EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

28 June 2016

(Dossier evaluation – Compliance check of a registration – Environmental exposure assessment and risk characterisation – Article 14 of the REACH Regulation)

Case number	A-015-2014
Language of the case	English
Appellant	BASF SE, Germany
Contested Decision	CCH-D-0000005118-76-02/F of 17 September 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 Sari Haukka (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the dispute

1. The Appellant is a registrant of the substance 2-ethylhexyl acetate (CAS No 103-09-3, EC No 203-079-1; hereinafter the 'Substance'). The present appeal is directed against a compliance check decision requiring the Appellant to perform an environmental exposure assessment and risk characterisation for the Substance on the basis of Article 14(4) of the REACH Regulation despite the fact that the Substance is classified as dangerous to human health but not to the environment (all references to Recitals, Articles and Annexes hereinafter concern the REACH Regulation unless stated otherwise).

Background of the dispute

2. The Appellant registered the Substance on 30 August 2010.
3. In its chemical safety report, submitted to the European Chemicals Agency (hereinafter the 'Agency') as part of its registration of the Substance, the Appellant indicated that the Substance fulfils the criteria as a skin irritant, Category 2: Irritant, in accordance with Annex I to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1; hereinafter the 'CLP Regulation'). According to the Contested Decision, in its registration dossier the Appellant also indicated that '*effects (mortality) are seen in the short term fish test at concentrations as low as 8 mg/L (LC50 fish=8.27 mg/L with fish being the most sensitive species)*' (hereinafter the 'observed environmental effects'). The observed environmental effects were not such as to lead to the classification of the Substance as hazardous to the environment under Annex I to the CLP Regulation.
4. In accordance with Article 14 and Sections 5 and 6 of Annex I, the Appellant performed a chemical safety assessment including an exposure assessment and associated risk characterisation for the Substance. However, both the exposure assessment and the associated risk characterisation submitted by the Appellant were limited to human health hazards. The Appellant did not prepare an exposure assessment and associated risk characterisation for environmental hazards on the basis that the Substance is classified as hazardous only in relation to human health under the CLP Regulation.
5. On 5 September 2013, the Agency initiated a compliance check of the Appellant's registration dossier. The scope of the compliance check was limited to the standard information requirements provided for by Section 8.3 of Annex VII and Sections 5.2.4 and 6.3 of Annex I. The draft decision was notified to the Appellant for comments on 19 November 2013 in accordance with Articles 41(3) and 50(1). The draft decision contained a request for a test on skin sensitisation and for inclusion in the chemical safety report of an environmental exposure assessment and risk characterisation. On 10 December 2013, the Appellant updated its registration dossier, providing further information on skin sensitisation. On 19 December 2013, the Appellant provided its comments on the draft decision, claiming that the environmental exposure assessment and risk characterisation were not required by the REACH Regulation.
6. Following consideration of the Appellant's comments and the dossier update the Agency concluded that the request for the test on skin sensitisation was no longer required as the effect was sufficiently addressed in the dossier update. However, the Agency considered that the Appellant's dossier was still non-compliant with respect to the environmental exposure assessment and risk characterisation request. The Agency amended the draft decision accordingly and notified it, together with the Appellant's

comments, to the Member State Competent Authorities (hereinafter the 'MSCAs') in accordance with Article 51(1). As no proposal for amendment was submitted, on 17 September 2014 the Agency adopted the Contested Decision pursuant to Article 51(3).

7. The Contested Decision, in the section entitled '*Information required*', provides that:

   '*Pursuant to Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation the Registrant shall submit in the chemical safety report:*

   Environmental exposure assessment and risk characterisation (Annex I, Sections 5.2.4 and 6.3).

   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 24 March 2015.'

8. In the section of the Contested Decision entitled '*Statement of Reasons*', the Agency explains that '*it is clear from the dossier that the Registrant has identified a hazard for the environment: effects (mortality) are seen in the short term fish test at concentrations as low as 8 mg/L (LC50 fish=8.27 mg/L with fish being the most sensitive species). Therefore, the Registrant is required to carry out the exposure assessment and subsequent risk characterisation also for the environment in order to address the hazard identified for the environment. […] Moreover, the [Guidance] specifies further (in Section 8.4.2.2) that "If there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous for the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment. […] Hence, quantitative exposure assessment, i.e. derivation of PECs, is mandatory for the water, sediment and soil environmental compartments".*' The Contested Decision further states that '*the identified hazard in this case has been demonstrated by mortality of fish […]*'.

