~~Confidential~~

Helsinki, 23 January 2024

Addressee
Registrant of JS_32588-76-4 as listed in Appendix 3 of this decision

Date of submission of the dossier subject to this decision
15 June 2017

Registered substance subject to this decision ("the Substance")
Substance name: N,N'-ethylenebis(3,4,5,6-tetrabromophthalimide)
EC/List number: 251-118-6

Decision number: Please refer to the REACH-IT message which delivered this communication (in format CCH-D-XXXXXXXXXX-XX-XX/F)

DECISION ON A COMPLIANCE CHECK

Under Article 41 of Regulation (EC) No 1907/2006 (REACH), you must submit the information listed below by ***1 February 2027***.

Requested information must be generated using the Substance unless otherwise specified.

Information required from all the Registrants subject to Annex IX of REACH

1. Soil simulation testing (Annex IX, Section 9.2.1.3.; test method: EU C.23/OECD TG 307) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

2. Sediment simulation testing (Annex IX, Section 9.2.1.4.; test method: EU C.24/OECD TG 308) at a temperature of 12°C. Non-extractable residues (NER) must be quantified and a scientific justification of the selected extraction procedures and solvents must be provided.

3. Identification of degradation products (Annex IX, Section 9.2.3.; test method: EU C.23/OECD TG 307 and EU C.24/OECD TG 308).

The reasons for the requests are explained in Appendix 1.

Information required depends on your tonnage band

You must provide the information listed above for all REACH Annexes applicable to you in accordance with Articles 10(a) and 12(1) of REACH. The addressees of the decision and their corresponding information requirements based on registered tonnage band are listed in Appendix 3.

You are only required to share the costs of information that you must submit to fulfil your information requirements.

How to comply with your information requirements

To comply with your information requirements, you must submit the information requested by this decision in an updated registration dossier by the deadline indicated above. You

must also **update the chemical safety report, where** relevant, including any changes to classification and labelling, based on the newly generated information.

You must follow the general requirements for testing and reporting new tests under REACH, see Appendix 4.

Appeal

This decision, when adopted under Article 51 of REACH, may be appealed to the Board of Appeal of ECHA within three months of its notification to you. Please refer to http://echa.europa.eu/regulations/appeals for further information.

Failure to comply

If you do not comply with the information required by this decision by the deadline indicated above, ECHA will notify the enforcement authorities of your Member State.

Authorised[1] under the authority of Mike Rasenberg, Director of Hazard Assessment

Appendix 1: Reasons for the requests
Appendix 2: Procedure
Appendix 3: Addressees of the decision and their individual information requirements
Appendix 4: Conducting and reporting new tests under REACH

[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 for the requests

Reasons related to the information under Annex IX of REACH

1. Soil simulation testing

1 Soil simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.3.) for substances with a high potential for adsorption to soil.

1.1. Triggering of the information requirement

2 A high potential for adsorption is indicated by lipophilicity e.g. when log Kow > 4, log Koc > 4 (Guidance on IRs and CSA R.7.9.4.3) or other mechanisms than driven by the lipophilicity e.g. ionising substances (at pH 4-9), surface active substances, substances that bind chemically with soil components.

3 The Substance has a high partition coefficient based on estimated log Kow = 9.8 and high adsorption coefficient based on estimated log Koc = 4.73 to 5.48 and therefore has high potential for adsorption to soil.

1.2. Information provided

4 You have adapted this information requirement by using Annex XI, Section 2. (testing is technically not possible). To support the adaptation, you have provided the following information:

(i) "*EBTBP's poor solubility has precluded development of specific methods of analysis* [and therefore you] *will not be able to quantitate levels in water, diet, tissue, soil or sediment*";

(ii) "*EBTBP's insolubility, high molecular weight, large molecular volume and folded configuration will limit it accessibility to bacteria*".

