EUROPEAN CHEMICALS AGENCY

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DECISION ON SUBSTANCE EVALUATION PURSUANT TO ARTICLE 46(1) OF REGULATION (EC) NO 1907/2006

For decan-1-ol, CAS No 112-30-1 (EC No 203-956-9)

Addressees: Registrant(s)[1] of decan-1-ol (Registrant(s))

This decision is addressed to all Registrants of the above substance with active registrations on the date on which the draft for the decision was first sent, with the exception of the cases listed in the following paragraph.

Registrant(s) meeting the following criteria are *not* addressees of this decision: i) Registrant(s) who registered the above substance exclusively as an on-site isolated intermediate under strictly controlled conditions and ii) Registrant(s) who cease manufacture/import of the above substance in accordance with Article 50(3)of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) before the decision is adopted by ECHA.

Based on an evaluation by National Institute of Health on behalf of Ministry of Health as the Competent Authority of Italy (evaluating MSCA), the European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 52 of the REACH Regulation.

This decision does not take into account any updates of the registrations of the Registrant(s) after 5 December 2012.

This decision does not imply that the information provided by the Registrant(s) in the registrations is in compliance with the REACH requirements. The decision neither prevents ECHA from initiating compliance checks on the dossiers of the Registrant(s) at a later stage, nor does it prevent a new substance evaluation process once the present substance evaluation has been completed.

I. Procedure

Pursuant to Article 45(4) of the REACH Regulation the Competent Authority of Italy has initiated substance evaluation for decan-1-ol, CAS No 112-30-1 (EC No 203-956-9) based on registrations dossiers submitted by the Registrant(s) and prepared the present decision in accordance with Article 46(1) of the REACH Regulation.

On the basis of an opinion of the ECHA Member State Committee and due to initial grounds for concern relating to: Environment/Suspected long term effects on the environment; Exposure/Wide dispersive use, high aggregated tonnage, potential to contaminate surface and groundwater, decan-1-ol was included in the Community rolling action plan (CoRAP) for substance evaluation pursuant to Article 44(2) of the REACH Regulation to be evaluated in 2012. The CoRAP was published on the ECHA website on 29 February 2012. The Competent Authority of Italy was identified to carry out the evaluation.

[1] The term Registrant(s) is used throughout the decision, irrespective of the number of registrants addressed by the decision.

In the course of the evaluation, the evaluating MSCA noted additional concerns regarding potential risk for workers in relation to the exposure during spraying.

The evaluating MSCA considered that further information was required to clarify the abovementioned concerns. Therefore, it prepared a draft decision pursuant to Article 46(1) of the REACH Regulation to request further information. It submitted the draft decision to ECHA on 28 February 2013.

On 4 April 2013 ECHA sent the draft decision to the Registrant(s) and invited them pursuant to Article 50(1) of the REACH Regulation to provide comments within 30 days of the receipt of the draft decision.

By 6 May 2013 ECHA received comments from Registrant(s) of which it informed the evaluating MSCA without delay.

The evaluating MSCA considered the Registrants' comments received and did amend Sections II and III of the draft decision since, following the comments, two requests were withdrawn from decision making (Biodegradation in water/sediment and soil; Bioncentration).

In accordance with Article 52(1) of the REACH Regulation, on 31 October 2013 the evaluating MSCA notified the Competent Authorities of the other Member States and ECHA of its draft decision and invited them pursuant to Articles 52(2) and 51(2) of the REACH Regulation to submit proposals to amend the draft decision within 30 days.

Subsequently, two Competent Authorities of the Member States and ECHA submitted proposals for amendment to the draft decision.

On 5 December 2013 ECHA notified the Registrant(s) of the proposal for amendment to the draft decision and invited them pursuant to Articles 52(2) and 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

The evaluating MSCA reviewed the proposals for amendment received and where considered appropriate the draft decision has been amended accordingly.

