ECHA
EUROPEAN CHEMICALS AGENCY

Decision number: CCH-D-2114350547-46-01/F Helsinki, 21 December 2016

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

For tetrabromophthalic anhydride, CAS No 632-79-1 (EC No 211-185-4), 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 dossier for tetrabromophthalic anhydride, CAS No 632-79-1 (EC No 211-185-4), submitted by [redacted]

This decision is based on the registration dossier 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 12 June 2014, the date upon which ECHA notified its draft decision to the Competent Authorities of the Member States pursuant to Article 51(1) of the REACH Regulation.

The scope of this compliance check was limited to the standard information requirements related to "Aquatic toxicity" and environmental hazard assessment (Annex IX, 9.1.5. and 9.1.6., and Annex I, Section 3.3. of the REACH Regulation). In reaction to the proposals for amendement from the [redacted] and [redacted] Competent Authorities within the 30 days of the receipt of the notification of the draft decision to the Competent Authorities of the Member States, the scope of this compliance check has been expanded to the standard information requirement of on Growth inhibition study aquatic plants and related environmental hazard assessment (Annex VII Section 9.1.2. of the REACH Regulation).

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

The compliance check was initiated on 28 February 2013 on the dossier submitted by the Lead Registrant at that time, i.e. [redacted].

On 13 May 2013 ECHA sent the draft decision to the Lead Registrant and invited him to provide comments within 30 days of the receipt of the draft decision. That draft decision was based on submission number [redacted].

On 11 June 2013 ECHA received comments from the Lead Registrant stating that an updated dossier will be submitted containing further justifications to fulfil the standard information related to Annex IX 9.1.5 and 9.1.6 and Annex I, section 3.3 of the REACH regulation.

On 12 June 2013 the Lead Registrant updated his registration dossier with the submission number [redacted].

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

On 12 June 2014 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, proposals for amendment were submitted.

On 18 July 2014 ECHA notified the Lead 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 proposals for amendment within 30 days of the receipt of the notification.

The ECHA Secretariat reviewed the proposals for amendment received and amended the draft decision.

On 28 July 2014 ECHA referred the draft decision to the Member State Committee.

By 18 August 2014, in accordance to Article 51(5), the Lead Registrant provided comments on the proposals for amendment. The Member State Committee took the comments of the Registrant on the proposals for amendment into account.

A unanimous agreement of the Member State Committee on the draft decision was reached on 1 September 2014 in a written procedure launched on 21 August 2014. ECHA took the decision pursuant to Article 51(6) of the REACH Regulation.

Meanwhile, the Lead Registrant [redacted] informed ECHA of his intention to cease manufacture of the registered substance (subsequently confirmed on 26 August 2014). As member of the consortium, [redacted] agreed to take on the Lead Registrant role (confirmed with a dossier update on 24 October 2014, submission number: [redacted]) and agreed to receive this decision on the registered substance.

II. Information required

A. Information in the technical dossier regarding effects on aquatic toxicity

Pursuant to Articles 41(1)(b), 41(3), 10(a)(vii), 12(1)(e), 13 as well as Annex IX of the REACH Regulation the Registrant is required to carry out the following studies using the indicated test methods and the registered substance subject to the present decision:

a. Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Algae, growth inhibition test, EU C.3./OECD 201);
b. Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
c. Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210),

as specified further under Section III.

Pursuant to Articles 41(1)(c), 41(3), 10(b) and 14 as well as Annex I, 3.3. of the REACH Regulation the Registrant shall submit the following information:

d. PNECs for the aquatic compartment on the basis of data from a., b. and c. above as it becomes available or by using only the aquatic acute toxicicty results to derive it and the CSR.

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 sound 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 Authorities of the Member States for possible enforcement.

B. Deadline for submitting the required information

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated IUCLID dossier to ECHA by **28 June 2018**.

At any time, the Registrant shall take into account that there may be an obligation to make every effort to agree on sharing of information and costs with other registrants.

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 requirement covering Annex VII, 9.1.2. and Annex IX, 9.1.5. and 9.1.6. as well as aspects related to the environmental hazard assessment. In accordance with Articles 10(a)(vii), (b), 12(1) and 14(1) of the REACH Regulation, the registration is required to contain this information.

a., b. and c. *Long-term aquatic toxicity testing on invertebrates and fish and Growth inhibition study aquatic plants*

According to column 1 of Section 9.1.2. of Annex VII and Sections 9.1.5. and 9.1.6. of Annex IX of the REACH Regulation, growth inhibition study aquatic plants, long-term toxicity testing on invertebrates and long-term toxicity testing on fish is required to fulfil the standard information requirements.

The Registrant initially proposed to adapt these information requirements on aquatic long-term toxicity of the substance by providing results obtained from the application of quantitative structure activity relationship models ((Q)SARs). According to Annex XI, Section 1.3. of the REACH Regulation the results of (Q)SARs may be used instead of testing when the following conditions are met:

- 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 model is provided.

