

**DECISION OF THE BOARD OF APPEAL  
OF THE EUROPEAN CHEMICALS AGENCY**

**25 May 2016**

*(Dossier evaluation – Compliance check – Intermediate)*

<b>Case number</b>	A-010-2014
<b>Language of the case</b>	English
<b>Appellant</b>	Nordenhamer Zinkhütte GmbH Germany
<b>Representative</b>	Hartmut Scheidmann Redeker Sellner Dahs Rechtsanwälte
<b>Contested Decision</b>	CCH-D-0000003820-79-03/F of 28 May 2014 adopted by the European Chemicals Agency pursuant to Article 41(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3; hereinafter the 'REACH Regulation')

**THE BOARD OF APPEAL**

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Ángel M. Moreno (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

**Decision**

**Summary of the dispute**

1. The Appellant is a registrant of the substance diarsenic trioxide (hereinafter the 'Substance' or 'diarsenic trioxide'). The present appeal is directed against a compliance check decision finding that diarsenic trioxide, as used in the Appellant's plant, does not qualify as an intermediate under Article 3(15) of the REACH Regulation.

## Background to the dispute

2. The Appellant operates a plant in Nordenham, Germany. The main raw materials processed in the Appellant's plant are ore concentrates which primarily contain 50-55% zinc, 30-33% sulphur, 2-10% iron, 1-4% lead, 1-4% silicate, 0.1-4% copper, and minor quantities of other elements. According to the Appellant, *'the plant is designed to transform as much of the raw materials as possible into products'*.
3. Diarsenic trioxide is used in the zinc electro winning process to produce copper concentrate, a chemical substance of unknown or variable composition, complex reaction products and biological materials (hereinafter 'UVCB'), and to eliminate metal impurities such as cobalt and nickel from the zinc electro winning solution, without the co-precipitation of the cadmium and zinc. Diarsenic trioxide reacts with copper, nickel, and cobalt sulphates, zinc powder and sulphuric acid to form insoluble arsenides which, together with certain metals, form 'copper residue', a UVCB. The copper residue is further treated and refined, which results in the production of copper concentrate. According to the Appellant, *'this is only one step of the complex processing of the raw materials. The remaining zinc sulphate solution is subject to another step of separation of cadmium and finally to an electrolytic process leading to the manufacturing of purified zinc'*.
4. The Appellant is of the opinion that diarsenic trioxide, in the use outlined above, falls within the definition of intermediate under Article 3(15) of the REACH Regulation (all references to Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise). Hence, the Appellant submitted a registration dossier for diarsenic trioxide as a transported isolated intermediate under Article 18.
5. Article 3(15) defines 'intermediate' as:

*'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):*

  - (a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;*
  - (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;*
  - (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites'.*
6. On 13 February 2012, acting on the basis of Article 36, the Agency requested the Appellant to provide further information on its registration of diarsenic trioxide as a transported isolated intermediate. On 13 April 2012, the Appellant provided documentation describing its use of diarsenic trioxide and the conditions of such use in its plant.

7. After reviewing the information provided by the Appellant, the Agency concluded that the Appellant's dossier for diarsenic trioxide does not fulfil the conditions of Article 3(15) in order for the Substance to be considered as an intermediate for the use in question, and thus the Appellant is not entitled to benefit from the reduced information requirements for transported isolated intermediates set out in the REACH Regulation. The Agency considered that the Appellant should have submitted a full registration pursuant to Article 10, and the information specified in that Article should be included in the Appellant's registration dossier for diarsenic trioxide.
8. On 14 February 2012, the European Commission included diarsenic trioxide in Annex XIV of the REACH Regulation, the list of substances subject to authorisation. Diarsenic trioxide is classified as a carcinogen category 1, R45 according to Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1–1355, hereinafter the 'CLP Regulation'), and is identified as a Substance of Very High Concern (hereinafter 'SVHC') according to Article 57(a) of the REACH Regulation. As a result of diarsenic trioxide's inclusion in Annex XIV of the REACH Regulation, diarsenic trioxide could not be used after 21 April 2015 unless an authorisation had been granted by the European Commission for its specific use.
9. On 3 June 2013, the Agency initiated a compliance check of the Appellant's dossier for diarsenic trioxide pursuant to Article 41. On 7 June 2013, the Agency sent the draft compliance check decision (hereinafter the 'draft decision') to the Appellant with an invitation to submit its comments, which it did on 5 July 2013. Subsequently, the Agency amended the 'Statement of reasons' section of the draft decision (hereinafter the 'revised draft decision').
10. On 13 November 2013, the Appellant submitted an application for the authorisation of the *'industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process'*. The Appellant indicated in its application that diarsenic trioxide is used in the zinc electro winning process *'to produce a copper concentrate and to eliminate metal impurities such as cobalt and nickel from the zinc electro winning solution, without the co-precipitation of the cadmium and zinc'*. The Appellant also noted that *'[the authorisation] application shall be carried out by way of precaution in order to avoid any legal downside. [...] But it shall be without prejudice to the standpoint of Nordenhamer Zinkhütte GmbH defended in the compliance check procedure that it uses diarsenic trioxide as an intermediate. Nordenhamer Zinkhütte GmbH explicitly adheres to this position'*.
11. On 6 March 2014, the Agency notified the revised draft decision to the Competent Authorities of the Member States (hereinafter the 'MSCAs') and invited them pursuant to Article 51(1) to submit proposals for amendment.
12. On 28 May 2014, as no proposals for amendment were submitted, the Agency adopted the Contested Decision pursuant to Article 51(3) and notified it to the Appellant. In the Contested Decision the Agency maintains its view that diarsenic trioxide as used in the Appellant's plant does not qualify as an intermediate.
13. On 4 September 2015, the European Commission adopted a decision granting an authorisation for the *'industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process'* to the