Procedure before the Board of Appeal

9. The Appellant brought this appeal on 15 December 2014. It requests the Board of Appeal to annul the Contested Decision and to order the refund of the appeal fee.

10. The Agency submitted its Defence on 18 March 2015, requesting the Board of Appeal to dismiss the appeal as unfounded.

11. Following consultation with the Parties, the appeal proceedings were stayed between 10 June 2015 and 1 September 2015, in accordance with Article 25 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').

12. The Appellant lodged its Observations on the Defence on 29 October 2015.

13. On 11 November 2015, following a change in the composition of the Board of Appeal, a new Rapporteur was appointed for this case.

14. On 15 January 2016, the Agency submitted its Observations on the Appellant's Observations on the Defence and its response to a set of written questions from the Board of Appeal. On 21 January 2016, the parties were informed of the Board of Appeal's decision to close the written procedure. Neither party requested a hearing to be held. On 15 February 2016, the Parties were notified of the Board of Appeal's decision that it was not necessary to hold a hearing in this case.

Reasons

15. The Appellant raises two pleas in law in support of its appeal, claiming that the Contested Decision lacks a legal basis and that it breaches the principle of legal certainty.

The first plea alleging that the Contested Decision lacks a legal basis

Arguments of the Parties

16. By its first plea, the Appellant claims that the Contested Decision was adopted without a legal basis. In the Appellant's view, Article 14 of the REACH Regulation and Annex I only require a registrant to perform an environmental exposure assessment and risk characterisation if the relevant substance is classified as hazardous to the environment under Annex I to the CLP Regulation.

17. According to the Appellant, the term '*hazard*' in Article 14 refers only to classified hazards within the meaning of the CLP Regulation. The Appellant argues that the Agency misinterpreted the term '*hazard*' in Article 14 to include observed adverse effects which do not fulfil the requirements for classification under the CLP Regulation. Consequently, an exposure assessment and risk characterisation can only be requested under Article 14 with respect to hazards for which a substance has been classified under the CLP Regulation. The Appellant points out that, in the present case, the observed environmental effects, mortality in fish, did not lead to classification of the substance under the CLP Regulation. Consequently, those environmental effects could not form the basis of a compliance check decision requiring an environmental exposure assessment and risk characterisation.

18. The Appellant further argues that the Guidance on Information Requirements and Chemical Safety Assessment – Part B: Hazard Assessment (version 2.1, December 2011; hereinafter the 'Guidance') is not in accordance with Article 14. The Appellant claims that Section 8.4.2.2 of the Guidance requires registrants to prepare a quantitative exposure assessment for the water, sediment and soil environmental compartments on the basis of the fact that '*[i]f there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous to the aquatic environment, an aquatic [Predicted No-Effect Concentration (hereinafter 'PNEC')] can nevertheless be derived thus indicating a hazard to the aquatic environment*.' According to the Appellant, '*the mere possibility to derive a PNEC gives no indication as to whether the REACH Regulation requires a full exposure assessment as the next step*'. In addition, the reference in the Guidance to the derivation of a PNEC for sediment and soil has no basis in Article 14 as no corresponding classification exists under the CLP Regulation. The Appellant therefore claims that, through the Guidance, the Agency has unlawfully extended the scope of the obligations imposed on registrants by the REACH Regulation.

19. Moreover, the Appellant claims that the Agency's interpretation of Article 14 would lead to unequal treatment. The Appellant argues that a registrant of a substance which is not classified under the CLP Regulation, but presents a concern for the environment, would not be required to perform the additional steps of environmental risk assessment under the REACH Regulation, namely environmental exposure assessment and risk characterisation. However, a registrant such as the Appellant, whose substance is classified under the CLP Regulation as dangerous to human health, but not to the environment, is required to perform those additional steps regarding environmental risk assessment.

20. The Appellant adds that, although its interpretation means that it is not obliged to perform an environmental exposure assessment and risk characterisation for the Substance, this does not allow it to ignore existing information on the environmental effects of the Substance. It points out in this regard that, in accordance with Article 31, information on the observed environmental effects of the Substance is included in the safety data sheet and consequently communicated in the supply chain.

