EUROPEAN CHEMICALS AGENCY

Helsinki, 5 November 2018

Addressee: [redacted]

Decision number: CCH-D-2114449813-43-01/F
Substance name: Tar acids, xylenol fraction
EC number: 284-895-5
CAS number: 84989-06-0
Registration number: [redacted]
Submission number: [redacted]
Submission date: 07/01/2016
Registered tonnage band: Over 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. **Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.; test method: Daphnia sp. Acute immobilisation test, EU C.2./OECD TG 202) with the registered substance;**

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

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

4. **Classification and labelling (Annex VI, Section 4.):**
   - apply classification and labelling on the registered substance for aquatic toxicity *or* provide a justification for not classifying.

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 ***13 May 2019***. You also have to update the chemical safety report, where relevant.

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

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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 Kevin Pollard, Head of Unit, Evaluation E1

[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

ECOTOXICOLOGICAL INFORMATION

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

Your registration dossier contains for multiple endpoints adaptation arguments in the form of a grouping and read-across approach under Annex XI, Section 1.5. of the REACH Regulation. ECHA has considered first the scientific and regulatory validity of your read-across approach in general before assessing the individual endpoints (sections 1, 2 and 3).

Grouping of substances and read-across approach

You have sought to adapt information requirements by applying a read-across approach in accordance with Annex XI, Section 1.5, for the endpoints:

- Short-term toxicity testing on aquatic invertebrates (Annex VII, Section 9.1.1.)
- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2)
- Short-term toxicity testing on fish (Annex VIII, Section 9.1.3)

According to Annex XI, Section 1.5., two conditions shall be necessarily fulfilled. Firstly, there needs to be structural similarity between substances which results in a likelihood that the substances have similar physicochemical, toxicological and ecotoxicological properties so that the substances may be considered as a group or category. Secondly, it is required that the relevant properties of a substance within the group may be predicted from data for reference substance(s) within the group (read-across approach). ECHA considers that the generation of information by such alternative means should offer equivalence to prescribed tests or test methods.

Based on the above, a read-across hypothesis needs to be provided. This hypothesis establishes why a prediction for a toxicological or ecotoxicological property is reliable and should be based on recognition of the structural similarities and differences between the source and registered substances[2]. This hypothesis explains why the differences in the chemical structures should not influence the toxicological/ ecotoxicological properties or should do so in a regular pattern. The read-across approach must be justified scientifically and documented thoroughly, also taking into account the differences in the chemical structures. There may be several lines of supporting evidence used to justify the read-across hypothesis, with the aim of strengthening the case.

Due to the different nature of each endpoint and consequent difference in scientific considerations (e.g. key parameters, biological targets), a read-across must be specific to the endpoint or property under consideration. Key physicochemical properties may determine the fate of a compound, its partitioning into a specific phase or compartment and largely influence the availability of compounds to organisms, e.g. in bioaccumulation and toxicity tests. Similarly, biotic and abiotic degradation may alter the fate and bioavailability of compounds as well as be themselves hazardous, bioaccumulative and/or persistent. Thus,

[2] Please see for further information ECHA *Guidance on information requirements and chemical safety assessment* (version 1, May 2008), Chapter R.6: QSARs and grouping of chemicals.

physicochemical and degradation properties influence the human health and environmental properties of a substance and should be considered in read-across assessments. However, the information on physicochemical and degradation properties is only a part of the read-across hypothesis, and it is necessary to provide additional justification which is specific to the endpoint or property under consideration.

The ECHA Read-across assessment framework foresees that there are two options which may form the basis of the read-across hypothesis[3]- (1) (Bio)transformation to common compound(s)- the read-across hypothesis is that different substances give rise to (the same) common compounds to which the organism is exposed and (2) Different compounds have the same type of effect(s)- the read-across hypothesis is that the organism is exposed to different compounds which have similar (eco)toxicological and fate properties as a result of structural similarity (and not as a result of exposure to common compounds).