Appellant (hereinafter the 'authorisation decision'). In the authorisation decision it is explained that, in accordance with Article 60(4), *'the overall benefits arising from the industrial use of diarsenic trioxide to produce a copper concentrate in the purification of the leaching solution in a zinc electro winning process outweigh the risks to human health or the environment arising from the use'* and that *'there are no suitable alternative substances or technologies in terms of their economic feasibility for the applicant'*.

### **Procedure before the Board of Appeal**

14. On 28 August 2014, the Appellant lodged the present appeal. The Appellant requests the Board of Appeal to annul the Contested Decision and to order the refund of the appeal fee.
15. On 3 November 2014, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.
16. On 12 December 2014, the Board of Appeal requested the Appellant to submit observations on the Defence and to respond to certain questions. On the same day, the Board of Appeal invited the Agency to respond to certain questions. The Appellant and the Agency duly lodged their submissions on 11 and 12 February 2015 respectively.
17. Following consultation with the Parties, the appeal proceedings were stayed between 10 June 2015 and 1 September 2015.
18. On 16 September 2015, the Parties were notified of the Board of Appeal's decision to close the written procedure. On 24 September 2015 and 30 September 2015 respectively, the Appellant and the Agency requested a hearing to be held. As a result, in accordance with Article 13 of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter 'the Rules of Procedure'), the Parties were summoned to a hearing, which was held on 14 January 2016. At the hearing, the Parties made oral presentations and responded to questions from the Board of Appeal.

### **Reasons**

19. In support of its appeal, the Appellant puts forward four pleas in law which allege (i) infringement of the Agency's Guidance on intermediates, version 2, December 2010 (hereinafter the 'Guidance'), (ii) infringement of Article 3(15) of the REACH Regulation, (iii) violation of the right to be heard and, (iv) incomplete access to the files of the compliance check procedure.

#### ***The first and second pleas, alleging infringement of the Guidance and of Article 3(15) of the REACH Regulation***

20. The Board of Appeal observes that the first and second pleas are closely related as they both concern, in essence, the interpretation of the term 'intermediate' for the purposes of the REACH Regulation. The Board of Appeal observes further that the factual claims

and arguments made by the Appellant and by the Agency in the course of the written procedure and during the hearing in relation to the first and the second pleas are similar and at times identical. It is therefore appropriate to examine the first and second pleas together.

### **Arguments of the Appellant**

21. The Appellant contends that by deciding that diarsenic trioxide, as used in the Appellant's plant, does not qualify as an intermediate, the Agency has deviated from the definition of intermediate in Article 3(15) and from the interpretation of the definition of intermediate as featured in Appendix 4 of the Guidance.
22. According to the Appellant, applying a restrictive reading of the interpretation of intermediate as given in Appendix 4 of the Guidance leads to the following conclusion: *'Substance (A) qualifies as intermediate if it is used in a chemical process the main aim of which is to transform substance (A) into substance (B) and if it is used for this main aim'*. Accordingly, the term 'main aim' relates to the transformation of the intermediate itself and not that of the production process in a plant as a whole. According to the Appellant, such an interpretation is consistent with the purpose of the reduced information requirements for the registration of intermediates in the context of the REACH Regulation, which is to provide for a less stringent regime with regard to substances which are destined to be transformed into other substances.
23. The Appellant claims that the Agency made an error of assessment in determining the main aim of the use of diarsenic trioxide in the present case. In the Contested Decision the Agency does not examine whether the main aim of the use of diarsenic trioxide is its transformation into copper residue and ultimately into copper concentrate. Rather, the Agency examines whether the main aim of the entire production process in the Appellant's plant is to manufacture copper concentrate. According to the Appellant, in contrast to the Agency's reasoning, it is irrelevant whether one of the end-products, copper concentrate or purified zinc, could be considered as the primary product or as a by-product of the Appellant's plant. This conclusion is supported by economic and technical arguments. As the raw materials subject to refinement contain a multiplicity of elements, any plant has to extract several substances not only for technical reasons but also in order to operate in an economically efficient and an environmentally sound way.
24. The Appellant adds that copper concentrate is a substance that the Appellant has registered, as a transported isolated intermediate, under the REACH Regulation. If a substance is transformed by chemical synthesis into another substance which has to be registered, and has been registered, its intermediate status cannot be denied. This fact alone illustrates that the argumentation of the Agency is inconsistent with the REACH Regulation.
25. Moreover, according to the Appellant, the approach followed by the Agency in the Contested Decision is not supported by valid arguments.
26. First, the justification given in the Contested Decision that an intermediate use *'cannot aim at manufacturing or processing a residue which is incidental to the main production process'* is invalid. 'Residue' is not a legal term in the context of the REACH Regulation. The term 'residue' is referred to in the Contested Decision because the Appellant has used it colloquially in its registration dossier. However, one cannot draw legal consequences from the Appellant's own use of the term 'residue'. It must also be borne

in mind that the responsible employees of the Appellant are neither lawyers nor native speakers of English.