By 7 January 2014 in accordance to Article 51(5), the Registrant(s) provided comments on the proposal(s) for amendment. In addition, the Registrant(s) provided comments on the draft decision. The Member State Committee took the comments on the proposal(s) for amendment of the Registrant(s) into account. The Member State Committee did not take into account the Registrants' comments on the draft decision as they were not related to the proposal(s) for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 21 January 2014 in a written procedure launched on 10 January 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

Pursuant to Article 46(1) of the REACH Regulation the Registrant(s) shall submit the following information using the indicated test methods/instructions and the registered substance subject to the present decision:

1. Risk assessment: Derivation of DNEL/DMEL both for systemic and local effects as specified in Section III;

2. Human exposure: Justification for assuming a default dermal absorption value of 10% as specified in Section III and resulting risk characterization for human health;

3. Adsorption/desorption (Test method: EU C.18/OECD 106);

4. Long-term toxicity on fish (Test method: OECD 210), unless the Registrant(s) can provide an adequate justification for why existing information indicates that this test is not needed;

5. Justification for deviating in use of default values in PNEC derivation for aquatic and terrestrial compartment;

6. Missing elements for environmental exposure assessment and the risk characterization as specified under Section III.6 below;

7. Missing information for soil compartment as specified under Section III.7 below;

8. Missing information on waste and related to risks possibly arising from the waste life cycle stage as specified under Section III.8 below;

Pursuant to Article 46(2) of the REACH Regulation, the Registrant(s) shall submit to ECHA by **27 August 2015** an update of the registration dossiers containing the information required by this decision.

At any time, the Registrant(s) shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other Registrant(s).

III. Statement of reasons

Based on the evaluation of all relevant information submitted on decan-1-ol and other relevant and available information, ECHA concludes that further information is required in order to enable the evaluating MSCA to complete the evaluation of whether the substance constitutes a risk to human health or the environment.

1. Risk assessment

In the risk assessment for human health, the Registrant(s) have chosen 1-hexanol as the category representative because shorter chain molecules are usually regarded as more toxic when compared to structural analogues with longer carbon chain lengths. The 13-week repeated dose study on 1-hexanol by (Sc. Assoc. 1966) has been used as the key study for deriving the Indicative Human No Effect Level (IHNEL) for the Long Chain Aliphatic Alcohol (LCAA) category. This study reported a NOAEL of 1127 mg/kg (bw).

In their response on the Draft Decision provided on 6 May 2013, the Registrant(s) propose to remove the deriving of IHNEL indicating the statement "No hazard identified" as it was

agreed within the Consortium not to derive DNELs (derived no effect levels) as no adverse effects had been reported in any of the studies, even at the highest recommended doses. The evaluating MSCA notes that despite what was reported by Registrant(s), adverse effects have been observed in two different studies (in a 90 day dermal toxicity study on fatty alcohol blend in rats - study report in 7.5.3. in the IUCLID dossier and in a developmental toxicity study in rat - study report in 7.8.2 in the IUCLID dossier in which maternal toxicity was observed).

In their comments on proposals for amendment (PfA) provided on 7 January 2014, the Registrant(s) indicate that no adverse systemic effects have been observed in the above mentioned studies. However, the evaluating MSCA is still of the opinion that the observed effects should be taken into account.

In particular in the 90-day dermal toxicity study the mean body weights were lower in the middle and high dose groups - 300 and 1000 mg/kg bw/day compared to the control group attributed to the test article, mean food consumption (evaluated as g/animal/day) was slightly but consistently decreased in the high dose group (1000 mg/kg bw/day in males) during the first two thirds of the study period attributed to the test article and it was reported that no remarkable statistically significant changes in organ weight were note for any of the organs except for the adrenals (data not reported). In the developmental toxicity study in rat a maternal LOAEL of 130 mg/kg bw/day (being this the lowest tested dose) was derived on the basis of neurological effects (such as lateral and abdominal position, unsteady gait, salivation, piloerection) and other clinical signs such nasal discharge and pneumonia.

Thus, according to the ECHA guideline on information requirements DNEL(s)/DMEL(s) (derived minimum effect levels) for systemic effects should be derived.

Moreover, according to the list of end-points of the peer review of the pesticide risk assessment of the active substance (European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance 1-decanol. EFSA Journal 2010;8(9):1715. [42 pp.] doi:10.2903/j.efsa.2010.1715. Available online: www.efsa.europa.eu/efsajournal.htm), 1-decanol is irritating to the skin (R38) based on the observation of severe local dermal irritation and secondary effects on bodyweights at the lowest dose level tested (90-day, rat: LOAEL(local) of 100 mg/kg bw/day). This is in accordance with the results of the studies reported by the Registrant(s) in the section 7.3.1 (Skin irritation/corrosion) and in the section 7.5.3 (repeated dose toxicity/dermal) of the IUCLID dossier.

