EUROPEAN CHEMICALS AGENCY

Helsinki, 7 December 2018

Addressee: [redacted]

Decision number: CCH-D-2114453248-46-01/F
Substance name: [3R-(3α,3aβ,7β,8aα)]-1-(2,3,4,7,8,8a-hexahydro-3,6,8,8-tetramethyl-1H-3a,7-methanoazulen-5-yl)ethan-1-one
EC number: 251-020-3
CAS number: 32388-55-9
Registration number: [redacted]
Submission number: [redacted]
Submission date: 16/08/2017
Registered tonnage band: 100-1000

DECISION ON A COMPLIANCE CHECK

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

1. **Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: OECD TG 408) in rats, modified to include urinalysis and a full histopathological examination which is to include immunohistochemical investigation of renal pathology to determine if the pathology is mediated by alpha-2u globulin nephropathy, with the registered substance;**

2. **Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.; test method: Aerobic mineralisation in surface water – simulation biodegradation test, EU C.25./OECD TG 309) at a temperature of 12 °C with the registered substance;**

3. **Identification of degradation products (Annex IX, 9.2.3.) using an appropriate test method with the registered substance;**

4. **Robust study summary for Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation flow-through fish test) in conjunction with Annex I, Section 3.1.5.;**

You have to submit the requested information in an updated registration dossier by ***15 June 2020***, except for the Sub-chronic toxicity study (90-day) study for which you have to submit the information by **16 December 2019**. You shall also update the chemical safety report, where relevant.

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

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

Appeal

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

Authorised[1] by **Claudio Carlon**, Head of Unit, Evaluation **E2**

[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

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

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

A "sub-chronic toxicity study (90 day)" is a standard information requirement as laid down in Annex IX, Section 8.6.2. of the REACH Regulation. Adequate information on this endpoint needs to be present in the technical dossier for the registered substance to meet this information requirement.

In the technical dossier you have provided a study record for a GLP-compliant subchronic dermal toxicity study (90-day) according to OECD TG 411 (2002) in rats using the registered substance (exposure duration 13 weeks, 7 days per week, 6-7 hours per day; dosages: 0, 50, 150, 300 mg/kg bw/day). The NOAEL was 300 mg/kg bw/day with only limited systemic observations:

- *"slightly, but statistically, higher activated partial thromboplastin time for males treated with 300 mg/kg bw/day"*;
- *"test material-related increases in kidney-to-body weight percentages were noted in group 3 and 4 males"*;
- *"in the kidneys of the males given 300 mg/kg bw/day, hyaline droplet formation was noted in the tubular epitheum"*.

However, ECHA considers that this study does not provide the information required by Annex IX, Section 8.6.2., because it was not conducted via the most appropriate route of administration.

Annex IX, Section 8.6.2., Column 2 of the REACH Regulation stipulates three cumulative conditions for considering the dermal route appropriate:
"The appropriate route shall be chosen on the following basis: Testing by the dermal route is appropriate if:
(1) skin contact in production and/or use is likely; and
(2) the physicochemical properties suggest a significant rate of absorption through the skin; and
(3) one of the following conditions is met:

- *toxicity is observed in the acute dermal toxicity test at lower doses than in the oral toxicity test, or*
- *systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies, or*
- *in vitro tests indicate significant dermal absorption, or*
- *significant dermal toxicity or dermal penetration is recognised for structurally-related substances."*

ECHA observes that:

- appropriate Risk Management Measures are recommended in the CSR and in IUCLID section 11 to protect against skin contact during production and/or use; in your comments on the draft decision you indicate that the registered substance is used in

consumer end-uses, such as washing and cleaning products and cosmetic products. ECHA acknowledges that skin contact is likely.

- the physicochemical properties do not suggest a significant rate of absorption through the skin; in your comments on the draft decision, you state that the physicochemical properties indicate that absorption via the dermal route is expected to be low. ECHA also observes that, in the ECHA *Guidance on information requirements and chemical safety assessment* (version 3.0, July 2017), Chapter R.7c, table R.7.12-3, with respect to dermal absorptionit is reported: *"if water solubility is between 1-100 mg/l absorption is anticipated to be low to moderate"* and for Log P values above 4 *"the rate of penetration may be limited by the rate of transfer between the stratum corneum and the epidermis, but uptake into the stratum corneum will be high"*. The water solubility and Log P of the registered substance are reported to be 6 mg/l and 5.9 respectively therefore suggesting low absorption through the skin into the systemic circulation. On this basis ECHA concludes that this criterion is not met.
- Additionally in the dossier
  - toxicity is not observed in the acute dermal toxicity study at lower doses than in the oral toxicity test (LD50 rat, oral, male/female = 4500 mg/kg bw and LD50 rat, dermal; males/female > 5000 mg/kg bw);
  - under the toxicokinetic endpoint you concluded that "*dermal absorption will not be higher than oral absorption*"; systemic effects or other evidence of absorption has not been observed in the skin/eye irritation studies;
  - there are no *in vitro* tests in the dossier which indicate significant dermal absorption;
  - there is no data provided which would suggest that significant dermal toxicity or dermal penetration is recognised for structurally-related substances.