27. Second, the reasoning in the Contested Decision that copper concentrate is a by-product whose processing downstream *'corresponds to a standard waste treatment operation'* and consequently cannot be qualified as the main aim of the production process is fundamentally misguided. The Agency's interpretation of waste treatment in terms of Article 3(14) of Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ 2003 L 312, 22.11.2008, p. 3, hereinafter the 'Waste Framework Directive') *'would lead to the strange result that any extraction of elements from raw materials in the extraction industry should qualify as a waste treatment operation'*. Furthermore, the Agency ignores that copper concentrate could not in any event be characterised as waste and a by-product at the same time because, according to Article 5(1) of the Waste Framework Directive, the terms are mutually exclusive. Importantly, the Contested Decision also ignores the finding that the qualification of copper concentrate as by-product must necessarily result in the categorisation of diarsenic trioxide as intermediate under Article 3(15).
28. Third, the Agency's argument in the Contested Decision that its reading of Article 3(15) is *'consistent with the general principle that derogations shall be interpreted restrictively'* is misleading. Article 3(15) does not provide for an exception. The concept of intermediate set out in Article 3(15) does not derogate from the notion of substance laid down in Article 3(1). Moreover, *'by stating that the process in which the intermediate is transformed has to pursue a main aim'*, the Contested Decision adds a new criterion to the definition of intermediate which is not included in Article 3(15). The Appellant also claims that additional evidence of the Agency's misguided interpretation of Article 3(15) can be found in a contextual reading of this Article. According to the principle of resource efficiency, and the principles of sustainability and environmental protection, which are enshrined in Article 3(3) of the Treaty on the European Union (OJ C 326, 26.10.2012, p. 1-390), extraction processes must be designed to retrieve as much of the elements contained in raw materials as possible; *'[t]o hold that intermediates can only be used for one main aim, [which is] for the manufacturing of one single substance, would disadvantage the producers that abide by these principles'*.
29. According to the Appellant, its concerns over the Agency's interpretation of intermediate in the present case are shared by the German MSCA. In its comments on the revised draft decision, the German MSCA explicitly points out that the *'criterion "definition of a main process" is not implemented in the [definition of an intermediate]'*. The German MSCA added that *'we are not totally convinced by the arguments of the [Agency]. But as we approved the [Guidance] we do not insist on our original interpretation that [diarsenic trioxide] should be regarded as intermediate'*. This shows, according to the Appellant, that the legal opinion of the Agency is not shared by all of the MSCAs.

### **Arguments of the Agency**

30. The Agency disputes the Appellant's claims. The Agency notes that, contrary to the assertion of the Appellant, the principle of restrictive interpretation requires a strict interpretation of the definition of intermediate under Article 3(15), as the definition of intermediate is the basis for the derogation from the standard information requirements under the REACH Regulation and from Title VII of the REACH Regulation on

Authorisation. The Agency also contests the Appellant's claim that it uses diarsenic trioxide with the intention of producing '*the residual compounds extracted from purified zinc*'. According to the Agency, in the present case, the use of diarsenic trioxide is essential in the zinc purification process. In that process, diarsenic trioxide is used to separate various compounds in order to allow the production of zinc. This separation process results in two outputs: firstly, purified zinc and, secondly, an inevitable residue composed of compounds that need to be removed in order to produce zinc. The production of such residual products is irrespective of the method used for the extraction of zinc. The formation of the copper residue '*cannot be avoided from the manufacturing of purified zinc*'. Furthermore, the absence of zinc in the ore being processed would mean that the formation of copper residue with the aid of diarsenic trioxide would not be a sensible or meaningful operation.

31. The Agency notes that the mere transformation of a substance into another substance is not in itself sufficient to qualify such a transformation as an intermediate use. In its view, the aim pursued by that transformation is a necessary condition. The intentional aspect introduced in the definition of intermediate in Article 3(15) by 'in order to' can only concern the purpose of the transformation, which must be primarily to synthesise a substance. In the absence of the intention to synthesise another substance as its main aim, the transformation alone cannot qualify it as an intermediate use. This approach is consistently supported by the Guidance. Examples 5 and 6 of the Guidance are concrete examples of substances which are not considered to be intermediates even though their use involves chemical reactions.
32. In addition, the Agency claims the Guidance sets out explicitly that when a process aimed at purifying a substance is based on the transformation of undesired compounds, the main aim of the process is the purification of the substance, not the production of residues from the transformation of the undesired compounds. In support of its claim the Agency refers to example 7 of the Guidance.
33. The Agency further claims that the main aim of the use of an intermediate cannot be the production of a residue, even if the latter is a by-product which has an economic value. The Agency agrees with the Appellant's understanding that the same product cannot be both a waste and a by-product. However, the Agency observes that its argumentation in the Contested Decision is only based on the finding that copper residue and copper concentrate are production residues. Under the Waste Framework Directive, both waste and by-products are residues from production processes. The argument of the Appellant does not therefore have any bearing on the finding that copper concentrate is a production residue from a process that has as its main aim the manufacture of purified zinc, irrespective of whether the copper concentrate qualifies as a waste or a by-product.
34. The Agency adds that the information submitted by the Appellant in support of the application for authorisation of its use of diarsenic trioxide confirms that copper concentrate is a residual product from the zinc manufacturing process in the form of a by-product. The application also confirms that the composition of copper concentrate may be such that it would not always allow the normal recovery of other metal compounds. The Appellant has no control over the specification of the residual product which may eventually be treated as hazardous waste if the recovery of compounds from it is not economically viable.
35. In response to the Appellant's argument that the use of diarsenic trioxide is not essential in the purification of zinc, the Agency contends that the Appellant has chosen to use

