EUROPEAN CHEMICALS AGENCY

Helsinki, 14 June 2018

Addressee: [redacted]

Decision number: CCH-D-2114405894-45-01/F
Substance name: Tall oil, potassium salt
EC number: 271-968-1
CAS number: 68647-71-2
Registration number: [redacted]
Submission number: [redacted]
Submission date: 21.04.2015
Registered tonnage band: 10 to 100 tonnes per year (submission number [redacted] with latest tonnage band)

DECISION ON A COMPLIANCE CHECK

Based on Article 41 of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA requests you to submit information on

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

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

3. **In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3; test method: OECD TG 476 or OECD TG 490) provided that both studies requested under 1. and 2. have negative results, with the registered substance;**

4. **Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1; test method: OECD 421/422) in rats, oral route with the registered substance;**

5. **Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Ready biodegradability – CO2 in sealed vessels (headspace test), OECD TG 310), with the registered substance; or**

   Ready biodegradability (Annex VII, Section 9.2.1.1; test method: CO2 evolution test, OECD TG 301B) with the registered substance; or

   Ready biodegradability (Annex VII, Section 9.2.1.1; test method: MITI test (I), OECD TG 301C) with the registered substance; or

   Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Closed bottle test, OECD TG 301D) with the registered substance; or

6. **Ready biodegradability (Annex VII, Section 9.2.1.1; test method: Manometric respirometry test, OECD TG 301F) with the registered substanceShort-term toxicity testing on fish (Annex VIII, Section 9.1.3; test method: Fish, acute toxicity test, OECD TG 203) with the registered substance;**

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

You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI 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 and conforming to the appropriate rules in the respective Annex, and an adequate and reliable documentation.

You are required to submit the requested information in an updated registration dossier by **21 February 2020**. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing.

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

Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/regulations/appeals.

Authorised[1] by Ofelia Bercaru, Head of Unit, Evaluation E3.

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

Appendix 1: Reasons

Grouping of substances and read-across approach

In the registration, you have adapted the standard information requirements for In vitro gene mutation study in bacteria (Annex VII, Section 8.4.1), In vitro cytogenicity study in mammalian cells (Annex VIII, Section 8.4.2.), In vitro gene mutation study in mammalian cells (Annex VIII, Section 8.4.3.), Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.), Ready biodegradability (Annex VII, Section 9.2.1.1.), Short-term toxicity testing on fish (Annex VIII, Section 9.1.3.), and Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.) by applying a read-across adaptation following REACH Annex XI, Section 1.5. The read-across is reflected in the following section.

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 following analysis presents your justification for the proposed grouping approach and read-across hypothesis, together with ECHA's analysis concerning the justification in both a generic and an endpoint-specific context.

ECHA notes that you have provided study records for the endpoints listed above conducted with the analogue substances crude tall oil (CAS no 8002-26-4) and potassium salts. However, you have not documented and justified the adaptations of the standard information requirements. Under each endpoint you have explained study-related issues such as which studies have been selected for the key/supporting studies and the test materials used in the studies. Regarding read-across hypothesis and justification, you have provided only general statements such as: "*this endpoint was addressed using a read across approach to structural analogues of the registered substance; studies are provided on both tall oil and soluble potassium salts. In this respect it is considered that the data submitted provides an adequate reflection of the test material*".

ECHA notes that the statements such as "*structural analogues*", "*adequate reflection of the test material*" and "*an accurate reflection of the total composition of the registered substance*" are not sufficient to justify the read-across approach for the following reasons:

The differences in structure and composition between the registered and analogue substances have not been established and no justification on why these similarities and differences constitute an adequate basis for prediction has been provided. More generally, ECHA notes that there is no documentation establishing a basis whereby relevant human health and environmental properties of the registered substance may be predicted from data for the analogue substance crude tall oil (CAS no 8002-26-4).

Similarly, the composition of the test material used to perform the studies reported for the substance crude tall oil, CAS no 8002-26-4, is not reported in the technical dossier. In the absence of this information, the relevance of the information generated using this test material in the context of this read-across approach cannot be established.

