ECHA
EUROPEAN CHEMICALS AGENCY

Helsinki, 2 September 2019

Addressee: [redacted]

Decision number: CCH-D-2114482145-49-01/F
Substance name: Amines, polyethylenepoly-, triethylenetetramine fraction
EC number: 292-588-2
CAS number: 90640-67-8
Registration number: [redacted]
Submission number: [redacted]
Submission date: 11/02/2019
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. **Assessment of the toxicokinetic behaviour of the substance (Annex VIII, Section 8.8.1.) with the registered substance;**

2. **In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1.; test method: Bacterial reverse mutation test, EU B.13/14. / OECD TG 471) with the registered substance;**

3. **In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2., test method: OECD TG 473) or in vitro micronucleus study (Annex VIII, Section 8.4.2, test method: OECD TG 487) with the registered substance;**

4. **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, provided that both studies requested under 2. and 3. have negative results;**

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

6. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance;**

7. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) in a second species (rat or rabbit), oral route with the registered substance.**

You are required to submit the requested information in an updated registration dossier by ***9 September 2021*** except for the information requested under point 5, the Sub-chronic toxicity study (90-day) which shall be submitted in an updated registration dossier by ***9 September 2020***. For each deadline, you shall also update the chemical safety report, where relevant. The deadlines have 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 and advice and further observations are provided in Appendix 3.

This decision does not address the information requirement of the Extended one-generation reproductive toxicity study according to Annex X, Section 8.7.3. of the REACH Regulation.

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 Ofelia Bercaru, Head of Unit, Hazard Assessment

[1] As this is an electronic document, it is not physically signed. This communication has been approved according to ECHA's internal decision-approval process.

Appendix 1: Reasons

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 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.

While you have not explicitely claimed an adaption, your registration dossier contains for multiple endpoints information that could be interpreted as an attempt to adapt the information requirement according to Annex XI, Section 1.5. of the REACH Regulation, grouping and read-across.
ECHA has assessed first the scientific and regulatory validity of your grouping and read-across approach in general before the individual endpoints (sections 1-7).

Grouping 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, subject to the current decision:

- Assessment of the toxicokinetic behaviour of the substance (Annex VIII, Section 8.8.1.);
- *In vitro* gene mutation study in bacteria (Annex VII, Section 8.4.1);
- *In vitro* cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.) or *in vitro* micronucleus study (Annex VIII, Section 8.4.2);
- *In vitro* gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.);
- Sub-chronic toxicity study (90-day) (Annex IX, Section 8.6.2);
- Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) in a first species; and
- Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species.

You consider to achieve compliance with the REACH information requirements for the registered substance Amines, polyethylenepoly-, triethylenetetramine fraction (CAS RN 90640-67-8; EC number 292-588-2) by using data on the source substances

- [redacted]
  one major constituent of the registered substance) and its hydrochloride salts:
  - dihydochloride salt: N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride with CAS RN 38260-01-4 and EC number 253-854-3; and
  - tetrahydrochloride salt: N,N'-bis(2-aminoethyl)ethane-1,2-diamine tetrahydrochloride with CAS RN 4961-40-4 and EC number 225-604-3.

ECHA notes that you have registered your substance as Substances of Unknown or Variable Composition, Complex reaction products and Biological materials (UVCB substances). You have provided the detailed composition of your substance in your IUCLID dossier, consisting of 10 different constituents with varying concentration ranges:

[redacted]

[redacted]

According to ECHA's understanding, your read-across approach is based on structural similarity between the registered UVCB substance and its major constituent [redacted] as free base **or** its di-/tetrahydrochloride salts.

Based on this structural similarity you assume that target and source substances have similar toxicological properties.

However, there is no documentation (i.e. read-across hypothesis and justification) provided for your read-across approach. Therefore, your dossier is lacking a basis for predicting relevant human health properties of the registered substance from data for the source substances.

In the absence of this information, ECHA cannot verify that the properties of the registered substance can be predicted from the data on the source substances. This incompliance with the general rules of adaptation set out in Annex XI, Section 1.5., alone leads to the rejection of you read-across approach.

