ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: TPE-D-0000003228-75-06/F Helsinki, 23 July 2013

DECISION ON A TESTING PROPOSAL SET OUT IN A REGISTRATION PURSUANT TO ARTICLE 40(3) OF REGULATION (EC) NO 1907/2006

For 2-piperazin-1-ylethylamine, CAS No 140-31-8 (EC No 205-411-0), 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 40(1) of the REACH Regulation, ECHA has examined the following testing proposals submitted as part of the jointly submitted registration dossier for the tonnage band of 1000 tonnes or more per year in accordance with Articles 10(a)(ix) and 12 (1)(e) thereof for 2-piperazin-1-ylethylamine, CAS No 140-31-8 (EC No 205-411-0), by [redacted] (Registrant):

- Repeated dose 90-day oral toxicity in rodents (OECD 408/EU B.26) by the oral route (drinking water);
- Pre-natal developmental toxicity study (OECD 414/EU B.31) in rats by the oral route (drinking water);
- Pre-natal developmental toxicity study (OECD 414/EU B.31) in rabbits by the oral route (drinking water);
- Two-generation reproductive toxicity study (OECD 416/EU B.35) in rats by the oral route (drinking water); and
- Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (OECD 222).

The present decision relates to the examination of the testing proposals for the purpose of fulfilling the information requirements for a sub-chronic toxicity (Annex IX, 8.6.2), for pre-natal developmental toxicity (Annex IX and X, 8.7.2) and for long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4). The testing proposal for fulfilling the information requirement for reproductive toxicity (Annex X, 8.7.3) is addressed in a separate decision although all these were initially addressed together in the same draft decision.

This decision is based on the registration dossier as submitted with submission number [redacted]. This decision does not take into account any updates after 18 January 2013, 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.

On 31 August 2010, pursuant to Article 40(1) of the REACH Regulation, ECHA initiated the examination of the testing proposals set out by the Registrant in the registration dossier for the substance mentioned above.

ECHA held a public consultation for the testing proposals from 14 February 2011 until 31 March 2011. A second public consultation was held from 21 October 2011 to 5 December 2011 further to an update of the testing plan that forms the basis for this decision. ECHA did receive information from third parties for endpoints covered by the present decision (see section III below).

On 9 August 2012 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 6 September 2012 ECHA received comments from the Registrant.
On 31 October 2012, the Registrant updated his registration dossier and removed one of the six originally submitted testing proposals.

ECHA considered the Registrant's comments received and the updated dossier. On basis of the comments and of the updated dossier, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 18 January 2013 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 to amend the draft decision within 30 days of the receipt of the notification.

Subsequently, Competent Authorities of the Member States submitted proposals for amendment to the draft decision inter alia concerning endpoints covered by the present decision.

On 21 February 2013 ECHA notified the Registrant of proposals for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on those proposals for amendment within 30 days of the receipt of the notification.

ECHA reviewed the proposals for amendment received decided to amend the draft decision with regard to an endpoint covered by the present decision (selection of route for the sub-chronic toxicity study).

On 4 March 2013 ECHA referred the draft decision to the Member State Committee.

On 25 March 2013 the Registrant provided comments on the proposed amendments. The Member State Committee took the comments of the Registrant into account.

The draft decision was split into two draft decision documents: one relating to the testing proposal to fulfil the information requirement for a two-generation reproductive toxicity (Annex X, 8.7.3) and one relating to the testing proposals to fulfil the information requirements for a sub-chronic toxicity study (90-day) study, pre-natal developmental toxicity and long-term toxicity on terrestrial invertebrates.

After discussion in the Member State Committee meeting on 24-25 April 2013, a unanimous agreement of the Member State Committee on the draft decision relating to the testing proposal for a repeated dose 90-day toxicity study, two pre-natal developmental toxicity studies and a long-term toxicity study on terrestrial invertebrates as modified at the meeting was reached on 25 April 2013. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

This decision does not imply that the information provided by the Registrant in his registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the registration dossier at a later stage.