ECHA further notes that no studies conducted with the registered substance have been provided except for the short-term toxicity study to aquatic invertebrates, and therefore the toxicokinetic behavior and toxicity profiles of the two substances cannot be compared.

You have provided studies conducted with potassium salts in order to predict the properties of the registered substance related to the potassium component of the registered substance. ECHA notes that in principle the approach addressing all different components of the registered substance is considered acceptable as part of the read-across approach. However, as you did not provide a justification for the proposed grouping approach and read-across hypothesis regarding the tall oil component of the registered substance, the studies conducted with potassium salts alone are not considered acceptable.

In your comments to the draft decision, you have indicated your intention to further refine and strengthen the read-across approach for human health endpoints, with a particular emphasis on the aspects of the adaptation identified and addressed by ECHA in the draft decision.

Based on the information provided by you in your comments ECHA is not in a position to determine whether the potential updated read-across approach referred to by you will comply with the requirements of Annex XI, section 1.5 of the REACH Regulation.

ECHA will further assess the information provided in an updated dossier in the Dossier Evaluation Follow-Up Process once the deadline set in the adopted decision has expired.

In the absence of any documentation supporting the proposed read-across approach, ECHA considers that you have failed to provide an adequate and reliable documentation of the applied method as required by Annex XI, Section 1.5 of the REACH Regulation. Therefore, ECHA is not in a position to conclude on the proposed read-across approach which could allow establishing that relevant properties of the registered substance can be predicted from those of the analogue substance. The proposed read-across has therefore to be rejected as not acceptable.

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

An "*In vitro* gene mutation study in bacteria" is a standard information requirement as laid down in Annex VII, Section 8.4.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You provided the following justification for the adaptation: *"No single study was selected as key on the basis that multiple studies have been provided to address the different types of genetic toxicity. Furthermore, this endpoint was addressed using a read across approach to structural analogues of the registered substance; studies are provided on both tall oil and soluble potassium salts. In this respect it is considered that the data submitted provides an adequate reflection of the test material."*

In the technical dossier you have provided study records for *in vitro* gene mutation study in bacteria (OECD 471) conducted with analogue substances crude tall oil (CAS no 8002-26-4) and potassium sulphate (CAS no 7778-80-5). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

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

In your comments to the draft decision, you indicate your intention to strengthen the read-across approach for this endpoint with a particular emphasis on the compositional and structural similarities between the registered substance and the source substance(s). In addition, ECHA understands that it is your intention to address the lack of toxicological studies conducted with the registered substance.

In the absence of an update of the documentation on the read-across approach ECHA is however not yet in the position to evaluate whether your intended update will meet the requirements. ECHA will further assess the information provided in an updated dossier in the Dossier Evaluation Follow-Up Process once the deadline set in the adopted decision has expired.

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

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

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

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You provided the following justification for the adaptation: *"No single study was selected as key on the basis that multiple studies have been provided to address the different types of genetic toxicity. Furthermore, this endpoint was addressed using a read across approach to structural analogues of the registered substance; studies are provided on both tall oil and soluble potassium salts. In this respect it is considered that the data submitted provides an adequate reflection of the test material."*

In the technical dossier you have provided study records for in vitro cytogenicity studies (OECD 473) conducted with analogue substances crude tall oil (CAS no 8002-26-4) and potassium sulphate (CAS no 7778-80-5). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be

accepted.

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

In your comments to the draft decision, you indicate your intention to strengthen the read-across approach for this endpoint with a particular emphasis on the compositional and structural similarities between the registered substance and the source substance(s). In addition, ECHA understands that it is your intention to address the lack of toxicological studies conducted with the registered substance.

In the absence of an update of the documentation on the read-across approach, ECHA is however not yet in the position to evaluate whether your intended update will meet the requirements. ECHA will further assess the information provided in an updated dossier in the Dossier Evaluation Follow-Up Process once the deadline set in the adopted decision has expired.

