EUROPEAN CHEMICALS AGENCY

Helsinki, 25 April 2018

Addressee: [redacted]

Decision number: CCH-D-2114407649-42-01/F
Substance name: Triisobutyl phosphate
EC number: 204-798-3
CAS number: 126-71-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 15/02/2013
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the REACH Regulation), ECHA requests you to submit information on:[1]

1. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2; test method: EU B.31./OECD TG 414) in a second species (rabbit), oral route with the registered substance;**

2. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;**

3. **Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Alga, growth inhibition test, EU C.3./OECD TG 201) with the registered substance;**

4. **Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.; test method: Fish, acute toxicity test, EU C.1./OECD TG 203) with the registered substance;**

5. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous exposure, OECD TG 305-I) with the registered substance;**

6. **Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment, as specified in Appendix 1, section 6.**

You 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 to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.

[1] No testing for endpoints listed in Annexes IX or X to the REACH Regulation may be started or performed at this moment: A decision only becomes legally effective and binding for you after it has been adopted according to Article 51 of the REACH Regulation. ECHA will take the decision either after the date it has become clear that Member State competent authorities have not made any proposals to amend the draft decision or, where proposals to amend it have been made, after the date the Member State Committee reached a unanimous agreement on the draft decision.

You have to submit the requested information in an updated registration dossier by **2 May 2019**. You also have to update the chemical safety report, where relevant.

The reasons of this decision are set out in Appendix 1. The procedural history is described in Appendix 2 and advice and further observations are provided in Appendix 3.

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.

Authorised[2] by Kevin Pollard, Head of Unit, Evaluation E1

[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 1: Reasons

1. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2., column 2) in a second species

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "pre-natal developmental toxicity study" (test method EU B.31./OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Annex IX, Section 8.7.2., column 2 provides that the decision on the need to perform a pre-natal developmental toxicity study on a second species at a tonnage level of 100 to 1000 tonnes per year should be based on the outcome of the first test and all other relevant and available data. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet these information requirements.

The technical dossier contains a pre-natal developmental toxicity study with rats by the oral route. This study fulfils the standard information requirement for a pre-natal developmental toxicity study in a first species (Annex IX, Section 8.7.2.). The study resulted in an "*overall incidence of malformed foetuses*" of "*2, 2, 3 and 8 in [dose] Groups 1 to 4 respectively. At 1000 mg/kg/day the increased incidence of malformations was primarily due to six foetuses with bilateral forelimb flexure (associated with distorted rib cage and thickened ribs in five of the six), however, this occurrence was confined to only two litters.*" In your interpretation of the results you explain that "*This syndrome tends to occur in clusters, i .e . more than one foetus in a litter is usually affected. The aetiology is unknown but the fact that, according to historical background data, similar defects occur randomly in control and negative test groups suggests a spontaneous event.*"

ECHA observes that no data on valid historical control groups has been included in the robust study summary to demonstrate the validity of this claim. In the absence of proof that this malformation is common in control animals of the same species and strain, and under similar conditions, ECHA does not agree with the interpretation. ECHA further observes that the incidence of bilateral forelimb flexure occurred in two separate litters of the top-dose, which makes a spontaneuous and non-treatment related aetiology less likely than if the finding had occurred in one litter, or in a second litter in another dose group.

Furthermore, you report "*At 1000 mg/kg/day, following initiation of treatment there was a slightly retarded bodyweight gain to Day 8 of pregnancy. Weight gain then paralleled that of controls until the end of the dosing period, after which parity with controls was regained by termination.*" ECHA considers that the slight and temporary retardation of body weight gain, and other findings (post-dosing salivation and wet fur), do not constitute maternal toxicity which could explain the observed developmental toxicity and/or allow to conclude that the developmental toxicity is a secondary non-specific consequence of the other toxic effects.

The observed developmental toxicity, in particular the bilateral forelimb flexure associated with distorted rib cage and thickened ribs, presents a concern which needs to be clarified by a pre-natal developmental toxicity study in a second species, as stipulated by the REACH Regulation, Annex IX, Section 8.7.2, column 2 (see also ECHA Guidance on information requirements and chemical safety assessment Chapter R.7a, Section R.7.6.2.3.2 (version 6.0, July 2017)).