In addition, ECHA notes that your read across approach does not address the following aspects that are considered crucial to establish why a prediction for a toxicological property is reliable and can be based on the structural similarities and differences between the sources and registered substance[2]:

- you have not provided any toxicological data on the registered substance. Your technical dossier only contains toxicological data on one of its main constituents, i.e. [redacted] and its di- and tetrahydrochloride salts;
- you have not provided any data on the toxicological properties for the other nine constituents of the registered substance, which are listed above (b-j).

In the absence of this information, it is not possible to establish the toxicity profile of the registered UVCB substance and compare the toxicity profile of target and source substances.

ECHA also notes that the proposed linear source substances are structurally significantly different from some constituents of the registered substance. In particular, in the absence of any scientific explanation why these substances should be considered structurally similar, ECHA considers that the cyclic piperazine derivatives are structurally significantly different from the proposed source substances.

[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.

Therefore, ECHA considers that you have not demonstrated that only the major constituent [redacted] or its hydrochloride salts can be used for predicting the toxicological properties of the registered UVCB substance. In other words, you have not shown that the other constituents of the registered UVCB substance - such as the cyclic piperazine derivatives - do not contribute to the toxicity of the registered substance.

In summary, you have not shown that the toxicological properties of the registered substance can solely be predicted from data on one main constituent in form of its free base or hydrochloride salts.

Hence, ECHA concludes that you have not established that relevant properties of the registered substance can be predicted from data on the analogue substance. Since your adaptation does not comply with the general rules of adaptation as set out in Annex XI, Section 1.5., it is rejected and it is necessary to perform testing on the registered substance.

In your comments to the draft decision you explain that for several studies wrong CAS number has been reported to identify the test material. You suggest that the originally reported test material ([redacted] i.e. the main constituent of the registered substance) in reality corresponds to the substance EC 292-588-2; CAS 90640-67-8 (i.e. the registered substance). Thus, studies on the registered substance would be available for several endpoints and there is no need to apply read-across or test the registered substance for these endpoints.

ECHA has assessed this information and concludes that (i) it is not possible to identify which substances have been tested; (ii) the provided information does not comply with the Commission Regulation (EC) No 440/2008 and with Article 3(28) as well as Annex I, section 1.1.4 of REACH. In particular, it does not identify the constituent of the tested material and does not give information on their quantitative occurrence or about the relevant properties of the constituents.
Consequently, no study with the registered substance is available for the above listed endpoints.

1. Assessment of the toxicokinetic behaviour of the substance (Annex VIII, Section 8.8.1.)

The assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information is a standard information requirement as laid down in Annex VIII, Section 8.8.1. of the REACH Regulation.

ECHA notes that the registration dossier does not provide any assessment on the toxicokinetics properties of the registered substance. Although REACH does not specifically require generation of toxicokinetic information, it does require that all relevant available information is used to assess the toxicokinetic behaviour of a substance, and that human health hazard assessment considers the toxicokinetic profile of the substance. The toxicokinetic profile of a substance describes its absorption, distribution, metabolism and excretion.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records of

(i) a toxicokinetic study (Gibbs, 1996) with one of the major constituent of the registered substance, [redacted] and
(ii) various toxicological studies (Kodoma, 1993; Maemura, 1998; Kobayashi, 1990; Jones, 1995; Takeda, 1995; Tanabe, 1996a and 1996b) with the analogue substance N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride (CAS RN 38260-01-4; EC number 253-854-4).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected.

Therefore, pursuant to Article 41(1)(b) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: assessment of the toxicokinetic behaviour of the registered substance to the extent that can be derived from the relevant available information (Annex VIII, 8.8.1.).

Notes for your consideration

Guidance on Toxicokinetics is available in ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, June 2017), Chapter R.7c, Section R.7.12.

