Decision number: CCH-D-0000003820-79-03/F Helsinki, 28 May 2014

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

For diarsenic trioxide, CAS No 1327-53-3 (EC No 215-481-4), 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 (hereinafter referred to as "the REACH Regulation").

This decision is based on the transported isolated intermediate registration as submitted with submission number [redacted], for the tonnage band of 10 to 1000 tonnes per year. This decision does not take into account any updates submitted after 6 March 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.

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

I. Procedure

Pursuant to Article 41(1) of the REACH Regulation ECHA has performed a compliance check of the registration for diarsenic trioxide CAS No 1327-53-3, EC No 215-481-4 (hereinafter referred to as "diarsenic trioxide"), submitted by [redacted] (the Registrant) as transported isolated intermediate in quantities of 10 to 1000 tonnes per year with registration Nr. [redacted].

1. Steps taken before the opening of the compliance check procedure

Prior to opening the present compliance check procedure, ECHA performed a verification of the intermediate status of the registered substance as used by the Registrant:

On 13 February 2012, a decision was sent by ECHA to the Registrant pursuant to Article 36(1) of the REACH Regulation (communication Nr. DEP-D-2114209469-44-01/F, hereinafter "the Article 36 decision"), concerning the registration of diarsenic trioxide submitted by the Registrant. More specifically, this decision aimed at requesting the Registrant to provide the information that was required to carry out his duties relating to the registration of diarsenic trioxide as transported isolated intermediate.

On 13 April 2012, the Registrant responded to ECHA's decision by providing, by email, documentation describing the nature of the use of diarsenic trioxide and the conditions of that use. ECHA reviewed the information provided by the Registrant and, based on this information, concluded that the dossier submitted for registration Nr. [redacted]

[redacted] does not fulfil the conditions of the definition of intermediates set out in Article 3(15) of the REACH Regulation. As a result, ECHA concluded that the Registrant is not entitled to benefit from the reduced information requirements set out for transported isolated intermediates (see Section III.1. of the present decision). Consequently, as Chapter 3 of Title II of the REACH Regulation (specific registration provisions for intermediates) does not apply, ECHA considers the registration as a full registration pursuant to Article 10 of the REACH Regulation and it shall include the information specified in that Article.

2. The procedural steps of the compliance check

The compliance check was initiated on 3 June 2013.

On 7 June 2013 ECHA sent the draft decision to the Registrant and invited him to provide comments within 30 days of the receipt of the draft decision.

On 5 July 2013 ECHA received comments from the Registrant.

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

On 6 March 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.

As no proposal for amendment was submitted, ECHA took the decision pursuant to Article 51(3) of the REACH Regulation.

II. Information required

Pursuant to Articles 41(1)(a) and 41(3) of the REACH Regulation the Registrant shall submit **the information as set out in Article 10 of the REACH Regulation for the registered substance subject to the present decision**.

ECHA notes that other registrants of the same substance have already submitted in their registration dossiers information from experimental studies involving vertebrate animals in order to fulfil the relevant information requirements. In accordance with Article 30(3) of the REACH Regulation, establishing an obligation to share available studies involving testing on vertebrate animals, the Registrant shall not perform new testing involving vertebrate animals in order to comply with the present decision where such data is already available and shall request this information from other registrants of the same substance. Furthermore, ECHA points out that pursuant to Article 30(1) of the REACH Regulation the Registrant may also request information not involving tests on vertebrate animals from other registrants of the same substance.

More specifically, Article 30(1) of the REACH Regulation imposes on the Registrant to request from other substance information exchange forum (SIEF) participants to share the studies involving tests on vertebrate animals already available. The Registrant and the other SIEF participants shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way.

In addition, the Registrant is reminded of the obligation imposed by Article 11 of the REACH Regulation on all the registrants of the same substance to submit registrations for the same substance jointly.

ECHA notes that no compliance check on the full (i.e. non-intermediate) registration of the Joint Submission has been performed.

Pursuant to Article 41(4) of the REACH Regulation the Registrant shall submit the information in the form of an updated registration to ECHA by **6 October 2014**.

III. Statement of reasons

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

Recital 41 of REACH Regulation stipulates that "*for reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates*". More specifically, the aim of Articles 17 and 18 of the REACH Regulation is to introduce a derogation to the submission of standard information requirements for certain isolated intermediates where the risk of exposure is potentially lower. This derogation is explicitly subject to conditions which, if not fulfilled, result in the obligation for the registration to include the standard information specified in Article 10 of the Regulation as any other registration.