diarsenic trioxide to enable the separation of zinc from other metallic compounds. In the context of the main aim of producing purified zinc, the Substance is used as a processing agent, as illustrated by example 3 of the Guidance. In support of its interpretation, the Agency also referred during the hearing to the recent judgment of the General Court in Case T-268/10 RENV, *PPG and SNF v ECHA*, EU:T:2015:698.

36. The Agency adds that the Contested Decision does not challenge the technical choices made by the Appellant in using diarsenic trioxide nor the importance of the economic value of using diarsenic trioxide for the manufacture of purified zinc through the production of the by-product copper concentrate. The Contested Decision merely aims at ensuring that the benefit of the derogation from Titles II and VII of the REACH Regulation, on Registration and Authorisation respectively, applies only where appropriate. Although the Appellant has a real economic interest in selling copper concentrate as a by-product, the main aim pursued by the production process in its plant is the manufacture of purified zinc.
37. With regard to the position of the German MSCA, the Agency notes that the German MSCA endorsed the Contested Decision without proposing any amendment. The German MSCA noted that *'zinc is obviously named as the aim of the overall complex synthesis process'* and confirmed that *'the [Guidance] seems to support the argument that the determination of the main aim in a complex process is essential to decide whether a substance within the complex manufacture process is an intermediate'*.

### **Findings of the Board of Appeal**

38. The Board of Appeal observes that the dispute between the Appellant and the Agency revolves around the definition of intermediate under Article 3(15). More precisely, the Appellant disputes the Agency's interpretation of Article 3(15) according to which the intermediate status of a substance is defined in relation to the 'main aim' driving the process in which the substance is used. The Appellant also contests the ensuing conclusion in the Contested Decision that diarsenic trioxide, as used in its plant and within the context of the chemical processing described in paragraph 3 above, does not qualify as an intermediate under Article 3(15) because the production of copper concentrate is not the 'main aim' of the production process in the Appellant's plant.
39. The Board of Appeal observes that the examination of the first and second pleas requires the interpretation of Article 3(15). As a preliminary point, it should be recalled that, in determining the scope of a provision of European Union law, its wording, context and objectives must all be taken into account (see, for example, Case C-453/14, *Vorarlberger Gebietskrankenkasse*, EU:C:2016:37, paragraph 27 and the case-law cited; Case T-521/14, *Sweden v Commission*, EU:T:2015:976, paragraph 57 and the case-law cited). However, there is in principle no need for interpretation of a provision, particularly in light of its context and purpose, when its scope can be determined with precision on the basis of its wording alone, the clear text being sufficient in itself (see Case T-521/14, *Sweden v Commission*, EU:T:2015:976, paragraph 59; see also, to that effect, Case C-383/14, *Sodiaal International*, EU:C:2015:541, paragraphs 20 and 24).
40. Article 3(15) provides that 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) [...]'*.



41. The Board of Appeal observes that a literal interpretation of the phrase '*in order to be transformed into another substance*' indicates that incidental transformation into another substance is not sufficient for a substance to qualify as an intermediate. The transformation into another substance is referred to as 'synthesis' and should be intentional.
42. Furthermore, from that literal interpretation of Article 3(15) the Board of Appeal identifies two clear requirements that need to be met cumulatively in order for a substance to qualify as an intermediate: (i) the substance must be manufactured for, and consumed in, a chemical process and (ii) there must be an intentional transformation of the substance into another substance in that chemical process. Whether a substance satisfies these two requirements needs to be determined on a case-by-case basis.
43. The Board of Appeal observes that the main dispute between the Appellant and the Agency concerns the interpretation of the second requirement, that of 'intentional transformation into another substance'. The Agency argues that the requirement of intentional transformation, and in particular the term 'in order to' in Article 3(15), should be interpreted strictly in light of the objectives of the REACH Regulation regarding the protection of human health and the environment. The Agency claims in its Defence that '*the definition of intermediate is the actual basis for the derogatory scheme*' from Titles II and VII of the REACH Regulation, on Registration and Authorisation respectively, and the definition should therefore be interpreted strictly. According to the Agency's strict interpretation of the requirement for intentional transformation, '*the substance must not only be transformed, but this transformation must mainly aim at manufacturing that substance*'. In this respect, the Agency notes in the Contested Decision that the '*intermediate status of a substance is defined in relation to the "main aim" driving the process where the substance is actually used [...]. The identification of the "main aim" of a chemical process is therefore central to the determination of the intermediate status of a substance*'. The Agency adds in its Defence that '*when the use of a substance within a process involves its chemical transformation, the "main aim" of this transformation must be the formation of the substance that the process aims at producing. In the absence of intention to form another substance as main aim, the transformation cannot qualify as an intermediate use*'.
44. In application of its interpretation of Article 3(15) to the present case, the Agency claims that zinc is a major source of revenue for the Appellant and the main aim of the production process in the Appellant's plant. In the Contested Decision, the Agency adds that the intention of using diarsenic trioxide '*is not to manufacture the "copper residue" but instead to ensure that the zinc electrolytical purification step is not compromised by the presence of the elements collected in the form of arsenides in the "copper residue"*'. [The Agency] therefore considers that the formation of the "copper residue" is not deliberately manufactured but it is a production residue resulting from the necessity to remove certain elements from the zinc sulphate solution before the zinc electrolysis is carried out. [The Agency] therefore considers that, within the zinc electrolysis plant, it is not possible to define a process mainly aiming at forming "copper residue" from diarsenic trioxide'. The Agency concludes that, as a result, diarsenic trioxide does not qualify as an intermediate.
45. The Board of Appeal observes that the interpretation suggested by the Agency in paragraphs 43 and 44 above with regard to the requirement for intentional transformation cannot be accepted. First, as seen from the analysis of Article 3(15) in

