ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114336130-67-01/F Helsinki, 19 July 2016

**DECISION ON A COMPLIANCE CHECK OF A REGISTRATION PURSUANT TO ARTICLE 41(3) OF REGULATION (EC) NO 1907/2006**

**For 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters, CAS No 71662-46-9 (EC No 275-809-7), registration number:** [redacted]

**Addressee:** [redacted]

The European Chemicals Agency (ECHA) has taken the following decision in accordance with the procedure set out in Articles 50 and 51 of Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation).

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters, CAS No 71662-46-9 (EC No 275-809-7), submitted by [redacted] (Registrant). The scope of this compliance check decision is limited to the standard information requirements of Annex VII, Section 7, Annex VIII, Sections 8.5 and 9.3, Annex IX, Sections 8.7.2 and 9.1-4, Annex X, Sections 9.4 and 9.5 of the REACH Regulation.

This decision is based on the registration as submitted with submission number [redacted], for the tonnage band of 1000 tonnes or more per year. This decision does not take into account any updates after the date when the draft decision was notified to the Registrant under Article 50(1) of the REACH Regulation.

This compliance check decision does not prevent ECHA from initiating further compliance checks on the present registration at a later stage. ECHA notes, in particular, that the information requirement of Annex IX/X, Section 8.7.3 has not been addressed in this decision.

The compliance check was initiated on 26 November 2014.

On 13 May 2015 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 19 June 2015 ECHA received comments from the Registrant agreeing to ECHA's draft decision regarding the information requirements 1-7, 10, 11, 14, 15, 16 and 17 but disagreeing with information requirements 8, 9, 12 and 13.

The Registrant updated his registration after the expiry of the deadline for updating mentioned above, and therefore too late in the decision making process for being considered. If still relevant, the dossier update will be considered by ECHA in line with its follow up process after the deadline established in the present decision has passed.

The ECHA Secretariat considered the Registrant's comments. The information is reflected in the Statement of Reasons (Section III) whereas no amendments to the Information Required (Section II) were made.

On 03 March 2016 ECHA notified the Competent Authorities of the Member States of its draft decision and invited them pursuant to Article 51(1) of the REACH Regulation to submit proposals for amendment of the draft decision within 30 days of the receipt of the notification.

Subsequently, a proposal for amendment to the draft decision were submitted.

On 08 April 2016 ECHA notified the Registrant of the proposal for amendment to the draft decision and invited him pursuant to Article 51(5) of the REACH Regulation to provide comments on the proposal for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposal for amendment and did not modify the draft decision.

On 18 April 2016 ECHA referred the draft decision to the Member State Committee.

By 10 May 2016, in accordance to Article 51(5), the Registrant provided comments on the proposal for amendment. In addition, the Registrant provided comments on the draft decision. The Member State Committee took the comments on the proposal for amendment of the Registrant into account. The Member State Committee did not take into account the Registrant's comments on the draft decision as they were not related to the proposal for amendment made and are therefore considered outside the scope of Article 51(5).

A unanimous agreement of the Member State Committee on the draft decision was reached on 23 May 2016 in a written procedure launched on 13 May 2016.

ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

II. Information required

## A. Information in the technical dossier derived from the application of Annexes VII to XI

Pursuant to Articles 41(1), 41(3), 10(a)(vi) and/or (vii), 12(1)( e), 13 and Annexes VII, VIII, IX, and X of the REACH Regulation the Registrant shall submit the following information using the indicated test methods and the registered substance subject to the present decision:

1. Melting/freezing point (Annex VII, Section 7.2.; test method: EU A.1./OECD 102);
2. Boiling point (Annex VII, Section 7.3.; test method: EU A.2./OECD 103);
3. Relative density (Annex VII, Section 7.4.; test method: EU A.3./OECD 109);
4. Vapour pressure (Annex VII, Section 7.5.; test method: EU A.4./OECD 104);
5. Flash-point (Annex VII, Section 7.9.; test method: as specified in Section III);
6. Self-ignition temperature (Annex VII, Section 7.12.; test method: EU A.15.);
7. Viscosity (Annex IX, Section 7.17.; test method: OECD 114);
8. Acute toxicity by dermal route (Annex VIII, Section 8.5.3.; test method:

EU B.3./OECD 402 or OECD 434);

9. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD 414) in rats or rabbits, oral route;

10. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD 305, using the aqueous or dietary exposure route;

11. Adsorption/desorption screening (Annex VIII, Section 9.3.1.; test method: Estimation of the Adsorption Coefficient (Koc ) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), OECD 121);

12. Long-term toxicity testing on aquatic invertebrates (Annex IX, Section 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20./OECD 211);

13. Long-term toxicity testing on fish (Annex IX, Section 9.1.6.1.; test method: Fish, early-life stage (FELS) toxicity test, OECD 210);

14. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.); using one or more of the following test methods: Sediment-water Chironomid toxicity using spiked sediment (OECD 218) or Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) or Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233);

15. Effects on terrestrial organisms – Long-term toxicity testing on terrestrial invertebrates (Annex X, Section 9.4.4.); using one of the following test methods: Earthworm reproduction test (*Eisenia fetida/Eisenia andrei*), OECD 222); or Enchytraeid reproduction test, OECD 220;

16. Effects on terrestrial organisms – Long-term toxicity testing on plants (Annex X, Section 9.4.6.); using either test method Terrestrial plants, growth test, OECD 208), (with as a minimum one monocotyledonous species other than Triticum aestivum and two dicotyledonous species other than Brassica alba and Lepidum sativum), or Soil Quality – Biological Methods – Chronic toxicity in higher plants, ISO 22030;

17. Effects on terrestrial organisms – Effects on soil micro-organisms (Annex IX, Section 9.4.2.; test method: Soil microorganisms: nitrogen transformation test, EU C.21./OECD 216).

Note for consideration by the Registrant:

*The Registrant may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI of the REACH Regulation. In order to ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring to and conforming with the appropriate rules in the respective Annex, and an adequate and reliable documentation.*

*Failure to comply with the request(s) in this decision, or to fulfil otherwise the information requirement(s) with a valid and documented adaptation, will result in a notification to the Enforcement Authorities of the Member States.*

**B. Deadline for submitting the required information**

Pursuant to Articles 41(4) and 22(2) of the REACH Regulation the Registrant shall submit to ECHA by **26 April 2019** an update of the registration dossier containing the information required by this decision, including, where relevant, an update of the Chemical Safety Report. The timeline has been set to allow for sequential testing as appropriate.

III. Statement of reasons

Pursuant to Article 41(3) of the REACH Regulation, ECHA may require the Registrant to submit any information needed to bring the registration into compliance with the relevant information requirements.

**Information in the technical dossier derived from the application of Annexes VII to XI**

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)( e) of the REACH Regulation, a technical dossier for a substance manufactured or imported by the Registrant in quantities of 1000 tonnes or more per year shall contain as a minimum the information specified in Annexes VII to X of the REACH Regulation.