In your comments on the draft decision, you report the result of an *in vitro* human skin permeation study ([redacted], 2001; [redacted]., 2013) conducted according to FDA/AAPS guidelines ([redacted], 1987) and in accordance with GLP performed on the radiolabelled material (0.2 mCi acetyl cedrene (93.2%), [carbonyl-14C]). You also indicate that the toxicokinetic analysis will be updated with the results of that study. Following 48 h exposure, the *in vitro* human skin permeation study showed that 11.3 ± 1.2% of the applied dose of acetyl cedrene (20 µl/cm^2 of a 1% solution in ethanol) had permeated into the receptor phase.

ECHA considers that the percentage of the applied dose which has permeated through the skin after 48 hours is not high, certainly in comparison with what would be expected after oral administration. Moreover, ECHA understands that the test material (acetyl cedrene) is meant to be the registered substance, but insufficient information is provided on the compositional specification of the test material (main constituent and impurities) to be compared with that of the registered substance. Finally, the *in vitro* study is conducted on humans while no information on skin absorption in rat is provided. It would be necessary to have information on rat dermal absorption in order to establish whether the dermal route is an appropriate route for testing in rat. On the basis of the arguments above, ECHA concludes that the criterion of significant dermal absorption is not met.

Having regard of all the above, the criteria of Annex IX, 8.6.2, Column 2 for considering the dermal route an appropriate route of exposure are not met.

In addition, ECHA has evaluated your arguments for this route to determine if it could be

the most appropriate route of exposure.

No experimental toxicokinetic data in rat has been provided showing that the registered substance is systemically available after dermal exposure. In Section 7.1.1 of the technical dossier you stated that "*dermal absorption is limited but local irritant effects may occur with repeated exposure*" and "*the physical state of MCK, the low vapour pressure (0.25 kPa at 25°C) and the molecular weight ([redacted]) indicates that dermal absorption is possible. The water solubility (6 mg/L at 23°C) indicates low to moderate absorption while the high log Kow (5.9 at 30°C) is an indication for a high uptake into the stratum corneum, but a limited rate of penetration into the lower layers of the epidermis and dermis*". Additionally, direct toxicokinetic data in the rat on the amount of dermal penetration and on other toxicokinetic parameters is not present in the dossier. With regards to the effects seen on the male rat kidneys in the 90-day dermal RDT study, ECHA notes that the presence of the effects in rat kidney does not provide quantitative toxicokinetic information about the dermal penetration of the registered substance, and that systemic effects may be caused by the registered substance per se or by its metabolites.

In your comments on the draft decision you underline the discrepancy between the sentences in the draft decision "*ECHA notes that no experimental data has been provided showing that the registered substance is systematically available after dermal exposure*" and "*ECHA accordingly considers that the kidney is a target organ of the registered substance*" based on the results of the 90-day dermal repeated dose toxicity study. ECHA agrees with your comment and has clarified the arguments in the paragraph above.

Furthermore, ECHA notes that the registered substance is classified as Skin Sensitiser 1B and in the endpoint study record of the sub-chronic dermal toxicity study (90-days) you reported: "*dermal irritation observations noted during the treatment phase included erythema, edema, atonia, desquamation, and fissuring for animals treated with the test material*" and "*incidence and severity increased in a dose-related manner and severity ranged from slight to severe or marked*". Such adverse effects on the skin result in unreliable dosing and penetration of the skin depending on the severity of effects, and in this case the local toxicity appears to be limiting the systemic availability and toxicity of the substance. This prevents a comprehensive evaluation of the systemic toxicity of the substance. Additionally, ECHA observes that the pre-natal developmental toxicity study suggests that the oral route is more toxic than the dermal route, since maternal toxicity was observed at 100 mg/kg bw/day (maternal NOAEL is 50 mg/kg bw/day) whereas 300 mg/kg bw/day is the NOAEL in the 90-day dermal RDT study.

