EUROPEAN CHEMICALS AGENCY

Helsinki, 10 January 2020

**Addressees**
Registrants of [redacted] listed in the last Appendix of this decision

**Date of submission for the jointly submitted dossier subject of this decision**
15/05/2013

**Registered substance subject to this decision, hereafter 'the Substance'**
Substance name: Benzyl benzoate
EC number: 204-402-9
CAS number: 120-51-4

**Decision number:** [Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/D)]

## DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (REACH), ECHA requests that you submit the information listed below by the deadline of ***19 April 2021.***

### A. Requirements applicable to all the Registrants subject to Annex IX of REACH[1]

1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method OECD TG 210) with the Substance

### Conditions to comply with the requested information

Each addressee of this decision is bound by the requests for information corresponding to the REACH Annexes applicable to their own registered tonnage of the Substance at the time of evaluation of the jointly submitted dossier.

To identify your legal obligations, please refer to the following:

- you have to comply with the requirements of Annexes VII, VIII and IX of REACH, if you have registered a substance at 100-1000 tpa;

Appendix A states the reasons for the request for information to fulfil the requirements set out in Annex IX of REACH.

The test material used to perform the required studies must be selected and reported in accordance with the specifications prescribed in Appendix entitled Observations and technical guidance.

You must submit the information requested in this decision by the deadline indicated above in an updated registration dossier and also update the chemical safety report, where relevant, including any changes to classification and labelling, based on the newly generated information. The timeline has been set to allow for sequential testing where applicable.

[1] Testing required under this Annex can only be started or performed after the decision has been adopted according to Article 51.

## Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, has to be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under: http://echa.europa.eu/regulations/appeals.

Approved[2] under the authority of Christel Schilliger-Musset, Director of Hazard Assessment

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

**Appendix A: Reasons for the requests to comply with Annex IX of REACH**

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes or more per year must contain, as a minimum, the information specified in Annexes VII-IX to the REACH Regulation.

## 1. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1)

Long-term toxicity testing on fish is a standard information requirement in Annex IX to REACH.

You have provided an adaptation based on QSAR prediction.

We have assessed this information and identified the following deficiencies.

*A. Assessment of the provided adaptation*

Annex XI, Section 1.3. states that results obtained from valid QSAR models may be used instead of testing when the following cumulative conditions are met, in particular:

1. results are derived from a QSAR model whose scientific validity has been established;
2. the substance falls within the applicability domain of the QSAR model;
3. adequate and reliable documentation of the applied method is provided; and
4. the results are adequate for classification and labelling and/or risk assessment.

According to ECHA's Practical guide "How to use and report (Q)SARs", section 3.4, a QSAR Model Reporting Format (QMRF) and a QSAR Prediction Reporting Format (QPRF) are required to establish the scientific validity of the model, to verify that the Substance falls within the applicability domain of the model, and to assess the adequacy of the prediction for the purposes of classification and labelling.

You have provided a QSAR prediction for this endpoint, concluding on the chronic effect concentration for fish and considering this value for the hazard assessment, including PNECs derivation. In support to the QSAR prediction in the registration dossier you have provided document [redacted] which provides results of the predictions of aquatic toxicity with parametric limitations of the applied QSAR(s).

We have assessed this information and identified the following issue(s):

1. You have not provided sufficient documentation for the QSAR prediction. In particular, you have not included a QMRF and/or a QPRF in your technical dossier. All of the OECD principles for a QSAR model to be considered scientifically valid (see ECHA Guidance R.6, Section R.6.1.3, and ECHA's Practical guide "How to use and report (Q)SARs", section 3.1), apart from the defined endpoint, are not adressed in the provided document. Further, you have not evaluated the validity of the prediction in the dossier or in the document attached in the dossier. Nevertheless, as the model being used is ECOSAR, the validity of the model can be assessed without the QMRF since this information is readily available in the Help file of the model. Furthermore, as the QPRF is not available, ECHA has assessed whether the Substance falls within the applicability domain of the model, and whether the results are adequate for classification and labelling and/or risk assessment.
2. The scientific validity of the model has not been established, because it does not fulfil the OECD principles for a QSAR model to be considered scientifically valid (see ECHA Guidance R.6):
    - The number of data points and of substances in the training set of the Esters

model of ECOSAR used to establish regression equation is too limited (4 data points for 4 substances), so the fit of the regression cannot be considered acceptable.

3. The Substance does not fall within the applicability domain of the model (see ECHA Guidance R.6, Section R.6.1.5, and ECHA's Practical guide "How to use and report (Q)SARs", section 3.2):
    - The Substance is not covered by the structures of the substances in the training set of the model. Even though there is one substance (CAS 85-68-7) in the training set which incorporates the structure of the Substance, that substance, however, is different because it also has two ester functional groups and an additional aliphatic chain attached to one of the benzene rings.

Thus, the results obtained from the QSAR model are not adequate to be used for classification and labelling and/or risk assessment. Consequently, the adaptation you provided does not fulfil the criteria specified in Annex XI, Section 1.3. and it is therefore rejected.

*B. Trigger for the new long-term fish toxicity study*

Annex I, Section 3.3.1. of the REACH Regulation requires to establish a PNEC (Predicted No-Effect Concentration) for each environmental sphere based on the available information and to apply an appropriate assessment factor to the effect values.

The ECHA Guidance R.10 provides further details and specifically provides default assessment factors that should be applied to derive PNECs.