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

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

An "*In vitro* gene mutation study in mammalian cells" is an information requirement as laid down in Annex VIII, Section 8.4.3. of the REACH Regulation, "if a negative result in Annex VII, Section 8.4.1. and Annex VIII, Section 8.4.2." is obtained. ECHA notes that the registration dossier does not contain acceptable study records for these information requirements. Therefore, adequate information on *in vitro* gene mutation in mammalian cells endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement provided that both studies requested under 1. and 2. have negative results.

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You provided the following justification for the adaptation: *"No single study was selected as key on the basis that multiple studies have been provided to address the different types of genetic toxicity. Furthermore, this endpoint was addressed using a read across approach to structural analogues of the registered substance; studies are provided on both tall oil and soluble potassium salts. In this respect it is considered that the data submitted provides an adequate reflection of the test material."*

In the technical dossier you have provided a study record for in vitro mammalian cell gene mutation tests (OECD 476) conducted with analogue substances crude tall oil (CAS no 8002-26-4) and potassium nitrate (CAS no 7757-79-1). However, as explained above in

Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

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

In your comments to the draft decision, you indicate your intention to strengthen the read-across approach for this endpoint with a particular emphasis on the compositional and structural similarities between the registered substance and the source substance(s). In addition, ECHA understands that it is your intention to address the lack of toxicological studies conducted with the registered substance.

In the absence of an update of the documentation on the read-across approach, ECHA is however not yet in the position to evaluate whether your intended update will meet the requirements. ECHA will further assess the information provided in an updated dossier in the Dossier Evaluation Follow-Up Process once the deadline set in the adopted decision has expired.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: *In vitro* mammalian cell gene mutation test (test method: OECD TG 476[2] or OECD TG 490[3]) provided that both studies requested under 1. and 2. have negative results.

4. Screening for reproductive/developmental toxicity (Annex VIII, Section 8.7.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

"Screening for reproductive/developmental toxicity" is a standard information requirement as laid down in Annex VIII, Section 8.7.1. of the REACH Regulation if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from *in vitro* methods that the substance may be a developmental toxicant. No such evidence is presented in the dossier. Therefore, adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided study records for a "combined repeated dose toxicity study with the reproduction/developmental toxicity screening test" (test method: OECD TG 422) conducted with an analogue substance tall oil (CAS 8002-26-4) and two non-guideline screening studies in rats and mice conducted with an analogue substance potassium chloride (CAS no 7447-40-7).

You have sought to adapt this information requirement according to Annex XI, Section 1.5.

[2] Only the OECD TG is mentioned since it has recently been updated while the corresponding EU test method has not yet been updated.
[3] Only the OECD TG is mentioned since it has recently been adopted while the corresponding EU test method has not yet been published.

of the REACH Regulation. You provided the following justification for the adaptation: "*This endpoint was addressed with a key combined repeated dose toxicity study with reproduction /developmental toxicity screening study being carried out on the read across material tall oil and one key and one supporting screening studies carried out in two rodent species on the read across material potassium chloride. The study conducted on potassium chloride in the rat was selected as key as a precaution on the basis that the NOAEL achieved in this study was lower than the NOEL reported for the study on tall oil. It is considered that these studies together are an accurate reflection of the total composition of the registered substance, Tall Oil, Potassium Salt.*"

The studies were conducted with analogue substances tall oil (CAS no 8002-26-4) and potassium chloride (CAS no 7447-40-7). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

According to the test methods OECD TG 421/422, the test is designed for use with rats. On the basis of this default assumption ECHA considers testing should be performed with rats.

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

In your comments to the draft decision, you indicate your intention to strengthen the read-across approach for this endpoint with a particular emphasis on the compositional and structural similarities between the registered substance and the source substance(s). In addition, ECHA understands that it is your intention to address the lack of toxicological studies conducted with the registered substance.

In the absence of an update of the documentation on the read-across approach, ECHA is however not yet in the position to evaluate whether your intended update will meet the requirements. ECHA will further assess the information provided in an updated dossier in the Dossier Evaluation Follow-Up Process once the deadline set in the adopted decision has expired.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision:
- Reproductive/developmental toxicity screening test (test method: OECD TG 421) in rats by the oral route, or
- Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test (test method: OECD TG 422) in rats by the oral route.