As a result, in order to benefit from the derogations foreseen by the REACH Regulation for transported isolated intermediates, the use of the substance must firstly meet the definition of transported isolated intermediate set out in Article 3(15) of the Regulation. Secondly, this derogation shall apply only if the strictly controlled conditions set out in Article 18(4) of the REACH Regulation are ensured during manufacturing and/or all identified use(s), including waste stage.

The determination as to whether the use of the registered substance satisfies these conditions is therefore a pre-requisite to the identification of the applicable information requirements (see, respectively, section 1 and 2 below).

1. Determination that the use of the registered substance does not fulfil the conditions of intermediate

   In the documentation provided in reply to ECHA's request for information pursuant to the Article 36 decision and in the comments pursuant to Article 50(1) of the REACH Regulation, the Registrant has specified that the registered substance is exclusively used in its zinc electrolysis plant. The Registrant has also provided details of the processing steps resulting from the use of diarsenic trioxide in that plant.

   According to this documentation, the Registrant considers that, for this specific use, the registered substance qualifies as an intermediate. On the contrary, ECHA concludes from the submitted information that the registered substance does not meet the definition of intermediate under REACH, as explained hereinafter.

   a. The conditions for a substance to fulfil the REACH intermediate definition

   Based on general principles of interpretation established by the European Court of Justice, derogations shall be interpreted restrictively. Pursuant to Article 3(15) of

the REACH Regulation, an intermediate "*means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis")*".

Based on this definition, the REACH Regulation lays down derogations for intermediates uses. These derogations concern firstly the possibility, pursuant to its Articles 17 and 18, to submit only reduced information as compared to other uses of the same substance. Secondly and of specific relevance in the present case, uses of substance as isolated intermediates are exempt from authorisation requirements pursuant to Article 2(8)(b). Diarsenic trioxide is included in Annex XIV of the REACH Regulation. As the definition given in Article 3(15) serves as a basis for the application of derogations listed in REACH Regulation for intermediates, a strict interpretation of the definition is justified.

Based on the above, the definition of intermediate has been further clarified in Appendix 4 of the Guidance on intermediates. That document agreed by ECHA, the European Commission and the Member States competent authorities, specifies the following:

> "*Whenever a substance (A) used in a chemical processing is not used in the manufacturing of another substance (B) in order to be itself transformed into that other substance (B), it is necessarily used in order to achieve another function than transformation, either as part of the manufacturing of another substance (B) (e.g. as catalyst, processing agent, solvent), or as part of another activity (e.g. as an individual step in the production process of an article). While this other function may still involve chemical modification of the substance (A) used in the process, this type of use cannot be considered as the manufacturing of another substance (B) from the transformation of substance (A). Therefore, as soon as the main aim of the chemical process is not to transform a substance (A) into another substance (B), or when substance (A) is not used for this main aim but to achieve another function, substance (A) used for this activity should not be regarded as an intermediate under REACH*" (emphasis added).

According to this Guidance, the intermediate status of a substance is defined in relation to the "main aim" driving the process where the substance is actually used. The use of the substance in the process shall be placed in the perspective of that "main aim" to determine if it eventually qualifies the substance as an intermediate.

The identification of the "main aim" of a chemical process is therefore central to the determination of the intermediate status of a substance. In the case concerned by the present decision, it is thus necessary to identify the main aim of the processing of diarsenic trioxide.

b. Determination of the "main aim" of the processing of diarsenic trioxide

The registered substance is exclusively used by the Registrant in a zinc electrolysis plant where zinc is purified from certain elements. More specifically, in its reply to ECHA's request pursuant to Article 36 of the REACH Regulation, the Registrant defines the process as follows:

[redacted]

[redacted]

The Registrant refers to four different processing steps resulting from the use of the registered substance diarsenic trioxide:

[redacted]

These four steps define all the possible process levels for this registration according to which the status of diarsenic trioxide as an intermediate can be determined. Indeed, one can determine the main aim of the use of diarsenic trioxide only in relation to four outputs from the process: [redacted]

ECHA notes that, in the documentation provided in reply to the decision pursuant to Article 36, the Registrant identifies the "[redacted]" as "*the substance manufactured from the intermediate*". This would indicate that the Registrant has concluded on the intermediate status of the registered substance in the perspective of the production of the "[redacted]". The Registrant has confirmed in his comments provided to ECHA pursuant to Article 50(1) of the REACH Regulation that the main aim of the use of the substance is production of the [redacted]. The Registrant notes also that "*the relevant chemical process to be regarded is the reaction of Diarsenic Trioxide –* [redacted]"".

