EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114288054-48-01/F Helsinki, 27 November 2014

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

For butan-2-ol, CAS No 78-92-2 (EC No 201-158-5), 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 butan-2-ol, CAS No 78-92-2 (EC No 201-158-5), 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 15 July 2013.

On 18 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 17 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 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 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.

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

By 18 August 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).

A unanimous agreement of the Member State Committee on the draft decision was reached on 1 September 2014 in a written procedure launched on 21 August 2014.

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

II. Information required

A. Information in the technical dossier related to the identity of the substance

Pursuant to Articles 41(1), 41(3), 10(a)(ii) and Annex VI, Section 2 of the REACH Regulation the Registrant shall submit the following information for the registered substance subject to the present decision:

1. Nuclear magnetic resonance spectral data or mass spectrum data (Annex VI, 2.3.5);

2. Information on optical activity and typical ratio of (stereo) isomers (Annex VI, 2.2.2).

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

Pursuant to Articles 41(1), 41(3), 10(a)(vii), 12(1)(e), 13 and Annexes IX and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance, butan-2-ol, subject to the present decision:

1. Sub-chronic toxicity study (90-day), inhalation route (Annex IX, 8.6.2.; test method: OECD 413) in rats;

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

C. 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. Documentation for the recommended personal protective equipment, i.e. gloves to be worn need to be specified clearly when handling the substance or mixture (Article 14(6), Annex I, 5.1.1., in conjunction with Annex II, 0.1.2. and 8.2.2.2.(b)(i))., including:

a. The type of material and its thickness, and
b. The typical or minimum breakthrough times of the glove material;

2. Revision of the consumer exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) to take account of the activities of consumers and the duration and frequency of their exposure to the registered substance. For further specifications of the requirement see Section III.C. below.

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 **5 December 2016**. The timeline has been set to allow for sequential testing as appropriate.

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 sound 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 requests in this decision, or to fulfil otherwise the information requirements with a valid and documented adaptation, will result in a notification to the Authorities of the Member States for enforcement.

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 related to the identity of the substance

Pursuant to Article 10(a)(ii) of the REACH Regulation, the technical dossier shall contain information on the identity of the substance as specified in Annex VI, Section 2 of the REACH Regulation. In accordance with Annex VI, Section 2 the information provided shall be sufficient to enable the identification of the registered substance.

1. Spectral data (nuclear magnetic resonance or mass spectrum) (Annex VI, 2.3.5)

"Spectral data" is an information requirement as laid down in Annex VI, Section 2.3.5. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the registration does not contain any nuclear magnetic resonance spectrum (NMR) or mass spectrum data for the identification of the main constituent of the registered substance which is required according to Annex VI, Section 2.3.5. of the REACH Regulation to identify the registered substance.

ECHA points out that the identity of the substance cannot be confirmed based exclusively on the infrared data. NMR spectroscopic analyses such as ^{1}H-NMR or ^{13}C-NMR are powerful tools for structure characterisation and elucidation due to characteristic chemical shifts and spin-spin coupling which also reflect the relative abundance of individual atoms. As all reported constituents contain characteristic hydrogen and carbon atoms, NMR is an appropriate analytical method to characterise the substance.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: nuclear magnetic resonance data such as ^{1}H-NMR or ^{13}C-NMR as specifically explained above. Alternatively, a mass spectrum including the corresponding interpretation of the fragmentation scheme can be provided. The Registrant shall ensure that the information is consistent throughout the dossier.

As for the reporting of the spectral data in the registration dossier, the information should be included in IUCLID section 1.4.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation, agreed to provide the requested information.

2. Information on optical activity and typical ratio of (stereo) isomers (Annex VI, 2.2.2)

"Information on optical activity and typical ratio of (stereo) isomers" is an information requirement as laid down in Annex VI, Section 2.2.2. of the REACH Regulation. Adequate information needs to be present in the technical dossier for the registered substance to meet this information requirement.

ECHA notes that the Registrant did not report any information on the ratio of stereoisomers, as required according to Annex VI, Section 2.2.2 of the REACH Regulation. More specifically, ECHA observes that the main constituent reported in the composition of the registered substance presents one stereocentre. It follows that the information requirement on the ratio of (stereo) isomers applies and is appropriate for the substance. Nevertheless this information is missing from the registration.