In the absence of adequate documentation in the dossier under initial assessment ECHA found that the Registrant had not demonstrated that the conditions of the adaptation of Annex XI, Section 1.3. of the REACH Regulation are fulfilled, and that ECHA therefore cannot accept the adaptation.

A further waiver as part of REACH Annex IX, Section 9.1, column 2 was provided by the Registrant for section 9.1.5 and 9.1.6 stating: '*The substance is used only as an intermediate for the production of another substance and as intermediate in the production of polymers. In the latter case, it will be chemically bound in the resulting polymers and not released into the environment. The two processes in which the substance is used, are designed in a way that no environmental releases to water occurs under normal production conditions. Therefore in accordance with Column 2 of 9.1. Annex IX of Regulation 1907/2006 it is concluded that the negligible exposure does not indicate a need to further investigate the effects on aquatic organisms.*'

This exposure consideration of Annex XI section 3.2 cannot be accepted as it is also stated in IUCLID section 3.5: '*PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises';* furthermore, in section 9 of the CSR, two exposure scenarios are provided for which the exposure considerations and exposure to air or water are not sufficiently justified.

As the adaptations could not be accepted, and as no other information was available in the dossier for the endpoints in question, ECHA has concluded that there are information gaps and that it is necessary to provide information for the endpoints in order to bring the registration dossier into compliance with relevant information requirements.

According to ECHA *Guidance on information requirements and chemical safety assessment* (version 1.2., November 2012), Chapter R7b, Figure R.7.8-4 page 56, 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. 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.

After receiving the draft decision, the Registrant submitted a dossier update providing further documentation on the QSAR models used. The updated dossier and the provided documentation of QSAR models in Annex XI section 1.3. were assessed by ECHA secretariat as outlined below:

- The substance does not fall within the applicability domain of the (Q)SAR model: The ECOSAR predictions for both substances give the following disclaimer: *Not Related to an Existing ECOSAR Class Definition. Estimates provided below use the Neutral Organics QSAR equations which represent baseline toxicity potential (minimum toxicity) assuming a simple non-polar narcosis model. Without empirical data on structurally similar chemicals, it is uncertain if this substance will present significantly higher toxicity above baseline estimates.*

- The QSAR predictions given for long-term aquatic tests are unreliable. The registrant produced ECOSAR predictions for TBPA and TBPA acid because he assumed that TBPA hydrolises quickly into TBPA acid. Note: the speed of this hydrolysis is not indicated in the registration dossier and no specific hydrolysis test has been provided.

Therefore these predictions are not reliable and do not fulfill Annex XI 1.3 criteria.

For the examination of the CSR section 9 and related endpoints :

- The data waiving of the long-term aquatic tests based on exposure considerations such as : *"no environmental releases to water occurs under normal production conditions."* is not sufficiently justified. However in IUCLID section 3.5 the following process category is selected: *"PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises"*. In addition the fact that this registration is not an isolated intermediate dossier is most probably due to the fact that the substance is not used under strictly controlled conditions. Furthermore within the CSR section 9, two exposure scenarios are provided:

- For the first scenario it is said that *"A wet cyclone scrubber is used to clean discharged air of TBPA particles. The discharged air is free of TBPA after the treatment and no releases to the environment via air are anticipated. Wet scrubbing works via the contact of target compounds or particulate matter with the scrubbing solution, e.g. water. The wastewater produced in the scrubber unit is disposed of offsite by an external partner. All solid waste is disposed of appropriately and treated as industrial waste. The release fractions for air, water and soil are zero."* However the fact that the 'contaminated' wastewater is handled by an external partner is not a sufficient justification for concluding that there will be zero emission to water.

- For the second scenario it is said that *"Discharged air passes a filter system. The filters have a reduction efficacy of 95%-98%. Aqueous waste is treated in an external sewage treatment plant and no releases to the environment via wastewater are expected. Sewage sludge containing TBPA is appropriately disposed off. All solid waste is disposed of appropriately and treated as industrial waste."* However the registrant does not explain what happens exactly with the sewage sludge. In addition, the substance has a low Koc and a high solubility, therefore it can be predicted that the substance will tend to stay in the water instead of adsorbing to sludge.

- In addition, the substance has a low Koc, a low vapour pressure and a high solubility. Therefore, even if the only emission of the substance is via powder air emission, this emission can re-deposit and accumulate in the water compartment. Therefore exposure to water cannot be fully excluded.

- The substance does not biodegrades rapidly. This might lead to long-term effects that are not detected via acute tests.

As a consequence, the data waiving of the long-term aquatic toxicity based on exposure considerations is not sufficiently justified in the rest of the dossier (CSR included) and is therefore rejected.