1.3. Assessment of the information provided

1.3.1. Testing not technically possible adaptation rejected

5 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 307, more specifically on the technical limitations of a specific method, shall always be respected.

6 The OECD TG 307 provides in particular that this test is applicable to water-soluble and poorly water-soluble compounds and for adsorptive to highly adsorptive substances without limitations regarding sorption to the soil. As regards to water solubility, no lower limit is specified under which the study would be not feasible.

7 You claim that, due to the Substance being highly insoluble, it will not be possible to quantify the presence of the Substance in soil. Further, you consider that the properties of the Substance lead to low bioavailability for bacterial degradation.

8 ECHA notes that you have provided no experimental evidence to support that developing an analytical method for the Substance is not feasible. Furthermore, your claim that the Substance has low bioavailability is not a relevant justification to omit the test based on technical infeasibility as it does not relate to technical limitations of the corresponding test method.

9 Your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method and therefore does not provide evidence to demonstrate that it is technically not feasible to conduct the required study.

10 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

1.4. Study design

11 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

12 In accordance with the specifications of OECD TG 307, you must perform the test using at least four soils representing a range of relevant soils (i.e. varying in their organic content, pH, clay content and microbial biomass).

13 In your comments to the draft decision, you refer to the OECD TG 307 and request ECHA to clarify that "*the 4 soil type requirements are only applicable for the kinetic part of the study determining half-lives*".

14 ECHA confirms that your interpretation of the OECD TG 307 is correct. Testing on four soil types is only required by the kinetic study where the degradation rate constants (and degradation half-lives) have to be determined.

15 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 307.

16 In accordance with the specifications of OECD TG 307, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

17 In your comments to the draft decision, you state that "[w]*hen working with radiolabeled substances NER's are normally quantified by measuring the non-extractable radioactivity by combustion and a mass balance will be calculated for each sampling interval. (OECD TG 307 par. 47). Thus, if the nature of the NERs needs to be identified, additional experiments and time will be needed. In addition, it is not clear how this should be done in practice if the radiolabeled material cannot be extracted without destroying it. Clear guidance by ECHA on the efforts/approaches to be taken should be given to avoid any challenges on the study design by ECHA about this in the final study report*."

18 ECHA first note that the OECD TG 307 specifies that is applicable to all chemical substances (non-labelled or radiolabelled) for which an analytical method with sufficient accuracy and sensitivity is available (with the exception of chemicals which are highly volatile from soil). Therefore, the use of a radiolabelled test material is not regarded as a mandatory

requirement of the test guideline. It remains your responsibility to choose which type of test material may be the most adequate to obtain reliable results.

19 As already explained above, by default total NER is regarded as non-degraded Substance. Further characterisation of NER is not a mandatory requirement. However, you may decide to conduct a differentiation of NER and take that information into account when calculating the degradation half-life(s). OECD TG 307 states that, when using a radiolabelled test material, "[a] *further characterisation of non-extractable radioactivity can be attempted using, for example, supercritical fluid extraction*".

20 For further guidance, you may consult:

- the background document on NERs extraction and identification (https://echa.europa.eu/documents/10162/17228/echa_discussion_paper_en.pdf/4185cf64-8333-fad2-8ddb-85c09a560f7c?t=1530014119781);
- the latest version of the Guidance on IRs and CSA, Chapter R.11 (under revision) (https://echa.europa.eu/documents/10162/2324909/ir_csa_r11_v4_pbt_msc_bpc_en.pdf/764d4093-dcff-7001-e448-eb468070ffd1?t=1687164065330) and in particular Section 11.4.1.1/5 and Appendix R.11-4;
- the Critical literature review of analytical methods applicable to environmental fate studies (https://echa.europa.eu/documents/10162/17228/pfab_750_06_wp4_echa_final_report_en.pdf/b3a7e562-bf9c-ef02-948f-eaf1b8f89e3f?t=1616407418970)

21 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 307; Guidance on IRs and CSA, Section R.11.4.1.).