The Registrant is therefore requested to report the ratio of the different isomers present in the composition of the registered substance.

Regarding how to report the composition of the registered substance in IUCLID, the Registrant shall specify the ratio of stereoisomers in the Remarks field of the repeatable block created for each group of constituents in IUCLID section 1.2. Alternatively, the Registrant can report separately each individual stereoisomer, including information on their typical, minimum and maximum concentration in IUCLID section 1.2.

The Registrant shall ensure that the information on the stereochemistry is verifiable and therefore supported by a description of the analytical methods used for the quantification, as required under Annex VI section 2.3.7 of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the information derived from the registered substance subject to the present decision: report the ratio of the different isomers present in the composition of the registered substance as specifically explained above. The Registrant shall ensure that the information is consistent throughout the dossier.

As for the reporting of the ratio of the different isomers present in the composition of the registered substance, the information should be included in IUCLID section 1.4.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation agreed to add information on optical activity.

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

Pursuant to Articles 10(a)(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, VIII, IX, and X of the REACH Regulation.

0. Read-across to methyl ethyl ketone

With regard to both information requirements covered by the present decision, the Registrant has sought to adapt the requirements by a proposed read-across to methyl ethyl ketone (MEK).

The Registrant provided the following justification for using studies on the proposed read-across substance to fulfil the information requirements: "*Read-across with MEK is justified, since MEK is the major metabolite of SBA and MEK has structural similarity with SAB. The metabolic relationship between SBA, established in pharmacokinetic studies, is discussed in detail in the toxicokinetic statement in Section 7.1.1.*" In the Section "Summary and discussion of repeated dose toxicity" of the Chemical Safety Report the following is stated by the Registrant. "*Metabolic data demonstrate that s-butanol is rapidly and extensively converted to methyl ethyl ketone via oxidation of the functional group by alcohol dehydrogenase in the liver. Thus methyl ethyl ketone may be used as an appropriate surrogate for s-butanol and vice versa considering that exposure to either substance would essentially result in exposure to methyl ethyl ketone.*"

ECHA has the following observations concerning this proposed read-across argument.

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*".

Annex XI, Section 1.5 requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. Furthermore it requires that an adequate and reliable documentation of the applied method shall be provided.

i. The proposed read-across depends entirely on the outcome of a single toxicokinetic study with rats, in which the animals were exposed via the oral route. No robust study summary of this study is provided by the Registrant, and therefore ECHA cannot fully assess whether this study indeed supports the claim made by the Registrant that "methyl ethyl ketone may be used as an appropriate surrogate for s-butanol and vice versa".

ii. The information provided by the Registrant on the toxicokinetic study indicates that under the exposure conditions of the study, the single dose did result in a substantial systemic exposure to the registered substance. ECHA concludes that this study does not support the notion that exposure to the registered substance equals exposure to MEK and that no other information is provided by the Registrant that points to the absence of systemic exposure to the registered substance.

iii. Based on the concise information provided by the Registrant, the plasma concentrations of the registered substance and its metabolites, including MEK, represent measures for systemic exposure. However, in repeated-dose toxicity studies, effects may be observed that do not depend on the concentration of the substance in the peripheral blood, but on exposure of tissues before the substance or its metabolites reach the peripheral blood. The toxicokinetic study with the registered substance does not provide information on this exposure.

iv. The repeated dose studies and the pre-natal developmental studies with MEK that serve as a starting point for read-across are both inhalation studies. The read-across is thus aimed at the replacement of an inhalation studies with the registered substance. ECHA notes that the toxicokinetics of the registered substance may depend on the exposure route. For instance, the possibility should be considered that the oxidation of the registered substance to MEK is largely confined to the liver. If this were indeed the case, oral exposure would lead to exposure of, and metabolism by the liver before the registered substance or its metabolites reach the peripheral blood, whereas inhalation leads to direct systemic exposure.

v. The information provided by the Registrant did not allow for a comparison of the toxicokinetics of MEK when the animals are directly exposed to this compound and when this compound is formed in the body from the oxidation of the registered substance. These situations may be accompanied by quantitative differences of the internal exposure to MEK.

