EUROPEAN CHEMICALS AGENCY

Helsinki, 16 April 2019

Addressee: [redacted]

Decision number: TPE-D-2114465979-23-01/F
Substance name: C16-(branched), C20-(branched) and C24-(branched)-alkanes
EC number: 700-992-1
CAS number: NS
Registration number: [redacted]
Submission number: [redacted]
Submission date: 09/11/2018
Registered tonnage band: Over 1000

DECISION ON A TESTING PROPOSAL

Based on Article 40 of Regulation ((EC) No 1907/2006) (the REACH Regulation), ECHA examined your testing proposal(s) and decided as follows.

While your originally proposed tests for Sub-chronic toxicity study (90-day), oral route (EU B.26./OECD TG 408), Extended One-Generation Reproductive Toxicity Study (OECD TG 443), Pre-natal developmental toxicity study (OECD TG 414) in first species rat and Pre-natal developmental toxicity study (OECD TG 414) in second species rabbit using the analogue substance "*the isolated fraction of C16 isomers (UVCB) of the substance C16-(branched), C20-(branched) and C24-(branched)-alkanes (Tetrabutane tech.).* ", Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) are rejected, you are requested to perform:

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats using the registered substance.**
2. **Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: OECD TG 414) in a first species (rat or rabbit), ora route using the registered substance.**
3. **Pre-natal developmental toxicity study (Annex X, Section 8.7.2.; test method: OECD TG 414) in a second species (rabbit or rat), oral route using the registered substance.**

You have to submit the requested information in an updated registration dossier by **23 April 2021**. You also have to update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

The reasons for 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.

The results of the Sub-chronic toxicity study (90-day) will be used, among other relevant information, to decide on the study design of the Extended one generation reproductive toxicity study. Therefore, your testing proposal for Extended one-generation reproductive toxicity study will be addressed after having received the results of the Sub-chronic toxicity study (90-day).

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 **Claudio Carlon**, 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

The decision of ECHA is based on the examination of the testing proposals submitted by you and scientific information submitted by third parties.

Grouping and read-across approach for toxicological information

The decision of ECHA is based on the examination of the testing proposals submitted by you for the registered substance tetrabutane, (EC no 700-992-1); (hereafter referred to as "target substance"). However, ECHA noted that although you have not claimed a read-across adaptation, the substance proposed for the testing is not the registered substance but "*the isolated fraction of C16 isomers (UVCB) of the substance C16-(branched), C20-(branched) and C24-(branched)-alkanes (Tetrabutane tech.).* ", Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0). Therefore, ECHA has considered first the scientific validity of the read-across hypothesis (preliminary considerations below), before assessing the testing proposed (sections 1,2 and 3, below).

Article 13(1) of the REACH Regulation requires information on intrinsic properties of substances on human toxicity to be generated whenever possible by means other than vertebrate animal tests, including from information from structurally related substances (grouping or read-across), "*provided that the conditions set out in Annex XI are met*".

According to Annex XI, Section 1.5. there needs to be structural similarity among the substances within a group or a category and furthermore, it is required that the relevant properties of a substance within the group can be predicted from the data for reference substance(s) by interpolation, and the data should be adequate for the purpose of classification and labelling and/or risk assessment. Furthermore, Annex XI, Section 1.5. lists several additional requirements, including that adequate and reliable documentation of the applied method is to be provided.

You have proposed to cover the standard information requirements for a sub-chronic toxicity study (90-days; Annex IX, Section 8.6.2.), pre-natal developmental toxicity study (Annex IX, Section 8.7.2.) and a pre-natal developmental toxicity study (Annex X, Section 8.7.2.) by performing the test with a source substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0).

ECHA observes that there is no documentation establishing a basis whereby relevant human health properties of the registered substance may be predicted from data for the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0). In the absence of any documentation supporting the proposed read-across approach, ECHA considers that you have failed to provide an adequate and reliable documentation of the applied method as required by Annex XI, Section 1.5 of the REACH Regulation. Therefore, ECHA is not in a position to evaluate the proposed read-across approach which could allow establishing that relevant properties of the registered substance can be predicted from those of the analogue substance. The proposed read-across has therefore to be rejected as not acceptable. Accordingly, it is necessary to perform testing on the registered substance.