21. Finally, the Appellant challenges the Contested Decision in so far as it states that the Agency '*considers the additional steps of exposure assessment and risk characterisation for any identified hazard irrespective of classification as a measure in line with the precautionary principle […]*'. According to the Appellant, the precautionary principle cannot constitute a legal basis for the Contested Decision and does not permit the Agency to extend the scope of Article 14(4).

22. The Agency disputes the Appellant's arguments. It concedes that the obligation to perform an exposure assessment and a risk characterisation applies only if a substance meets the criteria for classification under the CLP Regulation for any of the hazard classes listed in Article 14(4), first subparagraph, first indent, points (a) to (d) and Section 0.6.3 of Annex I. However, the Agency argues that once a substance is classified in accordance with the CLP Regulation for any of those hazard classes, the risk assessment required encompasses all hazards of the substance and is not limited to those hazards leading to classification under the CLP Regulation. The scope of the exposure assessment and of the risk characterisation provided for by Article 14(4), first subparagraph, second indent, points (a) and (b), and by Section 0.6.2 of Annex I, is therefore not limited to those hazards which lead to the classification of the substance under the CLP Regulation. In essence, according to the Agency, the classification of a substance under the CLP Regulation acts merely as a 'trigger' for a broader risk assessment under the REACH Regulation but does not limit the scope of that risk assessment. The Agency further argues that its interpretation of the scope of risk assessment is correctly reflected in the Guidance.

23. Consequently, in the Agency's view, the Contested Decision has a legal basis in Article 14 and Annex I.

Findings of the Board of Appeal

24. The Board of Appeal observes that the main point of dispute between the Appellant and the Agency concerns the interpretation of Article 14(4). More precisely, the Appellant does not accept the Agency's view that the classification of a substance under the CLP Regulation acts merely as a 'trigger' for a broader risk assessment under the REACH Regulation and does not limit the scope of the risk assessment to the hazards for which the substance was classified under the CLP Regulation. The Appellant contests the ensuing conclusion in the Contested Decision that, given the Substance is classified under the CLP Regulation as hazardous to human health while adverse effects to the environment were also observed, the Appellant should carry out an exposure assessment and risk characterisation for the environment as well as for human health.

25. The Board of Appeal observes that the examination of the first plea requires it to interpret Article 14 and in particular its fourth paragraph.

26. 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, *Knauer*, EU:C:2016:37, paragraph 27 and Case T-521/14, *Sweden* v *Commission*, EU:T:2015:976, paragraph 57). However, there is in principle no need for interpretation of a provision, particularly in the 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 *Sweden* v *Commission,* cited previously in this paragraph, paragraph 59; see also, to that effect, Case C-383/14, *Sodiaal International*, EU:C:2015:541, paragraphs 20 and 24).

27. The Board of Appeal will therefore proceed to examine the wording and, if necessary, the context and objective(s) of Article 14.

(i) Wording of Article 14

28. Article 14(3) provides that:

'A chemical safety assessment of a substance shall include the following steps:

a) human health hazard assessment;

b) physicochemical hazard assessment;

c) environmental hazard assessment;

d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.'

29. Article 14(4) further provides:

'If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

c) hazard class 4.1;

d) hazard class 5.1,

or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:

a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;

b) risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.'

30. The Board of Appeal notes that Article 14(3) requires an assessment of human health, physicochemical and environmental hazards of the substance as well as an assessment as to whether the substance is persistent, bioaccumulative and toxic (hereinafter 'PBT') or very persistent and very bioaccumulative (hereinafter 'vPvB'). If, as a result of this assessment, the substance is found to be PBT or vPvB or to meet the criteria for classification under the CLP Regulation for any of the hazard classes or categories listed in Article 14(4), the registrant is obliged to carry out the additional steps of exposure assessment and risk characterisation.

31. The Board of Appeal observes that the first subparagraph of Article 14(4) clearly explains that fulfilling the criteria for classification in any one of the relevant hazard classes or categories under the CLP Regulation is one of the two 'triggers' for the

additional steps of exposure assessment and risk characterisation, the other 'trigger' being the assessment of the substance as PBT or vPvB.

32. However, Article 14 does not explicitly define the scope of the obligation to perform an exposure assessment and risk characterisation. In particular, it is not clear from the wording of Article 14(4) whether the exposure assessment and risk characterisation should be limited to the hazards for which the substance was classified under the CLP Regulation or assessed to be a PBT or vPvB or whether it should include also other hazards that were identified during the assessment carried out pursuant to Article 14(3).