II. Testing required

The Registrant shall carry out the following proposed tests pursuant to Article 40(3)(a) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

1. Pre-natal developmental toxicity study in rats or rabbits (first species), oral route (Annex IX, 8.7.2; test method: EU B.31/OECD 414);
2. Pre-natal developmental toxicity study in rats or rabbits (second species), oral route (Annex X, 8.7.2; test method: EU B.31/OECD 414); and
3. Long-term toxicity on terrestrial invertebrates (Annex X, 9.4.4; test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222);

The Registrant shall carry out the following additional tests pursuant to Article 40(3)(c) of the REACH Regulation using the indicated test methods and the registered substance subject to the present decision:

4. Effects on soil micro-organisms (Annex IX, 9.4.2; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216);
5. Sub-chronic toxicity study (90-day) in rats, inhalation route (Annex IX, 8.6.2; test method: OECD 413);

while the originally proposed test for a sub-chronic toxicity study (90-day) in rats, oral route (test method: EU B.26/OECD 408) is rejected pursuant to Article 40(3)(d) of the REACH Regulation.

Once results of the requested toxicity test on terrestrial invertebrates are available, in accordance with Annex I of the REACH Regulation, the Registrant is required to revise the chemical safety assessment. He should furthermore consider whether there is a need to investigate further the effects on terrestrial organisms in order to fulfil the information requirements of section 9.4 of Annex IX, and if necessary, submit testing proposals for additional terrestrial toxicity tests. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirement of Annex IX, section 9.4.3 of the REACH Regulation.

The Registrant shall determine the appropriate order of the studies taking into account the possible outcome and considering the possibilities for adaptations of the standard information requirements according to column 2 provisions of the respective Annex and those contained in Annex XI of the REACH Regulation. In particular, the Registrant shall determine the need to perform the proposed test for a pre-natal developmental toxicity study in the second species (test method: EU B.31/OECD 414) taking into account the results of the first pre-natal developmental toxicity study conducted in the first species.

Pursuant to Articles 40(4) and 22 of the REACH Regulation, the Registrant shall submit to ECHA by **23 July 2016** an update of the registration dossier containing the information required by this decision.

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

III. Statement of reasons

The decision of ECHA is based on the examination of the testing proposals submitted by the Registrant for the registered substance and scientific information submitted by third parties.

1. Pre-natal developmental toxicity study in rats

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant proposed testing in rats. According to the test method EU B.31/OECD 414, the rat is the preferred rodent species. ECHA considers this species as being appropriate.

The Registrant proposed testing by the oral route. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has proposed a strategy for ECHA to consider before further tests on animals are requested. However, third parties were invited, as specified by Article 40(2) of the REACH Regulation to submit "scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal". As the proposal for a strategy as such cannot be regarded information or studies, ECHA concludes that this is not a sufficient basis to fulfil the data/information requirement.

Another third party has proposed to use a result of a nonlinear classification ANN QSAR Model for pre-natal developmental toxicity study. The third party has indicated that their information is confidential and this information is not provided to the registrant.

Compliance with the Annex XI section 1.3 requirements could not be established as the required information concerning the validity, adequacy for classification and labelling and documentation of the model was not provided. The submitted documents provide an indication that the descriptors of the predicted substance fall within the ranges of the individual descriptors, used for development of the model. However, the possibility that the substance does not fall in the applicability domain of the model for another reason could not be ruled out. The (Q)SAR Model Reporting Format (QMRF) does not provide sufficient information to deduce whether the training set was constructed from studies that cover the information requirements of the OECD 414 guideline, or important study aspects, such as the species, dose selection and number of animals used. In addition, the submitted QPRF does not contain any indication on the adequacy in relation to a defined regulatory purpose of the testing proposal.

Therefore, ECHA concludes that on this occasion, the information submitted does not meet the conditions for the adaptation on the basis of QSAR models set out in Annex XI, Section 1.3. Therefore, it cannot constitute an acceptable adaptation to standard information requirements.

c) Outcome

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study using the registered substance: Pre-natal developmental toxicity study in rats or rabbits (first species), oral route (test method: EU B.31/OECD 414).

The Registrant indicated in his comments to the draft decision that he agrees with the outcome of the examination of this testing proposal.

2. Pre-natal developmental toxicity study in rabbits

a) Examination of the testing proposal

Pursuant to Article 40(3)(a) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test.