In contrast, the oral route is both the default and the preferred route of administration, according to ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017), Chapter R.7a. The absorption by oral route is normally higher than for dermal, and there are indications that the substance has more potent systemic toxicity by the oral route from the PNDT study, in the absence of limiting local toxicity.

For the reasons set out in evaluating the column 2 criteria, and the reasons given above, ECHA concludes that the oral route of exposure is the most appropriate route of exposure in the meaning of Annex IX, 8.6.2., column 2.

In your comments on the draft decision, you have argued that "the dermal route [is] an appropriate route of exposure". ECHA has amended appendix I of the draft decision to address the arguments you have brought forward.

In your comments on the draft decision, you further asked ECHA to comment on the reversibility of the effects noted in the recovery group during the 90-day dermal RDT study. ECHA notes that both the pathologist and the [redacted] expert panel, who reviewed the study, suggest that the findings indicate alpha-2u-globulin-mediated nephropathy. It is for this reason that ECHA has requested definitive proof that alpha-2u-globulin is involved in the nepropathy. ECHA further notes that the dermal study submitted in your dossier is not performed by the most appropriate route (as explained above), and the reversibility of any effects does not change this.

In your comments on the draft decision you further refer to the ECHA *Guidance on information requirements and chemical safety assessment* (version 6.0, July 2017) R.7.a, Section R.7.5.4.3., where it is reported "*the concept of Threshold of Toxicological Concern (TTC) might be applied to reduce the use of animals and other evaluation resources*" for repeated dose toxicity studies, and to the safety evaluation conducted by the [redacted], which has proposed that if existing test data are considered insufficient and no read-across analogues with data have been identified, then an exposure-based threshold such as the TTC may be considered. ECHA notes that the ECHA Guidance R.7.a does not state that the TTC approach is an approved method of an exposure based adaptation since in Section R.7.5.4.3 the quotation is followed by: "*However, there are a number of limitations or drawbacks that should be taken into consideration in deciding if the concept is to be applied for industrial chemical substances and further discussions on the cut-off values are needed before integration into the guidance (see Appendix R.7-1 to Chapter R.7, in Chapter R.7c of the Guidance on IR&CSA; TemaNord, 2005).*" ECHA underlines that exposure based adaptations are possible as set out in REACH, Annex XI, Section 3.

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

ECHA has evaluated the most appropriate route of administration for the study. Based on the information provided in the technical dossier and/or in the chemical safety report, and on the arguments set out above, ECHA considers that the oral route - which is the preferred one as indicated in ECHA *Guidance on information requirements and chemical safety assessment* (version 5.0, December 2016) Chapter R.7a, Section R.7.5.4.3 - is the most appropriate route of administration. More specifically,

- The substance is a liquid of low vapour pressure (0.25 kPa at 25 °C). Uses with industrial and professional spray application (PROCs 7 and 11) are reported in the Chemical Safety Report. However, the reported concentrations are low (<1%). In addition ECHA observes that an appropriate hierarchy of control is applied including a combination of general and local exhaust ventilation, use of respiratory protection and occupational health and safety management systems.

Hence, the test shall be performed by the oral route using the test method OECD TG 408.

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

In the GLP-compliant subchronic dermal toxicity study (90-day) (2002) present in your registration dossier, adverse effects such as increases in kidney-to-body weight percentages

in group 3 and 4 of male rats and hyaline droplet formation in the tubular epitheum at 300 mg/kg bw/day were observed in the kidneys of male rats and not in female rats. The fact that these effects were only observed in male rats may indicate that the registered substance may induce alpha-2u-globulin-mediated nephropathy. ECHA accordingly considers that the kidney is a target organ of the registered substance. Since humans do not excrete alpha-2u-globulin and this mode of action is considered not relevant to humans the involvement of alpha-2u-globulin in the kidney effects is a key parameter for establishing the relevance of the kidney effects for risk assessment. For these reasons, ECHA considers that urinalysis is required to investigate kidney function (which is optional in paragraphs 3, 4 and 37 of OECD TG 408). Additionally, a full histopathological examination (paragraphs 3, 4, 45 and 47 of OECD TG 408), is required, including immunohistochemical investigation of renal pathology to determine if the pathology is indeed mediated by alpha-2u globulin.

Therefore, pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information derived with the registered substance subject to the present decision: Repeated dose 90-day oral toxicity study (test method: OECD TG 408) in rats, modified to include urinalysis and a full histopathological examination which is to include immunohistochemical investigation of renal pathology to determine if the pathology is mediated by alpha-2u globulin nephropathy.