Finally, Annex XI, Section 1.5. lists several additional requirements, which deal with the quality of the studies which are to be read-across.

You consider to achieve compliance with the REACH information requirements for the registered substance Tar acids, xylenol fraction using data of structurally similar substances p-cresol (EC No 203-398-6) for short-term toxicity to daphnia, short-term toxicity to fish and toxicity to algae (acute endpoint); and o-cresol (EC No 202-423-8) for toxicity to algae (chronic endpoint) (hereafter the 'source substances').

You use the following arguments to support the prediction of properties of the registered substance from data for source substances within the group: "*Endpoints derived for p-Cresol have been used for this mixed xylenol assessment. Since there are structural and physical chemical similarities between the cresols and the other molecules within the mixed xylenol grouping it is acceptable to assume that their ecotoxicological profiles would be similar.*" for short-term fish and daphnia toxicity endpoints and: "*Endpoints derived for p-Cresol (for the acute endpoint) and o-Cresol (for the chronic endpoint) have been used for this mixed xylenol assessment. Since there are structural and physical chemical similarities between the cresols and the other molecules within the mixed xylenol grouping it is acceptable to assume that their ecotoxicological profiles would be similar.*" for toxicity to algae. You do not provide further supporting evidence and documentation.

As an integral part of this prediction, you propose that the source and registered substance(s) have similar structure, physical chemical properties and ecotoxicological properties for the above-mentioned information requirements. ECHA considers that this information is your read-across hypothesis.

ECHA's evaluation and conclusion

Your proposed adaptation argument is that the similarity in chemical structure and in some of the physico-chemical and ecotoxicological properties between the source and registered substance(s) 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 and ecotoxicological properties do not necessarily lead to predictable or similar environmental properties in other endpoints. Your justification based on structural

[3] Please see ECHA's Read-Across Assessment Framework (https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across).

similarity, similar physico-chemical and ecotoxicological properties has not established why the prediction is reliable for the environmental end-points for which the read across is claimed.

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 environmental 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.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you have committed to update the registration dossier with data on broader basis of source substances and with detailed analogue read across justification by taking into account the full composition of the target UVCB substance. You have provided a description of the proposed read-across approach with your comments. However, as the approach and the data presented in your comments are currently not provided in the registration dossier ECHA cannot fully evaluate and make conclusions on the read-across approach proposed.

ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

In this regard ECHA points out that read-across approaches are assessed using the Read-Across Assessment Framework (https://echa.europa.eu/documents/10162/13628/raaf_en.pdf/) and its Considerations on multi-constituent substances and UVCBs (https://echa.europa.eu/documents/10162/13630/raaf_uvcb_report_en.pdf/). You should consider consulting these documents when developing your read-across justification.

As described above, further elements are needed to establish a reliable prediction for a toxicological or ecotoxicological property, based on recognition of the structural similarities and differences between the source and registered substances. This could be achieved (if it is possible) by a well-founded hypothesis of (bio)transformation to a common compound(s), or that the registered and source substance(s) have the same type of effect(s), together with sufficient supporting information to allow a prediction of environmental properties.

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

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

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

In the technical dossier you have not provided a study on the registered substance but on different constituents of the UVCB substance. However, ECHA notes, that the data is mostly from non-GLP old studies that are poorly reported. Moreover, ECHA notes that the study on xylenol mixture has different concentrations of xylenols than the registered substance and no justification has been provided on how this would affect the results of the study.

ECHA notes that the exposure duration of the source study that you have used in your read-across approach for short-term toxicity to aquatic invertebrates (6.1.3, KEY Kuehn, 1988, 1980 IUC4, reliability 3) is 24 hours. This study duration is shorter than the exposure period expected from a short-term toxicity study on aquatic invertebrates performed according to the OECD TG 202 where the foreseen exposure duration is 48 hours. Therefore, ECHA considers that this source study does not fulfil the requirement of Annex XI, Section 1.5. of the REACH Regulation for an exposure duration comparable to or longer than the corresponding test method referred to in Article 13(3).