Furthermore, according to Annex I, Section 6.4. of the REACH Regulation for any exposure scenario the risk to the environment can be considered to be adequately controlled if the exposure levels estimated do not exceed the appropriate PNEC.

In summary, the Chemical Safety Assessment (CSA) needs to assess and document that risks arising from the Substance are controlled and demonstrate that there is no need to conduct further testing (Annex I, Section 0.1; Annex IX, Section 9.1, Column 2).

For the derivation of PNECs for fresh and marine waters (these PNECs were furher used to derive PNECs for freshwater and marine sediments, and PNEC for freshwater was used to derive PNEC for soil) you have considered that information on long-term toxicity to fish is available for the Substance.

As noted above (section A), the information provided on long-term toxicity to fish is not adequate. Hence your dossier currently does not include adequate information to characterize the hazard property of the Substance. Therefore the information on the long-term toxicity to fish cannot be used for the derivation of PNECs for fresh and marine waters. Consequently, the risk characterisation for the environmental compartments based on revised PNECs by ECHA for fresh and marine waters (considering that no information on the long-term fish toxicity is available and following ECHA Guidance R.10) would indicate a risk, i.e. for some exposure scenarios, predicted environmental concentration in environmental compartments reported in the Chemical Safety Report (CSR) would exceed respective revised PNECs (e.g. for fresh/marine waters/sediments and soil compartments for Exposure Scenario - Industrial use of washing and cleaning products). Thus, for these exposure scenarios the risk of the Substance to the environment is not adequately controlled and consequently, the Chemical Safety Assessment indicates the need to investigate further the effects on aquatic organisms. Consequently, there is a data gap that needs to be filled in.

## Appendix B: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of registration dossiers after the date on which you were notified the draft decision according to Article 50(1) of the REACH Regulation.

The compliance check was initiated on 14 January 2019.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments within 30 days of the notification.

ECHA received only a comment from one of the addressees of the draft decision within the 30 days. This comment was not relevant to the content of the decision.This comment has therefore been addressed in a communication sent directly to the registrant concerned.

ECHA notified the draft decision to the competent authorities of the Member States for proposals for amendment.

ECHA received proposals for amendment and did not modify the draft decision.

ECHA invited you to comment on the proposed amendments and referred the modified draft decision to the Member State Committee.

Your comments on the proposed amendment(s) were taken into account by the Member State Committee.

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-67 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

**Appendix C: Observations and technical guidance**

1. This compliance check decision does not prevent ECHA from initiating further compliance checks at a later stage on the registrations present.

2. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of the Member States.

3. Test guidelines, GLP requirements and reporting

   Under Article 13(3) of REACH, all new data generated as a result of this decision needs to be conducted according to the test methods laid down in a European Commission Regulation or according to international test methods recognised by the Commission or ECHA as being appropriate.

   Under Article 13(4) of REACH ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.

   Under Article 10 (a) (vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide: 'How to report robust study summaries3'.

4. Test material
   Selection of the test material(s)

   The registrants of the Substance are responsible for agreeing on the composition of the test material to be selected for carrying out the tests required by the present decision. The test material selected must be relevant for all the registrants of the Substance, i.e. it takes into account the variation in compositions reported by all members of the joint submission. The composition of the test material(s) must fall within the boundary composition(s) of the Substance.

   While selecting the test material you must take into account the impact of each constituent/impurity is known to have or could have on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected test material must contain that constituent/ impurity.

   Technical reporting of the test material

   The composition of the selected test material must be reported in the respective endpoint study record, under the Test material section. The composition must include all constituents of the test material and their concentration values. Without such detailed reporting, ECHA may not be able to confirm that the test material is relevant for the Substance and to all the registrants of the Substance.

   Technical instructions are available in the manual "How to prepare registration and PPORD dossiers"[3].

5. List of references of the ECHA Guidance documents[4]

[3] https://echa.europa.eu/practical-guides
[4] https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Evaluation of available information
Guidance on information requirements and chemical safety assessment, Chapter R.4 (version 1.1., December 2011), referred to as ECHA Guidance R.4 in this decision.

QSARs, read-across and grouping
Guidance on information requirements and chemical safety assessment, Chapter R.6 (version 1.0, May 2008), referred to as ECHA Guidance R.6 in this decision.

ECHA Read-across assessment framework (RAAF, March 2017)[5]

Physical-chemical properties
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Toxicology
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

Environmental toxicology and fate
Guidance on information requirements and chemical safety assessment, Chapter R.7a (version 6.0, July 2017), referred to as ECHA Guidance R.7a in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7b (version 4.0, June 2017), referred to as ECHA Guidance R.7b in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.7c (version 3.0, June 2017), referred to as ECHA Guidance R.7c in this decision.

PBT assessment
Guidance on information requirements and chemical safety assessment, Chapter R.11 (version 3.0, June 2017), referred to as ECHA Guidance R.11 in this decision.

Guidance on information requirements and chemical safety assessment, Chapter R.16 (version 3.0, February 2016), referred to as ECHA Guidance R.16 in this decision.

[5] https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

**Appendix D: List of the registrants to which the decision is addressed and the corresponding information requirements applicable to them**

| Registrant Name | Registration number | (Highest) Data requirements to be fufilled |
|---|---|---|
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |
| [redacted] | [redacted] | [redacted] |