EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114289108-42-01/F Helsinki, 27 February 2015

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

For dimethylamine, CAS No 124-40-3 (EC No 204-697-4), 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 dimethylamine, CAS No 124-40-3 (EC No 204-697-4), submitted by [redacted] (Registrant).

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates submitted after 12 June 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

This 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 23 August 2013.

On 22 November 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 20 December 2013 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 12 June 2014 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendmends of the draft decision within 30 days of the receipt of the notification.

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

On 18 July 2014 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.

The present decision relates solely to a compliance check requesting information in form of for Predicted no effects level (PNEC) for marine sediment (Annex I, sections 3.0.4. and 3.3.), Clarification of whether or not further life-cycle steps (uses) resulting from the use of the registered substance in manufacturing of another substance are relevant and to be identified as uses, as specified in section III.B.2 below (Annex VI, 3.5. and Annex I, 5.0.), Revised environmental exposure assessment and risk characterisation as specified in section III.B.3 below (Annex I, sections 5. and 6. of the REACH Regulation) and Revised exposure assessment for all uses (except intermediate use which is under strictly controlled conditions) (Annex I, 5.2.4. and 6.3. of the REACH Regulation;). The other information requirement for a Two-generation reproductive toxicity study (Annex X, 8.7.3.) will be addressed in a separate decision although all information requirements were initially addressed together in the same draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014 the Registrant did not provide any comments on the proposals for amendment. However, the Registrant provided comments on the draft decision. 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 16-18 September 2014, a unanimous agreement of the Member State Committee on the draft decision relating to the request for PNEC for marine sediment, clarification of whether or not further life-cycle steps (uses) resulting from the use of the registered substance in manufacturing of another substance are relevant and to be identified as uses, revised environmental exposure assessment and risk characterisation, and revised exposure assessment for all uses (except intermediate use which is under strictly controlled conditions) was reached on 16 September 2014.

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)(e), 13 and Annex X of the REACH Regulation the Registrant shall submit the following information using the indicated test method and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.; test method: EU B.31./OECD 414) in rabbits, inhalation route;

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 in this decision, or to fulfil otherwise the information requirement 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. Predicted no effects level (PNEC) for marine sediment (Annex I, sections 3.0.4. and 3.3.);

2. Clarification of whether or not further life-cycle steps (uses) resulting from the use of the registered substance in manufacturing of another substance are relevant and to be identified as uses, as specified in section III.B.2 below (Annex VI, 3.5. and Annex I, 5.0);

3. Revised environmental exposure assessment and risk characterisation as specified in section III.B.3 below (Annex I, sections 5. and 6. of the REACH Regulation);

4. Revised exposure assessment for all uses (except intermediate use which is under strictly controlled conditions) (Annex I, 5.2.4. and 6.3. of the REACH Regulation;), to provide the reassurance that the long-term inhalation DNEL is not exceeeded at downstream user sites.

C. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **7 March 2016**.

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)(e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. Pre-natal developmental toxicity study (Annex X, 8.7.2.)

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

According to Annex XI section 1.1.2. of the REACH Regulation, data on human health and environmental experiments not carried out according to GLP or test methods referred to in Article 13(3) shall be considered equivalent to data generated by test methods corresponding to test methods referred to in Article 13(3) if the following conditions are met:

(1) adequacy for the purpose of classification and labelling and/or risk assessment;
(2) adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

There is information available on this endpoint only for a pre-natal developmental toxicity study in a first species for the registered substance in the technical dossier. However, there is inadequate information available for a pre-natal developmental toxicity study in a second species. Consequently there is an information gap for Annex X, Section 8.7.2. and it is necessary to provide information for this endpoint.

More specically, ECHA notes that the technical dossier contains a second pre-natal developmental toxicity study in mice by the intraperitoneal (i.p.) route, which is not the recommended route of administration according to the OECD TG 414 and its use in the present case has not been adequately justified. In additon the study used an insufficient numbers of male and female animals and maternal mortality was greater that 10% in the dose group 1.0 mmol/kg bw, which in accordance with the OECD test method could be considered to invalidate the study.

