EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114315814-52-01/F Helsinki, 08 March 2016

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

For Reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol, List No 911-254-5 (CAS No NS), 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 Reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol, List No 911-254-5 (CAS No NS), submitted by [redacted] (Registrant).

The scope of this compliance check decision is limited to the standard information requirements of Annexes VII to X, Section 9. of the REACH Regulation (ecotoxicological information) and of Annex I, Sections 3. to 6. of the REACH Regulation (Chemical Safety Report, specifically, environmental hazard assessment, PBT and vPvB assessment, environmental exposure assessment and environmental risk characterisation).

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 28 May 2014.

On 22 May 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.

By 29 June 2015 the Registrant did not provide any comments on the draft decision to ECHA.

On 3 September 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.

Subsequently, proposals for amendment to the draft decision were submitted.

On 9 October 2015, ECHA notified the Registrant of the proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposals for amendment within 30 days of the receipt of the notification.

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

On 19 October 2015 ECHA referred the draft decision to the Member State Committee.

By 9 November 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposals for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposals for amendment made and are therefore considered outside the scope of Article 51(5).

After discussion in the Member State Committee meeting on 7–11 December 2015, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 10 December 2015.

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

II. Information required

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

Pursuant to Articles 41(1), 41(3), 10(a)(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. 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). 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. The test results should correspond to the temperature of 12°C (285K);

2. Identification of degradation products for the registered substance, including each constituent and relevant impurities present in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable (Annex IX, Section 9.2.3.);

3. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305). The bioaccumulation or bioconcentration of each constituent and impurity present in concentrations at or above 0.1% (w/w) shall be assessed. This can be done simultaneously during the same study. For the PBT/vPvB assessment, the bioaccumulation or bioconcentration potential of degradation products shall also be investigated.

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. Information related to chemical safety assessment and chemical safety report

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

1. A revised PBT and vPvB assessment including PBT and vPvB assessment for the relevant constituents of the substance (including impurities) and for the relevant degradation products (Annex I, Section 4.) as further specified in Section III.B.1. of the present decision;

2. Revised environmental exposure assessment (Annex I, Section 5) and risk characterisation (Annex I, Section 6) to address all the life-cycle stages of the substance as further specified in section III.B.2 below.

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 **17 September 2018** an update of the registration dossier containing the information required by this decision. 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. 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 has waived testing on simulation testing on ultimate degradation in water using the following justification:
"*In accordance with column 2 of REACH Annex IX, the study does not need to be conducted since the chemical safety assessment indicates that there is no need to investigate further the degradation of the substance and its degradation products*".

ECHA notes that the Registrant has not provided any justification in his chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

According to Annex IX, Section 9.2.1.2., column 2 of the REACH Regulation, 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. ECHA notes that the registration dossier contains the result of a CO_2 Evolution Test (OECD 301B) which showed no significant biodegradation after 28 days. Also, the registration dossier indicates a water solubility of 169.5 mg/L at 20°C for the substance. Therefore the registered substance can neither be considered to be highly insoluble nor readily biodegradable. 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.

ECHA further notes that contrary to Annex XI, Section 3 of the REACH Regulation, direct and indirect exposure of the aquatic compartment cannot be excluded based on the reported uses of the substance (but also based on the not reported uses – see Section III.B.2 below). The Registrant has not presented any other adaptation to the current information requirement pursuant to Annex XI. Consequently, the general adaptation rules of Annex XI 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 Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % (w/w) are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore the biodegradation should be assessed for each constituent and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

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 2.0, November 2014) 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 2.1 October 2012) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Therefore, the test results, and in particular the degradation rates, should correspond to the temperature of 12°C (285K).

In the comments the Registrant provided after the proposals for amendments made by the Competent Authorities of the Member States, he has proposed to perform an inherent biodegradability test according to test guideline OECD 302 before conducting a simulation test. If the inherent biodegradability test shows significant degradation, the Registrant has proposed that he will then not perform a simulation test. If on the contrary the inherent biodegradability test is negative, he has proposed to perform a soil simulation test according to test guideline OECD 307. ECHA acknowledges the Registrant's comment and points out that an inherent biodegradability test would not meet the information requirement of Annex IX, Section 9.2. neither for the identification of degradation products, nor for the purpose of the PBT/vPvB assessment. Therefore ECHA considers that a simulation test is needed.

Furthermore, ECHA considers that the simulation test will have to be carried out in water according to test guideline 309. ECHA notes that the technical dossier reports a water solubility of 169.5 mg/L at 20°C for the registered substance. In addition, ECHA has verified that none of the relevant constituents or impurities is highly insoluble in water. Therefore, ECHA considers that a simulation test in water is relevant and is technically feasible for the registered substance. ECHA wants to point out that a simulation test performed in soil, as proposed by the Registrant, would possibly imply the formation of non-extractable residues (NER). Interpretation of NER is not straightforward and is still a topic of scientific and regulatory debate as there is currently no agreed method to assess NER further. ECHA Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.11: PBT/vPvB assessment, Version 2.0 November 2014 states that the formation of NER should be interpreted as removal instead of biodegradation per se but makes clear that removal alone is insufficient for the P/vP assessment (R.11.4.1.1). Therefore, ECHA considers that a simulation test in water is more appropriate for the registered substance than a simulation test in soil.

