EUROPEAN CHEMICALS AGENCY

~~HIGHLY RESTRICTED~~

Decision number: CCH-D-0000004884-64-04/F Helsinki, 26 August 2014

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

For ethylenediamine, ethoxylated and propoxylated, CAS No 26316-40-5 (EC No 500-047-1), 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 ethylenediamine, ethoxylated and propoxylated, CAS No 26316-40-5 (EC No 500-047-1), 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 6 March 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 19 July 2013.

On 8 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. That draft decision was based on submission number [redacted].

On 9 December 2013 ECHA received comments from the Registrant agreeing to ECHA's draft decision. The Registrant acknowledged the information gaps identified by ECHA for sub-chronic toxicity study (90-day), pre-natal developmental toxicity study and two-generation reproductive toxicity study and proposed a tiered approach for providing the required information. Regarding the required information related to the chemical safety assessment and the chemical safety report, the Registrant agreed to update the chemical safety report accordingly.

On 9 January 2014 the Registrant updated his registration dossier with the submission number [redacted].

The ECHA Secretariat considered the Registrant's comments and update.
On basis of this information, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 6 March 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 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 10 April 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 did not amend the draft decision.

The present decision relates solely to a compliance check examination for sub-chronic toxicity study (90-day) (Annex IX, 8.6.2.), a pre-natal developmental toxicity study (Annex X, 8.7.2), revised DNELs for workers and for the general population (Annex I, 1.4.1.), revised environmental exposure assessment for all exposure scenarios, scenario 1 and scenarios 2 to 11 (Annex I, sections 5 and 6). The other compliance check requirement consisting of a two-generation reproductive toxicity study is addressed in a separate decision although all endpoints were initially addressed together in the same draft decision.

On 22 April 2014 ECHA referred the draft decision to the Member State Committee.

Due to technical issues related to the Registrant's access to the PfAs received that were outside of his control, the Registrant was granted an extended deadline of 26 May 2014 in order to provide comments in accordance with Article 51(5).

On 26 May 2014, 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 10-13 June 2014, a unanimous agreement of the Member State Committee on the draft decision as modified at the meeting was reached on 12 June 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 Annexes VII, IX and X 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. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.; test method: EU B.26./OECD 408) in rats;

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral 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(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)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:

1. Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1.), as specified under section III.B.1. below;
2. Revised exposure assessment and risk characterisation for workers via dermal route or a justification why the efficiency values used for gloves are considered appropriate (Art. 41.1(c) of the REACH Regulation and Annex I, Section 5.2.4 and 5.2.5.) , as specified under section III.B.2. below;
3. Revised environmental exposure assessment and risk characterisation for all exposure scenarios (Annex I, sections 5 and 6), as specified under section III.B.3. below;
4. Revised environmental exposure assessment and risk characterisation for exposure scenario 1 (Annex I, sections 5 and 6), as specified under section III.B.4. below;
5. Revised environmental exposure assessment and risk characterisation for exposure scenarios 2 to 11 (Annex I, sections 5 and 6), as specified under section III.B.5. below.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration dossier containing the information required by this decision to ECHA by **2 September 2016**. 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)(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 IX and X of the REACH Regulation.

1. Sub-chronic toxicity study (90-day), oral route (Annex IX, 8.6.2.)

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. 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.

In the technical dossier the Registrant has provided a study record for a "repeated dose 28-day oral toxicity study" (test method: OECD 407). However, this study does not provide the information required by Annex IX, Section 8.6.2., because exposure duration is less than 90 days and the number of animals per dose group is significantly lower. Therefore, the sensitivity of a 28-day study is much lower than that of a 90-day study.

In addition, the Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is: "*In accordance with section 1 of REACH Annex XI, a sub-chronic repeated dose toxicity study is not required. In a short-term repeated dose toxicity study with ethylenediamine, ethoxylated and propoxylated no adverse effects were seen. A qualitative and quantitative evaluation of the toxicological properties of the substance, its core substance and repeating units indicates that while a study with longer exposure duration might produce information to refine the dose response relationship thereby enabling a more robust estimation of DNELs it would not generally change the hazard characterization. In view of the limited additional knowledge that data from a longer term exposure study would provide to improve the current risk and hazard characterization of the substance and the need to consider animal welfare, Therefore there is not trigger for a sub-chronic repeated dose toxicity study has no priority*".

ECHA notes that the Registrant has not specified which of the adaptation possibilities under Annex XI, section 1 he is referring to. In any case, the Registrant has not justified or demonstrated with data or information that the conditions of any of those possibilities are fulfilled.

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.

In light of the physical and chemical properties of the substance (liquid with low vapour pressure, classified as irritating to the eye and sensitising to the skin) and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is most appropriate.

According to the test method EU B.26/OECD 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD 408) in rats.