ECHA concludes that the pre-natal developmental toxicity study in mice does not meet conditions 1 and 2 of Annex XI section 1.1.2. as regards fulfilling the standard information requirement of a pre-natal developmental toxicity study.

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 test in the first species was carried out by testing a rodent species and ECHA therefore considers that the test in a second species should be carried out in a non-rodent species. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species and the test substance is usually administered orally. However, since the substance is a gas, ECHA considers that testing with the rabbit as a second species via the inhalation route is most appropriate.

The Registrant in his comments submitted according to Article 50(1) of the REACH Regulation stated that the data gap may be filled by weight-of –evidence (WoE) approach, using the afore-mentioned i.p. study, further supported by a read-across approach to data on C1 (methyl) amines (mono, di, tri) (MMA, DMA, TMA). "Vertical" read-across is proposed between the three substances. The Registrant gives the following justification for the read across: "*Although they do not form a category according to the number of alkyl rests on nitrogen atom (= primary, secondary or tertiary), they are similar in their physico-chemical properties. They are low molecular weight aliphatic amines which alkyl group is methyl. Monomethylamine (MMA, CAS 74-89-5) and DMA are gases, trimethylamine (TMA, CAS 75-50-3) is gaseous liquid; they are water soluble substances with similar logPow values. They are all substrates of Semicarbazide-Sensitive Amine Oxidase (SSAO). DMA and TMA are also substrates of monoaminooxidase (MAO), while MMA is metabolised only by SSAO. DMA is a degradation product of TMA or methylation product of MMA (reported in numerous publications).*" The experimental studies referred to by the Registrant for this read-across approach are OECD 422 studies for MMA and TMA respectively.

ECHA considers that the Registrant does not provide a read-across justification substantiated with experimental data demonstrating that the conditions of Annex XI section 1.5. were met. More specifically the Registrant has not demonstrated structural similarity, nor provided a comparison of all the relevant physico-chemical properties or toxicological data of the proposed analogue substances and the registered substance. Furthermore the studies on proposed analogue substances are according to OECD 422 guideline which does not provide the information required by Annex X, Section 8.7.2., because it does not cover key parameters of a pre-natal development study such as examination of foetuses for skeletal and visceral alterations. These studies are not included in the registration dossier as robust study summaries allowing an assessment of their findings and reliability. It is not clear whether the studies were conducted in a species other than the rat, which is the species of the first PNDT study.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rabbits by the inhalation route.

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 which shall document the chemical safety assessment conducted in accordance with Article 14(2) to (7) and with Annex I of the REACH Regulation.

Annex I sets out the general provisions for assessing substances and preparing chemical safety reports (CSR). ECHA has observed following omissions and inconsistencies in the CSR:

1. Predicted no effects concentration (PNEC) for marine sediment

Pursuant to Annex I, section 3.3.1. and 3.3.2. of the REACH Regulation, based on the available information, the PNEC for each enviormental sphere shall be established. If it is not possible to derive the PNEC, then this should be clearly stated and fully justified.

The PNEC for the marine sediment is not established in the dossier. The justification of the adaptation given by the Registrant is that it is not relevant due to the substance being subject to a continuous release process.

ECHA notes that the exposure of marine sediments is likely, as results of exposure estimation provided by the Registrant in the CSR indicate the exposure of marine sediments, i.e. the predicted environmental concentrations (PECs) are not equal to zero. Furthermore, ECHA observes that the PNEC for freshwater sediments is derived and risk characterisation for freshwater sediments is performed. This also indicates that exposure of sediments cannot be regarded as unlikely. Therefore, ECHA concludes that adaptation provided by the Registrant for not deriving the PNEC marine sediment is not acceptable and this PNEC shall be derived, and used in the CSA.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that the PNEC for the marine sediment will be established in the dossier. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant shall establish the PNEC for marine sediment. The CSR shall be amended accordingly.

2. Clarification of life-cycle of the substance

Pursuant to Article 10(a)(iii) of the REACH Regulation the technical dossier shall contain information on the manufacture and use(s) of the substance representing all the registrant's identified uses, as specified in Annex VI, Section 3 of the REACH Regulation. Pursuant to Annex I Section 5.0., exposure assessment, which is a part of the chemical safety assessment (CSA), shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses.