For the above reasons, ECHA concludes that the proposed read-across argument cannot be accepted as it does not fulfil the requirements of Annex XI, Section 1.5. of the REACH Regulation.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation referred to his original read across approach and the fact that based on a metabolism study of s-butanol in rats following oral administration the s-butanol is rapidly and extensively (~97%) metabolized to MEK. Thus MEK may be used as an appropriate surrogate for s-butanol and vice versa considering that exposure to either substance would essentially result in exposure to MEK. Furthermore the Registrant explained "*We have identified data from other substances that share a structural, metabolic and toxicological similarity with s-butanol, thus satisfying the conditions set out in Annex XI, Section 1.5. Accordingly, we intend to adapt the requested information requirements by a proposed read-across to the identified substance. We agree that this additional information will be submitted in the form of an updated registration dossier within the stipulated time period.*"

ECHA acknowledges the intention of the Registrant to adapt the information requirements through read-across. If the Registrant under his own responsibility and at his own risk includes such read-across approach in the dossier instead of the requested tests on the registered substance, ECHA will evaluate such adaptation in the follow-up process pursuant to Article 42 of the REACH Regulation (as to the relevant process, information is available in the "Follow up to dossier evaluation decisions" factsheet,

http://echa.europa.eu/documents/10162/13628/factsheet_dossier_evaluation_decisions_followup_en.pdf).

1. Sub-chronic toxicity study (90-day), inhalation 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.

The Registrant did not provide a 90-day repeated-dose toxicity study with the registered substance. Instead, the proposed analogue substance methyl ethyl ketone (MEK) was tested in a study equivalent to OECD 413 (inhalation, 90-day repeated-dose toxicity study). Firstly, the proposed read-across does not fulfil the conditions of Annex XI, Section 1.5. of the REACH Regulation (See Section III.B.0. above). ECHA concludes that the Registrant has not convincingly shown that the registered substance, when investigated in a 90-day repeated dose toxicity study, can itself not contribute to possible effects due to rapid metabolism to MEK and that any effects observed in such studies, with the registered substance, can only be caused by MEK and its metabolites. This conclusion is partly determined by the results of the single toxicokinetic study. Secondly, ECHA notes that a relatively high dose was tested in the submitted study on the proposed read-across substance. However, the Registrant did not provide information about the toxicokinetics at lower dose levels.

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.

In light of the physico-chemical properties of the substance, being a liquid with high vapour pressure and the information provided on the uses and human exposure, ECHA considers that testing by the inhalation route is most appropriate.

According to the test method OECD 413, 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: Sub-chronic inhalation toxicity: 90-day study (test method: OECD 413) in rats.

2. 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).

The Registrant has not provided any study record of a pre-natal developmental toxicity study in a second species in the dossier that would meet the information requirement of Annex X, Section 8.7.2. Instead, the Registrant has sought to adapt this information requirement.

The Registrant submitted a test on the substance methyl ethyl ketone performed in mice for the endpoint and provided this as supportive information. As indicated above (Section III.B.0.) the proposed read-across argument fails to fulfil the conditions of Annex XI, Section 1.5.

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.

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. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rabbit as a second species to be used.

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 rabbits by the oral route.

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

Pursuant to Articles 10(b) and and 14(1) of the REACH Regulation the registration shall contain a chemical safety report (CSR) 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. Documentation that risks to workers are adequately controlled

Article 14(6) as well as Annex I, 0.1., 5.1.1., 5.2.4. and 6.2. of the REACH Regulation require registrants to identify and apply appropriate measures to adequately control the risks identified in a 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.

Pursuant to Annex VI, section 5 and Annex II, section 0.1.2. of the REACH Regulation the information provided in the registration dossier shall be consistent with that in the Safety Data Sheet (SDS). The requirements of SDS are specified in Annex II of the REACH Regulation (amended by Commission Regulation (EU) No 453/2010).

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be indicated in the CSR. Annex II, section 8.2.2.2. (b)(i), requires the Registrant to describe the relevant RMM in detail (e.g. the type of gloves to be worn shall be clearly specified based on the hazard of the substance or mixture and potential for contact and with regard to the amount and duration of dermal exposure) in order to minimise the exposure for workers handling the registered substance. In particular, the following requirements for hand protection in order to avoid dermal exposure need to be provided consistently in the SDS and CSR:

- The type of material and its thickness,
- The typical or minimum breakthrough times of the glove material.