Additionally, you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. 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 XI, Section 1.5.
However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

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

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you have committed to update the registration dossier with data on broader basis of source substances and with detailed analogue read across justification by taking into account the full composition of the target UVCB substance. ECHA has addressed your comments in section "Grouping of substances and read-across approach" above. ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

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

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

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

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

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

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

In the technical dossier you have not provided a study on the registered substance but on different constituents of the UVCB substance. However, ECHA notes, that the data is mostly from non-GLP old studies that are poorly reported. Moreover, ECHA notes that the study on xylenol mixture has a different concentrations of xylenols than the registered substance and no justification has been provided on how this would affect the results of the study.
You have provided a key study for algae toxicity (6.1.5, KEY Bringmann, 1975), performed according to DEV L9 on the structurally-related substance o-cresol and you propose to read-across the properties to the registered substance. However, ECHA notes that a robust study summary is required under Article 10(a)(vii), and ECHA considers that the information provided in the endpoint study record does not meet the requirements of a robust study summary, as defined in Article 3(28). ECHA has provided a practical guide for "How to report robust study summaries", available at: http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf. ECHA considers there is not sufficient information to make an independent assessment of the study minimising the need to consult the full study report, and accordingly considers that for this study, you have failed to meet the requirement of Annex XI, Section 1.5. that adequate and reliable documentation of the applied method shall be provided. Moreover, ECHA guidance R.7.b Section 7.8.4.1 notes that "*The typical test duration for this study is 72 hours. However, 96 hours is also commonly reported. This should be used as an equally acceptable value. For existing substances often algae tests with a duration of >96 h are available. As it cannot be assumed that the algae are in the exponential growth phase during the whole exposure period, the result from such tests cannot be used, unless the available raw data show monotone exponential growth of the controls. This also applies to reported chronic NOEC values. Common examples of this are 7-day and 14-day reported values.*" You note in the registration dossier that "*In the OECD/ICCA HPV programm it was stated that it is unclear whether the algae S. quadricauda are within the exponential growth throughout the whole exposure period of 8 days. Accordingly, the study was assessed to be not reliable (reliability 3). However, the bluegreen algae Microcystis aeruginosa have a lower rate of reproduction compared to green algae and are still in the exponential growth rate under the experimental conditions after 8 d.*" However, you have not provided further evidence for your explanation. Therefore, ECHA cannot consider this study reliable. The other supporting studies on the same endpoint are not considered reliable for similar reasons.

Additionally, you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. 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 XI, Section 1.5.

However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

Therefore, your adaptation of the information requirement cannot be accepted.
In your comments on the draft decision according to Article 50(1) of the REACH Regulation you have committed to update the registration dossier with data on broader basis of source substances and with detailed analogue read across justification by taking into account the full composition of the target UVCB substance. ECHA has addressed your comments related to the proposed read-across in section "Grouping of substances and read-across approach" above. ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

Additionally for this information requirement, whilst the acceptability of the read-across approach and the reliability of the studies included in the comments to the draft decision cannot still be verified, ECHA already notes that the data on algal toxicity seem to consist largely of tests with a study duration of 48-h. This study duration is shorter than the exposure period expected from a Growth Inhibition Test on Freshwater Alga and Cyanobacteria performed according to the OECD TG 201. Therefore, ECHA considers that these source studies would not fulfil the requirement of Annex XI, Section 1.5. of the REACH Regulation for an exposure duration comparable to or longer than 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 ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

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

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

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

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

In the technical dossier you have not provided a study on the registered substance but on different constituents of the UVCB substance. However, ECHA notes, that the data is mostly from non-GLP old studies that are poorly reported. Moreover, ECHA notes that the study on xylenol mixture has a different concentrations of xylenols than the registered substance and no justification has been provided on how this would affect the results of the study.