22 In your comments to the draft decision, you state that "[i]*f a transformation product is determined at only one sampling time > 10%, not at the end of the incubation period and then disappears, it does not make sense to try to isolate and identify the transformation product, as it is obviously not persistent*". You therefore do not agree to this request.

23 ECHA notes that the OECD TG 307 specifies that "[m]*ajor transformation products should be identified and their concentrations should also be plotted against time to show their rates of formation and decline. A major transformation product is any product representing ≥ 10% of applied dose at any time during the study*". Therefore, ECHA maintains this information request.

2. Sediment simulation testing

24 Sediment simulation testing is an information requirement under Annex IX to REACH (Section 9.2.1.4.) for substances with a high potential for adsorption to sediment.

2.1. Triggering of the information requirement

25 A high potential for adsorption is indicated by lipophilicity e.g. when log K_{ow} >4, log $K_{oc,sediment}$ >4 (Guidance on IRs and CSA R.7.9.4.3) or by other mechanisms than driven by the lipophilicity e.g. ionising substances (at pH 4-9), surface active substances, substances that bind chemically with sediment components.

26 The Substance has a high partition coefficient based on estimated log K_{ow} = 9.8 and high adsorption coefficient based on estimated log K_{oc} = 4.73 to 5.48 and therefore has high potential for adsorption to sediment.

2.2. Information provided

27 You have adapted this information requirement by using Annex XI, Section 2. (testing is technically not possible). To support the adaptation, you have provided the following justification:

(i) "*EBTBP's poor solubility has precluded development of specific methods of analysis* [and therefore you] *will not be able to quantitate levels in water, diet, tissue, soil or sediment*";

(ii) "*EBTBP's insolubiiity, high molecular weight, large molecular volume and folded configuration will limit it accessibility to bacteria*".

2.3. Assessment of the information provided

2.3.1. Testing not technically possible adaptation rejected

28 According to Annex XI, Section 2, a study may be omitted if it is technically not feasible to conduct because of the properties of the substance. The guidance given in the test methods referred to in Article 13(3), in this case OECD TG 308, more specifically on the technical limitations of a specific method, shall always be respected.

29 The OECD TG 308 provides in particular that this test is applicable to water-soluble and poorly water-soluble compounds and highly sorptive substances to sediment. As regards to water solubility, no lower limit is specified under which the study would be not feasible.

30 You claim that, due to the Substance being highly insoluble, it will not be possible to quantify the presence of the Substance in sediment. Further, you consider that the properties of the Substance lead to low bioavailability for bacterial degradation.

31 ECHA notes that you have provided no experimental evidence to support that developing an analytical method for the Substance is not feasible. Furthermore, your claim that the Substance has low bioavailability is not a relevant justification to omit the test based on technical infeasibility as it does not relate to technical limitations of the corresponding test method.

32 Your claim does not take into account the specific technical limitations, or lack thereof, of the applicable test method and therefore does not provide evidence to demonstrate that it is technically not feasible to conduct the required study.

33 Based on the above, your adaptation is rejected and the information requirement is not fulfilled.

2.4. Study design

34 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

35 In accordance with the specifications of OECD TG 308, you must perform the test using two sediments. One sediment should have a high organic carbon content (2.5-7.5%) and a fine texture, the other sediment should have a low organic carbon content (0.5-2.5%) and a coarse texture. If the Substance may also reach marine waters, at least one of the water-sediment systems should be of marine origin.

36 The required test temperature is 12°C, which corresponds to the average environmental temperature for the EU (Guidance on IRs and CSA, Table R.16-8) and is in line with the applicable test conditions of the OECD TG 308.

