ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114309018-58-01/F Helsinki, 14 October 2015

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

**For benzyl alcohol, CAS No 100-51-6 (EC No 202-859-9), registration number: [redacted]**

[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 benzyl alcohol, CAS No 100-51-6 (EC No 202-859-9), 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 11 June 2015, 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 7 June 2013.

On 5 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 3 December 2013 ECHA received comments from the Registrant on the draft decision, concerning the information requirements of Annexes IX and X, Sections 8.4., 8.7.2. and 8.7.3., and Annex I, Sections 1.4.1., 5.2.2. and 5.2.4.

On 8 April 2014 the Registrant updated his registration dossier (submission number [redacted]).

The compliance check requirement to submit information of a two-generation reproductive toxicity study (EU B.35, OECD TG 416) or an extended one-generation reproductive toxicity study (EU B.56, OECD TG 443) has been removed from this draft decision due to the legislative amendments to the REACH Regulation regarding Annexes VIII, IX and X with the inclusion of the extended one-generation reproductive toxicity study (EOGRTS, EU B.56, OECD TG 443). In light of this, ECHA Secretariat did not consider further the Registrant's comments and update concerning the information requirement of Annex X, Section 8.7.3.

However, ECHA Secretariat did consider further the Registrant's comments and update concerning the information requirements of Annexes IX and X, Sections 8.4., 8.7.2. and Annex I, Sections 1.4.1., 5.2.2. and 5.2.4. On the basis of all this information and change of scope, Section II was amended. The Statement of Reasons (Section III) was changed accordingly.

On 11 June 2015 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 17 July 2015 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 27 July 2015 ECHA referred the draft decision to the Member State Committee.

By 17 August 2015, in accordance to Article 51(5), the Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 31 August 2015 in a written procedure launched on 20 August 2015.

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

## II. Information required

**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. Justification for the use of A and B Tables release factors in the exposure estimation of relevant exposure scenarios (Annex I, section 5.2.2.);
2. Documentation for the recommended personal protective equipment for handling the registered 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:
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.

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 **21 April 2016**.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

**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 (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. Justification for the use of A and B Tables release factors in the exposure estimation of relevant exposure scenarios (Annex I, section 5.2.2.)

Pursuant to sections 0.6.2. and 0.6.3. of Annex I of the REACH Regulation a chemical safety assessment performed by a Registrant shall include an exposure assessment in accordance to section 5 of Annex I. 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. Pursuant to the Annex I, section 5.2.1. of the REACH Regulation the exposure estimation entails three elements: emission estimation, assessment of chemical fate and pathways and estimation of exposure levels. Pursuant to the Annex I, section 5.2.2. of the REACH Regulation emission estimation shall be performed under the assumption that the risk management measures (RMMs) and operational conditions (OCs) described in the exposure scenario (ES) have been implemented. ECHA notes that these RMMs and OCs should be included in the ESs provided in a CSR.

According to the Guidance on information requirements and chemical safety assessment Chapter R.16: Environmental Exposure Estimation (Version 2.1, October 2012) the exposure scenario should contain adequate information (about operational conditions and risk management measures) based on which the assumed release factors and daily use rates can be justified. Exposure scenarios making reference to the A and B tables of the Technical Guidance Document (TGD, 2003), without providing more specific information on the conditions of use, are considered insufficient to meet the REACH requirements.

In the present case, the environmental exposure estimation for three industrial ESs (Pulp, Paper and Board industry, Photographic industry and Polymers industry) is based on release factors from A and B Tables (TGD, 2003). ECHA notes that a clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for the use of A and B Tables release factors in the exposure estimation is not provided in the CSR (e.g. which is the efficiency of RMMs reported in the ESs, whether or not A and B tables release factors used in the exposure estimation are reduced by those efficiencies).

ECHA observes that the Registrant included new information on release factors in the dossier update of 10 April 2014. ECHA underlines that according to Annex I, section 5.2.2., release factors and their justification shall reflect operational conditions (OCs) and risk management measures (RMMs) described in the ESs. ECHA considers that the justification for release factors should include as a minimum:

- overall background information, e.g. in which cases basic/raw data from surveys are used and/or an OECD Emission Scenario Document is quoted;

- if industry data is used, a description of the data collection and processing methods, as well as the method used for deriving release factors shall be included;
- if literature values are used, an assessment and comparison of OCs and RMMs recommended in the ESs and contained in the corresponding literature source shall be provided;
- if qualitative information is used, any additional information supporting the assumptions made in the justification of release factors shall be included.

ECHA points out that RMMs (taken into account in the exposure estimation) have to be clearly specified in each ES. These RMMs should contain information on the required or applicable RMMs efficiency and describe at least one example of a technology that can achieve this efficiency for the registered substance.

In the updated registration dossier, under relevant sections of the CSR, the Registrant provided a justification for the release factors used in the exposure estimation for above mentioned exposure scenarios. ECHA notes that provided description of the processes taking place within respective industry, which is used as the main argument to justify release factors, might be plausible.

