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Helsinki, 16 November 2016

Addressee: [redacted]

Decision number: CCH-D-2114347355-48-01/F
Substance name: bis(2-ethylhexyl) tetrabromophthalate
EC number: 247-426-5
CAS number: 26040-51-7
Registration number: [redacted]
Submission number: [redacted]
Submission date: 10.05.2013
Registered Tonnage band: Between 100 and 1000 tonnes/year

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. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2; test method: EU B.26/OECD TG 408) in rats with the registered substance;**

2. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14 /OECD TG 471) using one of the following strains: E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 with the registered substance;**

3. **Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.; test method: OECD TG 421 or 422) in rats, oral route with the registered substance;**

4. **Bioaccumulation in aquatic species (Annex IX, Section 9.3.2; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure/dietary exposure]) 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 of the REACH Regulation. In order 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 an adequate and reliable documentation.

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You are required to submit the requested information in an updated registration dossier by **23 November 2018**. You shall also 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. 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, shall 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/web/guest/regulations/appeals.

Authorised[1] by Ofelia BERCARU Head of Unit, Evaluation E3

[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.

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Appendix 1: Reasons

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.)**

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a sub-chronic toxicity study (90 day) in the dossier that would meet the information requirement of Annex IX, Section 8.6.2.

You have sought to adapt this information requirement. You provided the following justification for the adaptation "*In a subacute toxicity study with bis(2-ethylhexyl) tetrabromophthalate doses of 200, 2 000 or 20 000 ppm (= ca. 21.97, 223.4 or 2331 mg/kg/day) there were no significant changes in clinical signs, clinical chemistry, hematology, organ weights, or histopathology. None of the animals died due to the application of the test substance. Slightly low overall bodyweight gain was recorded for females receiving the highest dietary concentration of the test item. Males treated with the test substance were unaffected. Marginally low alanine amino-transferase activities were seen in females receiving the highest dietary concentration of the test substance, and marginally low phosphorus concentrations were seen in all females and males receiving the highest dietary concentration of the test substance. No significant functional or morphological effects are expected in a 90 day study. The NOAEL in the 28 day study was ca. 223.4 mg/kg bw/d. At 2331 mg/kg bw/d no severe effects were observed in the 28 day study. Due to the large differences in the applied doses of 21.97, 223.4 or 2331 mg/kg bw, it can be assumed, that the NOAEL is much higher than 223.4 mg/kg bw. The LOAEL is greater than the limit dose. For the derivation of the DNELs, factor 6 for extrapolation of exposure duration from subacute to chronic was considered. Addtional testing in a 90-day study with bis(2-ethylhexyl) tetrabromophthalate is therefore not required and is not justified either scientifically or on animal welfare grounds."*

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 8.6.2., column 2, 4th sub-paragraph, of the REACH Regulation. According to that provision, the study does not need to be conducted if the following cumulative conditions are met: (i) "*the substance is unreactive, insoluble and not inhalable", (ii) " there is no evidence of absorption", (iii) "no evidence of toxicity in a 28-day 'limit test'", and (iv) "limited human exposure*".

However, ECHA notes that in the current case the cumulative conditions (ii) and (iv) set out in Annex IX, 8.6.2., column 2, 4th sub-paragraph are not met. Specifically, ECHA observes the following:

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(i) According to the 28-day study ([redacted]), there was a "*slightly low overall bodyweight gain*" and "*marginally low alanine amino-transferase activities*" recorded for females receiving the highest dietary concentration of 2331 mg/kg/day of the registered substance, hence this shows that the substance can be absorbed by the organisms. Moreover, this is confirmed in the chemical safety report where it has been reported that "*a low absorption rate*" is assumed.
(ii) The test substance has been classified for wide dispersive indoor and outdoor use (ERC 8a; ERC 8c; ERC 8f; ERC 10a; and ERC 11a), used by professional workers as a one component foam (spray can/dose can), for laboratory use, and as a service life of plastic or rubber articles (indoor), used by both consumers and professionals.