As explained above, the information provided 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 with rats. According to the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit is the preferred non-rodent species. On the basis of this default assumption, ECHA considers that the test should be performed with rabbit as a second species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are 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 TG 414) in a second species (rabbit) by the oral route.

Notes for your consideration

ECHA notes that a revised version of OECD TG 414 may be adopted later on this year by the OECD. This revised version contains enhancements of certain endocrine disrupting relevant parameters. After the adoption of the revised version of the OECD TG 408 you should test in accordance with that version of the guideline as published on the OECD website for adopted test guidelines (https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-4-health-effects_20745788.

Even if you start testing before the guideline is published, it is appropriate to consider including these endocrine-sensitive parameters in your testing protocol in accordance with the proposed revised version of the draft guideline (see http://www.oecd.org/env/ehs/testing/section4-health-effects.htm).

2. Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Short-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex VII, Section 9.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for the key study (title of reference: "[redacted]"; static design of the test; no information on analytical monitoring of the test material is available). However, this study does not provide the information required by Annex VII, Section 9.1.1., because it is not adequate, as explained in the following.

ECHA observes that the effect levels for the key study reported in the dossier are estimated on the basis of nominal concentrations of the test material. At the same time, based on available information on the properties of the substance reported in the registration dossier, you concluded that the substance is surface active. As noted in the ECHA *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b* (version 4.0, June 2017) surface active substances can be lost from the aquatic test system. Consequently, ECHA considers that the substance has potential for being lost from the test system during aquatic toxicity testing. Thus, in order to gather adequate results for the purpose of classification/labelling and risk assessment, analytical verification of exposure concentrations of the substance is necessary for the aquatic toxicity testing, especially for the static test design. However, as noted above there is no information on analytical monitoring of the test material in the study available to you. Furthermore, possible influence of vehicle used in the test is not explained/reported in the registration dossier, as well as fulfilment of validity criteria is not confirmed. Therefore, ECHA considers that the results of the study reported in the registration dossier are not adequate for the purpose of classification/labelling and risk assessment, as required by section 1.1.2. of Annex IX and Annex I, section 3 to the REACH Regulation.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Daphnia sp. acute immobilisation test (test method EU C.2. / OECD TG 202) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.1.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *Daphnia* sp. Acute immobilisation test, EU C.2./OECD TG 202).

Notes for your consideration

Due to the surface active nature of the substance you should consult OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA *Guidance on information requirements and chemical safety assessment, Chapter R7b* (version 4.0, June 2017), Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity tests and for calculation and expression of the result of the tests.

3. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Growth inhibition study aquatic plants" is a standard information requirement as laid down in Annex VII, Section 9.1.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for the key study (title of reference: "[redacted]"; static design of the test; no information on analytical monitoring of the test material is available). However, this study does not provide the information required by Annex VII, Section 9.1.2., because it is not adequate as explained in the following.

ECHA observes that the effect levels for the key study reported in the dossier are estimated on the basis of nominal concentrations. Based on available information on the properties of the substance reported in the registration dossier you concluded that the substance is surface active. As noted in the ECHA *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b* (version 4.0, June 2017) the surface active substances can be lost from the aquatic test system. Consequently, ECHA considers that the substance has potential for being lost from the test system during aquatic toxicity testing. Thus, in order to gather adequate results for the purpose of classification/labelling and risk assessment, analytical verification of exposure concentrations of the substance is necessary for the aquatic toxicity testing, especially for the static test design. However, as noted above there is no information on analytical monitoring of the test material in the study available to you. Furthermore, possible influence of vehicle used in the test is not explained/reported in the registration dossier, as well as fulfilment of validity criteria is not confirmed. Therefore, ECHA considers that the results of the study reported in the registration dossier are not adequate for the purpose of classification/labelling and risk assessment, as required by Annex IX, Section 1.1.2. and Annex I, Section 3 to the REACH Regulation.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.
According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Algae growth inhibition test, EU C.3./OECD TG 201).

4. Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Short-term toxicity testing on fish" is a standard information requirement as laid down in Annex VIII, Section 9.1.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study records for two experimental studies of short-term toxicity for fish (titles of reference: "[redacted] and "[redacted]"; static design was applied for both reported studies; no information on analytical monitoring of the test material is available for both reported studies). However, those studies do not provide the information required by Annex VIII, Section 9.1.3., because they are not adequate as explained in the following.

ECHA observes that the effect levels for both studies reported in the dossier are estimated on the basis of nominal concentrations. Based on available information on the properties of the substance reported in the registration dossier you concluded that the substance is surface active. As noted in the ECHA *Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7b* (version 4.0, June 2017) the surface active substances can be lost from the aquatic test system. Consequently, ECHA considers that the substance has potential for being lost from the test system during aquatic toxicity testing. Thus, in order to gather adequate results for the purpose of classification/labelling and risk assessment, analytical verification of exposure concentrations of the substance is necessary for the aquatic toxicity testing, especially for the static test design. However, as noted above there is no information on analytical monitoring of the test material in the studies available to you. Furthermore, fulfilment of validity criteria is not confirmed in neither of studies. In addition, ECHA notes that the duration of the first of two reported studies is 48 hours only, while the results of fish toxicity study of, at least, 96 hours is used for the purpose of classification/labelling and risk assessment. Therefore, ECHA considers that the results of the studies reported in the registration dossier are not adequate for the purpose of classification/labelling and risk assessment, as required by Annex IX, Section 1.1.2. and Annex I, Section 3 to the REACH Regulation.

As explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) fish acute toxicity test (test method EU C.1. / OECD TG 203) is the preferred test to cover the standard information requirement of Annex VIII, Section 9.1.3.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you agreed to the request.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Fish, acute toxicity test (test method: EU C.1./OECD TG 203).

5. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

"Bioaccumulation in aquatic species, preferably fish" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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.

You have sought to adapt this information requirement. You provided the following justification for the adaptation: "*Based on GHS criteria, significant accumulation of triisobutyl phosphate in organisms is not to be expected (log Pow < 4).*" While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement according to Annex IX, Section 9.3.2., column 2.

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.3.2., column 2. First, ECHA notes that according to column 2 of section 9.3.2. of Annex IX of the REACH Regulation, the study on bioaccumulation in aquatic species need not be conducted only, if the substance has a low potential for bioaccumulation (for instance a log Kow <= 3) and/or a low potential to cross biological membranes. According to ECHA's *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) for surface active substances "*the classification of the bioconcentration potential based on hydrophobicity measures (such as log Kow) should be used with caution. [...] Measured BCF values are preferred.*" Thus, ECHA notes that the octanol-water partition coefficient value reported in the registration dossier is above 3 (i.e. 3.7) and that the prediction of bioaccumulation potential from this value for the substance in not considered reliable. Therefore, your adaptation of the information requirement cannot be accepted.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you have provided information on the bioaccumulation of the substance based on the QSAR (qualitative/quantitative structure-activity relationship) predictions using BCFBAF v3.01 model (from EPI Suite v4.11) and BCF base-line model v.02.09 (from Catalogic 5.11.19 platform version).

ECHA notes that the provided predictions are well documented and migh be plausible for the assessment of bioaccumulation of the substance. However, ECHA notes that this information is not currently available in the registration dossier.

Furthermore, ECHA's *Guidance on information requirements and chemical safety assessment, Chapter R.6* (May 2008) notes that "*in practice, there may be uncertainty in one or more of these aspects, but this does not preclude the use of the (Q)SAR estimate in the context of a Weight of Evidence approach, in which additional information compensates for uncertainties resulting from a lack of information on the (Q)SAR*". As noted above, prediction of the "*bioconcentration potential based on hydrophobicity measures*" should be used with caution for surface active substances. ECHA notes that provided QSAR estimations of bioconcentration factor are based on "*hydrophobicity measures*" of the substance.