In conclusion, ECHA is of the opinion that the substance is a skin irritant and therefore DNEL/DMEL for local effects (skin irritation) shall be derived.

2. Human exposure

The Registrant(s) in their registration dossier used a default dermal absorption of 10% to calculate human systemic exposures. The Registrant(s) in their response on the draft decision provided on 6 May 2013, accept that available evidence on uptake and distribution was not presented in IUCLID data set Section 7.1 Toxicokinetics and stated that additional discussion would also be added in 7.1.1 Basic toxicokinetics, as well as in the CSR exposure assessment (relevant Sections of Chapter 9) and that this will be updated.

However, the ECHA is still aware that a default value of 25%, as indicated in the EFSA guidance on Dermal Absorption may be applied for products containing >5% active substance (EFSA Journal 2012;10(4):2665). This value should be applied if no new scientific

evidence will be provided. ECHA notes that the additional information, as anticipated by the Registrant(s), will be properly evaluated once the registration dossier will be updated.

Therefore, pursuant to Article 46(1) of the REACH Regulation, Registrant(s) are required to perform a re-evaluation of all available information and update the exposure estimation accordingly.

3. Adsorption/desorption

On this endpoint the Registrant(s) provided the following justification for data waiving: "*In accordance with Column 2 of REACH Annex VIII, the adsorption/desorption screening test (required in Section 9.3.1) does not need to be conducted as the substance is readily biodegradable*". Moreover, in absence of reliable measured adsorption data available, the Registrant(s) reported only a calculated Koc value of 6330 obtained using a valid application of a well-established predictive method.

In order to address the initial concern posed by the substance relating to environment (suspected long-term effects on the environment) and exposure (wide dispersive use, high aggregated tonnage, potential to contaminate surface and groundwater), the Registrant(s) are required to provide further information on this endpoint.

The Registrant(s) might also take into account additional information supplied for the Koc of 1-decanol: in absence of available measured values, in the DAR UK Report (2009) a calculated Koc value (96 mL/g) was reported using the software PCKOCWIN version 1.66 (US EPA, 2000). In absence of measured data this calculated Koc value indicating a moderate mobility of 1-decanol can be considered an indication of data useful in modelling of potential contamination of surface and groundwater. In fact, although this Koc value is subject to a high degree of uncertainty, in the DAR UK Report (2009) it is indicated that, in absence of measured data, using a Koc value of 96 mL/g, as a representative calculated value, would be highly conservative with respect to the Koc of 6330 for the calculation of groundwater and surface water PEC (predicted effect concentration) values.

Following the examination of these information, ECHA considers that the currently available data submitted by the Registrant(s) on this endpoint are not sufficiently covering the information requirements to address the conclusion on adsorption potential for 1-decanol. Based on these considerations, the Registrant(s) are requested to provide reliable measured data on this endpoint needed to clarify the concern relating to the adsorption and mobility in soil of the registered substance. In their comments on the Draft Decision provided on 6 May 2013, the Registrant(s) proposed to perform an OECD 121 guideline study (Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC)), as first step in determining the adsorption coefficient.

ECHA notes that the additional information, as anticipated by the Registrant(s), will be properly evaluated once the registration dossiers will be updated. However, ECHA considers that an OECD test guideline 106 is a more appropriate test to obtain a reliable measured adsorption coefficient useful to address the conclusion on adsorption potential for decan-1-ol. Moreover, in ECHA Guidance R.7a it is reported that OECD 106 uses a range of actual soils and so represents more realistic scenario than the HPLC method (OECD 121).

Therefore, based on these assumptions, ECHA confirms the request on this endpoint.

Pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the substance subject to this decision: Adsorption/desorption using a Batch equilibrium method (test method: EU C.18/OECD 106).