1. Melting/freezing point (Annex VII, Section 7.2.)

"Melting/freezing point" is a standard information requirement as laid down in Annex VII, Section 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.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

"*Most of the physical and chemical properties were determined with the analogue substance 1,2 -Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation.*"

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014)[1] "*read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according to Article 8 (2) of CLP.*" Moreover, at page 32 of this guidance, the following is reported for this specific endpoint: "*For the determination of the melting point read-across is usually not possible. However interpolation may still be possible within homologous series.*"

[1] http://echa.europa.eu/documents/10162/13632/information_requirements_r7a_en.pdf

ECHA observes that the read-across adaptation provided by the Registrant is based on a one to one read-across (or analogue approach) and not on interpolation within homologues series. As explained in the Guidance, this read-across approach is not suitable to cover physico-chemical endpoints. The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Melting/freezing temperature (test method: EU A.1.) or Melting point / melting range (test method: OECD 102).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

2. Boiling point (Annex VII, Section 7.3.)

"Boiling point" is a standard information requirement as laid down in Annex VII, Section 7.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

*"Most of the physical and chemical properties were determined with the analogue substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2 -Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation."*

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014) "*read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according*

*to Article 8 (2) of CLP."* Moreover, at page 35 of this guidance, the following is reported for this specific endpoint: *"For the determination of the boiling point read-across is usually not possible. However interpolation may still be possible within homologous series."*

ECHA observes that the read-across adaptation provided by the Registrant is based on a one to one read-across (or analogue approach) and not on interpolation within homologues series. As explained in the Guidance, this read-across approach is not suitable to cover physico-chemical endpoints. The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Boiling temperature (test method: EU A.2.) or Boiling point (OECD 103).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

3. Relative density (Annex VII, Section 7.4.)

"Relative density" is a standard information requirement as laid down in Annex VII, Section 7.4. 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.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

*"Most of the physical and chemical properties were determined with the analogue substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2 -Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation."*

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014) "*read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according to Article 8 (2) of CLP.*" Moreover, at page 39 of this guidance, the following is reported for this specific endpoint: "*For the determination of the relative density read-across is usually not possible. However interpolation may still be possible within homologous series.*"

ECHA observes that the read-across adaptation provided by the Registrant is based on a one to one read-across (or analogue approach) and not on interpolation within homologues series. As explained in the Guidance, this read-across approach is not suitable to cover physico-chemical endpoints. The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Relative density (test method: EU A.3.) or Density of liquids and solids (OECD 109).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

4. Vapour pressure (Annex VII, Section 7.5.)

"Vapour pressure" is a standard information requirement as laid down in Annex VII, Section 7.5. 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.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

*"Most of the physical and chemical properties were determined with the analogue substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2 -Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation."*

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014) *"read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according to Article 8 (2) of CLP."* Moreover, at page 42 of this guidance, the following is reported for this specific endpoint: *"For the determination of vapour pressure read-across is usually not possible. However interpolation may still be possible within homologous series."*

ECHA observes that the read-across adaptation provided by the Registrant is based on a one to one read-across (or analogue approach) and not on interpolation within homologues series. As explained in the Guidance, this read-across approach is not suitable to cover physico-chemical endpoints. The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Vapour pressure (test method: EU A.4./OECD 104).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

5. Flash-point (Annex VII, Section 7.9.)

"Flash-point" is a standard information requirement as laid down in Annex VII, Section 7.9. 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.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

*"Most of the physical and chemical properties were determined with the analogue substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2 -Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only*

*exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation."*

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014) *"read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according to Article 8 (2) of CLP."* Moreover, at page 64 of this guidance, the following is reported for this specific endpoint: *"For the determination of the flash point read-across is usually not possible. However interpolation may still be possible within homologous series."*

ECHA observes that the read-across adaptation provided by the Registrant is based on a one to one read-across (or analogue approach) and not on interpolation within homologues series. As explained in the Guidance, this read-across approach is not suitable to cover physico-chemical endpoints. The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance subject to the present decision.

Appropriate test methods to determine the flash point of flammable liquids are listed in Annex I, Section 2.6.4.4. of the Regulation (EC) No 1272/2008. Pursuant to Annex I, 2.1. of the REACH Regulation the hazard assessment for phyiscochemical properties shall determine the classification of a substance in accordance with the CLP Regulation. Annex I, 2.2. of REACH sets out the minimum requirements for the assessment of the potential effects to human health from physical hazards including flammability. The flash-point is considered part of the flammability properties of a substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Flash-point. Appropriate test methods are listed in Regulation (EC) No 1272/2008 (the CLP Regulation), Annex I, Section 2.6.4.4.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

6. Self-ignition temperature (Annex VII, Section 7.12.)

"Self-ignition temperature" is a standard information requirement as laid down in Annex VII, Section 7.12. 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.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

*"Most of the physical and chemical properties were determined with the analogue substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2 -Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation."*

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014) *"read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according to Article 8 (2) of CLP."* Moreover, at page 107 of this guidance, the following is reported for this specific endpoint: *"For the determination of the auto-ignition temperature read-across is usually not possible. However interpolation may still be possible within homologous series."*

ECHA observes that the read-across adaptation provided by the Registrant is based on a one to one read-across (or analogue approach) and not on interpolation within homologues series. As explained in the Guidance, this read-across approach is not suitable to cover physico-chemical endpoints. The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Self-ignition temperature (test method: A.15 Auto-ignition temperature (liquids and gases)).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical

properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

7. Viscosity (Annex IX, Section 7.17.)

"Viscosity" is a standard information requirement as laid down in Annex VII, Section 7.17. 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.

The technical dossier does not contain relevant data to fulfil this information requirement. The Registrant sought to adapt the information requirement, by providing the following justification:

*"Most of the physical and chemical properties were determined with the analogue substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (CAS 68515-51-5). The analogue substance is similar to 1,2 -Benzenedicarboxylic acid, di-C8-10-alkyl esters with the only exception of the carbon chain range of C6 to C10 instead of C8 to C10. Therefore the physical and chemical properties are considered to be in the same ranges in the relevant endpoints and adequate for evaluation."*

ECHA points out that a read-across approach is not suitable to cover physico-chemical endpoints.

As specified on page 27 of the 'Guidance on Information Requirements and Chemical Safety Assessment', Chapter R.7a: Endpoint specific guidance (Version 3.0, August 2014) "*read-across for physicochemical properties is not generally recommended, since reliable data should normally be available or easily obtainable. This is particularly true for physical hazard related physicochemical properties for which reliable test data must be available according to Article 8 (2) of CLP.*" Moreover, at page 154 of this guidance, the following is reported for this specific endpoint: "*For the determination of the viscosity read across is not possible.*" The Registrant is therefore requested to submit the information for this endpoint using an appropriate test method on the registered substance.

As explained above, the information available 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. Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Viscosity of liquids (test method: OECD 114).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that "Studies for the required physical-chemical properties using the registered substance 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters will be added to the dossier."

The Registrant is reminded that this decision does not take into account any updates submitted after13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

8. Acute toxicity by dermal route (Annex VIII, Section 8.5.3.);

"Acute toxicity by dermal route" is a standard information requirement as laid down in Annex VIII, Section 8.5.3. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of an acute toxicity study with the registered substance subject to the present decision by the dermal route in the dossier that would meet the information requirement of Annex VIII, Section 8.5.3.