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. According to section 8.7.2 of Annex X subject to the Annex IX, 8.7.2 column 2 requirements of the REACH Regulation, a further pre-natal developmental toxicity study performed in a second species is required to fulfil the standard information requirements. The information available on this endpoint for the registered substance in the technical dossier does not meet these information requirements. Consequently there is an information gap and it is necessary to generate the data for this endpoint provided that, in the light of the outcome of the first pre-natal developmental study, the conditions for adaptations according to Annex X, 8.7. column 2, or according to Annex XI of the REACH Regulation are not met.

The Registrant proposed testing in rabbits. According to the test method EU B.31/OECD 414, the rabbit is the preferred non-rodent species. ECHA considers this species as being appropriate.

The Registrant proposed testing by the oral route. In the light of the physico-chemical properties of the substance and the information provided on the uses and human exposure, ECHA considers that testing by the oral route is appropriate.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained above – see section III.2.b - the information provided by third parties is not sufficient to fulfil this information requirement.

c) Outcome

The Registrant is requested to take into account the outcome of the pre-natal developmental toxicity study on the first species and all available data to determine if the conditions are met for adaptations according to Annex IX, 8.7.2 column 2, 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 these conditions for adaptation are not met, the Registrant shall carry out the proposed study pursuant to Article 40(3)(a) of the REACH Regulation using the registered substance: Pre-natal developmental toxicity study in rats or rabbits (second species), oral route (test method: EU B.31/OECD 414).

The Registrant indicated in his comments to the draft decision that he agrees with the outcome of the examination of this testing proposal.

3.– 4. Terrestrial toxicity

Pursuant to Article 40(3)(a) and (c) of the REACH Regulation, ECHA may require the Registrant to carry out the proposed test and to carry out additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI.

The Registrant must address the standard information requirements set out in Annex IX, section 9.4, for different taxonomic groups: effects on soil micro-organisms (Annex IX, section 9.4.2), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1), and short-term toxicity testing on plants (Annex IX, section 9.4.3). Column 2 of section 9.4 of Annex IX specifies that long-term toxicity testing shall be considered by the Registrant instead of short-term, in particular for substances that have a high potential to adsorb to soil or that are very persistent.

The information on the endpoint 'effects on terrestrial organisms' is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements.

a) Terrestrial Invertebrates (Annex IX, 9.4.1 and Column 2 of Annex IX, 9.4)

The Registrant proposed a long-term toxicity test on terrestrial invertebrates (OECD 222), with the following justification: *"Since invertebrates were the most sensitive group as indicated from aquatic toxicity data, a chronic earthworm study (limit test) is planned for this endpoint in accordance with REACh guidance for compounds in soil hazard category 3 (Table R.7.11 -2). Based on the outcome of this test and the screening level risk assessment, a decision will be rendered as to whether additional terrestrial toxicity testing is necessary for aminoethyl piperazine".* According to section R.7.11.5.3, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), substances that are ionisable or have a log K_{ow}/K_{oc} >5 are considered highly adsorptive,

whereas substances with a half-life >180 days are considered very persistent in soil. According to the evidence presented within the Registration dossier, the substance has a high potential to adsorb to soil ($logK_{oc}$ > 4) and therefore ECHA agrees that long-term testing is indicated (Column 2 of Section 9.4. of Annex IX). The proposed test is suitable to address the information requirement of Annex IX, section 9.4.1.

Furthermore, based upon the available aquatic toxicity information and the physico-chemical properties of the substance, and in relation to section R.7.11.6, Chapter R.7c of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008), ECHA considers that the substance would fall into soil hazard category 3. In the context of an integrated testing strategy for soil toxicity, the Guidance advocates performing an initial screening assessment based upon the Equilibrium Partitioning Method (EPM), together with a confirmatory long-term soil toxicity test. The PNECscreen is calculated through EPM on the basis of aquatic toxicity data only. ECHA notes that the strategy pursued by the Registrant is based on this approach.

Therefore, pursuant to Article 40(3)(a) of the REACH Regulation, the Registrant is required to carry out the proposed study: Long-term toxicity to invertebrates (Annex IX, 9.4.1, column 2); test method: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*) (OECD 222) using the registered substance.