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: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD 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. The test results should correspond to the temperature of 12°C (285K).

Note for consideration by the Registrant

The Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.4. and Figure R.11—3 on the PBT/vPvB assessment for further information on the integrated testing strategy for the persistence assessment of the registered substance.
The Registrant should revise the PBT/vPvB assessment when information on persistence is available.

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 indicates that the study does not need to be conducted if the substance is readily biodegradable.

ECHA notes that the registration dossier does not contain information on the degradation products or an acceptable adaptation for this standard information requirement pursuant to the specific adaptation rules of Column 2 of Annex IX, Section 9.2.3, Column 2 or the general adaptation rules of Annex XI.

According to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % (w/w) are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*". Therefore degradation products should be identified for each constituent and relevant impurity present in the registered substance in concentrations at or above 0.1% (w/w) or, if not technically feasible, in concentrations as low as technically detectable.

Therefore, pursuant to Article 41(1)(a) and (3) of the REACH Regulation, the Registrant is requested to identify the degradation products of the registered substance subject to the present decision including 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. This should be done by using an appropriate analytical method. When analytically possible, the identification, stability, behaviour, molar quantity of the metabolites relative to the parent compound should be evaluated. In addition, the degradation half-life, log Kow and potential toxicity of the metabolites may also be investigated.

3. Bioaccumulation in aquatic species (Annex IX, 9.3.2.)

"Bioaccumulation in aquatic species" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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 has provided a QSAR result (BCFWIN v2.17 model of EPI Suite v3.20) for the alleged read-across substance 2-tert-butyl-4,6-dimethylphenol (CAS: 1879-09-0, EC: 217-533-1), which corresponds to the main constituent of the registered substance (concentration [redacted]% (w/w)). The corresponding BCF reported in the dossier is 212.8. On this basis, the Registrant concluded that his substance is not bioaccumulative (not B).

ECHA notes that the Registrant has not assessed the bioaccumulation potential of every constituent in the registered substance. In particular, some impurities may have a potential for high bioaccumulation and may be PBT or vPvB. While not contesting the QSAR as such, ECHA considers that the results provided on the main constituent of the registered substance are not adequate for risk assessment, as well as for classification and labelling of the registered substance in terms of Annex XI, Section 1.3 laying down the criteria for QSAR.

The Registrant has also provided the following justification:
"*The substance CAS No. 1879-09-0 is one of the main components of the reaction mass of 2-tert-butyl-4,6-dimethylphenol and 4-tert-butyl-2,5-dimethylphenol and it is present in a concentration of more than [redacted]%. Therefore, the results obtained with the substance CAS No. 1879-09-0 can be used for the read-across approach. Based on estimated data on the analogue 6-tert-butyl-2,4-xylenol (CAS 1879-09-0), the read-across approach is applied. Using the BCFWIN v2.17 model of EPI Suite v3.20, the BCF was 212.8 (log BCF from regression-based method = 2.328). Log Kow used: 4.52 (estimated)*"

ECHA points out that Annex XI, Section 1.5. governing grouping of substances and read-across approach provides that a read-across approach must be justified by evidence that the read-across substance has properties similar to those of the registered substance. The Registrant has not provided such evidence.

It should also be noted that according to Annex XIII of REACH, the identification of PBT/vPvB substances shall take account of the PBT/vPvB-properties of relevant constituents of the substance. Impurities present in concentrations at or above 0.1 % (w/w) are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 33) of REACH Guidance document R.11 on PBT/vPvB assessment (version 2.0, November 2014) indicates that "*constituents, impurities and additives are relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice rooted in a principle recognised in European Union legislation*".

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

The OECD 305 test guideline (Bioaccumulation in Fish: Aqueous and Dietary Exposure) is recognised as being appropriate to meet the information requirement of Annex IX, Section 9.3.2.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: Bioaccumulation in fish: aqueous and dietary exposure (test method: OECD 305). The bioaccumulation or bioconcentration of each constituent and impurity present in concentrations at or above 0.1% (w/w) shall be assessed. This can be done simultaneously during the same study. For the PBT/vPvB assessment, the bioaccumulation or bioconcentration potential of degradation products shall also be investigated.

Note for consideration by the Registrant:
The Registrant is advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.11.4. and Figure R.11—4 on the PBT/vPvB assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. The Registrant should revise the PBT/vPvB assessment when information on bioaccumulation is available.

In addition, the Registrant is advised to consult the ECHA Guidance on the standard information requirements and chemical safety assessment (version 2.0, November 2014), Chapters R.4, 5, 6, R.7b and R.7c. Where the Registrant decides to adapt the testing requested 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, ECHA refers him to the advice provided in practical Guides 4, 5 and 6

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

Pursuant to Articles 10(b) and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) which shall document the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

1. A revised PBT and vPvB assessment (Annex I, Section 4.)

Pursuant to Sections 0.6.1. and 4 of Annex I of the REACH Regulation a chemical safety assessment (CSA) performed by a Registrant shall include the PBT and vPvB assessment. Section 4.0.1. of Annex I notes that the objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. Annex XIII of the REACH Regulation lays down the criteria for the identification of persistent, bioaccumulative and toxic substances (PBT substances), and very persistent and very bioaccumulative substances (vPvB substances) as well as the information that must be considered for the purpose of assessing the P, B, and T properties of a substance.