It seems that the Registrant has sought to adapt this information requirement by applying a read-across approach: In the technical dossier the Registrant has provided study records for acute toxicity studies in rats by the dermal route (OECD TG 402) with diundecylphthalate, CAS No 3648-20-2 and with 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters, EC No 271-094-0 and a non-guideline study with diundecylphthalate in rabbits. However, these studies do not provide the information required by Annex VIII, Section 8.5.3. for the registered substance subject to the present decision, because the Registrant did not provide a justification and adequate and reliable documentation to justify the read-across approach as required by Annex XI, 1.5. of the REACH Regulation. More explicitly, it is not explained based on which elements the different substances would be similar or follow a regular pattern as a result of structural similarity so that human health effects may be predicted from data for other substances.[2]

Therefore, the adaptation of the information requirement suggested by the Registrant cannot be accepted.

As explained above, the information available 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.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Acute dermal toxicity (test method: EU B.3./OECD 402 or OECD 434).

In the comments to the draft decision the Registrant disagreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

In his comments, the Registrant has argued that "*The available studies on the similar substances give sufficient information on the endpoint "Acute toxicity by the dermal rou*te." The Registrant also provided a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across

[2] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere documentation does not necessarily mean that a read-across approach may be acceptable to ECHA.

strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)".

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

ECHA acknowledges that read-across between different phthalates for the endpoint "Acute toxicity by the dermal route" may be feasible. However there are obvious weaknesses in the read-across justification e.g.:

- The toxicokinetic comparison is only based on theoretical considerations because "*experimental data are not available for the assessment of the toxicokinetic properties of the C8-C10 or the C6-C10-phthalate and read-across for toxicokinetic property assessment.*"
- Theoretical assessment of toxicokinetics requires good knowledge of the physico-chemical properties, however there seem to be discrepancies between calculated values used in the Registrant's read-across justification, e.g. a calculated water solubility of <0.001mg/L at 25°C values for the source substance "RA sub 1" (CAS 68515-51-5; 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters), and a measured water solubility value of of 11 mg/L at 23 °C and pH 5.5 reported in the registration dossier for the same substance and publicly available on ECHA's website.
- No information is given about potential systemic effects observed in the skin irritation studies in source or target substance.

The Registrant is reminded that this decision does not take into account any updates submitted after13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

9. Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.)

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. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

The Registrant has not provided any study record of a pre-natal developmental toxicity study with the registered substance subject to the present decision in the dossier that would meet the information requirement of Annex IX, Section 8.7.2.

It seems that the Registrant has sought to adapt this information requirement: In the technical dossier the Registrant has provided study records for pre-natal developmental toxicity studies in rats (reliable with restrictions) with 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (WITAMOL 110/LINPLAST 610 P), CAS No 68515-51-5, EC No 271-094-0, as key study, and with [redacted] L9 11P, CAS No 68515-43-5 endpoint summary as supporting study.

However, these studies do not provide the information required by Annex IX, Section 8.7.2., because the Registrant did not provide a justifaction and adequate and reliable documentation to justify the read-across approach as required by Annex XI, 1.5. of the REACH Regulation. More explicitly, it is not explained based on which elements the different

substances would be similar or follow a regular pattern as a result of structural similarity so that human health effects may be predicted from data for other substances.[3]

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

According to the test method EU B.31/OECD 414, the rat is the preferred rodent species, the rabbit the preferred non-rodent species and the test substance is usually administered orally. ECHA considers these default parameters appropriate and testing should be performed by the oral route with the rat or the rabbit as a first species to be used.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Pre-natal developmental toxicity study (test method: EU B.31./OECD 414) in rats or rabbits by the oral route.

In the comments to the draft decision the Registrant disagreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

In his comments, the Registrant has argued that "*The studies with the similar substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (WITAMOL 110/LINPLAST 610 P), CAS No 68515-51-5, EC No 271-094-0, as key study, and with [redacted] L9 11P, CAS No 68515-43-5 endpoint summary as supporting study provide sufficient information on the endpoint "pre-natal developmental toxicity". Those studies gave no indication of developmental effects.*" The Registrant also provided a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)". Further the registrant announced that a waiving argument for the second sepcies will be included in the dossier update.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

ECHA acknowledges that read-across between different phthalates for the endpoint "Reproductive toxicity" may be feasible. However there are obvious weaknesses in the read-across justification e.g.:

- The toxicokinetic comparison is only based on theoretical considerations because "*experimental data are not available for the assessment of the toxicokinetic properties of the C8-C10 or the C6-C10-phthalate and read-across for toxicokinetic property assessment.*"
- Theoretical assessment of toxicokinetics requires good knowledge of the physico-chemical properties, however there seem to be discrepancies between calculated values used in the Registrant's read-across justification, e.g. a calculated water solubility of <0.001mg/L at 25°C values for the source substance "RA sub 1" (CAS 68515-51-5; 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters), and a measured water solubility value of of 11 mg/L at 23 °C and pH 5.5 reported in the registration dossier for the same substance and publicly available on ECHA's website.

[3] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere documentation does not necessarily mean that a read-across approach may be acceptable to ECHA.

- The read-across justification does not contain any data that would allow to compare the toxicity profile after repeated exposure between the suggested key source substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters (WITAMOL 110/LINPLAT 610P), CAS N o 68515-51-5, EC No 271-094-0 and the target substance (the registered substance). This information however would be essential for the comparison of potential parental toxicity.
- The read-across justification document does not present any data on the source substances, [redacted] L911P, CAS No 68515-43-5 used for the suggested supporting study. Consequently there is no basis to assess the suitablility of this substance as source substance.
- The read-across justification does not explain why only one of the four substances presented in the data matrix is used for the human health assessment while all substances are used for environmental endpoints. Specifically the Registrant fails to explain the relevance or non-relevance of 'RA sub3', Dihexylphthalate, 1,2-Benzenedicarboxylic acid, dihexyl ester CAS No 84-75-3 for human health assessment and specifically the reproductive toxicity endpoint. The read-across justification document (section 'similar carbon chain length') conatains conflicting statements. The registrant argues that differences in carbon chain length between the proposed substances are of minor relevance: *"The additional read-across substances are either within the carbon chain range of the target substance, 1,2-Benzenedicarboxylic acid, dioctyl ester with a C8-structure, or else just have a slightly higher, 1,2-Benzenedicarboxylic acid, diundecyl ester (C11 chains), or slightly lower carbon chain length, 1,2-Benzenedicarboxylic acid, dihexyl ester, which contains only C6 components. The slight differences in carbon chain length are considered either of minor relevance, as they are still in a very narrow range, or else the data clearly shows a trend associated with the carbon chain length which is considered for the read-across approach."'* However a contrasting argument is provided in the same section regarding the read-across substance 1, i.e. an argument that differences in carbon chain length do have relevance*: "Any potential effects caused by the fraction based on C6-alcohol of the read across substance, would not be observed with the target substance."* Neither the registrant's comments nor the accompanying documentation contain any data to support the assumption that toxicity of the C6 phthalate (RA sub3) is not relevant in the assessment of the read-across to the registered substance. In this context it is important to note that Dihexyl phthalate, CAS No 84-75-3, EC No 2014-559-5 has a harmonised classification as Repr. 1B, H360FD.