As the Guidance advocates performing an initial screening assessment based upon the EPM, together with a confirmatory long-term soil toxicity test (the long-term toxicity to terrestrial invertebrates test, specified above), which the Registrant is requested to carry out by the present decision, ECHA considers that at this stage it is not possible to determine whether a test will be required to fulfil the standard information requirement in section 9.4.3 of Annex IX of the REACH Regulation.

Therefore, the Registrant shall determine the need to perform further terrestrial toxicity tests based on the outcome of the requested toxicity test on terrestrial invertebrates and the considerations set out in Table R.7.11-2, section R7.C of the ECHA *Guidance on information requirements and chemical safety assessment* (May 2008).

b) Soil microorganisms (Annex IX, section 9.4.2)

The hazard to soil microbial communities is a standard information requirement under Annex IX, section 9.4.2 of the REACH Regulation. ECHA notes that the registration dossier does not contain data for this endpoint and that the proposed test that ECHA accepted under subsection (a) above is not sufficient to address this standard information requirement. ECHA concludes that the effects on soil microorganisms need to be ascertained by performing a relevant test (test method: EU C.21 or OECD 216).

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the following additional study: Effects on soil micro-organisms (Annex IX, 9.4.2; test method: Soil microorganisms: nitrogen transformation test, EU C.21/OECD 216), using the registered substance.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4.3. does not apply for the present endpoint.

The Registrant indicated in his comments to the draft decision that he agrees with the outcome of the examination of the testing proposal for the long-term toxicity test on terrestrial invertebrates.
In his comments, the Registrant discussed the need for assessing the toxicity to soil micro-organisms as requested in ECHA's draft decision. The Registrant emphasised that micro-organisms exhibited a lower sensitivity in an acute toxicity test compared to other taxa. The Registrant considered that the focus of further long-term testing should therefore be on the most sensitive trophic level which he considered to be soil invertebrates. ECHA considers that the lower sensitivity of microorganisms observed in a respiratory inhibition test compared to other taxa does not constitute an adequate waiver for the information requirement on soil microorganisms as laid down in Annex IX, 9.4.2. ECHA notes that the registered substance was observed to be toxic or inhibitiory to the microbial inoculum in a key biodegradation study at concentrations lower that the EC50 for Daphnia and those causing effects on the different aquatic microorganisms studies. ECHA considers that the justification provided by the Registrant does not address this element and is not satisfactory to waive the information requirement on soil microorganisms. Therefore ECHA did not amend its draft decision for this endpoint.

The Registrant also further explained in his comments his strategy to assess effects of the registered substance on terrestrial invertebrates and concluded that the additional long-term toxicity testing on plants initially requested by ECHA in its draft decision is not necessary. ECHA reviewed the information provided by the Registrant and considers the testing strategy for long-term testing to terrestrial organisms proposed by the registrant as satisfactory for soil hazard category 3 substances. Therefore, ECHA has amended the draft decision to remove the request for a long-term toxicity testing on plants.

5. Sub-chronic toxicity study (90-day) in rats

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

The Registrant proposed testing in rats. According to the test method OECD 413 the rat is the preferred rodent species. ECHA considers this species as being appropriate.

The Registrant proposed testing by the oral route. ECHA originally considered the oral route to be appropriate and therefore accepted the proposed test. The Registrant indicated in his comments to the draft decision that he agreed with the outcome of the examination of this testing proposal. However, ECHA reconsidered its view on the most appropriate route after having received a proposal for amendment by a Member State: In the light of the physico-chemical properties of the substance (corrosivity) and the information provided on the uses and human exposure (i.e. industrial and non-industrial spraying; concentrations up to 25%), respiratory tract irritation after repeated exposure may occur. ECETOC TRA calculation resulted in extimated inhalation exposure concentrations of up to 3.23 mg/m^3 (long-term) and 10.77 mg/m^3 (acute). Furthermore, the calculated RCR are based on an

oral systemic NOAEL and are therefore not adequate to demonstrate that the risk for local effects on the respiratory tract is controlled.

The Registrant provided written comments on the proposal for amendment requiring the test to be conducted by the inhalation route. The Registrant confirmed in its comments its intention to perform a sub-chronic toxicity study via the oral route for animal welfare considerations and to generate data which can be used to define the test protocols for the other reproductive toxicity studies proposed.