Pursuant to the fifth introductory paragraph of Annex XIII, the identification of PBT/vPvB substances shall also take account of the PBT/vPvB-properties of relevant constituents of a substance and of relevant degradation products.

ECHA notes that the Registrant has summarised the outcome of the PBT and vPvB assessment of the substance in the CSR attached to the technical dossier as well as in Section 2.3 of IUCLID. The Registrant has concluded that the substance is considered to be persistent (P) and toxic (T) but not bioaccumulative (not B) and therefore that the substance is not PBT/vPvB. However, ECHA notes that only information on the main constituent (2-tert-butyl-4,6-dimethylphenol, CAS: 1879-09-0, EC: 217-533-1) has been evaluated for the bioaccumulation assessment. As already explained in Section III.A.3 above, some impurities may have a potential for high bioaccumulation and may be PBT or vPvB. In particular, based on external sources or QSAR screening, ECHA has initially identified the following impurities as potential PBT or vPvB constituents:

- 2,6-di-tert-butyl-4-ethylphenol (CAS: 4130-42-1, EC: 223-945-2), concentration: up to [redacted] (w/w);
- 2,4-di-tert-butyl-6-methylphenol (CAS: 616-55-7, EC: 210-485-2), concentration: up to [redacted] (w/w);
- 2,4-di-tert-butyl-6-(propan-2-yl)phenol (CAS: 22354-52-5, EC: none), concentration: up to [redacted] (w/w).

Every impurity present in concentrations at or above 0.1 % (w/w) is deemed to be relevant for the PBT/vPvB assessment.

Furthermore, ECHA notes that Article 14(1) of the REACH Regulation requires a PBT/vPvB assessment to be conducted for every substance produced or imported in more than 10 tonnes per year. According to the registration dossier, up to 1000 tonnes of the registered substance can be produced or imported per year and the total concentration of potential PBT/vPvB impurities could be up to [redacted]% (w/w), therefore up to 24 tonnes of potential PBT/vPvB impurities could be produced or imported.

Also, ECHA notes that there is no indication in the CSR or in the technical dossier that PBT/vPvB properties of any relevant degradation products were considered in the PBT and vPvB assessment. The information on degradation and on degradation products of the registered substance is incomplete (see Section III.A.1 and Section III.A.2 above). ECHA concludes that the consideration of degradation products of the registered substance in the PBT and vPvB assessment is missing.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to revise the PBT and vPvB assessment including PBT and vPvB assessment for the relevant constituents of the substance (including all impurities present in concentrations at or above 0.1 % (w/w)) and for the relevant degradation products.

2. Revised environmental exposure assessment (Annex I, Section 5) and risk characterisation (Annex I, Section 6) to address all the life-cycle stages of the substance

Article 10(a)(iii), in conjunction with Annex VI, Section 3.5. of the REACH Regulation require the Registrant to provide a description of the life-cycle of the substance by describing all the identified uses. In addition, according to Article 14(4) of the REACH Regulation, if the substance fulfils the criteria for any of the hazard classes of Annex I to Regulation (EC) No 1272/2008 listed in Article 14(4) of the REACH Regulation or is assessed to be a PBT or vPvB, the chemical safety assessment shall include an exposure assessment and risk characterisation.

The exposure assessment shall be carried out according to Section 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. The risk characterisation shall be carried out according to Section 6 of Annex I. The exposure assessment and risk characterisation shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

The substance is exclusively registered for use as additive (antioxidant) in jet fuel. The Registrant has provided exposure scenarios and an exposure assessment for the following uses:

- ES1: Manufacturing stage (industrial)
- ES2: Formulation stage (industrial)
- ES3: Professional end-use stage (i.e. during refilling aircraft fuel tanks)

In addition, the Registrant has provided a short discussion about potential exposure during the use of fuel (Section 9.5.2.2. of the CSR "Exposure estimation for Use of fuel"). ECHA acknowledges that the substance is eventually intended to be burnt with the fuel. However, ECHA also notes that during emergency situations excess fuel may have to be dumped into the atmosphere (fuel jettison) to reduce the overall weight of an aircraft to a safe landing weight. Though rare, this procedure is part of airline instructions during emergency situations and will result in releases to the environment. It is therefore a relevant stage in the life-cycle of the substance and it shall be addressed in the exposure assessment and risk characterisation of the substance.

Therefore, pursuant to Article 41(1) and (3) and Annex I Section 5 of the REACH Regulation, the Registrant is requested to revise the environmental exposure assessment (Annex I, Section 5) and the risk characterisation (Annex I, Section 6) to address all the life-cycle stages of the substance. In particular, potential impact of the substance to the environment during fuel jettison shall be assessed.

IV. Adequate identification of the composition of the tested material

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 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.