5. Ready biodegradability (Annex VII, Section 9.2.1.1.)

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

"Ready biodegradability" is a standard information requirement as laid down in Annex VII, Section 9.2.1.1. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

You have sought to adapt this information requirement. The justification of the adaptation given by you is: "*This endpoint was addressed using a read across approach to a structural analogue of the registered substance, distilled tall oil. Furthermore a data waiver is submitted for the potassium component of the registered substance. In this respect it is considered that the data submitted provides an adequate reflection of the test material.*"...

"*The biological oxygen demand for the test material was 43 and 60 % of the theoretical oxygen demand after 7 and 28 days, respectively. These results indicate that the test material is dominated by readily biodegradable compounds and contains recalcitrant chemicals as well.*
Under the conditions of this study, a biodegradation value of 60 % was obtained for the test material after 28 days. It is therefore considered to be readily biodegradable but failing the 10 day window.
In accordance with the Column 2 adaptation of Annex VII of Regulation (EC) 1907/2006 (REACH), it is considered justified to omit the ready biodegradability study (required in point 9.2.1.1) for the potassium component of the registered substance on the basis that it is inorganic.
Furthermore, it is considered that the potassium component of the registered substance will not inhibit the biodegradation of the tall oil on the basis that the activated sludge respiration inhibition test required in Annex VIII (point 9.4.1) conducted on potassium chloride clearly shows that this material does not inhibit microorganisms".

In the technical dossier you have provided study records for ready biodegradability study (OECD 301D) conducted with analogue substance distilled tall oil (CAS no 8002-26-4). However, as explained above in Appendix 1, section 0 of this decision, your read-across adaptation of the information requirement cannot be accepted.

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

In your comments to the draft decision you have indicated an intention to adapt the information requirement for this endpoint and provided "*validated read-across from structural analogues using the OECD QSAR Toolbox*" supported by "*Other relevant supporting information available in the public domain and QSAR predictions are also provided here as weight of evidence (WoE)*".

Regarding the read-across from structural analogues using the OECD QSAR Toolbox, you provided a report from QSAR Toolbox prediction as an attachment to the comments ([redacted]). In addition, you also provided an attachment "[redacted]" to the supporting evidence CATALOGIC 301C prediction. The target substances in these reports are identified as CAS 68647-71-2, tall oil, potassium salt (registered substance). However, only "*a representative structure for the UVCB substance*" was considered in the QSAR Toolbox read-across approach and in the CATALOGIC prediction (SMILES CCCCCCCCC=CCCCCCCCC(=O)O{-}.K{+}; molecular formula C18H34O2.K),

namely "[redacted], *which is one of the main constituents of TO K+ salt".*

ECHA notes that the substance composition in the technical dossier of the registered substance includes four constituents: 1) [redacted] (C18H33O2K) ca [redacted] % w/w; 2) [redacted] (C18H31O2K) ca [redacted] % w/w; 3) [redacted] (C20H25O2K) ca [redacted] % w/w; and 4) [redacted] (C20H30O2) ca [redacted]) % w/w.

ECHA notes that the representative structure selected for the read-across and predictions does not consider all of the constituents of the registered substance (e.g., constituent 4. [redacted] (C20H30O2) ca [redacted] % w/w). ECHA considers that constituents or impurities present in concentrations at or above 0.1 % are deemed to be relevant constituents of the substance. Indeed, Section R.11.4.1 (page 36) of REACH Guidance document R.11 on PBT/vPvB assessment (version 3.0, June 2017) indicates that *"Constituents, impurities and additives should normally be considered relevant for the PBT/vPvB assessment when they are present in concentration of ≥ 0.1% (w/w). This limit of 0.1% (w/w) is set based on a well-established practice recognised in European Union legislation to use this limit as a generic limit".* Therefore, all such constituents should be considered in the evaluation of the biodegradation potential of the registered substance.

Similar considerations apply to the other evidence provided by you in your comments, such as the QSAR prediction using BIOWIN models via EPI Suite.