ECHA concludes that the substance might have a potential for inhalation exposure, there is evidence of some form of absorption and there is a significant human exposure to the test substance, hence conditions (ii) and (iv) of column 2, of Annex IX, of Section 8.6.2., are not met.

Therefore, your adaptation of the information requirement is rejected.

Upon receipt of the draft decision you submitted comments explaining that indeed you adapted this information requirement according to Annex IX, Section 8.6.2., column 2, 4th sub-paragraph, of the REACH Regulation. You mentioned that conditions (i), (ii) and (iv) are all met. ECHA acknowledged that the initial draft decision mistakenly included a reference that criterion (i) was met. In any case, and as already elaborated above, ECHA notes that all the criteria need to be met for this adaptation to be applicable. According to the toxicokinetic data and the 28-day repeated dose toxicity study there is indeed evidence of absorption, even if it is reported as being low. As regards exposure, ECHA is of the opinion that the registered substance may still have a significant exposure to professional users.

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 has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 4.1, October 2015) Chapter R.7a, section R.7.5.4.3 - is the most appropriate route of administration. More specifically, the substance is a liquid of very low vapour pressure (<0.01kPa) and a very high boiling point (300°C). Even though the Process Categories may indicate potential inhalation exposure (PROC 10: Roller application or brushing) there are no respiratory tract specific effects to be expected. Moreover, according to the CSR "*the test material was only very slight irritating to the eyes and skin of rabbits, therefore a classification for skin and eye irritation is not justified*". Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

According to the test method EU B.26./OECD TG 408 the rat is the preferred species. ECHA considers this species as being appropriate and testing should be performed with the rat.

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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: Repeated dose 90-day oral toxicity study (test method: EU B.26./OECD TG 408) in rats.

2. In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. 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.

According to Article 13(3) of the REACH Regulation, tests required to generate information on intrinsic properties of substances shall be conducted in accordance with the test methods recognised by the Commission or ECHA.

Other tests may be used if the conditions of Annex XI are met. More specifically, Section 1.1.2 of Annex XI provides that existing data on human health properties from experiments not carried out according to GLP or the test methods referred to in Article 13(3) may be used if the following conditions are met:

(1) Adequacy for the purpose of classification and labelling and/or risk assessment;
(2) Adequate and reliable coverage of the key parameters foreseen to be investigated in the corresponding test methods referred to in Article 13(3);
(3) Exposure duration comparable to or longer than the corresponding test methods referred to in Article 13(3) if exposure duration is a relevant parameter; and
(4) adequate and reliable documentation of the study is provided.

According to paragraph 13 of the current OECD TG 471 test guideline (updated 1997) at least five strains of bacteria should be used: S. typhimurium TA1535; TA1537 or TA97a or TA97; TA98; TA100; S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). This includes four strains of *S. typhimurium* (TA1535; TA1537 or TA97a or TA97; TA98; and TA100) that have been shown to be reliable and reproducibly responsive between laboratories. These four *S. typhimurium* strains have GC base pairs at the primary reversion site and it is known that they may not detect certain oxidising mutagens, cross-linking agents and hydrazines. Such substances may be detected by E.coli WP2 strains or *S. typhimurium* TA102 which have an AT base pair at the primary reversion site.

You have provided a test from the year 1987 according to OECD TG 471 and GLP with an assigned reliability score of 1. The test used five different strains of S. typhimurium (TA 1535, TA 1537, TA 1538, TA 98 and TA 100) and it did not include tests with strains S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101). However, since the test was conducted, significant changes have been made to OECD TG guideline 471 so that additionally testing with S. typhimurium TA102 or E. coli WP2 uvrA or E. coli WP2 uvrA (pKM101) is now required.

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Therefore, the provided study does not meet the current guidelines, nor can it be considered as providing equivalent data according to the criteria in Annex XI, 1.1.2. of the REACH Regulation.

ECHA concludes that a test using E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 has not been submitted and that the test using one of these is required to conclude on in vitro gene mutation in bacteria.

In your comments to the draft decision you disagreed with the request of further testing with E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 as you have indicated that the registered substance is not an oxidizer, a hydrazine (derivative) or a cross-linking agent. However ECHA notes that testing with E. coli WP2 uvrA, or E. coli WP2 uvrA (pKM101), or S. typhimurium TA102 still needs to be performed as the information provided is not sufficient to determine whether the registered substance is not an oxidizing mutagen and/or a cross-linking agent.

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 bacterial reverse mutation test (test method EU B.13/14. / OECD TG 471) is appropriate to address the standard information requirement of Annex VII, Section 8.4.1. of the REACH Regulation.

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: Bacterial reverse mutation test (test method: EU B.13/14. / OECD TG 471) using one of the following strains: *E. coli* WP2 uvrA, or *E. coli* WP2 uvrA (pKM101), or *S. typhimurium* TA102.

3. Screening study for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH Regulation.

"Screening for reproductive/developmental toxicity" (test method OECD TG 421 or 422) is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have not provided any study record of a screening for reproductive/developmental toxicity in the dossier that would meet the information requirement of Annex VIII, Section 8.7.1.

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You have sought to adapt this information requirement. You provided the following justification for the adaptation: *"Bis(2-ethylhexyl) tetrabromophthalate was administered via the diet to three groups of ten male and ten female CD rats at concentrations of 200, 2 000 or 20 000 ppm (= ca. 21.97, 223.4 or 2331 mg/kg/day) for four weeks to asses its toxicity. At the end of the treatment period all animals were killed and a gross and microscopic examination of all major organs, including reproductive organs was conducted. There were no test substance-related toxic changes in organs weights of testes, ovaries and uterus (with cervix). No histopathological changes were found in epididymides, mammary glands - caudal, ovaries, prostate, testes, and uterus (with cervix) and all other examined organs. A development study according OECD TG 414 is planned after approval by ECHA. New findings in a screening reproductve study study are not expected and addtional testing in a screening study with bis(2-ethylhexyl) tetrabromophthalate is therefore not required and is not justified either scientifically or on animal welfare grounds."*

ECHA notes that in your justification you mention the findings of the 28-day study however this study cannot be used to determine fertility effects, weight of reproductive organs, and effects on offsprings. 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 VIII, Section 8.7.1., column 2, 4th sub-paragraph, of the REACH Regulation. According to that provision, the study does not need to be conducted if the following condition is met: *"a pre-natal developmental toxicity study (Annex IX, 8.7.2.) or, either an Extended One-Generation Reproductive Toxicity Study (B.56, OECD TG 443) (Annex IX, section 8.7.3.) or a two-generation study (B. 35, OECD TG 416), is available"*.

ECHA notes that indeed there is a final decision on a Testing Proposal Examination for a pre-natal developmental toxicity study, (final decision number TPE-D-2114299975-23-01/F), where you are expected to submit the updated dossier by 5 October 2016. However, to date, there is no data available on the pre-natal developmental toxicity, and because the data is not available, the adaptation is not valid.

Therefore, your adaptation of the information requirement is rejected.

In your comments on the draft decision you requested to postpone the compliance check procedure for this request until 5 October 2016, since by then the registration dossier will be updated with pre-natal developmental toxicity data. ECHA also notes your timetable for the completion of the pre-natal developmental toxicity test.
As already stated under the requests of this decision, you may adapt the testing requirements. However at the stage of MSCA referral, there is a data gap for a screening study for reproductive/developmental toxicity in the registration dossier and hence it is addressed in this decision.

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 methods OECD TG 421/422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

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 4.1, October 2015) R.7a, chapter 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:
Reproductive/developmental toxicity screening test (test method: OECD TG 421) in rats by the oral route
or
Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

Notes for your considerations

For the selection of the appropriate test, please consult ECHA *Guidance on information requirements and chemical safety assessment*, Chapter R.7a, section R.7.5 and 7.6 (version 4.1, October 2015).

4. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, [aqueous exposure/dietary exposure]).

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(d) and 13(4) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year shall contain as a minimum the information specified in Annexes VII to IX of the REACH 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.