4. Long-term toxicity on fish

The information on this endpoint is not provided by the Registrant(s) for the registered substance, but it needs to be present in the technical dossiers to address the initial concern relating to the suspected long-term effects on environmental compartments for 1-decanol. Consequently, also considering this information a standard requirement of the REACH Regulation, there is an information gap to provide a risk assessment for aquatic organisms and it is necessary to generate suitable data for this endpoint.

The Registrant(s) provided the following justification for data waiving: "*In accordance with Column 2 of REACH Annex IX, the long-term aquatic toxicity to fish study (required in Section 9.1.6) does not need to be conducted as the chemical safety assessment according to Annex I indicates that this is not necessary. Moreover, considerable technical difficulties would be expected in the conduct of such a test, due to the very rapid biotic removal of the substance from the test system (based on experience in the long-term invertebrate study)*". ECHA notes that this Registrants' statement disagrees with the literature information supplied from results by the experimental test available in the DAR UK Report (2009) on long-term toxicity to fish (Bottcher M., Wydra V., 2009), which gives an indication of measured data on chronic toxicity to fish available on 1-decanol. The Registrant(s) should provide reliable long-term toxicity study on fish in order to investigate further effects on aquatic organisms from additional data (e.g. NOEC value) which can be used to refine the predicted no effect concentration (PNEC) value and the resulting risk characterization for the aquatic compartment.

Moreover, according to ECHA Guidance R7.b "*among the currently available standardised test methods (OECD 210, 212, 215) the FELS toxicity test (OECD 210) is considered as the most sensitive of the fish tests. It covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation*". Therefore, in view of the OECD 210 test is considered as a most sensitive indicator of toxicity, the evaluating MSCA notes that the Registrant(s) should use the OECD 210 for generating new long term toxicity data on fish.

Therefore, pursuant to Article 46(1) of the REACH Regulation, the Registrant(s) are required to carry out the following study using the substance subject to this decision: Fish, early life stage (FELS) toxicity test (Test method: OECD 210), unless the Registrant(s) can provide an adequate justification for why existing information indicates that this test is not needed.

5. Justification for deviating in use of default values in PNEC derivation for aquatic and terrestrial compartment.

<u>PNEC values for aquatic compartment (freshwater and marine)</u>

Pursuant to Articles (10)b and 14 as well as Annex I, section 3.3.1. of the REACH Regulation the PNECs for each environmental sphere shall be established based on the available information.

To calculate the PNEC-freshwater the Registrant(s) provided an assessment factor (AF) value of [redacted]. According to ECHA Guidance R.10, this value is not correct; this A.F. may be applicable when a large dataset from long-term tests for different taxonomic groups is available and the Species sensitivity distribution, SSD, method is applied.

In this case the choice of 1000 as AF value is justified. In particular, according to ECHA

Guidance R.10 table R.10-4 (b): "*An assessment factor of 100 applies to a single long-term result (e.g. EC10 or NOECs) (fish or Daphnia) if this result was generated for the trophic level showing the lowest L(E)C50 in the short-term tests. If the only available long-term result (e.g. EC10 or NOECs) is from a species (standard or non-standard organism) which does not have the lowest L(E)C50 from the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus the hazard assessment is based on the short-term data with an assessment factor of 1000. However, the resulting PNEC based on short-term data may not be higher than the PNEC based on the long-term result available*".

Moreover, if the Registrant(s) considered the additional data above required on long-term toxicity to fish, it would be necessary to derive adequately the PNEC-freshwater according to ECHA Guidance R.10 table R.10-4.

Therefore, the Registrant(s) are required to provide an adequate justification for deviating in use of default values from recommendations made on ECHA Guidance R.10 in PNEC freshwater derivation; otherwise, the Registrant(s) are required to derive adequately the PNEC value, to refine the related risk characterization for the aquatic compartment and to update the CSR and the IUCLID technical dossier, accordingly.

To calculate the PNEC marine-water the Registrant(s) provided an AF value of [redacted]; according to ECHA Guidance R.10 this value is not correct; this AF is applicable when there are two long-term results (e.g. EC10 or NOEC) from freshwater or saltwater species representing two trophic levels + one long-term result from an additional marine taxonomic group. In this case it is justified the choice of 10000 as AF value. According to ECHA Guidance R.10, table R.10-5 (b): "(...) *If the only available long-term result (e.g. EC10 or NOEC) is from a species which does not have the lowest L(E)C50 in the short-term tests, it cannot be regarded as protective of other more sensitive species using the assessment factors available. Thus, the hazard assessment is based on the short-term data with an assessment factor of 10,000. However, normally the lowest PNEC should prevail*".