paragraphs 39 to 42 above, the wording of Article 3(15) does not include a reference to 'the main aim of a production process' as a consideration for a substance to qualify as an intermediate. The Board of Appeal notes that Article 3(15) does not differentiate between main aim of a plant or production process and the other aims of a plant or process. Second, as identified by the German MSCA, the Agency's interpretation raises the fundamental questions '*who does decide which process is the main process*' in a plant? '*Does the determination of the main process depend on the detailness of the process description given by the registrant? [...] The less information about the complexity of a process is given the easier a substance could be considered as an intermediate [...]. What are the criteria to define a main process? Should the yield of a substance be considered as a criterion or even the monetary value? Is there an objective basis for such decision? Is it possible to define more than one main process in a complex reaction?*' The Board of Appeal observes that the Agency's interpretation could lead to the conclusion that in complex and large, multi-step production processes in the metal and mineral industry, where several different metals and minerals may be derived or produced, only the substances that are transformed into the predominant metal or mineral of the plant would be considered to be intermediates under Article 3(15). The Board of Appeal observes that the predominance of a metal or mineral in a plant could also vary from time to time depending on factors such as market value and demand. This could mean that, following the interpretation of the Agency, a substance may be an intermediate at one point in time but not at another, depending on, for example, volatile external market factors such as market value and demand. The Board of Appeal considers that this cannot have been the intention of the legislator. The Agency's interpretation with regard to 'main aim' therefore amounts to an overly restrictive interpretation of the concept of intermediate, something that is unsupported by the letter and spirit of the REACH Regulation and ignores economic reality as well as, in this case, mineral and metal variability.

46. Furthermore, with regard to the derogation of intermediates from the standard information requirements, the Board of Appeal observes that such a derogation is not given automatically to all substances that meet the definition of intermediate within the meaning of Article 3(15), but only to those used under strictly controlled conditions, as explained in Articles 17(3) and 18(4). This is acknowledged by the Agency in the Contested Decision, where it is stated that '*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 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*'. Similarly, on page 40 of the Guidance it is explained that '*an intermediate is a substance used in the manufacturing of another substance on its own. The standard registration requirements should normally apply to that other substance manufactured (assuming it is used for purposes other than subsequent synthesis). Where relevant, the risks associated with the manufacture and use(s) of the other substance formed should be addressed in its registration. On the other hand, the registration of the intermediate is to cover the risks from its manufacture and use until it is reacted. REACH requires that the reduced registration information requirements specified in Article 17 and 18 only apply to intermediates manufactured and handled under the conditions set in these Articles. REACH therefore ensures the complete coverage of the risks throughout the supply chain*'. The Board of Appeal notes that by introducing the requirements for use under strictly controlled conditions the legislator has ensured that human health and the environment are not at

risk by the use of substances considered to be intermediates under the REACH Regulation.