ECHA and the Member State Committee members considered that the Registrant's comments on the proposal for amendments did not provide justified reasons why testing by the inhalation route is not the most appropriate route in the sense of Annex IX, 8.6.2. column 1.

Therefore, ECHA and the Member State Committee consider that testing by the inhalation route is more appropriate than testing by the oral route.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the public consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

A third party has proposed a weight-of-evidence approach suggesting that the available data on the registered substance is adequate to perform a hazard assessment of the registered substance. As part of this approach, the third party referred to the results from a combined repeated-dose / reproductive and developmental toxicity screening study conducted via the oral route with the registered substance and of a dermal 28-day repeated dose toxicity performed with the registered substance. The third party also referred to the conclusion of an OECD SIDS report published in 2005 addressing the toxicity of the registered substance.

ECHA has taken the information provided into account and concludes that it is insufficient for demonstrating that the conditions of Annex XI, Section 1.2 of the REACH Regulation are met. More specifically, the proposed weight-of-evidence approach is not sufficient to assume that the substance has or has not a particular dangerous property after sub-chronic administration of the substance and that the standard information requirement for a sub-chronic toxicity study (90-day) could be adapted.
Although ECHA recognises that the information as provided by the third party might be scientifically valid, it does not fulfil Annex XI requirements and is therefore not sufficient to allow ECHA to reject the testing proposal. Nevertheless, ECHA acknowledges that the Registrant may himself supplement under its own responsibility the argumentation and information provided by the third party in order to make use of adaptation possibilities. This would require that the Registrant documents, using several independent sources of information, that there is a sufficient weight of evidence leading to the assumption/conclusion that a substance has or has not particular dangerous properties, according to the criteria laid down in Annex XI of the REACH Regulation.

Another third party has proposed to use a result of a QSAR Model for Repeated dose 90-day oral toxicity study in rodents. The third party has indicated that their information is confidential and this information is, therefore, not provided to the registrant.

Compliance with the Annex XI section 1.3 requirements could not be established as the required information concerning the validity, adequacy for classification and labelling and documentation of the model was not provided. The submitted documents provide an indication that the descriptors of the predicted substance fall within the ranges of the individual descriptors, used for development of the model. However, the possibility that the substance does not fall in the applicability domain of the model for another reason could not be ruled out. The (Q)SAR Model Reporting Format (QMRF) does not provide sufficient information to deduce whether the training set was constructed from studies that cover the information requirements of the OECD 408 guideline, or important study aspects, such as the species, dose selection and number of animals used. In addition, the submitted QPRF does not contain any indication on the adequacy in relation to a defined regulatory purpose of the testing proposal.

Therefore, ECHA concludes that the information submitted does not meet the conditions for the adaptation on the basis of QSAR models set out in Annex XI, Section 1.3. Therefore, it cannot constitute an acceptable adaptation to standard information requirements.

c) Outcome

Therefore, pursuant to Article 40(3)(c) of the REACH Regulation, the Registrant is required to carry out the study using the registered substance: Sub-chronic toxicity study (90-day) in rats, inhalation route (test method: OECD 413). Pursuant to Article 40(3)(d) of the REACH Regulation, ECHA rejects the proposal by the Registrant to fulfil the endpoint by testing by the oral route (EU B.26/OECD 408).

IV. Adequate identification of the composition of the tested material

The process of evaluation of testing proposals set out in Article 40 of the REACH Regulation aims at ensuring that the generation of information is tailored to real information needs in order to prevent unnecessary testing. The information submitted in the registration dossier was sufficient to confirm the identity of the substance for the purpose of assessing the testing proposal. It is note, however that this information, or the information submitted by other Registrants of the same 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 proposed tests, 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 the joint Registrants of the same substance to agree with the tests proposed in the testing proposal (as applicable to their tonnage level) and to document the necessary information on its composition. The substance identity information of the registered substance and of the sample tested must enable ECHA to confirm the relevance of the testing for the substance actually registered by each joint Registrant. Finally, the studies must be shared by the joint Registrants concerned.

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

ECHA always reminds registrants 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 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.

VI. 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 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/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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Geert Dancet
Executive Director