37 In accordance with the specifications of OECD TG 308, non-extractable residues (NER) must be quantified. The reporting of results must include a scientific justification of the used extraction procedures and solvents (Guidance on IRs and CSA, Section R.7.9.4.1.). By default, total NER is regarded as non-degraded Substance. However, if reasonably justified and analytically demonstrated a certain part of NER may be differentiated and quantified as irreversibly bound or as degraded to biogenic NER, such fractions could be regarded as removed when calculating the degradation half-life(s) (Guidance on IRs and CSA, Section R.11.4.1.1.3.). Further recommendations may be found in the background note on options to address non-extractable residues in regulatory persistence assessment available on the ECHA website.

38 Relevant transformation/degradation products are at least those detected at ≥ 10% of the applied dose at any sampling time or those that are continuously increasing during the study even if their concentrations do not exceed 10% of the applied dose, as this may indicate persistence (OECD TG 308; Guidance on IRs and CSA, Section R.11.4.1.).

39 In your comments to the draft decision, you state that "[i]*f a transformation product is determined at only one sampling time > 10%, not at the end of the incubation period and then disappears, it does not make sense to try to isolate and identify the transformation product, as it is obviously not persistent*". You therefore do not agree to this request.

40 ECHA notes that the OECD TG 307 specifies that "[i]*n general, transformation products detected at ≥10% of the applied radioactivity in the total water-sediment system at any sampling time should be identified unless reasonably justified otherwise*". Therefore, ECHA maintains this information request, unless a reasonable justification for not providing it is provided.

3. Identification of degradation products

41 Identification of abiotic and biotic degradation products is an information requirement under Annex IX to REACH (Section 9.2.3.).

42 You have not submitted any information for this requirement.

43 Therefore, the information requirement is not fulfilled.

3.1. Study design

44 Simulation degradation studies must include two types of investigations (Guidance on IRs and CSA, Section R.7.9.4.1.):

(1) a degradation pathway study where transformation/degradation products are quantified and, if relevant, are identified, and

(2) a kinetic study where the degradation rate constants (and degradation half-lives) of the parent substance and of relevant transformation/degradation products are experimentally determined.

45 Identity, stability, behaviour, and molar quantity of the degradation/transformation products relative to the Substance must be evaluated and reported. In addition, identified transformation/degradation products must be considered in the CSA including PBT assessment.

46 You must obtain this information from the degradation studies requested in requests 1 and 2.

47 To determine the degradation rate of the Substance, the requested studies according to OECD TG 308 and 307 (requests 1 and 2) must be conducted at 12°C and at (a) test material application rates reflecting realistic assumptions. However, to overcome potential analytical limitations with the identification and quantification of major transformation/degradation products, you may consider running a parallel test at higher temperature (but within the frame provided by the test guideline) and at higher application rate (e.g. 10 times).

48 In your comments to the draft decision you "*reiterate that only relevant degradation products need to be identified and characterized if technically possible. Relevant degradation products are those above 10% or those with an increasing concentration reaching > 1% during the testing time (This value is used based on practical experience with other studies as the identification of lower concentrations is simply not possible). If there should be no indication of degradation and formation of degradation products above 10 or increasing to > 1%, respectively, of the total amount of radioactive material used under the test conditions required (12°C and respective relevant concentrations), there should be no need for further investigations. This is also not clear from the draft decision as a higher temperature is suggested as a potential option*."

49 ECHA acknowledges the technical difficulties that may be encountered when attempting to identify degradation products. The option to conduct a test at higher temperature in parallel to the kinetic study is aiming to mitigate issues related to the sensitivity of available analytical methods (as degradation product may be formed at higher rate when the test is conducted at higher temperature). This is offered as an option for your consideration and is therefore not a mandatory requirement.

References

The following documents may have been cited in the decision.