In your comments on the draft decision you agreed that in the dossier "*there is insufficient information and justification to predict relevant human health properties from the analogue substance Tetrabutane*". You also expressed your intention to submit the requested information related to the entire composition of the registered substance. Moreover, you have also indicated that you are considering to fulfil the information requirements using a

read-across adaptation.

ECHA notes that you have updated the dossier on 9 November 2018 (submission no. [redacted]). Under the testing proposals for the sub-chronic toxicity (90 day) study and the two prenatal developmental toxicity studies you indicated your intention to waive these studies. In the dossier you also indicated that the information for justification for data waiving "*will be submitted later based on ECHA draft decision on testing proposals (communication number TPE-D-2114444016-58-01/D*". You also changed the test material information with the identifiers of the registered substance.

ECHA acknowledges your intention to examine the information provided in the third party comments on the proposed structurally related substances and your consideration on using a category approach. However, ECHA notes that at this point in time of the decision-making process, considering that you did not provide the read-across justification in the dossier update, ECHA cannot evaluate the proposed category approach. Hence, the assessment for compliance with the REACH requirements of all the new information provided in the later update(s) of the registration dossier will only be performed at the follow-up evaluation stage, pursuant to Article 42 of the REACH Regulation (after the final decision is sent out by ECHA).

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

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

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. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a sub-chronic toxicity study (90 day) in rats by the oral route according to OECD TG 408 with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) with no further justification. In the absence of information, as explained above in section Grouping and read-across for toxicological information, ECHA is not in a position to conclude on the proposed read-across approach which could allow establishing that sub-chronic toxicity of the registered substance can be predicted from that of the analogue substance and therefore rejects the read-across adaptation.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Sub-chronic toxicity (90-day): oral. ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

You proposed testing by the oral route. Based on the information provided in the technical dossier and/or in the chemical safety report, ECHA agrees 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, the substance is a liquid of low vapour pressure and no uses with spray application are reported that could potentially lead to aerosols of inhalable size. Hence, the test shall be performed by the oral route using the test method EU B.26./OECD TG 408.

Therefore, ECHA considers that a study performed by the oral route with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.6.2. of the REACH Regulation.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information:

A third party has commented that "*According to the published Registration Dossier, this substances is registered at Annex VII. The proposed 90-day study is not a requirement at this tonnage band. If a study is required, read-across to structurally-related substances (category approach) should be investigated as a priority, in order to avoid unnecessary testing in vertebrate animals. It is noted that the published Registration Dossiers for the substances ?alkanes, C10-20-branched and linear? (EC 618-882-6, CAS 928771-01-1) and ?alkanes, C10-C17 branched and linear? (EC 931-082-4) include a 90-day oral toxicity study. Furthermore the published Registration Dossiers for the substances ?renewable hydrocarbons, C15-C18, branched alkanes? (EC 942-445-1) and ?renewable hydrocarbons, C17-C18, branched alkanes? (EC 942-446-7) contain a 90-day inhalation toxicity study. Additionally the substance is of low acute toxicity and is not an irritant or sensitiser. An OECD 422 screening toxicity study reports a NOAEL of 1000 mg/kg bw/d in the absence of any adverse effects of treatment. The substance is not classified for human health endpoints and therefore meets the definition of a ?low (sub)acute toxicity profile? according to Taylor et al (2014), Taylor & Andrew (2017). It is therefore unlikely that the proposed 90-day study will demonstrate a lower NOAEL for human-relevant effects. The value of the proposed 90-day study is therefore questioned.*"

With regard to the tonnage band requirements, as specified in "The link under 'View dossier'" of ECHA's website (https://echa.europa.eu/information-on-chemicals/testing-proposals/current), the "*Total Tonnage Band published does not necessarily reflect the registered tonnage band(s) and associated information requirement obligations. For the 'Total Tonnage Band' of the disseminated dossier, compiled data is calculated from the non-confidential quantities of a substance manufactured and/or imported by **all** registrants, excluding any quantity directly used as an intermediate to produce a different chemical.*" For the purpose of this evaluation the requirement for information on Sub-chronic toxicity study (90-day) applies.