In his comments, the Registrant indicated his intention to perform the test requested. Furthermore, ECHA notes that the Registrant intends to examine extra parameters in addition to default recommendations of the test guideline. ECHA would like to remind the Registrant that these extra parameters would not be accepted as a valid adaptation to the requirements of Annex X, 8.7.3. (two-generation reproductive toxicity study) because a repeated dose toxicity study does not cover key parameters required for a two-generation reproduction toxicity study like 10 week pre-mating period, not less than 20 pregnant females per group, post-natal evaluation of the F1 generation as well as breeding and evaluation of the F2 generation.

2. Pre-natal developmental toxicity study (Annex IX, 8.7.2.)

A "pre-natal developmental toxicity study" for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. 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 not provided any study record of a pre-natal developmental toxicity study in the dossier that would meet the information requirement of Annex IX, Section 8.7.2. Instead, the Registrant has sought to adapt this information requirement. The justification of the adaptation given by the Registrant is: "*Ethylenediamine, ethoxylated and propoxylated is not classifiable as hazardous in respect to its reproductive toxicity. There is sufficient information from a qualitative and quantitative understanding of the toxicological properties of the core substance, the repeating unit, and screening studies on the most bioavailable members of the category, such that testing for developmental toxicity is not necessary. In view of this, no further testing is proposed*".

Based on the above, it appears that the Registrant considers that information concerning other substances than the registered substance can be interpreted to meet the Annex IX, 8.7.2. information requirement. Thus, the justification of the adaptation given by the Registrant most closely relates to the adaptation possibility of Annex XI, 1.5. relating to grouping of substances and read-across approach. However, the Registrant has not provided a read-across justification assessing the structural similarity and a systematic comparison of toxicological properties that would allow predicting properties from analogue substances to the registered substance subject to the present decision. The Registrant has only provided an assessment of the toxicokinetic data of different substances grouped by the Registrant. In addition, the registration dossier does not contain any robust study summary for this endpoint. Without such information ECHA is not in a position to assess whether for the endpoint in questions the data on another than the registered substance subject to the present decision can be used in a prediction, i.e. whether the endpoint requirement can be considered to be met.

More information about how to prepare a grouping of substances and read-across approach under REACH can be found in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals and in the Practical guide 6: How to report read-across and categories.

Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

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.

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

In his comments, the Registrant indicated his intention to perform the test requested.

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: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

Notes for consideration by the Registrant:

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, 8.7.2.

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.

1. Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks or a full justification for not using the recommended assessment factors in DNEL derivation (Annex I, 1.4.1.)

Annex I, 1.4.1. of the REACH Regulation requires that the following factors shall, among others, be taken into account when deriving DNELs:

a) the uncertainty arising, among other factors, from the variability in the experimental information and from intra- and inter-species variation;
b) the nature and severity of the effect;

c) the sensitivity of the human (sub-)population to which the quantitative and/or qualitative information on exposure applies;
d) and that the DNELs reflect the likely route(s), duration and frequency of exposure.

The ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8 provides further details and specifically provides default factors which should be applied to derive DNELs in the absence of substance specific information.

The assessment factors (AF) applied by the Registrant and the default assessment factors recommended in the ECHA Guidance[1] are given in detail in Annex I attached to this decision.

ECHA observes that the Registrant has not followed recommendations of ECHA's Guidance R.8 and has not provided a full justification for the derivation of DNELs in line with Annex I, 1.4.1. Instead, the Registrant has applied less protective assessment factors than those recommended by the ECHA guidance for the intraspecies extrapolation and has not applied assessment factors to cover uncertainties due to remaining interspecies differences (i.e. not related to allometric scaling).

As explained above, the information provided on DNEL for the registered substance in the chemical safety report does not meet the general provisions for preparing a chemical safety report as described in Annex I, 1.4.1. because the assessment factors used are not in accordance with ECHA *Guidance on information requirements and chemical safety assessment* Volume 8, Chapter R.8. or are not fully justified. Consequently it is necessary to revise the DNELs or to provide a full justification.

The Registrant is given two options: The Registrant shall revise the DNELs for workers and for the general population by applying the assessment factors recommended by ECHA that are appropriate in this case. Subsequently, the Registrant shall re-assess related risks.

In the alternative, the Registrant shall, in accordance with Annex I, 1.4.1., provide a full justification for the DNELs derived for workers and for the general population provided in the chemical safety report by specifying how the factors a) to d) under Annex I, 1.4.1., also reported above, have been taken into account.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report either of the following information: Revised DNELs for workers and for the general population using the assessment factors recommended by ECHA and re-assessment of related risks *or* a full justification for not using the recommended assessment factors in DNEL derivation.

In his comments, the Registrant indicated his intention to revise the DNEL derivation once the results from the tests on vertebrate animals mentioned above are available, taking the respective results into account.