47. In addition, and with respect to the Agency's argument in the Contested Decision that '*it is essential that the status of the use of a substance as an intermediate is definitive*', the Board of Appeal observes that the use of a substance and the conditions of its use in a plant may change over time. Against this background, it is the duty of the registrant to consider whether a substance continues to be used as an intermediate and under strictly controlled conditions. The registrant has to draw the appropriate conclusions in the event of a change by updating its dossier in accordance with Article 22 and, if needed, by applying for an authorisation for a non-intermediate use. Beyond that, it is the task and the responsibility of national enforcement authorities to ensure compliance with the REACH Regulation regarding whether a substance for which an intermediate registration, pursuant to Article 17 or 18, has been submitted is being used as an intermediate and under strictly controlled conditions. In any event, if there is a concern about the safe use of a substance in general, then action can be taken under the REACH Regulation pursuant to the provisions on substance evaluation, dossier evaluation or restrictions. Furthermore, in addition to the REACH Regulation, there are other pieces of EU legislation, such as Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (OJ L 197, 24.07.2012, p. 1) and Directive 2004/37/EC of the European Parliament and the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 158, 30.04.2004, p. 50, as amended by Directive 2014/27/EU, OJ L 65, 5.3.2014, p. 1), which may provide a legal basis for preventive or corrective measures, including enforcement, if considered necessary and appropriate.
48. The Board of Appeal recalls that the legislator took into account all the objectives pursued by the REACH Regulation in establishing the definition of intermediate and decided that, if certain criteria are met, intermediates shall benefit from a less stringent regime under the REACH Regulation due to the limited risks for human health and the environment. This is recognised by the legislator in Recital 41 of the preamble to the REACH Regulation which states that '*[f]or reasons of workability and because of their special nature, specific registration requirements should be laid down for intermediates*'. That is, if a substance meets the requirements set out by the legislator in Article 3(15), it qualifies as an intermediate. It is neither for the Agency nor for the Board of Appeal to take on the role of the legislator and to add supplementary requirements to the definition of intermediate under Article 3(15).
49. In light of all the foregoing considerations, the Board of Appeal concludes that the definition of intermediate under Article 3(15) is not a matter of extensive or restrictive interpretation but a matter of ascertaining whether two cumulative requirements are met: (i) the substance must be manufactured for, and consumed in, a chemical process and (ii) the substance must be intentionally transformed into another substance.
50. In the case at issue, the Agency does not contest that diarsenic trioxide is a substance used for chemical processing in the Appellant's plant. Indeed, in response to the Board of Appeal's explicit question on this point during the hearing, the Agency responded that '*yes, from our point of view, diarsenic trioxide is a substance in this case*' and '*we would agree that the substance is used for chemical processing*'. The Board of Appeal therefore

finds that the first requirement of the definition of intermediate under Article 3(15) is met by diarsenic trioxide as used in the Appellant's plant.

51. As regards the second requirement of Article 3(15), that of intentional transformation, the Agency claims that the 'main aim' of the Appellant's plant is not to produce copper concentrate, but to produce purified zinc. Indeed, in the Contested Decision, the Agency notes that it *'does not consider that the manufacturing of "copper concentrate" resulting from the conditioning of a production residue is that "main aim" pursued by the Registrant in its manufacturing process. "Copper concentrate" 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, [the Agency] considers that an intermediate cannot aim at manufacturing or processing a residue which is incidental to the main production process'*. In line with this consideration, the Agency contends that diarsenic trioxide is not an intermediate because the main aim of its use in the production process is the purification of zinc and not its transformation into copper concentrate.
52. In this respect, the Board of Appeal notes that, as explained in paragraph 45 above, the wording of Article 3(15) does not include a reference to 'the main aim of a production process' as a consideration for a substance to qualify as an intermediate. Instead, the relevant process to be considered in order to determine the aim of the use of diarsenic trioxide in the Appellant's plant is the reaction of diarsenic trioxide with the raw materials. In order to answer the question as to whether a substance is intentionally transformed into another substance it is irrelevant whether the resulting substance is the only substance produced in a plant, the main substance of the plant in terms of revenue or quantity, or just one of the many substances produced in the plant. In any event and as already mentioned at paragraph 45 above, the Board of Appeal notes that the value of different metals fluctuates and it could be the case that the price of a metal or mineral goes down and that of other metals or minerals produced in the same plant goes up thereby potentially altering the 'main aim' of the plant.
53. In addition, the Board of Appeal observes that producing zinc is not the only economic goal of the Appellant in the plant in question. The Appellant's plant is designed and authorised to produce not only zinc, but also zinc sulphate solution, sulphuric acid, copper concentrate, lead and silver concentrate, cadmium, and calomel. The evidence presented in support of this appeal shows that the revenues received from the sale of products other than zinc are an essential contribution to the financial viability of the Appellant's plant.
54. The Board of Appeal also notes that, as the Appellant explained in its written submissions and during the hearing, the Appellant chose to use diarsenic trioxide in the zinc electrolysis process because it intended to produce copper concentrate in addition to zinc. The Agency did not dispute the fact that if the Appellant intended to produce only zinc and not copper concentrate, the zinc electrolysis process could be designed in a way that avoided using diarsenic trioxide. In the absence of the use of the Substance an unspecified and unusable material made up of copper, nickel, cobalt, cadmium and other substances would be produced instead of copper residue.
55. Furthermore, for the production of zinc neither copper concentrate nor copper residue needs to be produced. It is indicative in this respect that the authorised use of diarsenic trioxide in the Appellant's plant, granted by the European Commission on 4 September 2015, is *'to produce a copper concentrate in the purification of the leaching solution in the zinc electro winning process'*. The Appellant's intention to use diarsenic trioxide for

the production of copper concentrate is further shown by the evidence provided in the course of these appeal proceedings. In particular the Appellant deliberately modified the production process in its plant in order to produce copper concentrate with specific technical characteristics to meet the demands of its customers. It can be seen from the evidence submitted in support of this appeal that in 1995 the Appellant made a considerable investment to modify the plant and to install additional equipment in order to adjust the production of copper concentrate to market demands. The Board of Appeal finds therefore that it was a conscious and deliberate act by the Appellant to use diarsenic trioxide in the Appellant's plant to produce copper residue which is further processed into copper concentrate.