ECHA acknowledges that the third party has proposed a read across approach for you to consider.

ECHA notes that it is your responsibility to consider and justify any adaptation of the information requirements in accordance with the relevant conditions as established in Annex XI, Section 1.5.. Therefore, you may assess whether you can justify a read-across as

suggested by the third party. If the information requirement can be met by way of adaptation, you may include the adaptation argument with all necessary documentation according to Annex XI, Section 1.5. in an updated registration.

Furthermore, the third party suggested that a 90-day study would be of a questionable value given that the substance is of low acute toxicity and is not an irritant or sensitiser and has a NOAEL of 1000 mg/kg bw/d in an OECD 422 screening toxicity study. This can be broadly interpreted as a weight of evidence type of approach. However, ECHA notes that the information provided by the third party is insufficient for demonstrating that the conditions of Annex XI, Section 1.2. of the REACH Regulation are met. The third party claims that this general weight of evidence approach can be used to predict the sub-chronic toxic properties of a substance based on observed "low toxicity" in a sub-acute (short-term repeated dose) toxicity study if the substance fulfils certain other criteria described as a "low toxicity profile". However, ECHA notes that this predictive weight of evidence approach has shortcomings that prevent its application. First of all, ECHA notes that a weight of evidence approach requires substance-specific justification and cannot be addressed with a generic weight of evidence approach which e.g. does not explain whether it is applicable to the registered substance. Secondly, the proposed approach has a limited predictive power. It is based on two publications containing eighteen (Taylor K et al (2014) and ten (Taylor K & Andrew DJ (2017) substances respectively with a "low toxicity profile". Out of these substances, the prediction was incorrect for two and four substances respectively. Thirdly, ECHA notes that the proposed general weight of evidence approach that a substance will not have an effect in a sub-chronic toxicity study based on results of a sub-acute toxicity study is not appropriate for the following reasons. The study design of sub-acute toxicity studies and sub-chronic toxicity studies differ in relevant key parameters, which affect the uncertainty and relevance of the information obtained from these studies. For example, the reduced number of animals used in a sub-acute toxicity study (5 animals per sex and dose) compared to the sub-chronic toxicity study (10 animals per sex and dose) results in a lower statistical power of the sub-acute toxicity study to detect effects. Similarly, the duration of exposure in a sub-chronic toxicity study (90 days) covers a prolonged period of the animals' lifespan as compared to the sub-acute toxicity study (28 days). As a consequence of these differences in the study protocols, a sub-chronic toxicity study (90-day) may detect effects which were not observed in a sub-acute toxicity study (28 days). Therefore, the information provided by the third party is not sufficient to adapt the standard information requirement.

c) Outcome

Pursuant to Article 40(3)(d)(c) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Sub-chronic toxicity study (90-day) in rats, oral route (test method: OECD TG 408) while your originally proposed test for a Sub-chronic toxicity study (90-day) in rats, oral route (test method: OECD TG 408) with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) is rejected according to Article 40(3)(d) of the REACH Regulation.

Notes for your considerations:

You submitted a testing proposal for an Extended one-generation reproductive toxicity study (Annex X, 8.7.3.). However, this testing proposal is not addressed in this decision because the results of the Sub-chronic toxicity study (90-day) are considered crucial to inform on the study design of the Extended one-generation reproductive toxicity study. Therefore, you are required to perform the Sub-chronic toxicity study (90-day) first, and submit the results by the deadline indicated above.

Together with providing the results for the requested Sub-chronic toxicity study (90-day), you may also consider updating your testing proposal for the Extended one-generation reproductive toxicity study. The updated testing proposal should include a justification for the design of the Extended one-generation reproductive toxicity study following ECHA *Guidance on information requirements and chemical safety assessment* Chapter R.7a, Section R.7.6 (version 6.0, July 2017), taking into account the results of the Sub-chronic toxicity study (90-day).

