituents present in the analysed sample, and neither does it allow the quantification of the different constituents of the substance. Furthermore, there is no information on the possible presence or absence of residual *nonylphenol*, or other starting materials.

ECHA therefore concludes that the Registrant did not provide sufficient description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance.

The Registrant is accordingly requested to provide a description of the analytical methods used for the identification and quantification of the constituents and groups of constituents required to be reported in the composition of the registered substance. The description shall be sufficient for the methods to be reproduced and shall therefore include details of the experimental protocol followed, any calculation made and the results obtained. The Registrant should note that ECHA will consider any method that is suitable to verify the composition, including any indirect method involving chemical derivatisation of the substance or any analysis involving also considerations on the starting materials and the manufacturing process.

As for the reporting of the data in the registration dossier, the information shall be attached in IUCLID section 1.4.

The Registrant shall ensure that the analytical results obtained is consistent with the composition reported in the IUCLID dossier section 1.2.

Further information on how to report the analytical data in IUCLID can be found in the manual "How to prepare registration and PPORD dossiers" available on ECHA webpage (https://echa.europa.eu/manuals).

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 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

1. Simulation testing on ultimate degradation in water (Annex IX, 9.2.1.2.)

"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant provided an OECD 301 D TG GLP compliant used as Key study from 2013, where the findings were that the substance is not readily biodegradable with only 8.9 % degradation by O2 consumption after 28 days.

The Registrant has not provided any study record of simulation testing on ultimate degradation in water in the dossier that would meet the information requirement of Annex IX, Section 9.2.1.2.

The Registrant sought to adapt this information requirement according to Annex IX, Section 9.2.1.2., column 2, by providing the following justification for the adaptation: "According to column 2 of Annex IX further testing on biodegradation in water and sediment should be considered if the chemical safety assessment indicates the need to investigate further the degradation of the substance and its degradation products. From the available information, it was concluded that the substance is not readily biodegradable. Based hereon, it can be assumed that further testing on this endpoint will not change this conclusion. Furthermore the results from the CSA do not trigger a need for further investigation of biotic degradation."

The Registrant used a waiver based on the CSA that cannot be accepted as such; as he did not provide any exposure assessment nor risk characterisation on environment.

Furthermore, according to Annex IX, section 9.2.1.2., column 2 of the REACH Regulation, the simulation testing on ultimate degradation in water does not need to be conducted if the substance is highly insoluble in water or the substance is readily biodegradable. The data provided by the Registrant indicates for the registered substance a water solubility of 14,24 g/L at 20 °C and a 8,9 % biodegradation after 28 days. Therefore the registered substance can neither be considered to be highly insoluble nor readily biodegradable and consequently the specific rules for adaption presented in column 2 of Annex IX, section 9.2.1.2.of the REACH Regulation do not apply.

As explained above, the information available on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-9 (version 3.0, February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

Section R.11.4.1 of The Guidance on information requirements and chemical safety assessment R.11 on PBT/vPvB assessment (version 3.0, June 2017), indicates that *"constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w)"*. Individual concentrations < 0.1 % (w/w) normally need not be considered. Before conducting bioaccumulation testing it is necessary to conclude on the persistency information for all relevant constituents present in concentrations of ≥ 0.1% (w/w).
In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the "pelagic test" option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309). The biodegradation of each constituent and relevant impurity present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable shall be assessed. This can be done simultaneously during the same study.

Notes for consideration by the Registrant

Before conducting the requested test ECHA advises to consult the ECHA Guidance on information requirements and chemical safety assessment, Chapter R7b, Sections R.7.9.4

and R.7.9.6 (version 4.0, June 2017) and Chapter R.11, Section R.11.4.1.1 (version 2.0, November 2014) on PBT assessment.

In accordance with Annex I, Section 4, of the REACH Regulation the PBT assessment should be revised when results of the test detailed above is available. It is also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 4.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

2. Identification of degradation products (Annex IX, Section 9.2.3.)

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX of the REACH Regulation. Column 2 of Section 9.2.3. of Annex IX further states that the information does not need to be provided if the substance is readily biodegradable.

The Registrant did not provide any information on the degradation products in the dossier nor any adaptations as why such identification of the degradation products would not be needed. The results of the OECD 301 D TG study show that the substance is not readily biodegradable with only 8.9 % degradation by O2 consumption after 28 days without further information or consideration for analysis of the degradation products, using analytical methods in parallel to the processing the ready biodegradation test.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

Regarding appropriate and suitable test method, the methods will have to be substance specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition degradation half-life, log Kow and potential toxicity of the metabolite may be investigated.

Therefore, pursuant to Article 41(1)(a) 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:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

Notes for consideration by the Registrant

Before providing the above information it is advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R.7.b., Sections R.7.9.2.3 and R.7.9.4. These guidance documents explain that the data on degradation products is only required if information on the degradation products following primary degradation is required in order to complete the chemical safety assessment. Section R.7.9.4. further states that when substance is not fully degraded or mineralised, degradation products may be determined by chemical analysis.

B. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new study must be suitable for use by all the joint registrants. Hence, the

sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new study must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the study to be assessed.

C. 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 Claudio CARLON, Head of Unit, Evaluation E2

[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.