33. It is therefore apparent that the wording of Article 14 does not suffice, on its own, to determine with precision whether the scope of exposure assessment and risk characterisation is limited to hazards which lead to classification under the CLP Regulation or to the assessment of the substance as PBT or vPvB. The Board of Appeal will consequently proceed to interpret Article 14, and in particular the fourth paragraph thereof, in light of its context and objectives.

(ii) Context of Article 14

34. With regard to the context of Article 14, the Board of Appeal observes that Article 14 is part of Chapter I of Title II of the REACH Regulation. Title II concerns the registration of substances. Chapter I thereof sets the general obligation to register substances under the REACH Regulation (Articles 5 to 9) and describes the information that the registrant is required to provide when registering a substance (Articles 10 to 14).

35. Article 10 outlines the minimum information that must be submitted as part of a registration. Article 11 specifies the information to be submitted jointly when there are multiple registrants of the same substance. Article 12 outlines the information to be submitted depending on the tonnage of the substance manufactured in, or imported into, the European Union. Annexes VII to XI contain detailed provisions on the information requirements for each registration tonnage band. The information requirements are, generally speaking, greater and more demanding the higher the quantity of the substances manufactured in, or imported into, the EU, reflecting, in broad terms, that the higher the tonnage the greater the possible exposure. Article 13 sets the general rules to be followed for the generation of information on intrinsic properties of a substance. Finally, Article 14 requires that '*for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant*' a chemical safety assessment shall be performed and a chemical safety report completed. Annex I contains the general provisions for assessing substances and preparing chemical safety reports.

36. The Board of Appeal recalls that, according to Article 14(3), the first step of chemical safety assessment is hazard assessment. The registrant is required to identify and assess the human health, physicochemical and environmental hazards of the substance as well as to check for potential PBT or vPvB properties. Section 3 of Annex I contains detailed rules as regards the environmental hazard assessment.

37. According to Section 3 of Annex I, and in particular having regard to subsections 3.1, 3.2 and 3.3 thereof, the environmental hazard assessment comprises three steps. The first step is the evaluation of all available information, which includes '*the hazard identification based on all available information [and] the establishment of the quantitative dose (concentration)-response (effect) relationship*' (Section 3.1). The second step is the determination of whether the substance should be classified for a particular hazard class or category under the CLP Regulation (Section 3.2). The third step is the identification of the PNEC for each environmental sphere (Section 3.3).

38. The Board of Appeal observes that the identification of the hazards posed by the substance is explicitly required in Section 3.1 of Annex I as part of the environmental hazard assessment. In addition, it follows from the combination of Sections 3.1 and 3.2 that, after the first step of the environmental hazard assessment is concluded and all hazards have been identified, the registrant checks whether the identified hazards lead to the classification of the substance under the CLP Regulation, and establishes the PNEC for all the identified hazards for each environmental sphere.

39. Importantly, the identification of the hazards posed by a substance is based on all the information which is relevant and available to the registrant. The Board of Appeal notes that Article 12(1) and Annexes VII to XI expressly require that all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant shall be included in the registration dossier. It follows that '*available information*' for the purpose of identifying the hazards of a substance under Article 14(3) means the information available to the registrant when meeting the information requirements laid down in Annexes VII to XI in order to comply with Articles 10 and 12. Furthermore, Section 0.5 of Annex I foresees that '*[t]he chemical safety assessment shall be based on the information on the substance contained in the technical dossier and on other available and relevant information*'.

40. The Board of Appeal therefore finds that, pursuant to Article 14(3), when performing the environmental hazard assessment, a registrant is required to identify as a first step all hazards posed by the substance. Only after having identified all hazards, the question arises whether the available information on any of these hazards lead to the classification of the substance under the CLP Regulation. It is therefore clear to the Board of Appeal that the identification of hazards is a separate step from that of classification and labelling under the CLP Regulation. It is also clear to the Board of Appeal that, as the 'hazard identification' step precedes the step for determining whether the 'available information' leads to classification under the CLP Regulation, the term 'hazard' does not only mean those effects that lead to classification under the CLP Regulation.

41. The Board of Appeal notes that the finding in the previous paragraph is consistent with the provisions regarding human and physicochemical hazard assessment. It should be noted that the same process applies to human and physicochemical hazard assessment, which also require, as a first step, the identification of hazards and, subsequently, the comparison of the available information against the criteria of the CLP Regulation (see Sections 1.1 to 1.3 and Sections 2.4 and 2.5 of Annex I).