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

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

A pre-natal developmental toxicity study for a first species is a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation. The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study in rats according to OECD TG 414 by the oral route with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) with the following justification:

"TESTING PROPOSAL ON VERTEBRATE ANIMALS
A Prenatal Developmental Toxicity study for the first species is conducted as a standard information requirement as laid down in Annex IX, Section 8.7.2. of the REACH Regulation.

NON-CONFIDENTIAL NAME OF SUBSTANCE:
- Name of the substance on which testing is proposed to be carried out: Tetrabutane

CONSIDERATIONS THAT THE GENERAL ADAPTATION POSSIBILITIES OF ANNEX XI OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:
- Available GLP studies: A combined 28-day Oral Repeated Dose Toxicity Study with reproductive toxicity screening is available, which was conducted according to OECD TG 422, and in compliance with GLP. In this study, no test item-related changes were noted in the (histo)pathological examination of the reproductive organs.
- Available non-GLP studies: none available for toxicity to reproduction endpoint
- Historical human data: no data
- (Q)SAR: no data.
There are a large number of potential targets/mechanisms associated with reproductive toxicity which, on the basis of current knowledge, cannot normally be adequately covered by a battery of QSAR models. QSAR approaches are currently not well fitted-for-purpose for reproductive toxicity (according to Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a, Version 5.0, Dez 2016).
- In vitro methods: no accepted alternative in vitro methods to predict developmental toxicity for regulatory use are available (according to Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.7a, Version 5.0, Dez 2016).
- Weight of evidence: insufficient data existing

- Grouping and read-across: no read-across data available
CONSIDERATIONS THAT THE SPECIFIC ADAPTATION POSSIBILITIES OF ANNEXES VI TO X (AND COLUMN 2 THEREOF) OF THE REACH REGULATION ARE NOT ADEQUATE TO GENERATE THE NECESSARY INFORMATION:
- There are no column 2 adaptations for reproductive toxicity.

FURTHER INFORMATION ON TESTING PROPOSAL IN ADDITION TO INFORMATION PROVIDED IN THE MATERIALS AND METHODS SECTION:
- Details on study design / methodology proposed: a Prenatal Developmental Toxicity study in rodents according to OECD TG 414 will be conducted with Tetrabutane."

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) with no further read-across justification. In the absence of information, as explained above in section Grouping and read-across for toxicological information, ECHA is not in a position to conclude on the proposed read-across approach which could allow establishing that pre-natal developmental toxicity of the registered substance can be predicted from that of the analogue substance and therefore rejects the read-across adaptation.

ECHA considers that a study performed with the registered substance is appropriate to fulfil the information requirement of Annex IX, Section 8.7.2. of the REACH Regulation.

You proposed testing with the rat as a first species. 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 the rat or rabbit as a first species.

You proposed testing by the oral route. 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.

b) Consideration of the information received during third party consultation

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

Third party information:

A third party has commented that:"*According to the published Registration Dossier, this substances is registered at Annex VII. The proposed PNDT study is not a requirement at this tonnage band.*"

With regard to the tonnage band requirements, as specified in "The link under 'View dossier'" of ECHA's website (https://echa.europa.eu/information-on-chemicals/testing-proposals/current), the "*Total Tonnage Band published does not necessarily reflect the registered tonnage band(s) and associated information requirement obligations. For the 'Total Tonnage Band' of the disseminated dossier, compiled data is calculated from the non-confidential quantities of a substance manufactured and/or imported by **all** registrants, excluding any quantity directly used as an intermediate to produce a different chemical.*" For the purpose of this evaluation the requirement for information on Sub-chronic toxicity study (90-day) applies.

c) Outcome

Therefore, pursuant to Article 40(3)(d)(c) of the REACH Regulation, you are requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a first species (rats or rabbits), oral route (test method: OECD TG 414).

while your originally proposed test for a Pre-natal developmental toxicity study in rats, oral route (test method: OECD TG 414 with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) is rejected according to Article 40(3)(d) of the REACH Regulation.

Notes for your consideration

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, Section R.7.6.2.3.2

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

a) Examination of the testing proposal

Pursuant to Article 40(3)(d) and (c) of the REACH Regulation, ECHA may reject a proposed test and require the Registrant to carry out other tests in cases of non-compliance of the testing proposal with Annexes IX, X or XI.