Notes for your considerations:

The Extended one-generation reproductive toxicity study (EOGRTS) according to Annex IX, Section 8.7.3. is not part of this decision because the results of the Sub-chronic toxicity study (90-day) are considered crucial to inform on the study design of the EOGRTS. Therefore, the results of the Sub-chronic toxicity study (90-day) should be used, among other relevant information, to decide on the study design of the EOGRTS.

ECHA may therefore launch a separate compliance check at a later stage addressing the EOGRTS information requirement.

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

2. Simulation testing on ultimate degradation in surface water (Annex IX, Section 9.2.1.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.
"Simulation testing on ultimate degradation in water" is a standard information requirement as laid down in Annex IX, section 9.2.1.2. 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 IX, Section 9.2., column 2. You provided the following justification for the adaptation "In accordance with column 2 of REACH annex IX, further degradation testing does not need to be conducted as the chemical safety assessment does not indicate a need for further investigation."

However, ECHA notes that your adaptation does not meet the specific rules for adaptation of Column 2 of Annex IX, Sections 9.2 and 9.2.1.2.

According to Annex IX, Section 9.2.1.2, column 2 of the REACH Regulation, simulation testing on ultimate degradation in surface water does not need to be conducted if the substance is highly insoluble in water or is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable in OECD 301F (36% in 28 days) and is not highly insoluble (reported water solubility is 6 mg/l).

Furthermore, ECHA notes that you have not provided adequate justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to investigate further the degradation of the substance and its degradation products. As explained further below, ECHA considers that the information is needed for the PBT/vPvB assessment and for the identification of the degradation products in relation to the PBT/vPvB assessment.

The registered substance is listed on the CoRAP[2] and is deemed to fulfil the criteria as PBT/vPvB / Suspected PBT/vPvB. The evaluating member state summarises that *"MCK is not readily biodegradable, has a logKow of 5.9 and a BCF of 3920 was determined according to OECD 305. It can be concluded that the B and T criteria are probably met, and further elucidation of the P and T properties is needed. MCK may be a potential PBT."*

Therefore, 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 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, Chapter R.7b* (version 4.0, June 2017) Aerobic mineralisation in surface water – simulation biodegradation (test method EU C.25. / OECD TG 309) is the preferred test to cover the standard information requirement of Annex IX, Section 9.2.1.2.

One of the purposes of the simulation test is to provide the information that must be considered for assessing the P/vP properties of the registered substance in accordance with Annex XIII of the REACH Regulation to decide whether it is persistent in the environment. Annex XIII also indicates that "*the information used for the purposes of assessment of the PBT/vPvB properties shall be based on data obtained under relevant conditions*". The Guidance on information requirements and chemical safety assessment R.7b (version 4.0, June 2017) specifies that simulation tests "attempt to simulate degradation in a specific environment by use of indigenous biomass, media, relevant solids [...], and a typical temperature that represents the particular environment". The Guidance on information requirements and chemical safety assessment Chapter R.16 on Environmental Exposure Estimation, Table R.16-8 (version 3.0 February 2016) indicates 12°C (285K) as the average environmental temperature for the EU to be used in the chemical safety assessment. Performing the test at the temperature of 12°C is within the applicable test conditions of the

[2] https://echa.europa.eu/documents/10162/8db73c15-135d-4371-961a-87dc80dca1f6

Test Guideline OECD TG 309. Therefore, the test should be performed at the temperature of 12°C.

In the OECD TG 309 Guideline two test options, the "pelagic test" and the "suspended sediment test", are described. ECHA considers that the pelagic test option should be followed as that is the recommended option for P assessment. The amount of suspended solids in the pelagic test should be representative of the level of suspended solids in EU surface water. The concentration of suspended solids in the surface water sample used should therefore be approximately 15 mg dw/L. Testing natural surface water containing between 10 and 20 mg SPM dw/L is considered acceptable. Furthermore, when reporting the non-extractable residues (NER) in your test results you should explain and scientifically justify the extraction procedure and solvent used obtaining a quantitative measure of NER.

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: Aerobic mineralisation in surface water – simulation biodegradation test (test method: EU C.25./OECD TG 309).

Notes for your consideration

In accordance with Annex I, Section 4, of the REACH Regulation you should revise the PBT assessment when results of the tests detailed above are available. You are also advised to consult the ECHA Guidance on information requirements and chemical safety assessment (version 3.0, June 2017), Chapter R.11, Section R.11.4.1.1. and Figure R. 11-3 on PBT assessment for the integrated testing strategy for persistency assessment in particular taking into account the degradation products of the registered substance.