As additional evidence, in your comments, you refer to *"Initial Risk-Based Prioritization of HPV (High Production Volume) chemicals for the Tall Oil & Related Substances category, which includes TO K+ salt"*, by US EPA. You state that *"In the Supporting Documents to this prioritization (September, 2008), page 14, TO K+ salt is reported to show 78 % biodegradation in 28 days".* However, in the absence of read-across justification and robust study summaries of the existing data for this category in the registration dossier, ECHA is not in the position to evaluate the grouping, the constituents covered by the approach or the reliability of the supporting evidence.

Consequently, ECHA sees that as currently presented in the comments to the draft decision, the approach for the biodegradation endpoint does not provide sufficient evidence for the conclusion that the registered substance fulfils the ready biodegradation criteria.

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Ready biodegradability tests (test methods OECD TG 301 B, C, D and F and the OECD TG 310) are the preferred tests to cover the standard information requirement of Annex VII, Section 9.2.1.1.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision using one of the indicated test methods:

Ready biodegradability (test method: CO_2 evolution test, OECD TG 301B).
or
Ready biodegradability (test method: Ready biodegradability – CO_2 in sealed vessels (headspace test), OECD TG 310).
or

Ready biodegradability (test method: MITI test (I), OECD TG 301C).
or
Ready biodegradability (test method: Closed bottle test, OECD TG 301D).
or
Ready biodegradability (test method: Manometric respirometry test, OECD TG 301F).

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

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

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You provided the following justification for the adaptation: "*This endpoint was addressed using a read across approach to structural analogues of the registered substance and so no single study was selected. Two key studies are provided, one on crude tall oil and one on potassium chloride. In this respect it is considered that the data submitted provides an adequate reflection of the test material.*"

In the technical dossier you have provided study records for a short-term fish toxicity test (OECD 203 limit test) conducted with analogue substances distilled tall oil (CAS no 8002-26-4) and potassium chloride (CAS no 7447-40-7) (test according to OECD 203). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

You have indicated in your comments an intention to provide a "*validated and justified read-across prediction from structural analogues*", with a particular emphasis on the aspects of the adaptation identified and addressed by ECHA in the draft decision. You further state that "*validated prediction report in TPRF will be attached to the endpoint summary in the updated dossier*".

Regarding the substances to be covered in your prediction, you state that "*There is an experimental value of 260 mg/L (96-hour LC50 to fish) for* [redacted]*, which is the main constituent of TO K+ salt*". As already described in the reasoning for the request for ready biodegradability (request 5 in this decision), ECHA notes that the registered substance includes four constituents and all of them need to be covered in the prediction. ECHA understands that the approach presented in the comments to the draft decision does not cover all the constituents of the registered substance as described in the reasoning for request 5 of this decision.

Consequently, ECHA sees that as currently presented in the comments to the draft decision, the approach for this endpoint would not fulfil the information requirement for short-term toxicity to fish.

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

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

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

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

Pursuant to Articles 10(a)(vi) and/or (vii), 12(1)(c) and 13(4) of the REACH Regulation, a technical dossier registered at 10 to 100 tonnes per year shall contain as a minimum the information specified in Annexes VII to VIII of the REACH Regulation.

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

You have sought to adapt this information requirement according to Annex XI, Section 1.5. of the REACH Regulation. You provided the following justification for the adaptation: "*This endpoint was addressed using a read across approach to structural analogues of the registered substance. Two key studies are provided, one on distilled tall oil and one on potassium chloride. In this respect it is considered that the data submitted provides an adequate reflection of the test material.*"

In the technical dossier you have provided study records for algae growth inhibition test (OECD 201)conducted with analogue substances distilled tall oil (CAS no 8002-26-4) and potassium chloride (CAS no 7447-40-7). However, as explained above in Appendix 1, section 0 of this decision, your adaptation of the information requirement cannot be accepted.

You have indicated in your comments an intention to adapt the information requirement by "*by conducting a validated read-across prediction from analogues, using the OECD QSAR Toolbox v.3.3.17.*".