The Registrant is reminded that this decision does not take into account any updates submitted after13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

*Notes for consideration by the Registrant*

In addition, a pre-natal developmental toxicity study on a second species is part of the standard information requirements as laid down in Annex X, Section 8.7.2. for substances registered for 1000 tonnes or more per year (see sentence 2 of introductory paragraph 2 of Annex X).

The Registrant should firstly take into account the outcome of the pre-natal developmental toxicity on a first species and all other relevant available data to determine if the conditions are met for adaptations according to Annex X, Section 8.7. column 2, or according to Annex XI; for example if the substance meets the criteria for classification as toxic for reproduction

Category 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment, or alternatively, if weight of evidence assessment of all relevant available data provides scientific justification that the study in a second species is not needed. If the Registrant considers that testing is necessary to fulfill this information requirement, he should include in the update of his dossier a testing proposal for a pre-natal developmental toxicity study on a second species. If the Registrant comes to the conclusion that no study on a second species is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex X, Section 8.7.2.

10. Bioaccumulation in aquatic species (Annex IX, 9.3.2.)

"Bioaccumulation in aquatic species" is a standard information requirement as laid down in Annex IX, Section 9.3.2.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.

The Registrant has sought to adapt the information requirement of Annex IX, Section 9.3.2. of the REACH Regulation by means of providing results from a quantitative structure-activity relationship model ((Q)SAR). As the key study, the Registrant has provided an estimated BCF for the registered substance using EPIWIN (v 4.0). An estimated Log Kow value of 9.03 is used to calculate the BCF. The Registrant states that "BCF has been calculated using the computer program BCFBAF (v3.00). It is predicted that the substance has BCF of 341 L/kg wet weight. The substance is not bioaccumulative." As a supporting study, the Registrant has provided an estimated BCF for the read-across substance 1,2-Benzenedicarboxylic acid, mixed decyl and dodecyl diesters also using EPIWIN (v 4.0).

In accordance with Section 1.3. of Annex XI the conditions for this adaptation are the following:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

ECHA points out that the Registrant has failed to explain if the substance falls within the applicability domain of the (Q)SAR model, if the results are adequate for the purpose of classification and labelling and/or risk assessment and the Registrant has not provided adequate and reliable documentation of the applied method. Therefore the adaptation based on Annex XI, Section 1.3 of the REACH Regulation cannot be accepted.

For the adaptation to be acceptable, the Registrant would have to provide adequate and reliable documentation and to demonstrate that the first three conditions for applying the proposed adaptation are fulfilled. Guidance on how to report (Q)SAR studies is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6, section R.6.1. (pages 9-66, Version of May 2008) and in ECHA's Practical Guide 5: How to report (Q)SARs.

Furthermore, ECHA points out that the Registrant has failed to explain for the supporting study if the read-across substance falls within the applicability domain of the (Q)SAR model, if the results are adequate for the purpose of classification and labelling and/or risk assessment and the Registrant has not provided adequate and reliable documentation of the

applied method. The Registrant has also not explained why the read-across is justified in accordance with Annex XI, Section 1.5 of the REACH Regulation. [4]

As the conditions for adapting the information requirements in accordance with Annex XI, Section 1.3. or 1.5. of the REACH Regulation have not been fulfilled and no other information is available in the dossier for the endpoints in question, ECHA concludes that there is an information gap and that it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with relevant information requirements.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Bioaccumulation in fish: aqueous and dietary exposure (test method: OECD 305), using the aqueous or dietary exposure route.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

In his comments, the Registrant has outlined that he "*will show that the substance falls within the applicability domain of the (Q)SAR model, and that the results are adequate for the purpose of classification and labelling and/or risk assessment. Furthermore, adequate and reliable documentation of the applied method will be provided.*" The Registrant also provided a document containing the QSAR calculation that has not been available earlier.

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

ECHA notes that in their comments on the draft decision, the Registrant provided additional justification and documentation for the QSAR prediction of BCF for the registered substance. This includes justification that the registered substance falls within the applicability domain of the QSAR model and that the results are suitable for the purpose of classification and labelling and/or risk assessment. ECHA notes that when this information is included in an update of the registration dossier, it may be suitable to meet the conditions of Section 1.3. of Annex XI.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

11. Adsorption/desorption screening (Annex VIII, Section 9.3.1.)

Information on "adsorption/desorption screening" is a standard information requirement as laid down in Annex VIII, Section 9.3.1. 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.

The Registrant has sought to adapt the information requirements of Annex VIII, Section 9.3.1 of the REACH Regulation by means of providing results from a quantitative structure-

[4] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere justification does not necessarily mean that a read-across approach may be acceptable to ECHA.

activity relationship model ((Q)SAR). As the key study, the Registrant has provided an estimated Koc for the registered substance using EPIWIN (v 4.1). The Registrant states that "KOC has been calculated using the computer program KOCWIN (v2.00). It is predicted that the substance has a KOC of 256600 L/kg (MCI method, log KOC 5.409) and of 614000 (KOW method, log KOC 5.789)".

In accordance with Section 1.3. of Annex XI the conditions for this adaptation are the following:

- results are derived from a (Q)SAR model whose scientific validity has been established,
- the substance falls within the applicability domain of the (Q)SAR model,
- results are adequate for the purpose of classification and labelling and/or risk assessment, and
- adequate and reliable documentation of the applied method is provided.

ECHA points out that the Registrant has failed to explain if the substance falls within the applicability domain of the (Q)SAR model, if the results are adequate for the purpose of classification and labelling and/or risk assessment and the Registrant has not provided adequate and reliable documentation of the applied method. Therefore the adaptation based on Annex XI, Section 1.3 of the REACH Regulation cannot be accepted.

For the adaptation to be acceptable, the Registrant would have to provide adequate and reliable documentation and to demonstrate that the first three conditions for applying the proposed adaptation are fulfilled. Guidance on how to report (Q)SAR studies is available in ECHA's Guidance on information requirements and chemical safety assessment, Chapter R.6, section R.6.1. (pages 9-66, Version of May 2008) and in ECHA's Practical Guide 5: How to report (Q)SARs.

The Registrant also provides two supporting studies. These studies measured Koc using the test guideline OECD 121 for the read-across substances CAS 3648-20-2 and 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters. Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met". Annex XI, 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation. The Registrant has provided no justification for their read-across hypothesis. ECHA therefore concludes that the proposed read-across approach does not comply with the general rules of adaptation as set out in Annex XI, 1.5. [5]

As explained above, the information available 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.

Furthermore, ECHA notes that this substance has a high Log Kow value of 9.03 which would suggest a high potential to adsorb to soil. Distribution modelling results in Section 5.4.3 of the registration dossier predict that [redacted]% will partition to soil. Soil exposure can be anticipated due to wide dispersive use of the substance, despite the fact that the substance is readily biodegradable.

[5] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere justification does not necessarily mean that a read-across approach may be acceptable to ECHA.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Adsorption/desorption screening (Annex VIII, Section 9.3.1.); test method: Estimation of the Adsorption Coefficient (Koc ) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), OECD 121.