ECHA considers that information on obligatory RMMs should be consistent with justification of release factors provided by the Registrant. However, ECHA notes that obligatory RMMs which would allow limiting emissions of the registered substance to the level of release factors used in the exposure estimation are not specified in the above mentioned ESs. Thus, ECHA concludes that obligatory RMMs, which have to be implemented by the downstream users of the substance and which are taken into account while justifying release factors, are missing from the ESs.

Furthermore, ECHA considers that the Registrant failed to explain the derivation method of release factors. It is not clear whether values of release factors reported in the CSR are derived from industry survey or based on literature data or justified by qualitative assessment etc.

ECHA concludes that the additional justification which the Registrant provided on release factors is not acceptable for the following reasons:
- information on conditions of use and RMMs included in these three ESs is not consistent with the justification of release factors used in the exposure estimation;
- the method used for deriving release factors is not detailed enough.

Based on the above, the Registrant is requested to provide, for each relevant ESs, clear and detailed justification (e.g. based on RMMs and/or OCs and/or substance properties) for the use of A and B Tables release factors in the exposure estimation and the missing information, as specified above. Alternatively, the Registrant shall apply the default release factors, recommended for the corresponding Environmental Release Categories (ERCs), in the exposure estimation of the relevant industrial ESs (Pulp, Paper and Board industry, Photographic industry and Polymers industry). The CSR shall be amended accordingly.

2. Documentation for the recommended personal protective equipment for 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
   - The type of material and its thickness, and
   - The typical or minimum breakthrough times of the glove material.

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.

According to Annex I, 0.3., 0.5. and 5.1.1. the applied Risk Management Measures (RMM) have to be described in the CSR. The CSR needs to contain sufficient information to allow ECHA to gain assurance that the risks are adequately controlled and that appropriate risk management measures can be prescribed by actors in the supply chain. Accordingly, the supplier is required to describe the relevant RMM in detail in the Safety Data Sheet (SDS) in order to minimise the exposure for workers handling the registered substance (e.g. the type of gloves to be worn, protection equipment for parts of the body other than the hand or respiratory protection 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 exposure in accordance with Annex II, section 8.2.2.2.(b)(i), (ii) and 8.2.2.2.(c) respectively). The information provided in the SDS shall be consistent with information in the CSR (Annex II, section 0.1.2. of the REACH Regulation).

ECHA notes that specific detailed information on the recommended personal protective equipment is missing both from the CSR and from the information on safe use within the IUCLID dossier. In the CSR, the Registrant indicated the following: "chemically resistant gloves conforming to EN374 with basic employee training", while in IUCLID Section 11 the following is reported:" Chemical resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. After contamination with product change the gloves immediately and dispose of them according to relevant national and local regulations. Recommended: (< 1 hour) Butyl rubber - IIR, Fluorinated rubber - FKM, Polyvinyl chloride - PVC".

To ensure the safe use of a substance, Annex I Section 5.1.1. requires a description of the risk management measures to reduce or avoid direct and indirect exposure of humans. Gloves are reported in the CSR and IUCLID Section 11 as required personal protective equipment to prevent dermal exposure to the substance. Generally, gloves that are capable of preventing exposure to the skin for a pre-determined duration shall be specified. Typically, this information, as a minimum, has to specify the glove material and, depending on the exposure scenarios, may also need to include the breakthrough time and thickness of the glove material.

ECHA observes that the Registrant included information on the glove material types and on the breakthrough time of butyl rubber gloves. Nevertheless, further characteristics are lacking for each of the three specified glove materials: (i) thickness and (ii) typical or minimum breakthrough time.

Information on the specification of personal protective equipment shall be provided for all scenarios where the use of personal protective equipment is advised.

Therefore, pursuant to Article 41(1)(c) the Registrant is required to provide in the CSR a description of the gloves to be used when handling the pure substance. The information provided by the Registrant shall be sufficiently detailed to allow suppliers to fulfil their obligations specified under Annex II for the compilation of the safety data sheets.

**Deadline for submitting the required information**

In the draft decision communicated to the Registrant the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a two-generation reproductive toxicity study (Annex X, 8.7.3.), a pre-natal developmental toxicity study, Annex X, 8.7.2.), a transgenic rodent somatic and germ cell gene mutation assays (Annex X, 8.4.) and requirements related to Annex I, Sections 1.4.1., and 5.2.4. As these requests are not addressed in the present decision, ECHA considers that a reasonable time period for providing the required information in the form of an updated IUCLID dossier is 6 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

IV. Adequate identification of the composition of the tested material

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

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given by the joint registrants. It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition.

In addition, it is important to ensure that the particular sample of substance tested in the new studies is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studies must be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/web/guest/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[1] by Leena Ylä-Mononen, Diretor of Evaluation

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.