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

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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for Bacterial Reverse Mutation Assays (OECD TG 471; [redacted] 1987 A [redacted] 2000; [redacted] 1980; [redacted] 1979; [redacted] 2000; [redacted] 1993; Heinz, 1981 [redacted] 1992) with the one of the major constituent of the registered substance, [redacted]

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected and the information provided on this endpoint for the registered substance in the technical dossier does not meet the information requirement. Consequently, there is an information gap and it is necessary to provide information for this endpoint.

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

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Bacterial reverse mutation test (test method: EU B.13/14./ OECD TG 471)

3. *In vitro* cytogenicity study in mammalian cells or *in vitro* micronucleus study (Annex VIII, Section 8.4.2.)

An "*In vitro* cytogenicity study in mammalian cells or an *in vitro* micronucleus study" is a standard information requirement as laid down in Annex VIII, Section 8.4.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for
(i) combined *in vitro* Chinese Hamster Ovary (CHO) Mutation test, Sister Chromatid Exchange (SCE) test and assays for induction of Unscheduled DNA Synthesis (UDS), (similar to OECD TG 476, OECD TG 479 and OECD TG 482; [redacted] 1981 (5 studies); [redacted] 1979; [redacted] 1992 and [redacted] 1992) with the analogue substance, [redacted] and
(ii) *in vivo* Mammalian Erythrocyte Micronucleus tests (similar to OECD TG 474; [redacted] 1987; [redacted] 1992; Heinz, 1981) with the analogue substance, [redacted]

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and 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 chromosome aberration test (test method OECD TG 473) and the *in vitro* mammalian cell micronucleus test (OECD TG 487) are both appropriate to address the standard information requirement of Annex VIII, Section 8.4.2. of the REACH Regulation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian chromosome aberration test (test method: OECD TG 473) or *in vitro* mammalian cell micronucleus study (test method: OECD TG 487).

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

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 does not contain appropriate study records for this endpoint. Adequate information *on in vitro* gene mutation in mammalian cells will however need to be present in the technical dossier for the registered substance to meet this information requirement provided that both studies requested under 2. and 3. have negative results. ECHA set the deadline for provision of the information to allow for sequential testing.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study record(s) for

(i) combined, *in vitro* Chinese Hamster Ovary (CHO) Mutation test, Sister Chromatid Exchange (SCE) test and assays for induction of Unscheduled DNA Synthesis (UDS), (similar to OECD TG 476, OECD TG 479 and OECD TG 482; [redacted] 1981 (5 studies); [redacted] 1979; [redacted] 1992 and [redacted] 1992) with the analogue substance, [redacted] and
(ii) a Sex-linked Recessive Lethal Test in Drosophila melanogaster (OECD TG 477; [redacted] 1994) with the analogue substance, [redacted]

However, as explained above in Appendix 1, "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and 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 both studies requested under 2. and 3. have negative results.

5. 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.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for repeated dose toxicity studies via oral route with various length and quality:
(i) with one of the major constituent of the registered substance, [redacted] 1976; Stavreva, 1979); and
(ii) with the analogue substance N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride (CAS RN 38260-01-4; EC number 253-854-3); (Yanagisawa, 1998; Greenman, 1996 and Maemura, 1998).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and 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 6.0, July 2017) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically, even though the information indicates that human exposure to the registered substance by the inhalation route is likely, potential inhalation-specific effects are already addressed by deriving a long-term DNEL for inhalation and by performing a qualitative risk assessment for inhalation. Hence, the test shall be performed by the oral route using the test method OECD TG 408.

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

In your comment to the draft decision you agreed to perform the requested study.

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: OECD TG 408) in rats.

Notes for your considerations

The results of the Sub-chronic toxicity study (90-day), among other relevant information, are considered crucial to inform and decide on the study design of the extended one-generation reproductive toxicity study (EOGRTS). Therefore you may also consider updating your testing proposal for an Extended one-generation reproductive toxicity study in light of the results of the requested Sub-chronic toxicity study (90-day). The testing proposal should include a justification for its study design following ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017).