Notes for consideration by the Registrant

The results of the studies requested under section II.A. shall be taken into account when revising the DNELs.

[1] Link to ECHA guidance document R.8 is: http://echa.europa.eu/documents/10162/17224/information_requirements_r8_en.pdf

2. Revised exposure assessment and risk characterisation for workers via dermal route or a justification why the efficiency values used for gloves are considered appropriate (Art. 41.1(c) of the REACH Regulation and Annex I, Section 5.2.4 and 5.2.5.)

Pursuant to Article 41.1(c) of the REACH Regulation ECHA may verify that any required Chemical Safety Assessment and Chemical Safety Report comply with the requirements of Annex I and that the proposed risk management measures are adequate.

A chemical exposure assessment performed by a Registrant shall include an exposure assessment according to section 5 of Annex I of the REACH Regulation. Annex I, section 5.2.4 of the REACH Regulation, requires the Registrant to perform an estimation of the exposure levels for all human populations and each relevant route of exposure shall be addressed. Further, the estimation of exposure shall take account of implemented or recommended risk management, including the degree of containment. In addition, Annex I, section 5.2.5 of the REACH Regulation indicates that appropriate models can be used for the estimation of exposure levels.

ECHA notes that the Registrant has used ECETOC TRA to estimate exposure for a variety of worker exposure scenarios using efficiency for gloves of 98% to estimate the exposure via dermal route. However, ECHA notes that according to the guidance for the model used (ECETOC TR 114) the maximum pre-defined values are 95% for industrial users and 90% for professional users. The registrant has not included in the CSR any case specific justification (e.g. related to the substance or the specific recommended or implemented personal protection measures or based on relevant bio-monitoring data) for deviating from the recommended efficiency factor in using ECETOC TRA.

As explained above, the information provided on the dermal exposure estimates for the registered substance in the chemical safety report does not meet the requirements for preparing a chemical safety report as described in Annex I. Consequently, it is necessary to revise the dermal exposure estimates or to provide a justification explaining why in this specific case using higher efficiency values for gloves (98%) is considered appropriate.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit in the chemical safety report the following information: revised exposure assessment and risk characterisation for workers via dermal route using the pre-defined values for gloves efficiency stated above or a justification explaining why in this specific case using higher efficiency values for gloves (98%) is considered appropriate.

Notes for consideration by the Registrant

The revised DNELs requested under section II.B.1 shall be taken into account when assessing the related risks.

3. Revised environmental exposure assessment and risk characterisation for all exposure scenarios (Annex I, section 5)

Annex I, section 5 of the REACH Regulation requires the Registrant to generate 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 and shall consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in the Section 5 have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

Further, Annex I Section 0.4. of the REACH Regulation states that "*substances whose physicochemical, toxicological and ecotoxicological properties are likely to be similar or follow a regular pattern as a result of structural similarity may be considered as a group, or 'category' of substances. If the manufacturer or importer considers that the chemical safety assessment carried out for one substance is sufficient to assess and document that the risks arising from another substance or from a group or 'category' of substances are adequately controlled then he can use that chemical safety assessment for the other substance or group or 'category' of substances. The manufacturer or importer shall provide a justification for this*".

In the CSR, the Registrant has stated that "*as the production and use volumes of ethylenediamine, propoxylated were highest and the physic-chemical properties of ethylenediamine, propoxylated resulted in the highest Predicted Environmental Concentrations (PECs) the emission assessment for ethylenediamine, propoxylated was used as a basis for the other polyols*". In addition, the Registrant has provided the document "*ReadAcrosss_Jun2009-1e.pdf*" containing an assessment of the toxicokinetic data of the different substances belonging to the group of substances denominated "Polyols".

ECHA notes that the Registrant has used the exposure assessment derived for ethylenediamine, propoxylated, regarded as an analogue substance, but the justification given is not sufficient and the claims made in the justification are not supported by any data. More specifically, ECHA notes that the Registrant has not justified and documented the similarity of the environmental fate properties, the uses throughout the entire life cycle, including tonnages, operational conditions and risk management measures, and therefore the releases and fate in the environment, between the substance subject to the present decision and the analogue substance ethylenediamine, propoxylated. Therefore, ECHA cannot verify a prediction of properties between the two substances.

More information about how to prepare a grouping of substances and read-across approach under REACH can be found in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6: QSARs and grouping of chemicals and in the Practical guide 6: How to report read-across and categories.

In his comments, the Registrant consented to provide further justification for using data on an analogue substance in the environmental exposure assessment and risk characterisation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide a revised environmental exposure assessment and risk characterisation for all exposure scenarios using data from the registered substance. The chemical safety report shall be amended accordingly.