Moreover, if the Registrant(s) considered the additional data above required on long-term toxicity to fish, it would be necessary to derive adequately the PNEC-marine-water according to ECHA Guidance R.10 table R.10-5.

In order to address the initial environmental concern posed by the registered substance, the Registrant(s) are requested to give an appropriate justification for deviating in use of default values from recommendations made on ECHA Guidance R.10 in PNEC marine water derivation; otherwise, the Registrant(s) are required to derive adequately the PNEC value, to refine the related risk characterization for the aquatic compartment and to update the CSR and the IUCLID technical dossier, accordingly.

The PNEC values derived for freshwater or marine waters are based on the implicit assumption that environmental exposure is constant.

Referring to PNEC water in case of intermittent releases, in the IUCLID technical dossier, the Registrant(s) provided the following justification for data waiving: "*Intermittent releases are not applicable to the identified uses of the substance.*"

This justification is not acceptable taking into account that for 1-decanol in such cases the environmental exposure could occur on an intermittent basis, as reported for some exposure scenarios, e.g. in case of emissions from batch productions and for agrochemical

use. The PNEC water intermittent for such situations is normally derived by application of an assessment factor of 100 to the lowest L(E)C50 of at least three short term tests from three trophic levels. Therefore, in order to clarify the aquatic risk assessment, from short-term toxicity results available on aquatic species, the Registrant(s) are required to also derive the value of PNEC water in case of intermittent releases or to provide a more appropriate and detailed justification for PNEC water intermittent data waiving and to update the CSR and the IUCLID technical dossier accordingly. To calculate the PNEC sediment-freshwater the Registrant(s) provided an AF value of 1000; according to ECHA Guidance R.10 this AF value is correct. However, in order to clarify the aquatic risk assessment, the Registrant(s) are required to refine the PNEC-sediment-freshwater value, taking into account the specific requests on PNEC-freshwater above indicated.

To calculate the PNEC marine-sediment the Registrant(s) provided an AF value of 10000; according to ECHA Guidance R.10 this AF value is correct. However, in order to clarify the aquatic risk assessment, the Registrant(s) are required to refine the PNEC-marine-sediment value, taking into account the specific requests on PNEC marine-water above indicated.

In their comments on proposals for amendments submitted on 7 January 2014, the Registrant(s) provided further justifications regarding the AF used for PNEC derivation. At this stage, the evaluating MSCA notes the additional arguments, anticipated by the Registrant(s), that will be properly evaluated once the registration dossiers will be updated, as agreed by the Registrant(s) in their comments on the Draft Decision provided on 6 May 2013.

PNEC values for terrestrial compartment

To calculate the PNEC-soil the Registrant(s) provided an AF value of 1000; according to ECHA Guidance R.10 this AF value is correct. In the CSR, the short-term data of 133 mg/kg wwt used by the Registrant(s) to derive the PNEC soil is not correct; in the CSR and in the IUCLID dossier, it is indicated as the lowest short-term data a value of 98 mg/kg dw soil. This latest value should be used to derive the PNEC soil.

Moreover, the Registrant(s) should take into account that according to ECHA Guidance R.10, when only one test result with soil dwelling organisms is available, the risk assessment is performed both on the basis of this result using assessment factors and on the basis of the Equilibrium Partition Method (EPM); from both PECsoil/PNECsoil ratios the highest one is chosen for the risk characterization. Then, the Registrant(s) should adequately derive the PNEC soil using the Equilibrium Partition Method (EPM), taking into account the new value of PNEC-freshwater above required.

Therefore, the Registrant(s) are accordingly requested to give an appropriate justification for deviating in use of default values from recommendations made on ECHA Guidance R.10 in PNEC soil derivation; otherwise, the Registrant(s) are required to refine the PNEC soil value, the related risk characterization for terrestrial compartment and to update the CSR and the IUCLID technical dossier, accordingly.

6. Missing elements for environmental exposure assessment and risk characterization.

a) Request of justification for missing quantities (used amount), use descriptors (SU, PROC, PC, AC, ERC), Operational Conditions (OC) and Risk Management Measures (RMM) specifically for 1-decanol. The Registrant(s) generated each exposure scenarios using a category approach (as described in the CSR), estimating the releases into the environmental compartments and providing assumptions which are common for the

category. However, the Registrant(s) provided the quantitative exposure assessment for emissions to the environment for each member of the C6-C24 alcohols category.

In particular, for 1-decanol, the Registrant(s) provided the quantitative exposure assessment for emissions to the environment in an attached document to the registration dossier (Annex I: Environmental Releases, Exposures and Risk characterization"- C10 Chapter). In view of multiple justification for the use of category approach, the concerned Registrant(s) provide the quantities (used amount), the use descriptors (SU, PROC, PC, AC, ERC), the Operational Conditions (OC) and the Risk Management Measures (RMM) of total C6-C24 alcohols without indicating specific information related to 1-decanol. Instead, in the document "Annex I: Environmental Releases, Exposures and Risk characterization"- C10 Chapter, the Registrant(s) report specific section referred to C10 alcohol (1-decanol) which contains for each scenario summary tables reporting the releases to the environmental compartments, PEC values and related RCR values, all referred to 1-decanol. However, in the section C10- table "Summary of the releases to the environment", the Registrant(s) report different justifications about the provided data such as "estimated release for decan-1-ol" but also "estimated releases for specific chain length" or nothing justification for provided data.

The REACH Regulation requires the exposure estimation and risk characterisation of the single substance in its identified uses performing (in accordance with Annex I point 5.0) exposure assessment through an iterative process including two steps: 1) generation of exposure scenario(s); 2) exposure estimation. In this case, for 1-decanol, the Registrant(s) generated each exposure scenarios using a category approach (as described in the CSR), while the Registrant(s) referred to exposure estimation for each member of the C6-C24 alcohols category.

In particular, OC and RMM driving releases to environment were described in the respective exposure scenario using an only category approach. Consequently, the link of release and exposure estimates (provided for 1-decanol) to the exposure scenarios (provided for the category C6-C24) could not be established and so there is a lack of consistency and traceability between exposure scenarios and exposure estimates. Moreover, regarding the technical fate of substance and losses from process/use to waste, waste water and air, the Registrant(s) sometimes do not report any explanation or report explanation such as "see text" or "ESD for plastic additives" (e.g. ES14), without providing other information.

Taking into account that the exposure scenarios shall be attached to the Safety Data Sheet (in accordance with Article 31 of the REACH Regulation) and constitute an essential element for supporting safe use, the evaluation approach used by the Registrant(s) for exposure assessment is considered not acceptable.

Therefore, the Registrant(s) are required to provide in the CSR specifically for 1-decanol the following information: frequency, duration and amount of use, in accordance with Annex I 5.2.4 of the REACH Regulation. The Registrant(s) are also requested to update the CSR providing more detailed information about the fraction of applied amount lost from process/use. Moreover, the Registrant(s) are required to provide in the CSR specifically for 1-decanol the use descriptors (in particular ERCs) in accordance with Annex I of the REACH Regulation.

The Registrant(s) are requested to update the CSR describing in detail the exposure scenarios for 1-decanol which must be based on OCs/RMMs that reflect clearly the applied good practice for the sector of use related to 1-decanol, according to Annex I, 5.1.1. of the REACH Regulation.

b) Request of justification for missing regional PEC values for other compartment such as marine, soil and air. In the CSR the Registrant(s) report regional background PEC values only for freshwater and freshwater sediment compartment related to 1-decanol. In the CSR, regional PEC values for other compartment such as marine, soil and air are not reported by the Registrant(s) and a justification is not provided. The ECHA Guidance R.16 (R16.3.3) states that *"All regional releases associated with the different identified uses, both industrial and wide disperse sources, are cumulated to estimate the total regional release (kg/day) to surface water, wastewater, air and soil. The regional releases associated with the different identified uses are based on the tonnage at regional level for each use and the same release factors used at local scale".*

In the "Annex I: Environmental Releases, Exposures and Risk characterization" the Registrants indicate local PEC values without reporting the contribution of regional background (regional PEC values) for each compartment. Moreover, there are not clearly indicated the input data used for derivation of local concentration (C_{local}): in the CSR, referring to exposure assessment, the Registrant(s) provided input data related to LCAAs category while in the "Annex I: Environmental Releases, Exposures and Risk characterization" local release data (kg/day) are presented as values derived specifically for 1-decanol.