You have attached a QSAR Toolbox prediction report to your comments ([redacted]). The target substance in this report is identified as CAS 68647-71-2, tall oil, potassium salt (registered substance). However, only one representative structure for the UVCB substance was considered based on the prediction report (SMILES CCCCCCCCC=CCCCCCCCC(=O)O{-}.K{+}).

As already described in reasoning for the request for ready biodegradability (request 5 in this decision), ECHA notes that the registered substance includes four constituents and all of them need to be covered in the prediction. ECHA understands that the approach presented

in the comments to the draft decision does not cover all the constituents of the registered substance as described in the reasoning for request 5 of this decision.

Consequently, ECHA sees that as currently presented in the comments to the draft decision, the approach is not sufficient to fulfil the standard information requirements in the endpoint Growth inhibition study aquatic plants.

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

According to ECHA *Guidance on information requirements and chemical safety assessment, Chapter R.7b* (version 4.0, June 2017) Algae growth inhibition test (test method EU C.3. / OECD TG 201) is the preferred test to cover the standard information requirement of Annex VII, Section 9.1.2.

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

Note for your consideration

Should you decide to adapt any of the testing requested in the decision according to the provisions of Annex XI, section 1.5., you are encouraged to familiarise yourself with the ECHA Practical Guide "How to use alternatives to animal testing" (Version 2.0, July 2016), make use of the information provided in the ECHA Guidance on information requirements and chemical safety assessment Chapter R.6., and to evaluate the robustness of the updated read-across approach using the ECHA Read-Across Assessment Framework.

Deadline to submit the requested information in this decision

In the draft decision communicated to you, the time indicated to provide the requested information was 30 months from the date of adoption of the decision. This period of time took into account the fact that the draft decision also requested a sub-chronic toxicity (90-day) study (Annex IX, Section 8.6.2) and a pre-natal developmental toxicity study (Annex IX, Section 8.7.2). As these studies are not addressed any longer in the present decision due to the update of the tonnage band for the registration, ECHA considers that a reasonable time period for providing the required information in the form of an updated registration is 20 months from the date of the adoption of the decision. The decision was therefore modified accordingly.

Appendix 2: Procedural history

The compliance check was initiated on 19 October 2015.

The decision making followed the procedure of Articles 50 and 51 of the REACH Regulation, as described below:

ECHA notified you of the draft decision and invited you to provide comments.

ECHA took into account your comments. As you indicated in your comments a downgrade of the quantity of the manufacture/import of the registered substance to a tonnage band of 10-100 tonnes per year, ECHA considered information from submission number [redacted] of 26 July 2017 on the production and/or import volumes to verify this claim. On the basis of the information on the average production and/or import volumes (based on the figures for the preceding three years), ECHA changed the basis for the required standard information to a production and/or import of the registered substance in a volume of 10 to 100 tonnes per year. Compared to the initial draft decision, this has resulted in the removal of the following decision requests: sub-chronic toxicity (90-day), pre-natal developmental toxicity study in first species, simulation testing on ultimate degradation in surface water, soil simulation testing, identification of degradation products, bioaccumulation in aquatic species, long-term toxicity testing on fish and long-term toxicity testing on aquatic invertebrates.

As you were already initially notified (CCH-D-2114312794-49-01/D), this decision does not take into account any updates regarding studies and adaptations of standard information that were submitted after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

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

ECHA received proposal(s) for amendment and modified the draft decision.

ECHA invited you to comment on the proposed amendment(s).

ECHA referred the draft decision to the Member State Committee.

You provided comments only on the draft decision. Your comments were not taken into account by the Member State Committee as they were considered to be outside of the scope of Article 51(5).

The Member State Committee reached a unanimous agreement on the draft decision in its MSC-59 written procedure and ECHA took the decision according to Article 51(6) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

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

2. Failure to comply with the 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 your Member State.

3. In carrying out the test(s) required by the present decision it is important to ensure that the particular sample of substance tested is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured. If the registration of the substance covers different grades, the sample used for the new test(s) must be suitable to assess these. Furthermore, there must be adequate information on substance identity for the sample tested and the grade(s) registered to enable the relevance of the test(s) to be assessed.