ECHA observes that in Section 3.5 of the technical IUCLID dossier, which relates to the industrial use resulting in manufacture of another substance, the Registrant has identified that one of the technical functions of the substance is as a solvent. It should be noted that there are no identified uses in the section 3.5 of the technical IUCLID dossier by professional workers or consumers. ECHA notes that based on information provided in the technical registration dossier and in the CSR, uncertainty about a full life-cycle of the substance remains. ECHA notes that it can be expected that the substance used as a solvent might remain as a part of new manufactured products, meaning that further life-cycle steps of the substance may exist.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that more detailed information regarding substance residues in products and possible recycle/re-use steps of the substance will be gathered from customers an downstream users and depending on the output of these investigations, these will be established in the dossier. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide clarification whether or not further life-cycle steps (uses) resulting from the use of the substance in manufacturing of another substance are relevant and to be identified as uses. If further life-cycle steps are not considered relevant and not to be identifed as uses, a justification for such a conclusion shall be given. If new life-cycle steps (uses) are identified this should be accordingly taken into account in the CSA. The CSR and, if necessary section 3.5 of the technical IUCLID dossier, shall be amended accordingly.

3. Revised environmental exposure assessment and risk characterisation

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) or is assessed to be a PBT or vPvB, the chemical safety assessment (CSA) shall include an exposure assessment and risk characterisation. The exposure assessment shall be carried out according to section of 5 of Annex I and shall include exposure scenarios and exposure estimations for the registered substance. The exposure assessment 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. Annex I, section 6 of the REACH Regulation requires the Registrant to characterise the risk for each exposure scenario.

ECHA notes that according to the information provided in the technical registration dossier and in the CSR, the following information has not been provided or is not satisfactory:

(i) Combined risk assessment for the environment

Pursuant to the Annex I, section 6.2. of the REACH Regulation the risk characterisation shall consider the overall environmental risk caused by the substance by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

Chapter R.16: Environmental Exposure Estimation of the Guidance on information requirements and the chemical safety assessment (ECHA, version: 2.1, October 2012) specifies that since all releases to water from each identified wide disperse use will by default enter into the same sewage system, combined risk should be considered. It further notes that 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.

ECHA notes that a combined risk assessment for the environment has not been provided in the CSR in order to cover any exposures that may be related to the identified hazards. No professional or consumer uses have been identified in Section 3.5 of the technical IUCLID dossier. However, manufacturing, formulation and three uses at industrial sites are identified in this section of the technical IUCLID dossier. ECHA notes that there is no information provided in the CSR relating to whether or not any of the identified uses can take place on the same site. If this is the case, a combined risk assessment for the environment shall be performed and summarised in the CSR for the uses taking place at the same industrial site.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that a combined risk assessment will be performed and included in the dossier. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation, the Registrant is requested to provide a combined risk assessment for the environment in the CSR. In the alternative, a justification relating to why a combined risk assessment for the environment is not relevant shall be provided in the CSR. The CSR shall be amended accordingly.

(ii) Quantitative risk characterisation for marine sediment

Pursuant to Annex I, Section 6.2. of the REACH Regulation the risk characterisation shall consider the overall environmental spheres for which exposure is known or reasonably foreseeable under the assumption that the risk management measures (RMMs) described in the exposure scenarios (ES) have been implemented. The risk characterisation consists of a comparison of the predicted environmental concentrations in each environmental sphere with the related PNECs.

ECHA notes that a quantitative risk characterisation for marine sediment has not been provided in the CSR. As explained in Section III.1. above, results of exposure estimation provided by the Registrant in the CSR indicate the exposure of marine sediments, i.e. the PECs are not equal to zero. The Registrant is requested to derive the PNEC for marine sediments (see section II.B.1. above). Thus, ECHA concludes that, on the basis of the available PECs in marine sediments and the PNEC for marine sediments, quantitative risk characterisation for marine sediments should be performed and recorded in the CSR.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that a risk assessment for marine sediement will be implemented. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide a quantitative risk characterisation for marine sediments for each exposure scenario. The CSR shall be amended accordingly.

(iii) Proper risk characterisation ratios (RCRs) for soil and sediment

Pursuant to the Annex I, section 6.3. of the REACH Regulation risk characterisation includes a comparison of the predicted environmental concentrations in each environmental sphere with the predicted no-effect concentrations.