In the technical dossier you have provided a study record: "Bioaccumulation, Metabolism, and Biological Responses to Firemasters® 550 and BZ-54" (Bearr, J. S., 2010). However, this study does not provide the information required by Annex IX, Section 9.3.2., because it did not follow a GLP and OECD guideline. Therefore, the study does not provide sufficient information on bioaccumulation and it is not valid to fulfill the information requirement.

In your comments on the draft decision you provide further argumentation to justify the the reliability of the study provided in the dossier stating that appropriate guidelines were followed and that the results are applicable to the registered substance.

ECHA notes that you have not provided any significant argumentation to prove the reliability and similarity with the OECD 305 guideline study. The provided statements of reliability based on an assigned klimisch score of 2 and are deemed insufficient. Many parameters which are important for determination of validity such as dissolved oxygen content, pH, total organic carbon are not reported in the study.

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Additionally, the validity criteria for an OECD 305 test are not met. One of the validity criteria in the OECD 305 test is "*The mortality or other adverse effects/disease in both control and treated fish is less than 10% at the end of the test; where the test is extended over several weeks or months, death or other adverse effects in both sets of fish should be less than 5% per month and not exceed 30% in all*". The study in the dossier reports that "*On day 78, control and BZ-54 treatments had survival of 83% and 88% of their total population. Survival in the treatment was 63% for FM 550*". As the mortality in the control and in one of two treatments exceeds the "*no more than 5% per month*" limit allowed the study cannot be deemed valid.

You have also argued that a bioaccumulation test is not required as there is no potential for bioaccumulation based on factors including high partition coefficient (10.2), high molecular weight (706 g/mol) and QSAR predictions for BCF.

ECHA notes that no details are provided on the QSAR predictions and these are not present in the registration dossier so the validity of these predictions cannot be verified. Furthermore, while the molecular weight is high it is not so high as to preclude significant bioaccumulation as noted in the ECHA guidance on information requirements and chemical safety assessment Chapter R.11: PBT/vPvB assessment where a limit of >1100g/mol is set for a low likelihood of bioaccumulation (i.e. BCF <2000).

Finally, the eMSCA for the substance evaluation on this substance has noted in the justification for CoRAP inclusion that "*The substance is detected in top predators and other animals in remote areas, including polar bear, ringed seal, glaucous gull, kittiwake, common eider and Atlantic cod, Brown Trout, Harbor Seal, Brünnich's Guillemot and capelin, indicating the potential for bioaccumulation. The values reported for the substance in biota are often low, which harmonizes well with the tonnage band. However, related to the BMF value supplied from the registration, there should not be any detectable BEHTBP in biota*".

ECHA concludes that based on this evidence there is a bioaccumulation concern and that the study provided in the registration dossier is not valid.

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 2.0, November 2014) 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. Data obtained from a dietary study will also need to be used to estimate BCF values.

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ECHA notes that in your comments to the Member State Compentent Authority proposal for amendment on this request, you indicate that ..in general, you agree if technically feasible, an aquatic exposure test is preferable to a dietary exposure test in order to determine bioaccumulation of a substance in fish, however, you also indicate for the registered substance why an aquatic exposure study is technically not feasible and therefore unjustified in the case of the registered substance Bis(2-ethylhexyl) tetrabromophthalate, EC No 247-426-5 (CAS No 26040-51-7). However, in the draft decision, ECHA has still provided the Registrant the possibility to undertake the OECD 305 via the dietary 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: Bioaccumulation in fish: dietary exposure bioaccumulation fish test (test method: OECD TG 305-III)

Notes for your consideration

Before conducting the above test you are advised to consult the ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0, November 2014), Chapter R.11.4. and Figure R.11-4 on the PBT assessment for further information on the integrated testing strategy for the bioaccumulation assessment of the registered substance. You should revise the PBT assessment when information on bioaccumulation is available.

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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 13 April 2016.

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 did not amend the request(s).

ECHA notified the draft decision to the competent authorities of the Member States for proposal(s) for amendment.

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

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

In addition, you provided comments on the draft decision. These comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-50 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

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Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for start of substance evaluation in 2017.

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

3. Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of substance used for the new test(s) must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfill the information requirement for the range of substance composition 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 substance tested in the new test(s) 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 test(s) 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 test(s) to be assessed.