Helsinki, 29 April 2019

Addressee: [redacted]

Decision number: CCH-D-2114465754-39-01/F
Substance name: 2-(2H-benzotriazol-2-yl)-p-cresol
EC number: 219-470-5
CAS number: 2440-22-4
Registration number: [redacted]
Submission number subject to follow-up evaluation: [redacted]
Submission date subject to follow-up evaluation: 23 July 2018

DECISION TAKEN UNDER ARTICLE 42(1) AND ARTICLE 41 OF THE REACH REGULATION

By decision CCH-D-2114350442-58-01/F of 14 December 2016 ("the original decision") ECHA requested you to submit information by 21 March 2018 in an update of your registration dossier.

In accordance with Article 42(1) of Regulation (EC) No 1907/2006 (the 'REACH Regulation'), ECHA examined the information you submitted with the registration update specified in the header above, and concludes that

Your registration still does not comply with the following information requirement:

Bioaccumulation in aquatic species (Annex IX, Section 9.3.2.; test method: Bioaccumulation in fish: aqueous and dietary exposure, OECD TG 305, [aqueous exposure/dietary exposure])

Therefore, pursuant to 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:

Bioaccumulation in fish: aqueous and dietary exposure test (test method: OECD TG 305)

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.

You have to submit the requested information in an updated registration dossier by **5 June 2020. You also have to update the chemical safety report, where** relevant.

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 Wim De Coen, Head of Unit, Hazard Assessment

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

Appendix 1: Reasons

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

In the Decision CCH-D-2114350442-58-01/F of 14 December 2016 you were requested to provide a robust study summary for the bioconcentration study (OECD 305 C) on the registered substance including the missing information on the analytical methods and results (e.g. controls, mortalities, and any observed abnormal behaviour).

In your updated registration subject to follow-up evaluation, you provided a robust study summary of a 1998 study report of a study entiled:"[redacted]" by the [redacted].

You reported that the study was conducted according to OECD Guideline 305 C (Bioaccumulation: Test for the Degree of Bioconcentration in Fish) before 14 June 1996, and GLP. The test material used in the study was 2-(2'-hydroxy-5'-methylphenyl) benzotriazole, CAS 2440-22-4, EC No. 219-470-5, with purity: 99.9%.

The test organism used was *Cyprinus carpio* (Carp) and the study design was aqueous, natural freshwater, flow-through test with 8 week uptake duration but without a subsequent depuration phase. No reference substance was used (positive control). The nominal concentrations used in the study were: 1.0, 0.1 and 0.01 mg/L and a blank control.

The resulting bioconcentration factor (BCF) values ranged between 123-494 L/kg, 130-295 L/kg, and 44-220 L/kg for the test groups 1, 0.1, and 0.01 mg/L, respectively. The study reports BCF values based on the ratio of the test substance in fish compared to the concentration in the surrounding water phase. To avoid an underestimation of the BCF, the concentration of test substance in fish used for the calculation of the BCF must be the concentration at steady state. According to the latest OECD 305 test guideline (02 October 2012) steady state is reached when three successive analyses of the concentration in fish made on samples taken at intervals of at least two days are within ±20% of each other. As the available study does not report any data on the concentrations in fish, it cannot be verified if steady state was reached. Therefore, the reported BCF values might underestimate the true steady state BCF. Furthermore, as no depuration phase was included in the study, the kinetic BCF cannot be derived and used as comparison or as an alternative.

In conclusion, the study has deficiencies which might result in an underestimation of the bioaccumulative potential and the test results cannot be considered as adequate and reliable pursuant to the latest OECD TG 305.

You also concluded about the information available as follows: "At the current state of knowledge, a significant potential to bioaccumulate is not expected. However, the available experimental study on carp has some deficiencies which could result in an underestimation of the bioaccumulative potential. Therefore, to have final clarity on the bioaccumulative potential a BCF study according to the latest OECD 305 guideline is proposed." As a result of this conclusion you submitted a testing proposal to ECHA to cover the standard information requirement.

ECHA agrees with your conclusion that the information provided in the robust study summary is not adequate to meet the standard information requirement and cover the safe

use of your registered substance. However, ECHA considers that the testing proposal you submitted is inadmissible because the end-point for which you proposed testing is still subject to an ongoing compliance check process in the form of the follow-up evaluation and therefore, instead of the testing proposal examination, the compliance of the information is evaluated under compliance check.

Bioaccumulation in aquatic species, preferably fish, 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.

According to Annex IX the study need not be conducted if the substance has a low potential for bioaccumulation, for instance a logKow <3 and/or a low potential to cross biological membranes or direct and indirect exposure of the aquatic compartment is unlikely.

For your registered substance, direct or indirect exposure of the aquatic compartment cannot be ruled out. Furthermore, you have reported that substance has a high log Kow (Log Pow= 4.20 at 25°C and at pH 6.3) and based on the registered substance's molecular weight or its average molecular diameter, a hindered uptake through biological membranes is not likely. Therefore, the specific rules for column 2 adaptation possibilities according to Annex IX are not suitable for the registered substance.

As detailed above, the information requirement request in the compliance check decision (CCH-D-2114350442-58-01/F) is not met. 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.7c (version 3.0, June 2017), Bioaccumulation in fish: aqueous and dietary exposure (test method EU C.13. / OECD TG 305) is the preferred test to cover the standard information requirement of Annex IX, Section 9.3.2. ECHA Guidance defines further that results obtained from a test with aqueous exposure can be used directly for comparison with the B and vB criteria of Annex XIII of REACH Regulation and can be used for hazard classification and risk assessment. Comparing the results of a dietary study with the REACH Annex XIII B and vB criteria is more complex and has higher uncertainty. Therefore, the aqueous route of exposure is the preferred route and shall be used whenever technically feasible. If you decided to conduct the study using the dietary exposure route, you shall provide scientifically valid justification for your decision. You shall also attempt to estimate the corresponding BCF value from the dietary test data by using the approaches given in Annex 8 of the OECD 305 TG and in OECD Guidance Document on Aspects of OECD TG 305 on Fish Bioaccumulation, ENV/JM/MONO (2017)16. In any case you shall report all data derived from the dietary test as listed in the OECD 305 TG.

Therefore, pursuant to Article 42(1) and 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:

Bioaccumulation in fish: aqueous and dietary exposure test (test method: OECD TG 305)

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 9 months from the date of adoption of the decision. In your comments on the draft decision, you requested an extension of the timeline to 16 months. You sought to justify this request by needing time for sequential testing barring any unforeseen circumstances and time needed for the synthesis of the radioactive test material.

Furthermore, you stated that the laboratory capacity is generally booked several months in advance due to high volume of testing requests for bioaccumulation. ECHA-S notes that no proof of the obstacles in the laboratory capacity was added in your comments and as there is already a 3 month buffer calculated in the 9 month deadline originally foreseen for conducting the test according to OECD TG 305. Therefore, ECHA has only partially granted the request and set the deadline to 13 months from the date of the decision.

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 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 amended the deadline.

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

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

Appendix 3: Further information, observations and technical guidance

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

2. The Article 42(2) notification for the original decision is on hold until all information requested in the original decision has been received.

3. Failure to comply with the requests in this decision 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.