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

A "pre-natal developmental toxicity study" (test method OECD TG 414) for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation by providing study records for Developmental toxicity studies with various quality and exposure duration (similar to OECD TG 414):
(i) [redacted], 1984; [redacted] 1988; Szacki, 1974; Dobryszycka, 1975 and 1974; Korhonen, 1983; Cohen, 1983; with one of the analogue substance, [redacted] and
(ii) Keen, 1983 and 2000; with the analogue substance N,N'-bis(2-aminoethyl)ethane-1,2-diamine tetrahydrochloride (CAS RN 4961-40-4; EC number 225-604-3); and
(iii) Tanaka, 1992 and 1993; with the analogue substance N,N'-bis(2-aminoethyl)ethane-1,2-diamine dihydrochloride (CAS RN 38260-01-4; EC number 253-854-3).

However, as explained above in Appendix 1, section "Grouping and read-across approach" of this decision, your adaptation of the information requirement is rejected, and 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 OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default assumption ECHA considers testing should be performed with rats or rabbits as a first species.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a first species (rat or rabbit) by the oral route.

7. Pre-natal developmental toxicity study (Annex X, Section 8.7.2.) in a second species

Pre-natal developmental toxicity studies (test method OECD TG 414) on two species are part of the standard information requirements for a substance registered for 1000 tonnes or more per year (Annex IX, Section 8.7.2., column 1, Annex X, Section 8.7.2., column 1, and sentence 2 of introductory paragraph 2 of Annex X of the REACH Regulation).

ECHA notes that the technical dossier does not contain information on a pre-natal developmental toxicity study with the registered substance.

You have attempted to waive this standard information requirement and provided the following waiver justification: *"The available data show that TETA does not cause teratogenic or early to mid-of-pregnancy developmental defects at a top oral dose level of 750 mg/kg bw. Similarly, no developmental toxicity was seen in a dermal study at a top dose of 125 mg/kg bw. While not yet at the limit dose levels, these dose levels are deemed adequate for this corrosive industrial chemical for which oral exposure is an unlikely route anyway and for which dermal exposure will be avoided as much as possible because of the skin corrosivity. Studies with structural analogues suggest that at end of pregnancy, fetotoxic effects may occur. Such effects, if occuring at all, will be visible in the proposed OECD 416 study for fertility. (2-generation study)."*

However, your waiver justification does not meet the specific rules for the adaptation of Annex X, Section 8.7.2., column 2 or the general rules for adaptation of Annex XI. 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.

According to the test method OECD TG 414, the rat is the preferred rodent species and the rabbit the preferred non-rodent species. On the basis of this default consideration, ECHA considers testing should be performed with rabbits or rats as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) Chapter R.7a, Section R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: OECD TG 414) in a second species (rabbit or rat) by the oral route.

Notes for your consideration

You are reminded that before performing a pre-natal developmental toxicity study in a second species you must consider the specific adaptation possibilities of Annex X, Section 8.7., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species with other available information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement.

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 25 October 2018.

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.

You were notified in the draft decision that ECHA does not take into account any dossier updates after the draft decision was sent on 13 December 2018. You updated your registration with submission [redacted] on 11 February 2019. In your updated dossier (submission number [redacted]) you attempt to clarify the test material identity for several studies. Such data are, however, neither new or substantial and therefore cannot be taken into account. First, these data are not new because it relates to the test material of studies previously submitted by you. Second, these data are not substantial since there are not sufficient information to make an assessment and to identify the test material (same reason as for the information provided in your comments to the draft decision).

We note in addition some discrepancies in the information that you provided. In particular, you changed the test material identity for the study Gibbs 1986, by replacing the originally indicated [redacted] (one of the constituent of the registered substance) with EC 292-588-2; CAS 90640-67-8 (the registered substance). However, it is clearly indicated in the original publication (Gibbs et al, 1986) that the analogue TETA dihydrochloride (i.e. triethylenetetramine dihydrochloride) has been administered to the subjects.

ECHA took into account your comments and the updated dossier and did not amend the request(s).

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

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 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.