You have provided a study for short-term toxicity to fish (6.1.1, KEY, [redacted] 1969 IUC4, no guideline mentioned) on the structurally-related substance p-cresol and you propose to read-across the properties to the registered substance. However, ECHA notes that a robust study summary is required under Article 10(a)(vii), and ECHA considers that the information provided in the endpoint study record does not meet the requirements of a robust study summary, as defined in Article 3(28). ECHA has provided a practical guide for "How to report robust study summaries", available at: http://echa.europa.eu/documents/10162/13643/pg_report_robust_study_summaries_en.pdf. ECHA considers there is not sufficient information to make an independent assessment of the study minimising the need to consult the full study report, and accordingly considers that for this study, you have failed to meet the requirement of Annex XI, Section 1.5. that adequate and reliable documentation of the applied method shall be provided.

Additionally, you have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. 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 XI, Section 1.5.

However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

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

Additionally, there is no data on the constituents 2,5-xylenol, 2,3-xylenol and 3,5-xylenol. Moreover, you have stated that: *"Endpoints derived for p-Cresol have been used for this mixed xylenol assessment. Since there are structural and physical chemical similarities between the cresols and the other molecules within the mixed xylenol grouping it is acceptable to assume that their ecotoxicological profiles would be similar."* without further justification.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you have committed to update the registration dossier with data on broader basis of source substances and with detailed analogue read across justification by taking into account the full composition of the target UVCB substance. ECHA has addressed your comments in section "Grouping of substances and read-across approach" above. ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

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

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

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

4. Classification and labelling (Annex VI, Section 4.)

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

Pursuant to Article 10(a)(iv) of the REACH Regulation your technical dossier shall contain information on classification and labelling of the substance as specified in Annex VI, Section 4 of the REACH Regulation in conjunction with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation). Annex VI, section 4.1. clarifies that the hazard classification of the substance shall result from the application of Title I and II of the CLP Regulation. In addition, for each entry, the scientifically justified reasons why no classification is given for a hazard class or differentiation of a hazard class should be provided. According to Article 5(1) of Title I of the CLP Regulation, a substance shall be classified on the basis of available information.

Furthermore, the technical dossier must include the resulting hazard label for the substance in line with Title III of the CLP Regulation (Annex VI, section 4.2 of the REACH Regulation) and the specific concentration limits and M-factors, where applicable, resulting from the application of Article 10 of the CLP Regulation (Annex VI, Section 4.3 of the REACH Regulation).

ECHA notes that the constituents 2,4-xylenol ([redacted]), 2,5-xylenol ([redacted]), 2,3-xylenol ([redacted]), 2,6-xylenol ([redacted] and 3,4-xylenol ([redacted] have a harmonised classification of Aquatic Chronic 2 with hazard statement H411 (see Annex VI of Regulation (EC) No 1272/2008).
ECHA Guidance Section 4.1.4 on the Application of the CLP Criteria version 5.0, July 2017 explains that if "*valid test data on the mixture as a whole (for all three trophic levels) are not available, classification should be considered based on individual components using the summation method.*" that is further described in the same Annex, Section 4.1.4.7. When applying the summation method to the classified constituents of the substance, the sum exceeds the threshold for classifying the whole substance in the same hazard category as those constituents. Hence, ECHA considers that on the basis of the available information the same classification should be applied for the whole substance.

In your comments on the draft decision according to Article 50(1) of the REACH Regulation you have committed to update the registration dossier with classifying the registered substance according to the summation method in IUCLID Section 2.1. ECHA will assess the latest dossier update in the follow-up process according to Art 42 of the REACH Regulation whether the provisions of Annex XI, Section 1.5 are met.

Furthermore, the technical dossier does not contain scientifically justified reasons relating to why the substance has not been classified in accordance with the available study/studies. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to classify and label the registered substance taking into account the information above. In the alternative, you are required to provide scientifically justified reasons why no such classification is given. You are reminded that also for a differentiation of a hazard class, scientifically justified reasons need to be provided.

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 21 June 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 did not amend the request(s).

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.