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days. In his comments, the Registrant has outlined that he "*will show that the substance falls within the applicability domain of the (Q)SAR model, and that the results are adequate for the purpose of classification and labelling and/or risk assessment. Furthermore, adequate and reliable documentation of the applied method will be provided.*" The registrant also provided a document containing the QSAR calculation that has not been available earlier. Furthermore, the registrant referred to the read-across justification document provided with his comments "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)".

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

ECHA notes that in their comments on the draft decision, the Registrant provided additional justification and documentation for the QSAR prediction of Koc. This includes justification that the registered substance falls within the applicability domain of the QSAR model and that the results are suitable for the purpose of classification and labelling and/or risk assessment. ECHA notes that when this information is included in an update of the registration dossier, it may be suitable to meet the conditions of Section 1.3. of Annex XI.

Regarding the read-across assessment for environmental endpoints please see section III, 12 and 13.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

12. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.)

"Long-term toxicity testing on aquatic invertebrates" is a standard information requirement as laid down in Annex IX, Section 9.1.5. 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.

The Registrant has sought to adapt the information requirements of Annex IX, Section 9.1.5. of the REACH Regulation by means of providing results from a read-across substance, Diundecyl phthalate CAS 3648-20-2.

The Registrant provided as the key study a GLP compliant study indicated as reliability 2, "no guideline followed", ([redacted]). Under flow through conditions, daphnids were exposed to a range of concentrations for 21 days. The number of live offspring /surviving parent was assessed. The Registrant states that "the NOEC for survival and reproduction of daphnids exposed to a mean measured concentration of 0.059

mg/l (maximal used concentration) were comparable to the survival & reproduction of daphnids in the control group." ECHA notes that some key information about the study which is required in order to assess its validity and reliability is not included in the registration dossier. The purity of the test substance Diundecyl phthalate is not reported. The test solution was prepared by dissolving the test substance in acetone but no solvent control results are reported. No information is provided for the controls on the mean number of living offspring produced per parent animal surviving at the end of the test. Furthermore, it is reported that during the first 14 days of the test the daphnids in the 0.059 and 0.029 mg/l groups were seen to be entrapped on the surface of the water in the aquaria. It is considered by the Registrant that a thin layer of insoluble test substance was present on solution's surface and therefore the concentration range included exposure levels that approximated the water solubility limit. It is not clear how the presence of undissolved material affected the study results.

In addition, the Registrant also provides three other studies with the read-across substance Diundecyl phthalate.

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met". Annex XI, 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation.

The Registrant has provided no justification and no adequate and reliable documentation for their read-across hypothesis as required by Annex XI, 1.5. of the REACH Regulation. More explicitly, it is not explained based on which elements the different substances would be similar or follow a regular pattern as a result of structural similarity so that environmental effects may be predicted from data for other substances.[6].

In the comments to the draft decision the Registrant disagreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

In his comments, the Registrant has outlined that he "*agrees that some key information about the key study are missing and will add and/or change the information accordingly. The purity of the test substance was greater than 95 %, no solvent was used during the test and the control data is available (Rhodes et al., 1995). Since no effects were observed in the highest concentration tested, the entrapment of the daphnids on the surface during the first two weeks of the study is considered to have had no impact on the validity and reliability of the study. The Registrant will show that the respective endpoint is adequately covered by the available experimental and literature data.*" Furthermore, the Registrant has provided with his comments a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)".

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

[6] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere documentation does not necessarily mean that a read-across approach may be acceptable to ECHA.

In their comments on the draft decision, the Registrant provided a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)". Table 2 in this document summarises relevant physico-chemical data for the registered substance and for four source substances.

ECHA notes that the registration dossier for the source substance RA sub 1 (CAS 68515-51-5; 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters) which is publicly available on ECHA's website indicates a measured water solubility value of 11 mg/L at 23 °C and pH 5.5. This result is much higher than the QSAR prediction for this substance of <0.001 mg/l at 25 °C presented in Table 2 of the Registrant's document. There is also a measured Log Kow for this substance of 8.2 at 20 °C and pH 7 which is within the range of predicted values included in Table 2, 8.54-10.5. A range of physico-chemical properties could be anticipated for this source substance since it is a multi-constituent substance.

Furthermore, ECHA notes that the registration dossier for Diundecyl phthalate, branched and linear EC 287-401-6, CAS 85507-79-5, which is publicly available on ECHA's website, contains a measured water solubility result for Diundecyl phthalate CAS 3648-20-2 of 1.11 mg/l at 25 °C (pH not specified). Diundecyl phthalate CAS 3648-20-2 is another of the source substances used for read-across by the registrant (RA sub 2). According to Table 2 of the justification document provided by the Registrant, the water solubility for CAS 3648-20-2 is predicted to be <0.001 mg/l at 25 °C. This predicted value is much lower than the measured data for CAS 3648-20-2.

Water solubility and Log Kow are important parameters for assessing the read-across of aquatic ecotoxicity data. The discrepancy between water solubility results presented in the Registrant's justification document compared with the measured values for two source substances calls into question whether the read-across of results on long-term toxicity to aquatic invertebrates is justified. Based on the current information, the read-across cannot be accepted but this discrepancy could be further investigated for the read-across justification.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

*Notes for consideration by the Registrant*

ECHA notes that it is not possible to judge which is the most sensitive taxa from the available short-term aquatic toxicity tests on fish and invertebrates with the registered substance since no effects were observed up to the water solubility limit.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0., November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4) if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the *Daphnia* study is to be conducted first. If based on the results of the long-term *Daphnia* study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may

need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

13. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.)

"Long-term toxicity testing on fish" is a standard information requirement as laid down in Annex IX, Section 9.1.6. of the REACH Regulation. Adequate information on Fish, early-life stage (FELS) toxicity test (Annex IX, 9.1.6.1.), or Fish, short-term toxicity test on embryo and sac-fry stages (Annex IX, 9.1.6.2.), or Fish, juvenile growth test (Annex IX, 9.1.6.3.) needs to be present in the technical dossier for the registered substance to meet this information requirement.
The Registrant has sought to adapt the information requirements of Annex IX, Section 9.1.6.1. of the REACH Regulation by means of providing results from a read-across substance, Diundecyl phthalate CAS 3648-20-2.

The Registrant provided as the key study a GLP compliant study indicated as reliability 2, equivalent or similar to Guideline EPA OPPTS 850.1400 (Fish Early life Stage Toxicity Test) ([redacted]). The Registrant concluded that "Long-term toxicity to fish with the structurally related substance Diundecyl phthalate has been determined in a fish early life stage test with rainbow trout. Under the conditions of the test the NOEC, based on the mean measured concentration, was 0.30 mg/l, the highest concentration investigated and regarded as the maximum water solubility under the test conditions."

Article 13(1) of the REACH Regulation provides that information on intrinsic properties of substances may be generated by means other than tests. Such other means include the use of information from structurally related substances (grouping of substances and read-across), "provided that the conditions set out in Annex XI are met". Annex XI, 1.5. requires a structural similarity among the substances within a group or category such that relevant properties of a substance within the group can be predicted from the data on reference substance(s) within the group by interpolation.