Therefore, you should explain how surface active properties were considered when estimating bioconcentration factor from models based on log Kow as well as further lines of evidence (e.g. experimental information on bioaccumulation available for similar to the registered substances etc.) should be considered and reported in the registration dossier to support provided QSAR estimations.

Thus, as explained above, the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7c* (version 3.0, June 2017) bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision Bioaccumulation in fish: aqueous exposure bioconcentration fish test (test method: OECD TG 305-I).

6. Exposure assessment and risk characterisation (Annex I, Sections 5. and 6.) for environment

In accordance with Articles 10(b) and 14(1) of the REACH Regulation, the registration must contain a chemical safety report (CSR) which documents the chemical safety assessment (CSA) conducted in accordance with Article 14(2) to (7) and with Annex I to the REACH Regulation.

Annex I, Section 5 of the REACH Regulation requires the Registrant to generate exposure scenarios and exposure estimations for the registered substance. The exposure assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the identified hazards.

Annex I, Section 6 of the REACH Regulation requires you to characterise the risk for each exposure scenario and to consider the human population (exposed as workers, consumer or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is known or reasonable foreseeable, under the assumption that the risk management measures described under exposure scenario in Section 5 of the same Annex have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for the overall releases, emissions and losses from all sources to all environmental compartments.

In the CSR you provided, the exposure assessment for the environment is missing. You claimed that no exposure assessment is necessary for the environment by stating that "*as no environmental hazard was identified no environmental-related exposure assessment and risk characterization was performed*".

ECHA notes that you have self-classified substance for human health as Skin Sens. 1B according to the CLP Regulation. Therefore, according to Article 14(4) and Annex I, section 0.6, as the substance meets the criteria for classification the CSA shall include two additional steps, meaning that Exposure assessment and Risk characterisation is required.

With regard to the scope of the required exposure assessment, as stated above and in accordance with Annex I, section 5.0., it has to cover all hazards that have been identified according to sections 1 to 4 of Annex I of REACH Regulation. ECHA's *Guidance on information requirements and chemical safety assessment*, Part B: Hazard Assessment, Section B.8.4. (pages 47 to 48) (version 2.1, December 2011) states that "*if no adverse effects have been observed in studies at the highest recommended concentration/doses tested, this would normally indicate that no hazard has been identified and no DNEL or PNEC can be derived and hence exposure assessment for that route of exposure, type of effect or protection target would not be needed*".

ECHA notes that adverse effects were observed in some of the environmental toxicity studies. In particular, *e.g.* in the short-term toxicity studies to aquatic invertebrates an EC50 of 11 mg/L was obtained and you concluded in the registration dossier that "*triisobutyl phosphate is considered to be acutely harmful to aquatic organisms. Effects of triisobutyl phosphate towards fish and algae were found in the same range providing a LC50 (96h) between 17.8 and 21.5 mg/L for fish and an EC50 (72h) of 34.1 mg/L for algae*". Furthermore, inhibition of microorganisms activity by the substance at concentrations below 1000 mg/l is reported in the registration dossier (e.g. 30 min EC50 of 443 mg/l). This indicates that the quantitative exposure assessment, *i.e.* derivation of predicted environmental concentrations (PECs), and risk characterisation, i.e. comparison of PECs with respective predicted no-effect concentrations (PNECs), is mandatory for the water, sediment and soil environmental compartments as well as for sewage treatment systems/plants (STPs).

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you agreed to the request.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to generate quantitative exposure assessment for the water, sediment and soil environmental compartments as well as for STPs and revise the risk characterisation accordingly.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 24 July 2017.

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.

In your comments you agreed to perform requested aquatic toxicity tests and requested exposure assessment and risk characterisation for environment if relevant hazards are identified. ECHA took your comments into account and did not amend these requests.

ECHA took into account your comment on requested bioaccumulation study and did not amend the request.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

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 your Member State.

3. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported 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 the substance tested in the new tests 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 or imported by each registrant.

If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.