56. The Board of Appeal also notes that, as acknowledged in the authorisation decision authorising the use of diarsenic trioxide in the Appellant's plant for the production of copper concentrate, currently there are no suitable alternative substances or technologies in terms of their economic feasibility for the Appellant to produce copper concentrate. Moreover, the authorisation decision adds that the Risk Assessment Committee confirmed that *'the risk management measures and operational conditions as described in the [authorisation application], provided they are applied in practice, are effective in limiting the risk'*. The Board of Appeal finds that if the Appellant wishes to produce copper concentrate then the process used is, currently, the only viable option. In light of the above, it is clear to the Board of Appeal that, by modifying its plant, the Appellant intended to produce copper concentrate.
57. The Agency's argument that copper concentrate should be considered as a 'by-product' under the Waste Framework Directive and as a result diarsenic trioxide cannot be an intermediate is also rejected. During the hearing, the Agency confirmed that it does not consider copper concentrate as waste under the Waste Framework Directive, but rather as a by-product of the zinc purification process. The Board of Appeal notes in this respect that a by-product qualifies as a substance under the REACH Regulation whilst 'waste' does not. Article 3(15) requires that an intermediate is transformed into another substance, without limiting its scope of application to the most profitable substance produced in the plant. The definition also does not exclude by-products from its meaning of 'another substance'. The Board of Appeal finds therefore that whether copper concentrate is a by-product in the Appellant's plant or not does not have any impact on the conclusion as to whether diarsenic trioxide is an intermediate under Article 3(15).
58. In addition, the Board of Appeal finds that the judgment of the General Court in case T-268/10 RENV and the Guidance do not support the Agency's interpretation of Article 3(15) in the case at issue.
59. With regard to the General Court's ruling in Case T-268/10 RENV, the Board of Appeal makes the preliminary observation that both the substance that is the subject of that case, acrylamide, and the manufacturing process involved in that case are very different from the substance used and the process carried out in the Appellant's plant. In particular, in the case before the Board of Appeal there is no sealing function or end-use function as in the acrylamide case decided by the General Court. Moreover, the function of diarsenic trioxide is much more than a cleaning agent for the purification of zinc; diarsenic trioxide is used in the Appellant's plant with the intention to produce copper concentrate (see paragraphs 54, 55 and 56 above). Consequently, the case before the General Court must be distinguished from the factual context of the present appeal.
60. The Board of Appeal notes however that, in its judgment in Case T-268/10 RENV, the General Court makes some useful observations with respect to the interpretation of the

definition of intermediate, which are consistent with the Board of Appeal's interpretation of Article 3(15). First, the General Court applies a literal interpretation of Article 3(15). Indeed, in paragraph 54 of its judgment the General Court states that '*an intermediate is a substance that is manufactured for chemical processing and consumed in or used in that processing in order to be synthesised*'. Second, in paragraph 66 of its judgment, the General Court adds that '*the classification of a substance as an intermediate depends on the intended purpose of its manufacture and use*'. According to the General Court, the key point in the definition of intermediate in Article 3(15) is whether the substance in question is used in order to be synthesised, that is whether the substance is used with the intended purpose of being transformed another substance.

61. In paragraph 68 of its judgment, the General Court adds that according to the definition of intermediate laid down in Article 3(15), '*it is necessary to take into account the intended objective of the manufacture and use of that substance in order to determine whether it has the status of intermediate*'.
62. Bearing the General Court's interpretation of the definition of intermediate in mind, the Board of Appeal recalls that, as explained by the Appellant and accepted by the Agency during the hearing, the use of diarsenic trioxide is not necessary for the purification of zinc. Importantly, it is not contested that the Appellant deliberately added diarsenic trioxide in the production process and modified its production plant with the intention of producing another substance, copper concentrate. This was in addition to the production of zinc, with both substances, amongst others, being produced in the same plant at more or less the same time. As the Appellant explained in the course of these proceedings, this was done to make the plant more efficient and profitable as well as to reduce waste. The Appellant's plant would be far less efficient if no other products than zinc were produced and placed on the market. The Appellant explained that its continued operation of the plant is based on the premise that more substances than zinc will be produced. The Appellant has provided evidence that the yearly revenue from the production of copper concentrate corresponds to 1/6 of the plant's yearly revenue. The Board of Appeal observes that, in addition to increasing the efficiency of the plant, this operational decision also results in the reduction of waste from the process of zinc purification which is fully in line with the EU objectives for prevention and reduction of waste and the promotion of a circular economy.
63. The Board of Appeal further observes that the Agency's interpretation of Article 3(15) in the case at hand goes beyond that set out in the Guidance, and in particular Appendix 4 thereof. The Board of Appeal recalls, first of all, that the Guidance is not binding and cannot overrule the REACH Regulation. In any event, the Board of Appeal notes that the Guidance is in line with the wording of Article 3(15) and does not foresee the same strict interpretation as that advocated by the Agency in the Contested Decision. Indeed, page 34 of the Guidance refers to the definition in Article 3(15) and in particular to the phrase '*used [...] in order to be transformed into another substance*' and states that an intermediate '*is used in the manufacturing of another substance where it is itself transformed into that other substance. This other substance should be different from the intermediate used in the process. The definition of "intermediate" substance should therefore be understood to cover such transformation of this intermediate into another substance which is considered as "manufacturing" of that other substance in the sense of Article 3(8) REACH*'. This statement is consistent with the Board of Appeal's interpretation of Article 3(15) explained in paragraph 49 above.