Guidance on information requirements and chemical safety assessment (Guidance on IRs & CSA)

Chapter R.4 Evaluation of available information; ECHA (2011).
Chapter R.6 QSARs, read-across and grouping; ECHA (2008).
Appendix to Chapter R.6 for nanoforms; ECHA (2019).
Chapter R.7a Endpoint specific guidance, Sections R.7.1 – R.7.7; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Chapter R.7b Endpoint specific guidance, Sections R.7.8 – R.7.9; ECHA (2017).
Appendix to Chapter R.7b for nanomaterials; ECHA (2017).
Chapter R.7c Endpoint specific guidance, Sections R.7.10 – R.7.13; ECHA (2017).
Appendix to Chapter R.7a for nanomaterials; ECHA (2017).
Appendix R.7.13-2 Environmental risk assessment for metals and metal compounds; ECHA (2008).
Chapter R.11 PBT/vPvB assessment; ECHA (2017).
Chapter R.16 Environmental exposure assessment; ECHA (2016).

Guidance on data-sharing; ECHA (2017).
Guidance for monomers and polymers; ECHA (2023).
***Guidance on intermediates*;** ECHA (2010).
All guidance documents are available online: https://echa.europa.eu/guidance-documents/guidance-on-reach

Read-across assessment framework (RAAF)

RAAF, 2017 Read-across assessment framework (RAAF); ECHA (2017).
RAAF UVCB, 2017 Read-across assessment framework (RAAF) – considerations on multi- constituent substances and UVCBs; ECHA (2017).

The RAAF and related documents are available online:
https://echa.europa.eu/support/registration/how-to-avoid-unnecessary-testing-on-animals/grouping-of-substances-and-read-across

***OECD Guidance documents* (OECD GDs)**

OECD GD 23 Guidance document on aquatic toxicity testing of difficult substances and mixtures; No. 23 in the OECD series on testing and assessment, OECD (2019).
OECD GD 29 Guidance document on transformation/dissolution of metals and metal compounds in aqueous media; No. 29 in the OECD series on testing and assessment, OECD (2002).
OECD GD 150 Revised guidance document 150 on standardised test guidelines for evaluating chemicals for endocrine disruption; No. 150 in the OECD series on testing and assessment, OECD (2018).
OECD GD 151 Guidance document supporting OECD test guideline 443 on the extended one-generation reproductive toxicity test; No. 151 in the OECD series on testing and assessment, OECD (2013).

Appendix 2: Procedure

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

ECHA followed the procedure detailed in Articles 50 and 51 of REACH.

The compliance check was initiated on 07 March 2023.

The deadline of the decision is set based on standard practice for carrying out OECD TG tests. It has been exceptionally extended by 12 months from the standard deadline granted by ECHA to take into account currently longer lead times in contract research organisations.

ECHA notified you of the draft decision and invited you to provide comments. ECHA took into account your comments and did not amend the requests.

In your comments on the draft decision, you requested an extension of the deadline to provide the requested information from 36 to 42 months from the date of adoption of the decision. You justify the request by referring to the Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and state that 12 months should be granted for the update of the CSR in addition to the time required to conduct the requested studies. You also refer to difficulties in synthetizing a radiolabelled test material and to the limited availability of Contract Research Organisations (CROs). You have provided no documentary evidence to justify the extension.

With regard your statement relates to the Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020, ECHA notes that you have not provided any reference to the section of that document you are referring to. ECHA assumes that you are referring to Article 7 entitled 'Updates or amendments of the chemical safety report or the guidance on safe use' which states that "*In a case falling within point (g) of Article 22(1) of Regulation (EC) No 1907/2006, the registration shall be updated and submitted to the Agency by no later than 12 months from the date when the need to update or amend the chemical safety report or the guidance on safe use referred to in Section 5 of Annex VI to that Regulation was identified*". However, this provision refers to the responsibility of registrant to keep their dossier up to date on their own initiative and not to dossier update triggered following a compliance check decision. In the later case, the registration dossier, including the CSR, must be updated with the additional information requested by the deadline set in the decision. Furthermore, ECHA notes that the deadline set in the draft decision already includes an extension to account for longer lead times in contract research organisations. In the absence of documentary evidence to justify the extension, ECHA cannot assess the validity of your claim. Therefore, ECHA has not amended the deadline.