For the purpose of ensuring that the eventual status of the registered substance as an intermediate is fully exhaustive, ECHA has reviewed systematically the specific use of diarsenic trioxide in the Registrant's zinc electrolysis plant in the perspective of the four possible process levels described above.

i. [redacted] does not qualify the use of diarsenic trioxide as an intermediate use

The Registrant specified that "[redacted]".

[redacted]

ECHA therefore concludes [redacted] alone does not qualify diarsenic trioxide as an intermediate under REACH.

ii. [redacted] does not qualify the use of diarsenic trioxide as an intermediate use

The Registrant specified in his defitinion of the process that [redacted]

[redacted] In line with Article 3(15) of the REACH Regulation and as underlined in Appendix 4, chapter 2, of the Guidance on intermediate, a necessary condition for a substance to be an intermediate is that it is itself transformed into a manufactured substance.

ECHA therefore concludes that, [redacted], diarsenic trioxide does not meet the definition of intermediate.

[redacted]

iii. [redacted] does not qualify the use of diarsenic trioxide as an intermediate use

According to the information submitted by the Registrant, [redacted]

In accordance with this description, the intention of this process step is not to manufacture [redacted]. ECHA therefore considers that [redacted]

[redacted]

ECHA therefore considers that, within the zinc electrolysis plant, it is not possible to define a process mainly aiming at [redacted], diarsenic trioxide can therefore not be regarded as an intermediate.

iv. [redacted] does not qualify the use of diarsenic trioxide as an intermediate use

According to the Registrant's documentation, [redacted]

In addition, in his comments provided to ECHA pursuant to Article 50(1) of the REACH Regulation, the Registrant argues that the "*Zinc electrolysis plant is not an entire, single chemical process but a complex plant consisting of a lot of chemical and physical processes to manufacture several substances*". The Registrant also states that "*the relevant chemical process to be regarded is the reaction of Diarsenic Trioxide –* [redacted]".

Analogues to the formation of "[redacted]", ECHA does not consider that the manufacturing of "[redacted]" resulting from the conditioning of a production residue is the "main aim" pursued by the Registrant in its manufacturing process. "[redacted]" is rather an inevitable consequence of the purification of zinc as it relates to the necessity to remove certain elements from the zinc sulphate solution before the zinc electrolysis is carried out.

However, ECHA considers that an intermediate use cannot aim at manufacturing or processing a residue which is incidental to the main production process.

This position is consistent with the general principle that derogations shall be interpreted restrictively, which shall also apply to the interpretation of intermediate use as it serves as a basis for derogations, notably, under the Registration and Authorisation Titles of the REACH Regulation.

The main aim of a production process can only be determined in relation to the manufacture of deliberate products, such as purified zinc, not in relation to production residues. Indeed, a production residue is simply an unavoidable output of the main process. As a residue is not a product deliberate produced, it cannot be the main aim of a production process. A production residue is something other than a product that the manufacturing process deliberately seeks to produce.

As pointed out in the Commission Communication on Waste and by-product, "*even where a material is considered to be a production residue, the Court has indicated that it is not necessarily a waste* [...] *the ECJ has set out a three part test that a production residue must meet in order to be considered as a by-product*".[1] Accordingly, a manufacturer may still decide to dispose of a production residue as a waste or to treat it so as to enable its downstream use as a by-product, depending on the market conditions at that time. The treatment of a by-product does not pursue the same primary aim of manufacturing a deliberate substance. It is rather an incidental process aiming to enable the downstream use of an residue, instead of its dispoal. As a matter of fact, the valorisation of an unavoidable residue cannot be the primary intention of a production process.

In the present case, the information provided by the Registrant demonstrates that the "[redacted]" is a production residue.