42. The interpretation of Article 14(3) set out in paragraph 40 above is also supported by Section 2 of Annex II, which describes the information on the hazards of a substance or mixture which must be included in a safety data sheet. In accordance with Section 2.1 of Annex II, any classification which arises from the application of the classification rules in the CLP Regulation is among the information which must be included in the safety data sheet. In addition, Section 2.3 of that Annex, entitled '*Other hazards*', explicitly requires that '*[i]nformation shall be provided on other hazards which do not result in classification but which may contribute to the overall hazards of the substance or mixture […]*'. The safety data sheet therefore needs to include information on all hazards identified and not just those leading to classification pursuant to the CLP Regulation.

43. For all the reasons laid out in paragraphs 34 to 42 above, the Board of Appeal concludes that the registrant is required to identify as a first step all hazards posed by the substance without, at this stage, having regard to considerations related to the CLP Regulation.

44. As noted above, Article 14(4) imposes an obligation to perform the additional steps of exposure assessment and risk characterisation as part of the chemical safety

assessment for substances fulfilling the criteria for any of the hazard classes or categories listed in Article 14(4), as set out in Annex I to the CLP Regulation, or which are assessed to be PBT or vPvB.

45. Whilst Article 14(4) does not explicitly define the scope of the exposure assessment and risk characterisation, Section 0.6.3 of Annex I clearly states that '*the chemical safety assessment shall also include steps 5 and 6 in accordance with Section 5 and 6 of this Annex*'.

46. Section 5 of Annex I, which contains detailed provisions on exposure assessment, contains useful clarifications in this regard. In particular, Section 5.0 of that Annex provides that the objective of the exposure assessment is to make a quantitative or qualitative estimate of the dose/concentration of the substance to which humans and the environment are or may be exposed. Importantly, Section 5.0 of Annex I adds that '*[t]he assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover any exposures that may relate to the hazards identified in Sections 1 to 4*'.

47. The Board of Appeal recalls that Sections 1 to 4 of Annex I concern the four areas of a chemical safety assessment listed in Article 14(3), namely human health hazard assessment, physicochemical hazard assessment, environmental hazard assessment and PBT/vPvB assessment. The Board of Appeal finds that, as the identification of hazards under Article 14(3) is based on all information available to the registrant and is not limited to those endpoints covered by the CLP Regulation or to PBT/vPvB assessment, the exposure assessment and the risk characterisation, if triggered pursuant to Article 14(4), must concern all the hazards that were identified as part of the chemical safety assessment in accordance with Article 14(3).

48. The exposure assessment and the associated risk characterisation are not therefore limited to the hazard classes or categories for which the substance meets the classification criteria under the CLP Regulation.

49. This conclusion is reinforced by Section 3.0.2 of Annex I, which specifies the effects of the substance on the environment which the hazard assessment shall consider under Article 14(3). This section states that '*[t]he environmental hazard assessment shall consider the potential effects on the environment, comprising the (1) aquatic (including sediment), (2) terrestrial and (3) atmospheric compartments, including the potential effects that may occur (4) via food-chain accumulation. In addition, the potential effects on the (5) microbiological activity of sewage treatment systems shall be considered'.* The Board of Appeal observes that, as acknowledged by the Appellant, some of the effects on the environment covered by Section 3.0.2, including the effects on soil and sediment, are not subject to classification under the CLP Regulation. However, the absence of classification criteria under the CLP Regulation for certain endpoints does not mean, by itself, that there is no hazard or that a hazard should not be considered further. On the contrary, the fact that the REACH Regulation provides for the assessment of some hazards despite the fact that they cannot lead to classification under the CLP Regulation supports the conclusion that CLP classification acts as a 'trigger' for the obligation to perform the additional steps of risk assessment, namely exposure assessment and risk characterisation, but does not limit their scope. In other words, if the logic put forward by the Appellant was followed, some environmental effects would not lead to a further exposure assessment and associated risk characterisation no matter how severe those effects might be.

50. For the reasons laid out in paragraphs 34 to 49 above, the Board of Appeal considers that the context of Article 14 indicates that the scope of the additional steps of chemical safety assessment under the REACH Regulation, namely exposure assessment and risk characterisation, is not limited to those hazards which lead to classification under the

CLP Regulation. The Board of Appeal will next consider the objective of Article 14 as part of its interpretation of that Article.