3. Identification of degradation products (Annex IX, 9.2.3.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.

The identification of the degradation products is a standard information requirement according to column 1, Section 9.2.3. of Annex IX 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 biodegradation section in the technical dossier does not contain any information in relation to the identification of degradation products, nor an adaptation in accordance with column 2 of Annex IX, Sections 9.2 or 9.2.3. or with the general rules of Annex XI for this standard information requirement.

According to Annex IX, Section 9.2.3., column 2 of the REACH Regulation, identification of degradation products is not needed if the substance is readily biodegradable. ECHA notes that based on the information in the technical dossier, the registered substance is not readily biodegradable as already discussed in section 2 above.

Furthermore, ECHA notes that you have not provided any justification in your chemical safety assessment (CSA) or in the technical dossier for why there is no need to provide

information on the degradation products. ECHA considers that this information is needed in relation to the PBT/vPvB assessment and risk assessment.

As explained above, the information provided 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.

Regarding an appropriate and suitable test method, the methods will have to be substance-specific. When analytically possible, identification, stability, behaviour, molar quantity of metabolites relative to the parent compound should be evaluated. In addition, degradation half-life, log Kow and potential toxicity of the metabolite may be investigated. You may obtain this information from the relevant degradation study also requested in this decision, or by some other measure. You will need to provide a scientifically valid justification for the chosen method.

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:

Identification of the degradation products (Annex IX, Section 9.2.3.) by using an appropriate and suitable test method, as explained above in this section.

4. Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.)

In accordance with Articles 10(a) and 12(1) of the REACH Regulation, a technical dossier registered at 100 to 1000 tonnes per year must contain, as a minimum, the information specified in Annexes VII to IX to the REACH Regulation. The information to be generated for the dossier must fulfil the criteria in Article 13(4) of the same regulation.
Pursuant to Article 10(a)(vii) of the REACH Regulation, the information set out in Annex VII to XI must be provided in the form of a robust study summary. Article 3(28) defines a robust study summary as a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report. Guidance on the preparation of the robust study summaries is provided in the Practical Guide on "How to report robust study summaries".

A Bioaccumulation in aquatic species study 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.

You have provided a study record for a OECD 305 Fish bioconcentration test in Rainbow trout with metheyl cedryl ketone (-14C) to meet the standard information requirement of Annex IX, Section 9.3.2.

However, ECHA notes that, contrary to Article 3(28) of the REACH Regulation, the documentation of this study is insufficient and does not allow an independent assessment of the adequacy of this study, its results and its use for hazard and PBT assessment.

In particular there is no indication from the study summary whether the lipid normalisation and growth correction were carried out. ECHA notes that information on the fish lipid content and growth is critical to inform the PBT assessment given that the results of the study indicate that there is bioaccumulation potential with BCF value 3920. Therefore, you need to provide a complete robust study summary.

Pursuant to Article 41(1) and (3) of the REACH Regulation, you are requested to submit the following information: Robust study summary for the OECD 305 Fish bioconcentration test in Rainbow trout with metheyl cedryl ketone.

Appendix 2: Procedural history

For the purpose of the decision-making, this decision does not take into account any updates of your registration after the date when the draft decision was notified to you under Article 50(1) of the REACH Regulation.

The compliance check was initiated on 19 June 2018.

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

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

ECHA took into account your comments and did not amend the requests.

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

As no amendments were proposed, ECHA took the decision according to Article 51(3) of the REACH Regulation.

Appendix 3: Further information, observations and technical guidance

1. The substance subject to the present decision is provisionally listed in the Community rolling action plan (CoRAP) for the start of substance evaluation in 2019.

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

3. Failure to comply with the requests in this decision, or to otherwise fulfil the information requirements with a valid and documented adaptation, will result in a notification to the enforcement authorities of your Member State.

4. In relation to the information required by the present decision, the sample of the substance used for the new tests must be suitable for use by all the joint registrants. Hence, the sample should have a composition that is suitable to fulfil the information requirement for the range of substance compositions manufactured or imported by the joint registrants.

   It is the responsibility of all joint registrants who manufacture or import the same substance to agree on the appropriate composition of the test material and to document the necessary information on their substance composition. In addition, it is important to ensure that the particular sample of the substance tested in the new tests is appropriate to assess the properties of the registered substance, taking into account any variation in the composition of the technical grade of the substance as actually manufactured or imported by each registrant.

   If the registration of the substance by any registrant covers different grades, the sample used for the new tests must be suitable to assess these grades. Finally there must be adequate information on substance identity for the sample tested and the grades registered to enable the relevance of the tests to be assessed.