In the CSR, the Registrant indicated the following for hand protection: *Where required, protective gloves should conform to the standard EN374.* The Registrant also provided additional good practice advice in those cases where it was determined that the use of gloves was not required to generate the predicted quantitative estimates of exposure below the DNEL.

In section 11 of the technical registration dossier in the part for Exposure controls/personal protection, the following is stated:

Hand Protection: Any specific glove information provided is based on published literature and glove manufacturer data. Glove suitability and breakthrough time will differ depending on the specific use conditions. Contact the glove manufacturer for specific advice on glove selection and breakthrough times for your use conditions. Inspect and replace worn or damaged gloves. The types of gloves to be considered for this material include:
If prolonged or repeated contact is likely, chemical-resistant gloves are recommended. If contact with forearms is likely, wear gauntlet-style gloves. Nitrile, CEN standards EN 420 and EN 374 provide general requirements and lists of glove types.

To ensure the safe use of a substance it is essential to have detailed guidance on risk management measures, e.g. personal protective equipment. Although the gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance and the material type of gloves to be worn is specified, thickness and typical or minimum breakthrough time when handling the substance are not.

It is recognised that many exposure scenarios for the registered substance will result in exposure to a mixture of chemicals and the appropriate advice on the specific glove requirements for these undefined situations will be within the safety data sheets relating to product formulations. The selection of glove will be determined by the most relevant components of those mixtures and further specification of this information is not required within the CSR or section 11 of IUCLID.

Therefore, pursuant to Article 41(1)(c) and the typical or minimum breakthrough time for the glove type recommended. with regard to the amount and duration of dermal exposure.

Notes for consideration by the Registrant:

Regarding how to report the gloves specifications, the information should be included both in section 11 of the technical IUCLID dossier (Guidance on Safe Use) which is the disseminated part of the dossier and in the CSR where the appropriate measures to adequately control the risk are to be reported.

It is the responsibility of the Registrant to ensure consistency of the information within the CSR, and between the CSR, IUCLID section 11 and the safety data sheet.

2. Revision of the consumer exposure assessment and risk characterisations (Annex I, Sections 5 and 6) to take account of the activities of consumers and the duration and frequency of their exposure to the registered substance.

According to Annex I, Section 5.2.4 of the REACH Regulation the estimation of exposure shall take into account duration and frequency according to operational conditions. According to Annex I, Section 6.3 the risk characterization consists of a comparison of the exposure of each human population known to be or likely to be exposed with the appropriate DNEL.

ECHA notes that in his consumer exposure calculations, the Registrant has used a function within the exposure tool to average out exposure firstly over one day, and then over a year, in order to compare the resulting average "long-term systemic exposure" to a corresponding DNEL and achieve risk characterisation ratios below 1. However, as noted in the REACH Guidance on information requirements and chemical safety assessment, (ECHA (November 2012); Chapter R.8: Characterisation of dose [concentration]-response for human health, p.8): 'The actual daily dose is independent of the exposure frequency. This means that if for a certain scenario, worker or consumer exposure is for instance only for a number of days per year, the exposure value is the actual dose on the exposure days, and not the daily dose averaged out (and thus divided!) over the whole year.' Therefore, the long term exposure to be compared to the DNEL long term is not the exposure level calculated by averaging exposure events over the year, but the actual daily exposure. The annual averaging factor appears to have been used for a number of the exposure scenarios reported within the CSR.

The Registrant, in his comments submitted according to Article 51(1) of the REACH Regulation stated the consumer exposure assessment conducted for SBA was based on ECHA's Guidance on information requirements and chemical safety assessment chapter R15: consumer exposure estimate. Chapter R15 identifies the use frequency as one of the potential modifiers which can be applied to refine the exposure assessment according to p.7 of Oct 2012 version 2.1 Chapter R-15: consumer exposure estimation:

"It is to be noted that for products used infrequently, use frequency should not be used to average out exposure over a longer time period. In the first instance, exposure should be calculated for the actual duration of an event (event exposure) and then expressed as that concentration per day.
If the derived risk characterisation ratio (RCR) is lower than 1, the conclusion of the assessment is that there is no relevant risk even from the acute exposure. If the derived RCR is above 1, the assessment may be refined by using available data on event exposure, frequency, duration of exposure and other information to refine the exposure estimate. Only in situation where a substance is classified for its acute systemic toxicity, the derivation of an acute DNEL and the assessment of peak exposure would be required."