(iii) Objective of Article 14

51. The REACH Regulation, as is clear from Article 1 thereof, aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

52. The Board of Appeal recalls that Article 14 forms a part of the registration obligations and pursues the same objectives as the overall duty of registration. According to the Court of Justice of the EU, the main objective of the obligation to register laid down in Article 6 is to ensure a high level of protection of human health and the environment (see Case C–558/07, *S.P.C.M. and Others*, EU:C:2009:430, paragraph 45 and Case T–135/13, *Hitachi Chemical Europe and Others* v *ECHA*, EU:T:2015:253, paragraph 46; see also Case A-006-2014, *International Flavors & Fragrances*, Decision of the Board of Appeal of 27 October 2015, paragraph 44).

53. Pursuant to Recital 19, '*the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures*'. The Board of Appeal further notes that, according to the first sentence of Article 1(3), the REACH Regulation *'is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment'* (see, to that effect, Case C–472/14, *Canadian Oil Company Sweden and Rantén*, EU:C:2016:171, paragraphs 29 and 30).

54. The objective of Article 14(4) is therefore to ensure a high level of protection of human health and the environment by requiring manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to the substances in question and to develop and recommend appropriate risk management measures, provided that those substances are classified in accordance with the CLP Regulation for at least one of the hazard classes or categories listed in Article 14(4) or are assessed to be PBT or vPvB.

55. If the interpretation of Article 14 proposed by the Appellant were to be accepted, some identified hazards would not need to be followed up through further assessment merely because they do not meet the thresholds for classification under the CLP Regulation even if the substance was otherwise classified under the CLP Regulation, or because those hazards are not mentioned in Article 14(4). That interpretation would not be consistent with the objective of Article 14.

56. Furthermore, if the interpretation of Article 14 proposed by the Appellant were to be accepted the obligation to perform an exposure assessment and risk characterisation in the frame of chemical safety assessment would only apply for endpoints for which classification criteria have been defined under the CLP Regulation. As the CLP Regulation does not address an exhaustive list of endpoints, the Board of Appeal considers that an interpretation limiting the scope of risk assessment under Article 14(4) only to those endpoints covered by the CLP Regulation would not be consistent with the objective of that provision.

57. The Appellant also points out that information on the observed environmental effects of the Substance is included in the safety data sheet and consequently communicated in the supply chain in accordance with Article 31. However, that argument is irrelevant

since the mere inclusion of information on the observed environmental effects of the Substance in the safety data sheet is not sufficient to assess a potential risk and to identify appropriate risk management measures.

58. In fact, the identification of a potential risk is based on a combination of hazard and exposure information (see, to that effect, Case A-005-2014, *Akzo Nobel and Others*, Decision of the Board of Appeal of 23 September 2015, paragraph 61). The assessment of the potential risk posed by a hazardous substance, and the subsequent identification and application of appropriate risk management measures consequently requires the additional steps of the chemical safety assessment, namely an exposure assessment and associated risk characterisation. This conclusion is in line with Article 14(6) according to which '*[a]ny registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31*'.

59. The Board of Appeal therefore considers that the obligation to perform an exposure assessment and risk characterisation in relation also to those hazards which do not lead to classification under the CLP Regulation, when the conditions of Article 14(4) are fulfilled, contributes to the achievement of the objective of Article 14, namely to ensure a high level of protection of human health and the environment.

(iv) Conclusion to be drawn from the interpretation of Article 14 and related assessment of the first plea

60. On the basis of the literal, contextual and teleological interpretation of Article 14 (see sections (i), (ii) and (iii) above), the Board of Appeal finds that the scope of the exposure assessment and risk characterisation provided for by Article 14(4) is not limited to hazards which lead to classification under the CLP Regulation.

61. In the present case, the Substance is classified as dangerous to human health in accordance with Annex I of the CLP Regulation.

62. In addition to human health hazards, according to the Contested Decision and not contested by the Appellant, the Appellant has identified a hazard to the environment in its chemical safety assessment, namely '*effects (mortality) […] in the short term fish test at concentrations as low as 8 mg/L (LC50 fish=8.27 mg/L with fish being the most sensitive species)*'. Although these environmental effects do not lead to classification under the CLP Regulation, the fact remains that the ecotoxicity data submitted by the Appellant in order to meet the information requirements of Chapter I under Title II indicate that the Substance poses a hazard to aquatic organisms.

