ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 13 January 2017

Addressee: [redacted]

Decision number: CCH-D-2114350946-40-01/F
Substance name: sodium 3-nitrobenzenesulphonate
EC number: 204-857-3
CAS number: 127-68-4
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11.09.2015
Registered tonnage band: 100-1000T

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. **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;**

2. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.; test method: OECD TG 476 or TG 490) with the registered substance;**

3. **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;**

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

5. **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.**

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.

You are required to submit the requested information in an updated registration dossier by **22 July 2019**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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.

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Who performs the testing

Based on Article 53 of the REACH Regulation, you are requested to inform ECHA who will carry out the study/ies on behalf of all Registrant(s) within 90 days. Instructions on how to do this 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/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.

Appendix 1: Reasons

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

Pursuant to Articles 10(a) and 12(1) 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. 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 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 1989 according to OECD TG 471 and GLP with an assigned reliability score of 2. The test used four different strains of S. typhimurium TA 1535, TA 1537, 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.

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.

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 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 complete 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.

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

Pursuant to Articles 10(a) and 12(1) 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. 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.

ECHA notes that the registration dossier contains negative results for both these information requirements, although information is currently missing on the 5th strain in the *in vitro* gene mutation study in bacteria, as described above. Therefore, adequate information *on in vitro* gene mutation in mammalian cells needs to be present in the technical dossier for the registered substance to meet this information requirement provided that the study requested under request 1 has negative results.

You have sought to adapt this information requirement. You provided the following justification for the adaptation: "Negative results from a bacterial gene mutation assay (Ames) were obtained. The clastogenicity assay in CHL cells also showed a negative result. No valid data are available for the mammalian cell gene mutation assay.

However, for this type of assay the metabolic activation is achieved mostly in the culture medium and the membrane passage and intracellular bioavailability of the critical metabolites is considered to be very low due to their electric charge. Hence, the propensity of the Salmonella gene mutation assays (Ames) to detect potential mutations from such a compound is considered to be much higher. Hence, the priority of conducting a mammalian cell gene mutation assay is considered to be low. Furthermore, the material has sensitizing properties and therefore requires a limitation of exposure."
While you have not explicitly claimed an adaptation, you have provided information that could be interpreted as an attempt to adapt the information requirement Annex XI, Section 1.2 (Weight of evidence).

However, ECHA notes that your adaptation does not meet the general rule for adaptation of Annex XI; Section 1.2. because there is insufficient evidence to support the notion that the substance would not have a particular dangerous property for the following reasons. While the electric charge of the substance may impact its bioavailability, there is no information to support that the substance, or any of its potential metabolites, are not bioavailable. Furthermore, there is no information available on what "critical metabolites" may be produced as a result of metabolic activation. Finally, while the sensitizing properties of the substance may require limitation of exposure, there is no supporting information in the dossier to demonstrate that testing can be omitted based on exposure considerations (e.g. substance tailored exposure driven testing, Annex XI, 3). Indeed the information on the uses and exposure of the substance in your dossier indicate that some exposure is likely.

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), provided that the study requested under 1. has negative results.

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

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.

In the technical dossier you have provided study records for the following studies:

- A 28 day repeated dose toxicity study (BASF 1993), on rats, 5 animals per sex per dose, via the oral route, done according to OECD TG 407, on the registered substance (study 1)
- A 2 year repeated dose toxicity study (Wernick, 1975), on beagle dogs, 6 animals per sex per dose, via the oral route. No particular guideline was indicated. The test was performed on a hair dye formulation containing 2.25% of the registered substance (study 2)
- A 2 day toxicity study, on cats, via the intravenous route. No particular guideline was cited (study 3)
- A 2 day toxicity study, on rabbits, via the intravenous route. No particular guideline was cited (study 4)

However, none of these studies provide the information required by Annex IX, Section 8.6.2., for the following reasons:

- Studies 1, 3 and 4 do not provide the information required by Annex IX, Section 8.6.2., because the exposure duration is less than 90 days in each of these studies.
- Study 2, while it covers exposure duration longer than 90 days, has been performed on a hair dye formulation containing 2.25% of the registered substance. The top dose in this study was 97.5 mg/kg/bw of the formulation, which equates to an exposure of 2.2 mg/kg/bw of the registered substance. No effects were observed in the study and no NOAEL could be derived. The dose level of the registered substance is considered too low to allow for conclusions to be drawn on the potential effects of the registered substance in a 90 day repeated dose toxicity study.
- In all the studies cited, the number of animals per dose group is significantly lower than the number required in a 90-day study (10 animals per sex per dose group). Therefore, the sensitivity of these studies is much lower than that of a 90-day study.

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 solid with particle size distribution (granulometry) in the range of 75 micrometer to 600 micrometer and it is water soluble. Uses with industial spray application are reported in the chemical safety report. However, the reported concentrations are low <[redacted]%. 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.

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.

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

"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.

Instead, in the technical dossier you have provided study records for the following studies:

1) A 2-year repeated dose toxicity study (Wernick, 1975), on beagle dogs, via the oral route. No particular guideline was indicated. The test was performed on a hair dye formulation containing 2.25% of the registered substance. The study has been marked as a read-across study from an analogue.
2) A two generation study (Dodd, 1987), on rats with the analogue substance nitrobenzene. The test was performed according to "internal Protocol of Bushy Run Research Center (BRRC) and approved by the Sponsor (BRAC Project 83-73-30501)"
3) A waiving statement with the following justification for data waiving: "Nitrobenzene showed testicular toxicity and a reduction of male fertility already in the F0 generation in the course of a 2 gen study at an exposure level of 200 mg/m³ (inhalation) which is equivalent to 57.6 mg/kg bw if one calculates with a 100% resorption rate and an inhalation rate of 0.8 ml/min/kg in the rat. Nitrobenzene-3-sulphonate, however, did not cause testicular toxicity in the course of a 4 weeks rat feeding study. This is an expected relation since the bioavailability of nitrobenzene-3-sulphonate is considered to be much lower. (This is also reflected by the absence of methemoglobinemia in the course of the 28 day study.) Hence, there is no suspicion of a selective reproductive toxicity and further testing on reproductive toxicity is considered to be of low priority. (Basically, the same conclusion is also obtained for developmental toxicity which, however, was negative with nitrobenzene.) "

The information provided is not suitable for fulfilling the information requirements for the following reasons:

- **The chronic toxicity study:**

The chronic toxicity study (Wernick, 1975) was performed with a hair dye formulation containing 2.25% of the registered substance, with the following doses: 1950 ppm (0.005% of the registered substance) and 7800 ppm (0.02% of the registered substance). No further information has been provided on the composition of the test material. The doses of the registered substance are too low to allow for any conclusions on the toxicity of the registered substance in a screening study.

- **The Read-across adaptation**

You have not provided a justification for why the 2-generation study on the analogue nitrobenzene can be used to fulfil the information requirements for a screening study for the target (registered) substance sodium nitrobenzene sulphonate.

In addition to the absence of a justification for the read-across, ECHA points out the following deficiencies of the approach you proposed:

Annex XI, Section 1.5. provides that "substances whose physicochemical, toxicological and eco-toxicological properties are likely to be similar or follow a regular pattern as result of structural similarity may be considered as a group or 'category' of substances. One pre-requisite for a prediction based on read-across therefore is that the substances involved are structurally similar and are likely to have similar properties. One important aspect in this regard is the analysis of the data matrix to compare the properties of source and target substances and to establish whether indeed they are similar or follow a regular pattern.

Structural similarity is a prerequisite for applying the grouping and read-across approach, but ECHA does not accept in general or in this specific case that structural similarity per se is sufficient to enable the prediction of human health properties of a substance, since structural similarity does not always lead to predictable or similar human health properties. Hence, elements are missing from the read-across adaptation approach such as a well-founded hypothesis of (bio)transformation to a common compound(s), or that different compounds have the same type of effect(s), to allow a prediction of human health properties that does not underestimate risks.

ECHA points out that while there is structural similarity between source and target substances, there are also structural differences. The registered substance contains a sulphonate group. You have not considered what impact these structural differences may have on the toxicity of the registered substance, or on the possibility to read-across from the source to the target substance. ECHA notes that you state in your waiving argument that "the bioavailability of nitrobenzene 3-sulphonate is considered to be much lower". ECHA understands that this argument is based on the charge introduced by the sulphonate group. However, this argument does not consider what impact the sulphonate group may have on the toxicity of the registered substance, apart from the hypothesised reduction in bioavailability.

Likewise, ECHA considers that having similar physico-chemical and basic toxicological properties is a prerequisite for the use of the grouping and read-across approach according to Annex XI, Section 1.5., but is not by itself a sufficient basis to be able to predict the properties of the registered substance. Specifically, substances may have similar physico-chemical properties, but entirely different human health properties. Therefore this is not a reliable basis for prediction. In respect of the comparison of toxicological properties, ECHA considers that substances may have similar toxicological properties for one endpoint, but different toxicological properties for another endpoint. Hence it is necessary to have a basis for predicting the properties of the registered substance. ECHA notes that in any case, you have not provided information showing similarity in physico-chemical and/or toxicological properties of the source and target substances.

Finally, ECHA notes that in the Chemical Safety Report (CSR) you state the following "There is no need to cross-red the results to nitrobenzene-3-sulfonate since the sulfonate substituent greatly decreases the intracellular bioavailability and half-life time in relation to nitrobenzene." Based on this, it appears that you consider the read-across of the results from the source to the target substance is not justified.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. However, for the reasons as set out above, and additionally considering the overall weight of all the arguments, ECHA considers that there is not a reliable basis whereby the human health effects may be predicted from data for the reference substance(s) within the group by interpolation to other substances in the group (read-across approach). Therefore, this adaptation of the information requirement is rejected.

- **The waiving statement:**

Finally, regarding your waiving statement, ECHA notes that the argument provided is not a valid argument according to the specific rules for adaptation in column 2 of Annex VIII, or the general rules of adaptation in Annex XI. ECHA notes that although nitrobenzene sulphonate did not cause testicular toxicity in a 28 day study, compared to the effects observed in the 2-generation toxicity study for nitrobenzene (which showed testicular toxicity and a reduction of male fertility already in the F0 generation at a dose of 57.6 mg/kg/bw), ECHA notes that in the two generation study the males were exposed for 12 weeks (10 weeks pre-mating and 2 weeks mating), compared to an exposure period of 4 weeks in a 28 day study, and so the results may not be comparable. It is therefore not possible to conclude that the registered substance will not have effects in a screening study on reproductive/developmental toxicity. The 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 the test methods OECD TG 421 and TG 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 solid, ECHA concludes that testing should be performed by the oral route.

5. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species

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 provided the following justification for data waiving:
"No selective adverse effects on development have been observed with nitrobenzene. The sulphonate group in nitrobenzene-3-sulphonate makes the molecule much less likely than nitrobenzene to achieve a significant bioavailibility. (This is also reflected by the absence of methemoglobinemia in the course of the 28 day study.) Therefore, the developmental toxicity/teratogenicity potential is considered to be even less than in case of nitrobenzene and, hence, the necessity to carry out a study is considered to be of low priority."

You also provided the following supporting studies using read-across substances:

1) Chronic toxicity study (Wernick, 1975) in rats, via the oral route, with a hair dye formulation containing 2.25% Sodium m-Nitrobenzenesulfonate (reliability 4)
2) Chronic toxicity study (Wernick, 1975) in rabbits, oral, with a hair dye formulation containing 2.25% Sodium m-Nitrobenzenesulfonate (reliability 2)
3) Developmental toxicity study (Tyl, 1984) according to OECD TG 414, reliability 2, GLP compliant, on rats, inhalation route using a read-across from a supporting substance (Nitrobenzene)
4) Developmental toxicity study (Bio/dynamics, 1984) according to OECD TG 414, reliability 2, no data on GLP, on rabbits, inhalation route using a read-across from a supporting substance (Nitrobenzene)

ECHA notes that the same deficiencies regarding the dosing of the chronic study identified in the request for a screening for reproductive/developmental toxicity study addressed above under section 4. also apply to the use of the study for fulfilling the information requirement on PNDT. Furthermore, ECHA's analysis on the read-across from nitrobenzene to nitrobenzene sulphonate for a screening for reproductive/developmental toxicity study addressed above under 4also apply for the read-across of the PNDT studies from nitrobenzene to the registered substance (Bio/dynamics, 1984 and Tyl, 1984 studies).

You have sought to adapt this information requirement according to Annex XI, Section 1.5. You are using nitrobenzene, as a read-across substance to justify the data waiving for the developmental toxicity endpoint for the test substance. However ECHA notes that the adaptation provided does not meet the general rule for adaptation of Annex XI, Section 1.5. You failed to provide a justification document for the read-across. Hence the 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 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 4.1, October 2015) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a solid, 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.

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 15 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 did not receive any comments by the end of the commenting period.

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

You did not provide any comments on the proposed amendment(s).

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

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 2018.

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 the 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 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 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.

5. In relation to the experimental stud(y/ies) the legal text foresees the sharing of information and costs between Registrant(s) (Article 53 of the REACH Regulation). You are therefore required to make every effort to reach an agreement regarding each experimental study for every endpoint as to who is to carry out the study on behalf of the other Registrant(s) and to inform ECHA accordingly within 90 days from the date of this decision under Article 53(1) of the REACH Regulation. This information should be submitted to ECHA using the following form stating the decision number above at:
https://comments.echa.europa.eu/comments_cms/draftdecisioncomments.aspx?CaseNumber=CCH1_01-2119965131-44-0002

   Further advice can be found at http://echa.europa.eu/regulations/reach/registration/data-sharing . If ECHA is not informed of such agreement within 90 days, it will designate one of the Registrants to perform the stud(y/ies) on behalf of all of them.