In his comments on the proposals for amendment, the Registrant indicated that "*rapid hydrolysis of registered substance in the algae medium is expected. As an algae study can only be performed in a static system, the study will in fact be performed on the corresponding acid*".

ECHA acknowledges the Registrant's comments but would like to advice the Registrant that in accordance with the OECD Guidance Document on Aquatic Toxicity Testing of Difficult Substances and Mixtures, ENV/JM/MONO (2000)6 and ECHA Guidance on information requirements and chemical safety assessment (version 1.2., November 2012), Chapter R7b, table R. 7.8-3 pp 56, if the substance is likely to be unstable, a decision to test the parent substance and/or its possibly identified degradation products should be based on a consideration of the half-life of the substance under test and real-world conditions.

Therefore, pursuant to Article 41(3) of the REACH Regulation, the Registrant is requested to submit information using the following test methods on the registered substance:

- Growth inhibition study aquatic plants (Annex VII, Section 9.1.2.; test method: Algae, growth inhibition test, EU C.3./OECD 201);
- Long-term toxicity testing on aquatic invertebrates (Annex IX, 9.1.5.; test method: *Daphnia magna* reproduction test, EU C.20/OECD 211); and
- Long-term toxicity testing on fish (Annex IX, 9.1.6.1.; test method: Fish, early-life stage toxicity test, OECD 210).
  If based on the integrated testing strategy (described above) the Registrant comes to the conclusion that no further investigation of effects on fish is required, he should update his technical dossier by clearly stating the reasons for adapting the standard information requirement of Annex IX, Section 9.1.6.

d. *PNECs for the aquatic compartment*

Annex I, Section 3.3. of the REACH Regulation requires the Registrant to establish predicted no effect concentrations (PNEC(s)) for the registered substance, covering each environmental sphere, including the aquatic compartment.

(i) PNECs to be revised

ECHA notes that, the registration submitted by the Registrant contains PNECs for the aquatic compartment for freshwater and intermittent releases. ECHA notes furthermore that the information provided by the Registrant for the endpoints of Annex IX, Sections 9.1.5. and 9.1.6. derived from (Q)SAR model was used as available data for the derivation of the PNECs. The use of this data is however only acceptable when the conditions of Annex XI, Section 1.3. are fulfilled, which is not the case as demonstrated under subsections III.a., b. and c. above.

Furthermore, in the derivation of the PNECs the Registrant has applied an assessment factor (AF) of 10.

The footnote to Annex I, Section 3.3.1. provides information on the application of assessment factors to cover the uncertainty associated with the available data, indicating that an assessment factor of 1000 is typically applied to the lowest of three short term L(E)C50 values derived from species representing different trophic levels and a factor of 10 is applied to the lowest of three long-term NOEC values derived from species representing different trophic levels. This is further explained in the ECHA Guidance Chapter R.10.

ECHA concludes that the Registrant's choice of an AF is not in line with the provisions of the footnote to Annex I, Section 3.3.1. and of ECHA Guidance chapter R.10, Section R.10.3.1.2 and therefore not acceptable.

Consequently, these aquatic PNECs are invalid. The Registrant shall therefore provide revised aquatic PNEC derivations for freshwater and intermittent releases in line with the provisions of Annex I as indicated above, in particular by applying an appropriate and fully justified AF. They shall be kept updated, along with the whole Chemical Safety Report. In particular, when data becomes available from the studies required under Section II.a. and b. it shall be taken into consideration in an updated derivation of the PNECs. For choosing the appropriate Assessment Factor the Registrant shall take into account the footnote to Annex I, Section 3.3.1. and also ECHA Guidance chapter R.10, Section R.10.3.1.2.

(ii) Further PNEC derivation

ECHA also notes that the registration submitted by the Registrant contains otherwise no PNEC for the aquatic marine compartment.

Instead of providing a PNEC the registrant sought to justify why not providing a PNEC stating in the PNEC field: 'TBPA is unlikely to enter the marine environment based on its pattern of use'. However, pursuant to Annex I, Section 3.3.2. the only reason for not deriving PNEC(s) is to fully justify why it is not possible to do so. The Registrant has not provided such justification and therefore is required to derive PNECs as required by Annex I, Section 3.3.1., including the PNEC for the aquatic marine compartment.

The Registrant shall therefore also provide aquatic PNEC derivations for the aquatic marine compartment in line with the provisions of Annex I and the specifications provided for the other two PNECs above (see subsection (i) above).

IV. Adequate identification of the composition of the tested material

ECHA stresses that the information submitted for identifying the substance has not been checked for compliance with the substance identity requirements set out in Section 2 of Annex VI of the REACH Regulation.

In carrying out the studies 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 studies 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 studies to be assessed.

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://echa.europa.eu/appeals/app_procedure_en.asp. The notice of appeal will be deemed to be filed only when the appeal fee has been paid.

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.