The Registrant has provided no justification for their read-across hypothesis as required by Annex XI, 1.5. of the REACH Regulation. More explicitly, it is not explained based on which elements the different substances would be similar or follow a regular pattern as a result of structural similarity so that environmental effects may be predicted from data for other substances.[7]

As explained above, the information available 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.

Regarding the long-term toxicity testing on fish pursuant to Annex IX, section 9.1.6.1, ECHA considers that the FELS toxicity test according to OECD 210 is the most sensitive of the standard fish tests available as it covers several life stages of the fish from the newly fertilised egg, through hatch to early stages of growth and should therefore be used (see ECHA *Guidance on information requirements and chemical safety assessment* (version 2.0., November 2014), Chapter R7b, Figure R.7.8-4). The test method OECD 210 is also the only suitable test currently available for examining the potential toxic effects of bioaccumulation (ECHA Guidance R7b, version 2.0., November 2014). For these reasons, ECHA considers the FELS toxicity test using the test method OECD 210 as appropriate and suitable.

[7] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere documentation does not necessarily mean that a read-across approach may be acceptable to ECHA.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Fish, early-life stage (FELS) toxicity test (test method: OECD 210).

In the comments to the draft decision the Registrant disagreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

In his comments, the Registrant has argued that he *"will show that the respective endpoint is adequately covered by the available experimental data with the read across substance Diundecyl phthalate and additional literature data."* Furthermore, the Registrant has provided with his comments a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)".

Irrespective of whether the newly provided information may be sufficient to meet the information requirement addressed in this decision, ECHA can already point out the following:

In their comments on the draft decision, the Registrant provided a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)". Table 2 in this document summarises relevant physico-chemical data for the registered substance and for four source substances.

ECHA notes that the registration dossier for the source substance RA sub 1 (CAS 68515-51-5; 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters) which is publicly available on ECHA's website indicates a measured water solubility value of 11 mg/L at 23 °C and pH 5.5. This result is much higher than the QSAR prediction for this substance of <0.001 mg/l at 25 °C presented in Table 2 of the Registrant's document. There is also a measured Log Kow for this substance of 8.2 at 20 °C and pH 7 which is within the range of predicted values included in Table 2, 8.54-10.5. A range of physico-chemical properties could be anticipated for this source substance since it is a multi-constituent substance.

Furthermore, ECHA notes that the registration dossier for Diundecyl phthalate, branched and linear EC 287-401-6, CAS 85507-79-5, which is publicly available on ECHA's website, contains a measured water solubility result for Diundecyl phthalate CAS 3648-20-2 of 1.11 mg/l at 25 °C (pH not specified). Diundecyl phthalate CAS 3648-20-2 is another of the source substances used for read-across by the registrant (RA sub 2). According to Table 2 of the justification document provided by the Registrant, the water solubility for CAS 3648-20-2 is predicted to be <0.001 mg/l at 25 °C. This predicted value is much lower than the measured data for CAS 3648-20-2.

Water solubility and Log Kow are important parameters for assessing the read-across of aquatic ecotoxicity data. The discrepancy between water solubility results presented in the Registrant's justification document compared with the measured values for two source substances calls into question whether the read-across of long-term fish toxicity results is justified. Based on the current information, the read-across cannot be accepted but this discrepancy could be further investigated for the read-across justification.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

*Notes for consideration by the Registrant*

ECHA notes that it is not possible to judge which is the most sensitive taxa from the available short-term aquatic toxicity tests on fish and invertebrates with the registered substance since no effects were observed up to the water solubility limit.

Before conducting any of the tests mentioned above in points 12-13 the Registrant shall consult the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b, Section R.7.8.5 to determine the sequence in which the aquatic long-term toxicity tests are to be conducted and the necessity to conduct long-term toxicity testing on fish.

According to ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b (Section R.7.8.5., including Figure R.7.8-4), if based on acute aquatic toxicity data neither fish nor invertebrates are shown to be substantially more sensitive, long-term studies may be required on both. In such case, according to the integrated testing strategy, the Daphnia study is to be conducted first. If based on the results of the long-term Daphnia study and the application of a relevant assessment factor, no risks are observed (PEC/PNEC<1), no long-term fish testing may need to be conducted. However, if a risk is indicated, the long-term fish study needs to be conducted.

14. Long-term toxicity to sediment organisms (Annex X, Section 9.5.1.)

"Long-term toxicity to sediment organisms" is a standard information requirement as laid down in Annex X, Section 9.5.1. 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.

ECHA notes that the Registrant has sought to adapt the long-term toxicity testing on sediment organisms using the following justification: " In accordance with REACH Regulation 1907/2006, Annex X, Column 2, studies of the effects on sediment organisms need not be conducted if exposure assessment indicates a concern for exposure to that environmental compartments. It is proposed that testing is waived as, although the substance has a high Kow of 9.03 and a high capacity to adsorb to soil and sediment, it can be regarded as being readily biodegradable indicating that it will not remain in the environment."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on sediment organisms further because the substance is readily biodegradable and will not remain in the environment. However, ECHA notes that no environmental exposure assessment and risk characterization have been provided in the chemical safety assessment, but ERCs for wide-dispersive uses are indicated in the CSR, which would suggest that exposure of the sediment compartment is likely. Therefore, considering also the high adsorption potential of the registered substance (calculated Log Kow 9.03), it is not possible to exclude that there is a risk to sediment organisms due to long-term exposure.

ECHA notes further that in order for an adaptation of Annex X, 9.5.1. Column 1 provisions to be justified, the Registrant would have to demonstrate by means of the Chemical Safety

Report (CSR) that the conditions of an adaptation possibility (Annex XI) are fulfilled. In establishing this, in some cases and as explained in ECHA Guidance on information requirements and chemical safety assessment (R.7.B, version 2.0, November 2014, Section R.7.8.7.), Registrants may use the EPM as part of a weight-of-evidence to adapt the standard information requirement.

However, according to ECHA Guidance on information requirements and chemical safety assessment (R.7.B, version 2.0, November 2014, Section R.7.8.7.) the EPM cannot be used in a weight of evidence approach for substances that are highly insoluble and for which no effects are observed in aquatic studies. For such substances at least one sediment study has to be performed. ECHA notes that as is shown in the aquatic studies in the technical dossier no effects were observed in any of the aquatic studies performed. In addition, as the substance has a reported water solubility of <0.1 mg/l (0.00005572 mg/L and 0.00013684 mg/L by two QSAR estimation methods) ECHA considers that long-term sediment testing is indicated for the registered substance.
ECHA notes that the Registrant has not demonstrated that available data would lead to the conclusion that the substance is or is not toxic to sediment organisms (Annex XI, 1.2.). In fact, the present substance has a high potential to adsorb to sediment. Therefore, as the standard information requirements for long-term sediment testing have not been adapted in a justified manner, testing is required.