4. Revised environmental exposure assessment and risk characterisation for exposure scenario 1 (Annex I, sections 5 and 6)

In addition to the general requirements of Annex I, Section 5 and 6 outlined under section III.B.3. above, ECHA notes that according to Article 3(37) of the REACH Regulation, exposure scenario is defined as "*the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle an how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment*".

Pursuant to Articles 10(b) and 14(4) as well as Annex I, section 5.1.1. of the REACH Regulation, generated exposure scenarios shall cover a description of the operational conditions and risk management measures applied to reduce or avoid direct and indirect exposure to humans and the different environmental compartments to the substance.

In the CSR provided, the Registrant states that "*according to specific information from producers 70-90% of ethylenediamine, ethoxylated and propoxylated is removed in the STP. As a worst-case assumption the lower limit of 70% removal is taken into account*".

In addition, the Registrant has calculated the PEC for sewage treatment plants (STP) based on the concentration of the substance in the STP effluent (Clocaleff), thus assuming that the concentration in the STP takes into account the removal rate of 70%.

ECHA notes that considering the registered substance has been identified to be not readily biodegradable, not volatile and not adsorptive, it is not clear under which circumstances a removal rate of 70% can occur. Therefore, there seems to be an inconsistency between the assumed removal efficiency of 70% and the physical and chemical and environmental fate properties of the registered substance.

ECHA also notes that according to the process categories (PROCs) provided by the Registrant, for exposure scenario 1 there will be intermittent releases. Thus, according to ECHA's Guidance on information requirements and chemical safety assessment (Version 2.1, 2012), chapter R.16., section R.16.6.5.6., pages 56 to 58, the approach used by the Registrant is not acceptable for intermittent releases. If the interval between two releases is long enough (typically more than one month), adaptation of the activated sludge cannot be assumed to be maintained and the specific microorganisms that were capable to biodegrade the compound may be completely lost. If the activated sludge is de-adapted, the concentration in the aeration tank will then increase during the discharge period. Therefore for intermittent releases, the concentration in the STP influent (i.e. zero removal rate) is more representative for deriving the PEC for STP.

In his comments, the Registrant indicated his intention to provide in the CSR supporting data to justify the removal efficiency in sewage treatment plants.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to provide a revised environmental exposure assessment and risk characterisation including a justification able to explain a removal rate of 70% in the sewage treatment plants and a revised calculation of PEC for sewage treatment plants considering the influent instead of the effluent for exposure scenario 1. The chemical safety report shall be amended accordingly.

5. Revised environmental exposure assessment and risk characterisation for exposure scenarios 2 to 11 (Annex I, sections 5 and 6)

In addition to the general requirements of Annex I, Section 5 and 6 outlined under section III.B.3. above, ECHA notes that pursuant to Articles 10(b) and 14(4) as well as Annex I, section 5.1.1. of the REACH Regulation, generated exposure scenarios shall cover a description of the operational conditions and risk management measures applied to reduce or avoid direct and indirect exposure to humans and the different environmental compartments to the substance.

In the CSR provided, the Registrant assumes zero release to waste water for exposure scenarios 2 to 11. For industrial uses (applicable to all exposure scenarios), the Registrant states that "*the formulation of ethylenediamine, ethoxylated and propoxylated is a dry process therefore the emission factor to waste water was set to zero*". For professional and/or consumer uses (applicable to scenarios 5, 6, 7, 8, 9 and 11), the Registrant states that "*ethylenediamine, ethoxylated and propoxylated are always used in combination with a molar excess of isocyanates, and thus, there should be practically no possibility for release of "free polyol" once these products are reacted and cured*".

ECHA notes that the Registrant's assumption that no emission to waste water occurs for scenarios 2 to 11 is not consistent with the operational conditions and risk management measures indicated in the registration dossier. The Registrant has not described the operational conditions and risk management measures to achieve zero release to waste water. As a comparison, even for exposure scenario 1, which is for a dry process, the Registrant has assumed that emissions to waste water will occur during maintenance and cleaning operations at least once a year. This is in contradiction with the assumption made for exposure scenarios 2 to 11.

In his comments, the Registrant indicated his intention to provide in the CSR a description of the operational conditions and risk management measures to achieve zero release to waste water.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to describe of the operational conditions and risk management measures to be applied for exposure scenarios 2 to 11. The description shall be such that the exposure estimation and the risk characterisation included in the Chemical Safety Report are justified. If the Registrant comes to the conclusion that other elements for the Chemical Safety Report are inconsistent with the description required by the present decision, he shall revise the risk characterisation.

C. Deadline for submitting the information

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 36 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested another study (Two-generation reproductive toxicity study or Extended one-generation reproductive toxicity study, Annex X, 8.7.3). As this study is not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID5 dossier is 24 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://echa.europa.eu/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