64. As regards the 'main aim' pursued by the use of a potential intermediate, the Board of Appeal observes that the main aim according to the Guidance is different from the interpretation of main aim used by the Agency in the Contested Decision. The Guidance says in page 34 that the main aim of the relevant chemical process in which a substance is used must be its transformation into another substance. The Guidance adds in the same page that a substance is not considered to be an intermediate if the substance is used *'for other processes than for synthesising another substance'*. In other words, the 'main aim' in the Guidance relates to the relevant chemical process in which a substance is used and not to the entire production process in a plant which is the Agency's interpretation in the Contested Decision. Moreover, the Board of Appeal's interpretation of Article 3(15) is consistent with the Guidance which explains at page 35 that *'any substance used in a manufacturing process of another substance (B) but which is not itself transformed into that substance (B), for instance a solvent, cannot be an intermediate'*. Importantly, the Board of Appeal observes that, in page 40, where the Guidance sets the requirements to be met for a substance to qualify as an intermediate, the Guidance does not include a requirement for 'one main aim' to be pursued by the substance. Instead, the Guidance concludes that *'a substance is an intermediate if all following conditions are met: the substance is manufactured to be itself converted into another substance on an industrial site; the outcome of the chemical processing is another manufactured substance on its own but not another substance in an article'*. The Board of Appeal notes that the conclusion in the Guidance is in line with the wording of Article 3(15), and the Board of Appeal's interpretation of this article with regard to the 'main aim' pursued by the use of a potential intermediate.
65. The Board of Appeal concludes that the Agency misinterpreted Article 3(15) in the present case and erred in law in deciding that diarsenic trioxide is not an intermediate on the premise that the production of copper residue and subsequently copper concentrate does not constitute the 'main aim' of the production process in the Appellant's plant.
66. The Board of Appeal recalls that both Parties agree that diarsenic trioxide is a substance used for chemical processing. Therefore, the first requirement of Article 3(15) is met by the use of the Substance in the present case. The Board of Appeal has also found that diarsenic trioxide is intentionally used by the Appellant with the aim of producing copper residue and subsequently copper concentrate.
67. The Board of Appeal notes that, in accordance with Article 3(15), to conclude whether the Substance is used by the Appellant as an intermediate, it needs to be ascertained whether diarsenic trioxide is transformed into copper residue or copper concentrate or whether instead it simply helps in their production. The Board of Appeal observes that the Agency did not make a thorough assessment of this important issue during the compliance check procedure. Instead, after finding that the 'main aim of the production process' in the Appellant's plant is the production of zinc, the Agency erroneously limited its assessment in this respect to determining whether diarsenic trioxide is transformed into zinc. It is indicative in this regard that, in the Contested Decision, the Agency solely states that *'diarsenic trioxide is not itself transformed into the manufactured purified zinc'* and does not examine whether diarsenic trioxide is transformed into copper residue or copper concentrate. In the Contested Decision, the Agency concludes that the formation of copper residue and copper concentrate do not qualify the use of diarsenic trioxide as an intermediate use on the erroneous basis that *'copper residue is not deliberately manufactured but is a production residue'* and *'copper concentrate is rather an inevitable consequence of the purification of zinc'*.

68. Similarly, in its written submissions, when comparing the use of diarsenic trioxide by the Appellant with examples 3, 5, 6 and 7 of the Guidance to show that diarsenic trioxide is not used as an intermediate, the Agency in every case refers to the relevance and importance of the 'main aim' of the Appellant's production process which the Board of Appeal has found is erroneous. The Agency does not examine, as it should have, whether diarsenic trioxide is intentionally transformed into copper residue, copper concentrate or any other substance.
69. Therefore, the case needs to be remitted to the Agency for re-evaluation. The Agency will need to ascertain, in a manner consistent with the General Court criteria as expressed in Case T-268/10 RENV, in particular whether diarsenic trioxide is used in that processing in order to be transformed into copper residue or copper concentrate. The Board of Appeal further observes that, in assessing whether the second requirement of Article 3(15) is met, that of intentional transformation into another substance, the Agency should be guided by the findings of the Board of Appeal in the present case. In particular, the Board of Appeal recalls that the production of copper residue and subsequently copper concentrate in the case at issue is intentional and not incidental and clearly constitutes an aim of the Appellant's use of diarsenic trioxide.
70. In view of all the above, the Board of Appeal finds that the Contested Decision is not in compliance with Article 3(15) of the REACH Regulation and must therefore be annulled. The Board of Appeal remits the case to the competent body of the Agency for re-evaluation.

### ***Other pleas raised by the Appellant***

71. As the Board of Appeal has found in favour of the Appellant it is not necessary for the purposes of the present appeal to consider the Appellant's third and fourth pleas as set out in paragraph 19 above.

### **Other issues under examination**

#### **Refund of the appeal fee**

72. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the decision is rectified in accordance with Article 93(1) of the REACH Regulation or the appeal is decided in favour of an appellant.
73. As the Board of Appeal has decided the appeal in favour of the Appellant in the present case the appeal fee shall be refunded.



On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Annuls decision CCH-D-0000003820-79-03/F adopted by the Agency on 28 May 2014**
- 2. Remits the case to the competent body of the Agency for re-evaluation**
- 3. Orders the refund of the appeal fee.**

Mercedes ORTUÑO

Chairman of the Board of Appeal

Alen MOČILNIKAR

Registrar of the Board of Appeal