Therefore, in this specific case, ECHA notes that the Registrant has not justified an adaptation.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision:

Sediment-water Chironomid toxicity using spiked sediment (Test method: OECD 218) OR

Sediment-water Lumbriculus toxicity test using spiked sediment (Test method: OECD 225) OR

Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by stating that he *"agrees that the substance has a high potential to adsorb to sediments and will therefore conduct a test on sediment toxicity according to the most appropriate test protocol. A justification for the choice of the respective test protocol will be provided. The Registrant will ensure that the sample has a composition that is within the specifications of the substance composition and that the particular sample of the substance tested is appropriate to assess the properties of the registered substance. Adequate information on substance identity will be provided."*

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

*Notes for consideration by the Registrant*

The Sediment-water Chironomid toxicity using spiked sediment (OECD 218), Sediment-water Lumbriculus toxicity test using spiked sediment (OECD 225) and Sediment-Water Chironomid Life-Cycle Toxicity Test Using Spiked Water or Spiked Sediment (OECD 233) are in principle each considered capable of generating information appropriate for the fulfilment of the information requirements for sediment long-term toxicity testing. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity, substance properties and uses. ECHA considers that it is the Registrant's responsibility to choose the most appropriate test protocol and to give a justification for the choice. The Registrant may carry out more than one of the sediment tests defined in Section II above if he considers that further testing is required. While ECHA at this stage only requires one test, based on newly available data it may consider whether further tests are required to fulfil the standard information requirement.

Furthermore, both water and sediment exposure scenarios are described in the OECD 233 Test Guideline. The Registrant is advised to consult the OECD 233 Test Guideline and the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R7b (Section R.7.8.10.1) for the selection of the appropriate method of spiking.

15. – 17. Effects on terrestrial organisms

"Effects on terrestrial organisms" is a standard information requirement as laid down in Annexes IX and X, section 9.4., of the REACH Regulation. Adequate information on effects on soil micro-organisms (Annex IX, section 9.4.2.), short-term toxicity testing on invertebrates (Annex IX, section 9.4.1.), long-term toxicity testing on invertebrates (Annex X, section 9.4.4.), short-term toxicity testing on plants (Annex IX, section 9.4.3.) and long-term toxicity testing on plants (Annex X, section 9.4.6.) needs to be present in the technical dossier for the registered substance to meet the information requirements.

15. Terrestrial invertebrates (Column 2 of Annex IX, Section 9.4. and Annex X, Section 9.4.4.)

Short-term toxicity to terrestrial invertebrates
For the endpoint of short-term toxicity to invertebrates (Annex IX, Section 9.4.1.), the Registrant provides as the key study a GLP compliant study according to test guideline EU Method C.8 (Toxicity for Earthworms: Artificial Soil Test) on the registered substance (Scholz, 1994). The study was with Eisenia foetida and after 14 days no mortality up to the highest concentration of 1000 mg/kg dw was observed. The study is assigned reliability 2 by the Registrant.

A supporting study with the read-across substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters, CAS 68515-51-5, also showed no mortality on Eisenia foetida after 14 days up to the highest concentration of 1000 mg/kg dw. ECHA notes that the Registrant has not justified why the read-across is appropriate in accordance with Annex XI, Section 1.5 of the REACH Regulation.

Long-term-toxicity to terrestrial invertebrates
The Registrant provides no information for the endpoint of long-term toxicity to invertebrates (Annex X, Section 9.4.4.) and instead provides the following waiving justification: "In accordance with REACH Regulation 1907/2006, Annex IX, Column 2, studies of the effects on terrestrial organisms need not be conducted if direct and indirect

exposure of the soil compartment is unlikely. It is proposed that testing is waived as, although the substance has a high Kow of 9.03 and the potential for high adsorption to soil, it can be regarded as readily biodegradable indicating that it will not remain in the environment."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on terrestrial organisms further because it is readily biodegradable and will not remain in the environment. However, ECHA notes that no environmental exposure assessment and risk characterization have been provided in the chemical safety assessment, but Environmental Release Categories (ERCs) for wide-dispersive uses are indicated in the CSR, which would suggest that exposure of the terrestrial compartment is likely. Furthermore, the Registrant's fugacity modelling results reported in Section 5.4.3 of the registration dossier predict [redacted]% partitioning of the registered substance to soil. Therefore, considering also the high adsorption potential of the registered substance (calculated Log Kow 9.03), it is not possible to exclude that there is a risk to terrestrial organisms due to long-term exposure.
The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted.

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

According to section R.7.11.6., Chapter R.7c of the ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), where there is adequate data available to sufficiently derive a PNEC for aquatic organisms, this PNEC can be used in a screening assessment for soil risks through the use of the Equilibrium Partitioning Method (EPM) approach.

The Registrant has considered that it is unfeasible, with the currently available information, to derive a PNEC for aquatic organisms. Consequently, it is not possible to waive the standard information requirements for the terrestrial compartment through an initial screening assessment based upon the EPM, mentioned in Column 2 of Annex IX, section 9.4. Since a screening assessment for terrestrial organisms is not possible, testing for effects on all terrestrial organisms indicated in section 9.4 of Annex IX is considered necessary.

The earthworm reproduction test (OECD 222), Enchytraeid reproduction test (OECD 220), and Collembolan reproduction test (OECD 232) are each considered capable of generating information appropriate for the fulfilment of the information requirements for long-term toxicity testing to terrestrial invertebrates. ECHA is not in a position to determine the most appropriate test protocol, since this decision is dependent upon species sensitivity and substance properties. However ECHA notes that when log Kow >5 and log Koc >4, as in this case, the test OECD 232 is not appropriate as the dominant route of exposure for Collembolans is via pore water.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Earthworm reproduction test (Eisenia fetida/Eisenia andrei) (test method: OECD 222), or Enchytraeid reproduction test (test method: OECD 220).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by acknowledging that the substance has a high potential to adsorb to soil, which, in combination with a wide dispersive use, could result in exposure of the terrestrial compartment. The Registrant stated: "*Although the ready biodegradability, environmental fate and available acute earthworm studies, with the substance itself and the read-across substance, where no mortalities or effects were observed up to the highest concentration tested, are available, the Registrant will conduct a test assessing the long-term toxicity towards terrestrial invertebrates. The Registrant will ensure that the sample has a composition that is within the specifications of the substance composition and that the particular sample of the substance tested is appropriate to assess the properties of the registered substance. Adequate information on substance identity will be provided.*"

Furthermore, in the comments on the draft decision, the Registrant provided a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)". ECHA has not assessed this read-across justification in detail for the endpoint of short-term toxicity to terrestrial invertebrates since a reliable short-term study on the registered substance is already available.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

16. Terrestrial plants (Annex X, Section 9.4.6.)

For the endpoint of short-/long-term toxicity to terrestrial plants (Annex IX, Section 9.4.3. and Annex X, Section 9.4.6.), the Registrant provides as the key study a GLP compliant study according to test guideline OECD 208 on the registered substance ([redacted]). The study tested three different species: Triticum aestivum (monocotyledonous species), Brassica alba (dicotyledonous species) and Lepidum sativum (dicotyledonous species). The study is assigned reliability 2 by the Registrant. ECHA notes that this study tested only three species, one monocotyledonous species and two dicotyledonous species.

OECD guideline 208 (Terrestrial plants, growth test) considers the need to select the number of test species according to relevant regulatory requirements, and the need for a reasonably broad selection of species to account for interspecies sensitivity distribution. For long-term toxicity testing, ECHA considers six species as the minimum to achieve a reasonably broad selection. Long-term toxicity testing shall be conducted with species from different families, as a minimum with two monocotyledonous species and four dicotyledonous species, selected according to the criteria indicated in the OECD 208 guideline.