Pre-natal developmental toxicity studies on two species are part of the standard information requirements for 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).

The information on this endpoint is not available for the registered substance but needs to be present in the technical dossier to meet the information requirements. Consequently there is an information gap and it is necessary to provide information for this endpoint.

You have submitted a testing proposal for a pre-natal developmental toxicity study in a second species (rabbits) according to EU OECD TG 414 by the oral route with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) with a the justification similar as the one provided above for the first species.

ECHA requested your considerations for alternative methods to fulfil the information requirement for Reproductive toxicity (pre-natal developmental toxicity). ECHA notes that you provided your considerations and you applied read-across to fulfil the respective information requirement, and no other alternative methods were available. ECHA has taken these considerations into account.

ECHA has evaluated your proposal to perform the test with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) with no further read-across justification. In the absence of information, as explained above in section Grouping and read-across for toxicological information, ECHA is not in a position to conclude on the proposed read-across approach which could allow establishing that pre-natal developmental toxicity of the registered substance can be predicted from that of the analogue substance and therefore rejects the read-across adaptation.

ECHA considers that a study performed with the registered substance is appropriate to fulfil the information requirement of Annex X, Section 8.7.2. of the REACH Regulation.

You proposed testing with the rabbit as a second species. 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 the rabbit or the rat as a second species, depending on the species tested in the first pre-natal developmental toxicity study.

You proposed testing by the oral route. 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.

ECHA received third party information concerning the testing proposal during the third party consultation. For the reasons explained further below the information provided by third parties is not sufficient to fulfil this information requirement.

The third party information received is the same as that which was submitted for a pre-natal developmental toxicity in the first species, as described above in Appendix 1. Section 2., and has been explained under that section.

c) Outcome

Therefore, pursuant to Article 40(3)(d)(c) of the REACH Regulation, you are thus requested to carry out the proposed study with the registered substance subject to the present decision: Pre-natal developmental toxicity study in a second species (rabbit or rat), oral route (test method: OECD TG 414).

while your originally proposed test for a Pre-natal developmental toxicity study in a second species in rabbit, oral route (test method: OECD TG 414) with the analogue substance Tetrabutane (dest.) 2017 CAS No 93924-49-3 (EC No 300-244-0) is rejected according to Article 40(3)(d) of the REACH Regulation.

d) *Notes for your consideration*

Before performing a pre-natal developmental toxicity study in a second species you should consider the specific adaptation possibilities of Annex X, Section 8.7.2., column 2 and general adaptation possibilities of Annex XI. If the results of the test in the first species or any other new information enable such adaptation, testing in the second species should be omitted and the registration dossier should be updated containing the corresponding adaptation statement and underlying scientific justification.

For the selection of the appropriate species you are advised to consult ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a, Section R.7.6.2.3.2.

Deadline to submit the requested Information

In the draft decision communicated to you the time indicated to provide the requested information was 18 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 24 months. You indicated that you require additional time to be able to determine whether the proposed category evaluation approach can be used. ECHA considers that the extra time would allow you to evaluate all available information before conducting the studies. Therefore, ECHA has granted the request and set the deadline to 24 months.

Appendix 2: Procedural history

ECHA started the testing proposal evaluation in accordance with Article 40(1) on 12 December 2017.

ECHA held a third party consultation for the testing proposals from 28 February 2018 until 16 April 2018. ECHA received information from third parties (see Appendix 1).

This decision does not take into account any updates after **26 November 2018**, 30 calendar days after the end of the commenting period.

You updated your registration on 9 November 2018. ECHA took the information in the updated registration into account, and did not amend the draft decision. The updated information is reflected in the Reasons (Appendix 1).

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 requests and 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 took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. This decision does not imply that the information provided in your registration dossier is in compliance with the REACH requirements. The decision does not prevent ECHA from initiating a compliance check on the 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 the Member States.

3. In carrying out the tests required by the present decision, it is important to ensure that the particular sample of substance tested 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. If the registration of the substance covers different grades, the sample used for the new tests must be suitable to assess these.

   Furthermore, 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.