According to requirements indicated in Annex I, 5.2.4. of the REACH Regulation and in the ECHA Guidance R.16, the Registrant(s) are requested to provide the regional PECs for missing compartments, to indicate specifically for 1-decanol the input data used for derivation of local concentration (C_{local}) or to properly justify their omission and to update the CSR accordingly.

Therefore, taking into account the missing information above requested and according to requirements indicated in Annex I, 5.2. of the REACH Regulation, the Registrant(s) are required to refine the local PECs values for each compartment and to update accordingly the relative quantitative exposure assessment and risk characterization.

c) Request of justification for using several ERCs for one life-cycle stage. In the CSR, in some exposure scenarios (ES5a, 5b, 5c, 6a, 6b, 9b, 13a, 13b) more than one ERC are referred to different life-cycle stages (industrial use, wide dispersive use). As general rule, the ECHA Guidance on information requirements and chemical safety assessment, Part D, and R16 Section R.16.3.1.2 reports that releases to the environment are instead assessed at site level or at level of life-cycle stages for which exposure scenarios need to be developed. The same ECHA Guidance mentions that (R.16.2.1.1) *"Releases from uses in industrial settings are assessed as independent point source releases; it means that each identified use of the substance is assumed to occur at a different site. However, in some cases, it is needed to combine those assessments in the "combined risk" section of the CSR, e.g. when manufacture and formulation take place at the same site".*

The Registrant(s), according to Annex I, 5.0. of the REACH Regulation, are requested to generate separate exposure scenarios for each life-cycle stage described in the exposure scenario or to provide a proper justification for using several ERCs for one life-cycle stage, in which case the combined risks from the same site should also be addressed.

d) Request of reporting all the identified uses of 1-decanol for ES6. Referring to ES6a "Metalworking fluids/rolling oils (industrial)" and ES6b "Metalworking fluids/rolling oils (professional)", in the "Annex I: Environmental Releases, Exposures and Risk

characterization" - C10 Chapter the Registrant(s) reported: "*Scenario not relevant for EU use pattern of decan-1-ol*". However, in the CSR the Registrant(s) reported the category approach and so they provide the exposure scenarios for all LCAAs.

Moreover, in the IUCLID file, which should be referred to 1-decanol, the Registrant(s) reported the exposure scenario "Metalworking fluids/rolling oils (industrial)" and "Metalworking fluids/rolling oils (professional)". The Registrant(s) are requested to report exactly all the identified uses of 1-decanol and to update the CSR and the IUCLID dossier, according to Annex I 0.3 of the REACH Regulation.

e) Request of justification for the lack input data used for the calculation of local PEC marine water value. Referring to the environmental surroundings characteristics for ES8, in the CSR the Registrant(s) state that "*No specific information available. The technical guidance default scenario for municipal WWTP and receiving water are used in the model. It is understood that receiving waters would typically be in freshwater locations only and marine receiving environment is not characterized in this scenario*".

Moreover, in the "Annex I: Environmental Releases, Exposures and Risk characterization"- C10 Chapter, the Registrant(s) provide a local PEC marine water value without justifying how this data is obtained, also in view of the lack of the value of regional PEC marine water. Therefore, according to the requirements of Annex I of the REACH Regulation, the Registrant(s) are requested to provide, for ES8, the input data used for the calculation of local PEC marine water value or to give appropriate justification for the lack of data and to update the CSR, accordingly.

7. Missing information on soil compartment

Request of information on derivation of the values of local release (Kg/d) and local PEC for the soil compartment. In the "Annex I: Environmental Releases, Exposures and Risk characterization"- C10 Chapter the Registrant(s) for all exposure scenarios, except ES14 (Agrochemical use), do not report any direct release to soil from point sources.