ECHA concludes that whilst the information provided by the Registrant is considered as scientifically valid for three different species, with only three species tested, it is not sufficient to fulfil all the requirements of section 9.4.6 of Annex X of the REACH Regulation. Since the available study on the registered substance tested only three species, one monocotyledonous species and two dicotyledonous species, ECHA considers that the study

only meets the information requirement of short-tem toxicity to plants (Annex IX, Section 9.4.3.) and is not adequate for the endpoint of long-term toxicity to terrestrial plants (Annex X, Section 9.4.6.).

The Registrant also provides a supporting study with the read-across substance 1,2-Benzenedicarboxylic acid, di-C6-10-alkyl esters, CAS 68515-51-5. This study was also conducted according to test guideline OECD 208 and tested three different species: Triticum aestivum (monocotyledonous species), Brassica alba (dicotyledonous species) and Lepidum sativum (dicotyledonous species). ECHA notes that the Registrant did not provide a justification and adequate and reliable documentation to justify the read-across approach as required by Annex XI, 1.5. of the REACH Regulation. More explicitly, it is not explained based on which elements the different substances would be similar or follow a regular pattern as a result of structural similarity so that environmental effects may be predicted from data for other substances.[8]

As explained above, the information available on the endpoints of toxicity to terrestrial plants (Annex X, 9.4.6.) for the registered substance in the technical dossier does not meet all of the information requirements. Consequently there is a information gap and it is necessary to provide information for this endpoint.

In this specific case due to the available adequate information, ECHA considers that further testing of three species as the minimum to achieve a reasonably broad selection. Testing shall be conducted with species from different families, with as a minimum one monocotyledonous species other than Triticum aestivum and two dicotyledonous species other than Brassica alba and Lepidum sativum. The Registrant can consider if testing on additional species is required to cover the information requirement (see the Evaluation Progress Report 2012 pp 34-35; http://echa.europa.eu/documents/10162/13628/evaluation_report_2012_en.pdf).

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Terrestrial plants, growth test (test method: OECD 208), with at least three species tested (with as a minimum one monocotyledonous species other than Triticum aestivum and two dicotyledonous species other than Brassica alba and Lepidum sativum), or, Soil Quality – Biological Methods – Chronic toxicity in higher plants (test method: ISO 22030).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by conducting the requested additional testing with species from different families, with one monocotyledonous species other than *Triticum aestivum* and two dicotyledonous species other than *Brassica alba* and *Lepidum sativum*.

Furthermore, in their comments on the draft decision the Registrant provided a document with a rationale and justification for the read-across strategy of the registered substance, "Rationale & justification for the read-across strategy of 1,2-Benzenedicarboxylic acid, di-C8-10-alkyl esters (CAS No. 71662-46-9, EC No. 275-809-7)". ECHA has not assessed this read-across justification in detail for the endpoint of long-term toxicity to terrestrial plants

[8] ECHA notes that all conditions of Annex XI, 1.5. have to be met in order to meet the criteria for this adaptation. I.e. a mere documentation does not necessarily mean that a read-across approach may be acceptable to ECHA.

since the Registrant has agreed to the requested additional testing with the registered substance subject to the present decision.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

17. Effects on soil micro-organisms (Annex IX, Section 9.4.2.)

The Registrant has waived the standard information requirements of Annex IX, Section 9.4.2.) using the following justification: "In accordance with REACH Regulation 1907/2006, Annex IX, Column 2, studies of the effects on terrestrial organisms need not be conducted if direct and indirect exposure of the soil compartment is unlikely. It is proposed that testing is waived as, although the substance has a high Kow of 9.03 and a high potential to adsorb to soil, it can be regarded as readily biodegradable indicating that it will not remain in the environment."

In his proposed adaptation the Registrant claims that there is no need to investigate the effects on terrestrial organisms further because it is readily biodegradable and will not remain in the environment. However, ECHA notes that no environmental exposure assessment and risk characterization have been provided in the chemical safety assessment, but ERCs for wide-dispersive uses are indicated in the CSR, which would suggest that exposure of the terrestrial compartment is likely. Furthermore, the Registrant's fugacity modelling results reported in Section 5.4.3 of the registration dossier predict [redacted]% partitioning of the registered substance to soil. Therefore, considering also the high adsorption potential of the registered substance (calculated Log Kow 9.03), it is not possible to exclude that there is a risk to terrestrial organisms due to long-term exposure.

The justification for waiving provided by the Registrant does not meet the criteria of either the specific adaptation rules of Column 2 of Annexes IX and X, Section 9.4, or the general adaptation rules of Annex XI. Therefore, the adaptations cannot be accepted.

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

According to ECHA Guidance on information requirements and chemical safety assessment (version 2.0, November 2014), Chapter R.7C, Section R.7.11.3.1., p115, the nitrogen transformation test is considered sufficient for most non-agrochemicals.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, the Registrant is requested to submit the following information derived with the registered substance subject to the present decision: Soil microorganisms: nitrogen transformation test (test method: EU C.21./OECD 216).

In the comments to the draft decision the Registrant agreed with the information requirement in the draft decision. In addition, he indicated his intention to address the information requirement in an update of the registration within the following 90 days.

The Registrant outlined in the comments to the draft decision how he could address the information requirement by conducting a nitrogen transformation test according to OECD 216 to cover this endpoint.

The Registrant is reminded that this decision does not take into account any updates submitted after 13 May 2015. All the new information in the later update(s) of the registration dossier will however be assessed for compliance with the REACH requirements in the follow-up evaluation pursuant to Article 42 of the REACH Regulation.

*Notes for consideration by the Registrant*

ECHA notes that the results from the toxicity test(s) on aquatic invertebrates and fish requested under subsection 12 and 13 of the present Decision may allow the subsequent derivation of a PNECwater. Consequently, the Registrant may consider the ITS as recommended in section R.7.11.6., of the above-mentioned Guidance and determine the need for further testing on terrestrial organisms. If the Registrant concludes that no further investigation of effects on terrestrial organisms is required, he should update his technical dossier by clearly stating the reasons for adapting the information requirements of section 9.4. of Annexes IX and X, of the REACH Regulation.

ECHA emphasises that the intrinsic properties of soil microbial communities are not addressed through the EPM extrapolation method and therefore the potential adaptation possibility outlined for the information requirement of Annex IX, Section 9.4. does not apply for the present endpoint.

IV. Adequate identification of the composition of the tested material

In relation to the information required by the present decision, the sample of substance used for the new studies must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is within the specifications of the substance composition that are given 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 substance tested in the new studies 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 by each registrant. If the registration of the substance by any registrant covers different grades, the sample used for the new studiesmust be suitable to assess these grades.

Finally there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the studies to be assessed.

V. Information on right to appeal

An appeal may be brought against this decision to the Board of Appeal of ECHA under Article 51(8) of the REACH Regulation. Such an appeal shall be lodged within three months of receiving notification of this decision. Further information on the appeal procedure can be found on ECHA's internet page at http://www.echa.europa.eu/regulations/appeals. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

Authorised[9] by Ofelia Bercaru, Head of Unit, Evaluation

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