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

As no amendments were proposed, ECHA adopted the decision under Article 51(3) of REACH.

Appendix 3: Addressee of this decision and their corresponding information requirements

In accordance with Articles 10(a) and 12(1) of REACH, the information requirements for individual registrations are defined as follows:

- the information specified in Annex VII to REACH, for registration at 1-10 tonnes per year (tpa), or as a transported isolated intermediate in quantity above 1000 tpa;
- the information specified in Annexes VII and VIII to REACH, for registration at 10-100 tpa;
- the information specified in Annexes VII, VIII and IX to REACH, for registration at 100-1000 tpa.;
- the information specified in Annexes VII to X to REACH, for registration at more than 1000 tpa.

Registrant Name	Registration number	Highest REACH Annex applicable to you
[redacted]	[redacted]	[redacted]

Where applicable, the name of a third-party representative (TPR) may be displayed in the list of recipients whereas ECHA will send the decision to the actual registrant.

Appendix 4: Conducting and reporting new tests for REACH purposes

1. Requirements when conducting and reporting new tests for REACH purposes

1.1 Test methods, GLP requirements and reporting

(1) Under Article 13(3) of REACH, all new data generated as a result of this decision must be conducted according to the test methods laid down in a European Commission Regulation or to international test methods recognised by the Commission or ECHA as being appropriate.
(2) Under Article 13(4) of REACH, ecotoxicological and toxicological tests and analyses must be carried out according to the GLP principles (Directive 2004/10/EC) or other international standards recognised by the Commission or ECHA.
(3) Under Article 10(a)(vi) and (vii) of REACH, all new data generated as a result of this decision must be reported as study summaries, or as robust study summaries, if required under Annex I of REACH. See ECHA Practical Guide on How to report robust study summaries (https://echa.europa.eu/practical-guides).
(4) Under the introductory part of Annexes VII/VIII/IX/X to REACH, where a test method offers flexibility in the study design, for example in relation to the choice of dose levels or concentrations, the chosen study design must ensure that the data generated are adequate for hazard identification and risk assessment.

1.2 Test material

Before generating new data, you must agree within the joint submission on the chemical composition of the material to be tested (Test Material) which must be relevant for all the registrants of the Substance.

(1) Selection of the Test material(s)

The Test Material used to generate the new data must be selected taking into account the following:

- the variation in compositions reported by all members of the joint submission,
- the boundary composition(s) of the Substance,
- the impact of each constituent/impurity on the test results for the endpoint to be assessed. For example, if a constituent/impurity of the Substance is known to have an impact on (eco)toxicity, the selected Test Material must contain that constituent/impurity.

(2) Information on the Test Material needed in the updated dossier

- You must report the composition of the Test Material selected for each study, under the "Test material information" section, for each respective endpoint study record in IUCLID.
- The reported composition must include all constituents of each Test Material and their concentration values.

With that detailed information, ECHA can confirm whether the Test Material is relevant for the Substance and whether it is suitable for use by all members of the joint submission.

Technical instructions on how to report the above is available in the manual on How to prepare registration and PPORD dossiers (https://echa.europa.eu/manuals).

In your comments to the draft decision, you argue that "[t]*he composition of the substance of different registrants is part of the confidential information that will not easily be shared between registrants*." You further state that "*even the non-labelled material has a very high purity*" and that "*significant impurities of concern may have to be addressed by the co-registrants having this impurity*." You conclude that "*the requirement for the test substance is not applicable to the test requested by the draft decision*."

ECHA emphasizes that it is you responsibility to select a test material that is relevant for the other registrants concerned, if any. You are however reminded that under point 3 of Article 11 to REACH a registrant may submit the information referred to in Article 10(a)(vi) or (vii) separately if, for instance, submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment.