ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 18 June 2018

Addressee: [redacted]

Decision number: CCH-D-2114408322-63-01/F
Substance name: Heptanal, 2-(phenylmethylene)-, (2E)-
EC number: 800-696-3
CAS number: 78605-96-6
Registration number: [redacted]
Submission number: [redacted]
Submission date: 31/10/2017
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. **Spectral data (Annex VI, Section 2.3.5.);**
   - **Nuclear magnetic resonance or mass spectrum**
   - **Infra-red spectrum**
   - **Ultra-violet spectrum**
2. ***In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or OECD TG 490) with the registered substance;**
3. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**
4. **Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: Daphnia magna reproduction test, EU C.20./OECD TG 211) with the registered substance;**
5. **Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD TG 210) with the registered substance;**

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.

You have to submit the requested information in an updated registration dossier by **25 June 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[1] by **Claudio Carlon**, Head of Unit, Evaluation **E2**

[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.

Appendix 1: Reasons

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.

1. Spectral data (Annex VI, Section 2.3.5.)

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

"Spectral data" are a formal 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 to confirm the composition of the substance and thus its identity.

The registration dossier does not contain full set of analytical data for the registered substance. No Ultra-violet spectrum (UV), Infra-red (IR) spectrum, nuclear magnetic resonance (NMR) spectrum (or alternatively to this last one, Mass spectrum (MS)), as required under Annex VI Section 2.3.5 of the REACH Regulation have been submitted. Moreover, a scientifically based justification for not including this information has not been included.

ECHA regards this required information scientifically necessary for the identification of the registered substance. In particular, without such information, the E configuration of the substance cannot be verified. The configuration cannot be verified by the provided gas chromatography either, due to the lack of standards.

Therefore, you are requested to submit UV, IR and NMR (or, alternatively to this last one, MS) spectra generated on the substance subject to the present decision. A full interpretation of the spectra, including peak assignment, should be provided in order to confirm the structure of the substance. In addition, the description of the analytical methods used for recording the spectra needs to be provided in the dossier in line with the requirements under Annex VI Section 2.3.7 of the REACH Regulation. The description of the methods shall be in such detail to allow the methods to be reproduced. You shall ensure that the information is consistent with the information provided throughout the dossier.

In your comments to the draft decision, you have expressed your agreement to this request.

Regarding how to report the spectral data, the information shall be attached in section 1.4 of the IUCLID dossier.

2. In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.)

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.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained.

In the technical dossier you have provided a study record for "*The possible role of a,ß-unsaturated carbonyl compounds in mutagenesis and carcinogenesis*" ([redacted] 1993). This publication includes various assessments of genotoxicity ([redacted] 1993), no test guideline and GLP followed, with an assigned reliability score of 2. One of the test materials tested in this study is the registered substance. You reported that one of the assays conducted in this study (publication) was an alkaline elution assay to detect single strand breaks using mouse leukaemia cells (L1210 cells). However, this study does not provide the information required by Annex VIII, Section 8.4.3. As already discussed under Appendix I, Sections 2 and 3 of this decision, the information in this study record does not provide adequate and reliable documentation.

Hence, the information in the technical dossier for this endpoint cannot be used to fulfil the standard information requirement of Annex VIII, Section 8.4.3 since the adaptation of Annex XI, Section 1.1.2.(4) is not met.

Therefore, your adaptation of the information requirement is rejected.

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.

ECHA considers that the *in vitro* mammalian cell gene mutation tests using the *Hprt* and *xprt* genes (OECD TG 476) and the *in vitro* mammalian cell gene mutation tests using the thymidine kinase gene (OECD TG 490) are appropriate to address the standard information requirement of Annex VIII, Section 8.4.3.

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: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476 *or* OECD TG 490).

In your comments on the draft decision you indicate that you plan to fulfil this information requirement by using a GLP-compliant mouse lymphoma assay conducted according to OECD TG 476 with the source substance hexyl cinnamic aldehyde (EC 639-566-4). ECHA considers that the read-across from hexyl cinnamic aldehyde is acceptable. However, as you did not provide any study record that fulfils the standard information requirement according to Annex VIII, Section 8.4.3. ECHA still considers that currently there is an information data gap.

ECHA reminds you that this decision does not take into account any updates submitted after 31 October 2017. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation (after ECHA has sent the final decision).

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3. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first 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. 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 according to Annex XI, Section 1.5. of the REACH Regulation by providing a study record for a Pre-Natal (Segment II) Toxicity Study in the Sprague-Dawley Rats, oral (gavage) route (no test guideline followed; non-GLP) with the analogue substance(s) cinnamic aldehyde (CAS no. 104-55-2).

You use the following arguments to support the prediction of properties of the registered substance from data for the source substance: similarity in the chemical structure, physico-chemical and toxicologcal properties as well as similar toxicokinetic behaviour. As an integral part of this prediction, you propose that the source and registered substances have similar properties for the above-mentioned information requirements. ECHA considers that this information is your read-across hypothesis.

Your proposed adaptation argument is that the similarity in chemical structure and in some of the physico-chemical and toxicological properties and toxicokinetics behaviour between the source and registered substance is a sufficient basis for predicting the properties of the registered substance for other endpoints. Structural similarity is a prerequisite for applying the grouping and read-across approach. However, similarity in chemical structure and similarity of some of the physico-chemical/ toxicological properties does not necessarily lead to predictable or similar human health properties in other endpoints. Your justification based on structural similarity, similar physico-chemical, toxicological properties and toxicokinetics has not established why the prediction is reliable for the pre-natal developmental toxicity endpoint for which the read across is claimed.

Specifically, ECHA notes that the source substance cinnamic aldehyde differs in important physicochemical properties such as Log Kow (2.22 vs 4.7 for the target) and water solubility (soluble 1400 mg/L vs 4 mg/L for the target). ECHA notes that you failed to explain how the differences in these properties could affect the prediction. The repeated dose toxicity data shows a NOAEL of ~30 mg/kg bw/day (oral subchronic) for the target substance and 540 mg/kg bw/day(2-y study) for the source substance. These data are suggestive for differences in toxicity for the source substance compared to the target. Indications for a difference in the toxicological potencies was also noted for the reproductive toxicity endpoint.

Based on the above, ECHA concludes that the evidence presented in the provided justification and in the data matrix does not support a similar or regular pattern of toxicity as a result of structural similarity. Therefore it cannot be verified that the proposed group/analogue substances can be used to predict properties of the registered substance.

Additionally, ECHA has taken into account all of your arguments together. ECHA firstly notes that you have not provided a reasoning as to why these arguments add to one another to provide sufficient basis for read-across. Secondly, the defects of each individual argument are not mitigated by the other arguments you have provided, and so ECHA considers that the arguments when taken all together do not provide a reliable basis for predicting the properties of the registered substance.

Therefore, ECHA considers that this grouping and read-across approach does not provide a reliable basis whereby the human health effects of the registered substance may be predicted from data for reference substance(s) within the group. Hence, this approach does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5. of the REACH Regulation.

Additionally, ECHA notes that some deficiencies have been identified in the study provided with the source substance, such as a short exposure duration (gestation days 7 to 17) and an insufficient number of pregnant females tested (14 to 16 pregnant females). ECHA notes that the maternal exposure should at least last from implantation to one or two days before the expected delivery of both rodent species. In addition, according to OECD TG 414, each tested group "*should contain a sufficient number of females to result in approximately 20 female animals with implantation sites at necropsy. Groups with fewer than 16 animals with implantation sites may be inappropriate*."

Consequently, the study fails to meet the second and third conditions set out in Annex XI, Section 1.1.2., since it does not provide adequate and reliable coverage of key parameters foreseen to be investigated in the corresponding OECD test guideline 414 and the exposure duration is shorter than the one in the corresponding test method referred to in Article 13(3).

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 the test method EU B.31./OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first 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 first species (rat or rabbit) by the oral route.

In your comments on the draft decision you provided a new read-across approach. ECHA notes that the source substance cinnamic aldehyde (CAS no. 104-55-2), which was originally proposed as the source substance to be used for this particular endpoint, is no longer proposed. In your comments you have agreed to perform a pre-natal developmental study (OECD 414) in the rat with the registered substance. However, you also indicated that

you will investigate whether there is an available study with the read-across substance hexyl cinnamic aldehyde prior to commissioning any study with the registered substance.

ECHA reminds you that all the new information in the later update(s) of the registration dossier will be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation (after ECHA had sent the final decision).

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 414 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).

4. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.)

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.

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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 according to Annex IX, Section 9.1.5., column 2. You provided the following justification for the adaptation:
"In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently, in accordance with Column 2 of REACH Annex IX, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment. Further to this the substance is also known to be readily biodegradable and so no long term persistence in the environment is foreseen."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.5., column 2 nor of Annex I because of the following reasons:

1. In the technical dossier you have provided a study record for a Daphnia acute immobilisation test ([redacted], 1992, OECD 202). However, this study does not provide the information required by Annex VII, Section 9.1.1., because the concentration of test material dropped during the 48-hours of the study and the results are expressed

in terms of nominal concentrations. Expressing the EC50 in terms of nominal concentrations could underestimate the toxicity. Therefore, ECHA considers the results of this study as not reliable.

2. As the results of this study were used to determine the PNEC and some RCRs are around [redacted], there might be a concern with hazard identification as provided by you in your chemical safety assessment.
3. Furthermore, the water solubility of the registered substance is reported to be between 0,5 – 4 mg/L. Therefore, according to REACH Annex VII, Section 9.1.1, column 2, long-term aquatic toxicity study on Daphnia (Annex IX, section 9.1.5) shall be considered because the substance is poorly water soluble.

Therefore, your adaptation of the information requirement cannot be accepted.

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 magna* reproduction test (test method EU C.20. / OECD TG 211) is the preferred test to cover the standard information requirement of Annex IX, Section 9.1.5.

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 magna reproduction test (test method: EU C.20./OECD TG 211).

In your comments to the draft decision you stated that you plan to fill this information requirement by reading across to a GLP-compliant OECD 221 study on an analogue substance hexylcinnamic aldehyde. ECHA considers that read-across from the source substance hexyl cinnamic aldehyde to the registered target substance amyl cinnamic aldehyde is acceptable. However, ECHA notes that you did not provide the mentioned study (OECD guideline 221) on the source substance hexyl cinnamic aldehyde in your comments. Hence, currently ECHA considers that there is still an information gap.

ECHA reminds you that all the new information in the later update(s) of the registration dossier will be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation (after ECHA had sent the final decision).

Notes for your consideration

Once results of the test on long-term toxicity to aquatic invertebrates are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

Due to the low solubility of the substance in water 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* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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

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.

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) 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 according to Annex IX, Section 9.1.6., column 2 and Annex I. You provided the following justification for the adaptation: *"In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) exposure estimation is not necessary. Consequently, in accordance with Column 2 of REACH Annex IX, the study does not need to be conducted as all identified uses of the substance are assessed as safe for the environment. Further to this the substance is also known to be readily biodegradable and so no long term persistence in the environment is foreseen."*

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Annex IX, Section 9.1.6., column 2 or Annex I because of the following reasons:

1. In the technical dossier you have provided a study record for a EU Method C.1 (Acute Toxicity for Fish) ([redacted], 1993). However, this study does not provide the information required by Annex VIII, Section 9.1.3., because the concentration of the test material was not monitored. Both of the studies on short-term acute toxicity to Daphnia and algal growth tests have shown considerable loss of test material over 48 and 72 hours respectively. Therefore, it is likely that after 24 hours in this semi-static exposure acute fish test there will also have been losses. Expressing the EC50 in terms of nominal concentrations could underestimate the toxicity. Therefore, ECHA considers the results of this study as not reliable.
2. Therefore, it is not possible to conclude that the chemical safety assessment does not indicate a need to further investigate the effects on aquatic organisms.
3. Furthermore, the water solubility of the registered substance is reported to be between 0,5 – 4 mg/L. Therefore, according to REACH Annex VIII, Section 9.1.3, column 2, long-term aquatic toxicity study on fish (Annex IX, section 9.1.6) shall be considered because the substance is poorly water soluble.

Therefore, your adaptation of the information requirement cannot be accepted.

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 early-life stage (FELS) toxicity test (test method OECD TG 210), fish short-term toxicity test on embryo and sac-fry stages (test method EU C.15. / OECD TG 212) and fish juvenile growth test (test method EU C.14. / OECD TG 215)

are the preferred tests to cover the standard information requirement of Annex IX, Section 9.1.6.

However, the FELS toxicity test according to OECD TG 210 is more sensitive than the fish, short-term toxicity test on embryo and sac-fry stages (test method EU C.15 / OECD TG 212), or the fish, juvenile growth test (test method EU C.14. / OECD TG 215), as it covers several life stages of the fish from the newly fertilized egg, through hatch to early stages of growth (see ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), *Chapter R7b).*

Moreover, the FELS toxicity test is preferable for examining the potential toxic effects of substances which are expected to cause effects over a longer exposure period, or which require a longer exposure period of time to reach steady state (ECHA *Guidance Chapter R7b,* version 4.0, June 2017).

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, early-life stage (FELS) toxicity test (test method: OECD TG 210).

In your comments to the draft decision you have indicated that you intend to perform a study (OECD 210) with the registered substance; however, you also indicated that you will investigate the potential availability of a study with the read-across substance hexyl cinnamic aldehyde prior to commissioning any study with the registered substance.

Notes for your consideration

Once results of the test on long-term toxicity to fish are available, you shall revise the chemical safety assessment as necessary according to Annex I of the REACH Regulation.

ECHA notes that there are no reliable short-term studies available on aquatic invertebrates or on fish for the registered substance. Therefore the Integrated testing strategy (ITS) outlined in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.0, June 2017), Chapter R7b (Section R.7.8.5 including Figure R.7.8-4), is not applicable in this case and the long-term studies on both invertebrates and fish are requested to be conducted. As the registered substance has a reported low water solubility, long-term studies are indicated.

Due to the low solubility of the substance in water 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* (version 4.0, June 2017), Chapter R7b, Table R.7.8-3 summarising aquatic toxicity testing of difficult substances for choosing the design of the requested ecotoxicity test(s) and for calculation and expression of the result of the test(s).

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 28 September 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.

ECHA took into account your comments and amended the requests and the deadline.

You were notified that the draft decision based on the registration with submission number [redacted], does not take into account any updates after 23 October 2017. You updated your registration with submission number [redacted] on 31 October 2017. In your update you have clarified the identification of your registered substance and the tested materials. Given the exceptional circumstances, ECHA has taken into account the update when processing this decision.

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.

4. If the required tests are conducted with an analogue substance in the context of a read-across approach, the identity of the test material used to perform the test should be specified in line with the ECHA's Practical Guide on "How to use alternatives to animal testing to fulfil your information requirements" (chapter 4.4). This is required to show that the test material is representative of the analogue substance identified in the read-across approach and used to predict the properties of the registered substance.