Firstly, Article 3(14) of the Waste Framework Directive defines waste treatment as "*recovery or disposal operations, including preparation prior to recovery or disposal*". In addition, Article 3(15) of the Directive defines recovery as "*any operation the principal result of which is waste serving a useful purpose by replacing other materials which would otherwise have been used to fulfil a particular function, or waste being prepared to fulfil that function, in the plant or in the wider economy*". Annex II of the Directive sets out a non-exhaustive list of recovery operations, including the "*reclamation of metals and metal compounds*" or the "*reclamation of organic substances which are not used as solvents*". However, based on the information provided by the Registrant, the "[redacted]" is supplied to a operator that only recovers from this residue different valuable components (used by a customer for production of copper, nickel, cobalt and arsenic compounds). Therefore, the processing of the "[redacted]" downstream corresponds to a standard waste treatment operation.

Secondly, ECHA notes that the documentation provided by the Registrant confirms ECHA's understanding, as it presents the "[redacted]" as a by-product: "*this by-product is called* [redacted]" (Point 11b of the Registrant reply to ECHA's request purusant to Article 36). Thirdly, whilst the REACH Regulation does not provide a definition of by-product, a by-product is defined by the "Waste Framework Directive 2008/98/EC as "*a substance* [...] *resulting from a production process, the primary aim of which is not the production of that item*" (emphasis added). Based on the information provided by the Registrant, there is no aim to manufacture the "[redacted]" and, hence, the "[redacted]". The Registrant simply has no choice to produce this unavoidable residue. In accordance with this definition, the formation of the "[redacted]" does not constitute the "main aim" of a process under which diarsenic trioxide is transformed, but is merely a production residue of that process.

Finally, in order to guarantee the legal certainty of the benefit of derogations under the Registration and Authorisation Titles, it is essential that the status of the use of a susbtance as an intermediate is definitive. However, in so far as the fate of by-products only depends on market conditions that may change over the time, ECHA believes that in order to ensure the definitive status of the

[1] Communication from the Commission to the Council and the European Parliament on the Interpretative Communication on waste and by-products, COM/2007/0059 final, pages 6-7.

intermediate use of a substance, an intermediate use shall not result in a by-product.

Based on the above, ECHA concludes that the use of diarsenic trioxide in the production of the "[redacted]", a production residue, cannot be considered as an intermediate use. Even if ECHA welcomes the iniative to valorisation of residues into recoverable products, the fact that the Registrant uses diarsenic trioxide in the production of a residue in order to enable the recovery of its compounds is not relevant to qualify this substance as an intermediate.

Following the analysis of the four possible process levels which were identified by the Registrant, the use of diarsenic trioxide within the zinc electrolysis plant "*is not to transform* [this substance] *into another substance" and* diarsenic trioxide "*is not used for this main aim* [i.e. purification of zinc] *but to achieve another function"* (Guidance on intermediate mentioned above). As a result, ECHA concludes that the registered substance does not meet the definition of intermediate.

This conclusion is in line with the assessment of the information on the use of diarsenic trioxide in the manufacture of zinc metal provided during the public consultation on ECHA's second Annex XIV recommendation (1 July – 30 September, 2010) as documented in the response to comments and in the background document for diarsenic trioxide available on ECHA's website (17 December 2010)[2].

2. The identification of the applicable information requirements

As the registered substance is not used as an intermediate, the provisions of Chapter 3 of Title II of the REACH Regulation are not applicable and the registration is to be considered in light of Article 10 of the REACH Regulation. The Registrant has not submitted all the information required pursuant to Article 10 of the REACH Regulation.

Therefore, pursuant to Articles 41(1)(a) and 41(3) of the REACH Regulation the Registrant shall submit the information as set out in Article 10 of the REACH Regulation for the registered substance subject to the present decision.

ECHA stresses that pursuant to Article 10(a)(vi) and (vii) and Article 12(1) of the REACH Regulation the minimum information required to be included in the registration dossier depends on the annual tonnage in which the Registrant imports and/or manufactures the registered substance. In his registration dossier the Registrant has indicated an annual tonnage range between 10 and 1000 tonnes per year. If the Registrant manufactures or imports 100 – 1000 tonnes per year, Article 12(1)(d) would be applicable, whereas if he manufactures or imports less than 100 tonnes per year, Article 12(1)(c) would be applicable.

[2] http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/2nd-recommendation/-/substance/513/search/+/term

IV. 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.

[redacted]

Leena Ylä-Mononen
Director of Evaluation