The Registrant further remarks that "*the comments received from ECHA appear to suggest that we should not average over the year for infrequent events (e.g. a few times per year). Rather, daily exposure values should be used to compare against the long term DNEL based on ECHA's guidance Chapter R8. Characterization of dose [concentration]- response for human health."*

Furthermore, the Registrant indicated a need for more general discussion between ECHA and industry around this issue and consequently requested ECHA to uphold the dossier evaluation procedure for this case.

In response, ECHA considers that its Guidance correctly and consistently reflects the REACH requirement that registrants have to assess consumer exposures realistically.

The Registrant has a proposed long-term DNEL (inhalation) for the general population of 52 mg/m^3. In the case of the proposed use of the registered substance in [redacted] (up to [redacted]% s-butanol), the predicted exposure over the duration of the task (6 hours), depending on selection of and modification to default model parameters (ECETOC and Consexpo), is more than two orders of magnitude above this level. Even though the use may be infrequent it does not appear reasonable to divide the value for task-based exposure first by 4 to provide exposure averaged over a day, and then again by 365 to average exposure over a year to compare with a long term DNEL.

The Decision requests a revision of the presentation of the exposure estimates so that it is more apparent what the predicted concentrations are during the actual period of the task. There is no specific request to generate an acute DNEL as this is usually produced to assess inhalation risks against exposures of less than 15 minutes for inhalation. In this case the exposure is for 6 hours.

ECHA guidance R.15.2.5. states:

"However, in practice, daily, weekly and monthly consumer exposures can be considered as repeated exposures and assessed against a chronic DNEL. This is due to the following considerations:

- *It would require substantial data about consumer behaviour to justify that the vast majority of consumers (say 90%) use a product so rarely and for such short time that assessment against an acute DNEL only would be justified.*
- *The establishment of an acute DNEL is cumbersome and resource-intensive. Usually it can be assumed that effects occurring after single short term exposure are prevented if the long-term DNEL is not exceeded (Chapter R.8)."*

ECHA Guidance R.8 states:

"Note that the repeated exposure resulting from a certain exposure scenario is to be expressed as the actual daily dose, bearing in mind that for workers a day is 8 hours, for human via the environment a day is 24 hours, and for consumers a day is 1-24 hours (depending on the scenario, e.g., type of consumer product). The actual daily dose is independent of the exposure frequency. This means that if for a certain scenario, worker or consumer exposure is for instance only for a number of days per year, the exposure value is the actual dose on the exposure days, and not the daily dose averaged out (and thus divided!) over the whole year."

Further it is also noted ECHA Guidance R.15 (p.9) provides an example that is closely analoguous to this case, but with a much shorter period of exposure and in this case for a single product type the comparison is with the chronic DNEL.

Peak exposures are normally defined as less than 15 minutes and the Registrant concern over an acute DNEL would relate to that situation if the substance was classified for acute effects.

The Registrant argument over acute exposure is incorrect and as quoted in ECHA Guidance R.8.1.2.5 *"For inhalation exposures for periods longer than 15 minutes, the long term DNEL should be used"*.

Hence ECHA confirms the need for the risk characterisation to be based on comparison with the chronic DNEL.

With reference to the Registrant's request to put on hold the decision-making of this case in order to allow for discussions, ECHA notes that the present decision sufficiently clearly explains the requirements. The overall timespan from the final decision (24 months) is adequate to address the consumer exposure issues. Any discussion on developing further the approaches to consumer exposure does not affect the decision-making, which is aimed to bring the registration in compliance with REACH requirements.

For the reasons indicated above, ECHA did not amend the information request on the basis of the Registrant's comments and ECHA did not suspend the decision-making.

Therefore pursuant to Article 14(4) and Annex I, Sections 5 and 6 of the REACH Regulation, the Registrant is requested to provide in the CSR revised exposure estimations, i.e. actual daily doses and risk characterisations for exposures to take account of the duration and frequency of exposure resulting from the registered substance within consumer products.

IV. Adequate identification of the composition of the tested material

In relation to the information required by Section II.B. of the present decision, the sample of substance used for 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/appeals/app_procedure_en.asp. 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