Moreover, in the "Annex I: Environmental Releases, Exposures and Risk characterization"- C10 Chapter, the local PEC soil value is reported without any information about the related regional background value. Referring to some exposure scenarios (e.g. ES4, ES8, ES9a, ES9b and ES9c, ES10, ES14), the Registrant(s) in the CSR provide also the assumption that the recovery of sludge for agriculture or horticulture is applied (in the ES14 this assumption is referred only for the consumer use and comments are not reported for the professional use). The ECHA Guidance R.16 states that the calculation of local PEC for the soil compartment is given for the following exposure routes: application of sewage sludge in agriculture and dry and wet deposition from the atmosphere.

Therefore, the Registrant(s) should clearly justify how the values of local release (Kg/d) and local PEC soil are derived for the soil compartment, also taking into account the above mentioned assumptions. Moreover, in view of the representative use of 1-decanol as plant growth regulator, the Registrant(s) are also required to refine the environmental exposure assessment to soil compartment.

8. Missing information on waste and related to risks possibly arising from the waste life-cycle stage.

Request of more specific waste related information. Taking into account that the exposure scenario assessment is referred to a category approach as mentioned above, the Registrant(s) do not provide total amount for 1-decanol and so it is not possible identify the relative fraction of the registration volume of the substance becoming waste that is treated by the waste treatment process, for which the assessment is carried out.

Moreover, for some exposure scenarios (e.g. ES4 and ES8) in the CSR, e.g. "Waste related measures", the Registrant(s) report that "*no significant local exposures or significant contribution to environmental background concentrations are expected*" without providing any quantification.

In view of the relevance of waste stage within the exposure assessment, detailed and specific information on types, fraction amount of substance becoming waste and composition of waste occurring on manufacture and use of the substance are needed in order to support the derivation of exposure estimate and control of risk along any use and life cycle stage of the registered substance, identified with an environmental concern for widespread use, high aggregated tonnage and potential to contaminate surface and groundwater.

According to Annex I, 5.2. of the REACH Regulation, the Registrant(s) should provide in the CSR more specific waste related information including relative fraction of used amounts of substance as waste.

IV. Adequate identification of the composition of the tested material

The substance identity information submitted in the registration dossiers has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation. In relation to the required tests, the sample of substance used for the new studies shall have a composition that is within the specifications of the substance composition that are given by all Registrants. It is the responsibility of all the Registrants to agree on the tested materials to be subjected to the tests subject to this decision and to document the necessary information on composition of the test material. The substance identity information of the registered substance and of the sample tested must enable the evaluating MSCA and ECHA to confirm the relevance of the testing for the substance subject to substance evaluation. Finally, the studies must be shared by the Registrant(s).

V. Avoidance of unnecessary testing by data- and cost- sharing

Avoidance of unnecessary testing and the duplication of tests is a general aim of the REACH Regulation (Article 25). The legal text foresees the sharing of information between Registrants. Since several Registrants of the same substance are required to provide the same information, they are obliged to make every effort to reach an agreement for every endpoint as to who is to carry out the test on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation.

If ECHA is not informed of such agreement within 90 days, it shall designate one of the Registrants to perform the tests on behalf of all of them. If a Registrant performs a test on behalf of other Registrant(s), they shall all share the cost of that study equally and the

Registrant performing the test shall provide each of the others concerned with copy/copies of the full study report(s).

This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/SEDraftDecisionComments.aspx

Further advice can be found at http://echa.europa.eu/datasharing_en.asp.

VI. General requirements for the generation of information and Good Laboratory Practice

ECHA always reminds Registrant(s) of the requirements of Article 13(4) of the REACH Regulation that ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice (GLP). National authorities monitoring GLP maintain lists of test facilities indicating the relevant areas of expertise of each facility.

According to Article 13(3) of the REACH Regulation, tests that are required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the European Chemicals Agency as being appropriate. Thus, the Registrant(s) shall refer to Commission Regulation (EC) No 440/2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 as adapted to technical progress or to other international test methods recognised as being appropriate and use the applicable test methods to generate the information on the endpoints indicated above.

VII. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Articles 52 and 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 the ECHA's internet page at http://echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Jukka Malm
Deputy Executive Director

Annex: List of registration numbers – This annex is confidential and not included in the public version of this decision