ECHA notes that the Registrant in his CSR has reported PECs in soil/sediment as a mass of the substance in a wet weight of soil/sediment, while PNECs are reporteded as a mass of the substance in a dry weight of soil/sediment. ECHA notes that for calculation of RCRs, the PEC and the PNEC values should use the same units.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that RCRs for the compartments soil and sediment will be updated by taking an appropriate modification factor into consideration to ensure the equality of the units for PEC and PNEC. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide revised RCRs for soil/sediment which would be calculated using the PEC and the PNEC values with the same units. The CSR shall be amended accordingly.

(iv) Justification of release factors

Pursuant to the Annex I, section 5.2.1. of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions described in the exposure scenario have been implemented. These RMMs and operational conditions should be included in the exposure scenarios provided in a CSR.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (ECHA, version: 2.1, October 2012) the exposure scenario should contain information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Furthermore, the Guidance indicates that sector specific environmental release categories (spERCs) developed by industrial sector organisations can be used in place of the conservative default environmental release categories (ERCs) of ECHA guidance. As far as possible, spERCs have to be linked to the RMM and the operational conditions driving the release estimation.

In the present case, in the CSR the Registrant has provided five exposure scenarios: 1) Production of chemicals (manufacture and distribution); 2) Use as intermediate; 3) Industrial use resulting in manufacture of another substance; 4) Use as processing aid (catalyst) in polymerization reactions; and 5) Use as monomer in Epoxy.

ECHA notes that, in order to cover any exposures that may be related to the identified hazards, exposure estimation as stated by the Registrant in the CSR is based on release factors given by site specific RMMs for exposure scenario 1, on release factors given by specific RMMs for exposure scenario 2 and on sector specific environmental release category (spERC) release factors for exposure scenarios 3, 4 and 5.

ECHA considers that no clear and detailed justification (e.g. based on RMMs and/or operational conditions and/or substance properties) of other than default ERC release factors used in exposure estimation has been provided in the CSR. For example, technics (for air emissions control) and efficiency of RMMs (technics) for air and water emissions control are not specified.

Furthermore, ECHA notes that according to the information provided in the CSR, the Registrant has used for the environmental exposure estimation for exposure scenario 5 release factors from the European Solvent Industry Group and their User's trade associations spERC 4.20.v1. The Registrant indicates in the CSR that "for further information please refer to the appropriate spERC factsheet". However, according to the developer of spERC, the referenced spERC 4.20.v1 is encoded under generic exposure scenario "Polymer Production". ECHA notes that there is no factsheet named "Polymer Production" provided on the spERC developer website. Thus, it is not clear which factsheet is relevant for this spERC 4.20.v1, i.e. ES 5.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that in order to justify the relevant release factors, specific and detailed information on RMMs and/or OCs will be provided. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide in all exposure scenarios, where non-default ERC release factors are used for exposure estimation, a clear and detailed justification (e.g. based on RMMs and/or operational conditions and/or substance properties) for the non-default ERC release factors used in the exposure estimation. The CSR shall be amended accordingly.

(v) Applicability of the the spERC

Pursuant to the Annex I, section 5.2.1. of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions described in the exposure scenario have been implemented. These RMMs and operational conditions should be included in the exposure scenario provided in a CSR.

ECHA notes that according to the information provided in the CSR, the Registrant has used for the environmental exposure estimation for exposure scenario 4 (Use as processing aid (catalyst) in polymerization reactions) release factors from the spERC named as "Distribution of substance – Industrial". The scope of the SpERC given in the factsheet available at the spERC developer website is following "Loading (including marine vessel/barge, rail/road car and IBC loading) and repacking (including drums and small packs) of substance, including its sampling, storage, unloading and associated laboratory activities". ECHA concludes that it is not clear why this spERC is relevant for the processing of the registered substance in polymerisation reactions.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that the chemical safety report will be amended accordingly. ECHA acknowledges the Registrant's comments, however the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide a justification in the CSR relating to how the spERC for "Distribution of substance – Industrial" is applicable for the use as processing aid (catalyst) in polymerisation reactions. Alternatively, exposure estimation for the use of the substance as a processing aid (catalyst) in polymerization reactions should be made and these should be based on relevant ERC default release factors, which could be refined on the basis of RMMs and/or operational conditions and/or substance properties. The CSR shall be amended accordingly.

(vi) Clarification of tonnages used for local environmental exposure assessment

Pursuant to Annex I, section 5.2.1. of the REACH Regulation, the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels.

ECHA notes that according to the information provided in the CSR, the Registrant provided exposure scenarios for the different identified uses of the substance. The tables describing the operational conditions contain information regarding the expected number of sites within Europe where the single use takes place and also the total tonnage of the substance for the use within the EU. This information is also mirrored in the technical dossier. ECHA notes that it remains unclear in the Exposure Scenarios contained in the CSR what are the annual tonnages which were used for the environmental exposure assessment at the local level. As a result the calculated PECs cannot be retraced, as it is not clear what is the input parameter for the tonnage used at each local level respectively and how it was derived (geometric mean, largest customer known to the registrant, median, use of EU-total tonnage at single site). For example in ES 2 ("Use as intermediate") the Registrant assumes a tonnage of nearly [redacted] tons per year for this use and he states that use will take place at [redacted] sites within the EU.

Therefore, pursuant to Article 41(1) and 41(3) of the REACH Regulation the Registrant is requested to provide in all exposure scenarios, the tonnage per site used for environmental exposure estimation. The CSR shall be amended accordingly.

4. Revised exposure assessment and risk characterisation

Article 14(6) as well as Annex I, 0.1., 5.2.4. and 6.2.-6.4. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in the CSR. The exposure shall be estimated and risks shall be characterised in the CSR under the assumption that relevant risk management measures have been implemented. Annex I 5.2.5 states that appropriate models can be used for the estimation of exposure levels.

The ECHA Guidance on information requirements and chemical safety assessment Chapter R.14: Occupational Exposure Estimation (ECHA, version: 2.0, May 2010) advises that estimation of exposure can be made from either (a) actual exposure measurements or (b) exposure estimation by analogous situations or exposure models.

In the present case, ECHA notes that according to the information provided in the technical registration dossier and in the CSR, the registered substance is a vapour at normal temperature and pressure. The Registrant has used the ECETOC TRA model for estimating exposure, however this model should not be used for gases, as stated in ECETOC's own guidance on domain of reliable applicability: "The TRA tool does not predict exposure to gases". ECHA considers that both inhalation and dermal exposure estimates may be unreliable. There are currently no modelling techniques available for determining occupational inhalation exposure to gases. Therefore, in this case, the requirement to provide an assessment of exposure is most likely to be met through presentation of actual workplace measurements which could demonstrate no/minimal/limited exposure in accordance with the RMM and strictly controlled conditions mentioned within the CSR for the substance, as described in the above Guidance. Dermal exposure is most likely to be over-estimated in this case and, other than provision of advice on appropriate risk management measures need not be developed further.

Accordingly, ECHA concludes that the Registrant has submitted RCRs for this substance that are unreliable because the modelling is outside the domain of the applicability of the model used. The model used is not appropriate and therefore resulting estimates are not appropriate for comparison with the DNEL.

The Registrant, in his comments submitted according to Article 50(1) of the REACH Regulation, stated that exposure estimates will be revised with actual exposure measurements and/or exposure estimation by analogous situations or exposure models. ECHA acknowledges the Registrant's comments, and particularly the Registrant's suggestion of using actual exposure measurements of analogous processes as part of the revised exposure estimations. However the Registrant's dossier was not updated, so the requirement remains in the decision.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide a revised CSR with appropriate exposure estimations for identified uses (except intermediate use which is under strictly controlled conditions). A revised risk characterisation is required to demonstrate that the long-term inhalation DNEL is unlikely to be exceeded at downstream user sites and to demonstrate safe use. The CSR shall be amended accordingly.

C. Deadline for submitting the required information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested other studies. As these studies are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 12 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted by other joint registrants for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation

In relation to the information required by the present decision, the sample of substance used for the new studies 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 studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies 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 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/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

[redacted]

Leena Ylä-Mononen
Director of Evaluation