63. Article 14(4) therefore requires the Appellant to perform an environmental exposure assessment and risk characterisation for the hazard identified during the environmental hazard assessment pursuant to Article 14(3), despite the fact that the hazard in question does not lead to classification under the CLP Regulation.

64. This conclusion is not called into question by the arguments of the Appellant as regards the alleged breach of the principle of equal treatment, the alleged extension of obligations imposed on the registrants through the Guidance or the allegedly extensive application of the precautionary principle.

a. The alleged breach of the principle of equal treatment

65. As regards the alleged breach of the principle of equal treatment, the Appellant claims that there would be unequal treatment if a registrant for a substance which is not classified under the CLP Regulation, but presents a concern for the environment, would not be required to perform an exposure assessment and risk characterisation for the hazards identified during the assessment conducted under Article 14(3). On the other hand, a registrant such as the Appellant, whose substance is classified under the CLP Regulation as dangerous to human health, is required to perform an exposure assessment and risk characterisation not only for the human health hazard but also for environmental hazards which do not lead to classification under the CLP Regulation.

66. The Board of Appeal acknowledges that the interpretation given to Article 14 must not breach the principle of equal treatment which is a general principle of European Union law enshrined in Articles 20 and 21 of the Charter of Fundamental Rights of the European Union. According to settled case-law, that principle requires that comparable situations must not be treated differently and that different situations must not be treated in the same way unless such treatment is objectively justified (Case C-550/07 P, *Akzo Nobel Chemicals and Akcros Chemicals* v *Commission*, EU:C:2010:512, paragraphs 54 and 55).

67. However, a breach of the principle of equal treatment as a result of different treatment presumes that the situations concerned are comparable, having regard to all elements which characterise them. The elements which characterise different situations, and hence their comparability, must in particular be determined and assessed in the light of the subject-matter and purpose of the European Union act which makes the distinction in question. The principles and objectives of the field to which the act relates must also be taken into account (see Case T-260/11, *Spain* v *Commission*, EU:T:2014:555, paragraph 93 and the case-law cited).

68. With regard to the elements of fact which characterise the two situations to which the Appellant alludes, the Board of Appeal observes that the Appellant's substance is classified as hazardous for human health under the CLP Regulation, whereas the substance in the Appellant's hypothetical example (see paragraph 65 above) is not.

69. Moreover, as regards the legal elements which characterise the two situations, the Board of Appeal notes that the difference between the two situations stems directly from the REACH Regulation. In Article 14(4) the legislator chose to require exposure assessment and risk characterisation for all hazards identified under Article 14(3) for substances which meet the classification criteria for any of the hazard classes or categories listed in Article 14(4)(a) to (c), or which are assessed to be PBT or vPvB.

70. The Board of Appeal further notes that the REACH Regulation follows a similar approach with regard to the level of information required under Article 12. In that context, the information requirements vary depending on the quantity of the substance that is manufactured or imported per year per manufacturer or importer, reflecting considerations of exposure, risk, and proportionate administrative burden on the registrants.

71. As a consequence, the two situations to which the Appellant refers are not comparable and the interpretation of Article 14, set out in paragraph 60 above, does not lead to unequal treatment. The argument put forward by the Appellant with regard to equal treatment must therefore be rejected.

b. The alleged extension through the Guidance of the obligations imposed on the registrants

72. The Appellant raises two separate arguments in relation to the Guidance. First, the Appellant argues that the Agency has unlawfully extended the scope of the obligations imposed on registrants by the REACH Regulation through the Guidance.

73. The Board of Appeal notes in this regard that the interpretation of Article 14 as laid out in paragraph 60 above is correctly reflected in Section B.8.1 of the Guidance. That Section explains that '*exposure assessment has to cover **all** hazards that have been identified according to sections 1 to 4 of Annex I of REACH. For the sake of clarity it should be noted that such identified hazards necessitating exposure assessment are of three types: hazards for which there are classification criteria and there is information to establish that the substance meets the criteria and is therefore classified; hazards for which there are classification criteria and there is information on these properties of the substance showing that it does have these properties, but the severity of the effects is lower than the criteria for classification and so the substance is not classified; hazards for which currently no classification criteria exist, but there is information to show that the substance has such hazardous properties*'. As a consequence, the Appellant's argument is unfounded.

74. Second, the Appellant argues that the Contested Decision is flawed insofar as it finds that the derivation of a PNEC demonstrates the existence of a hazard to the environment. More specifically, the Appellant challenges the wording of Section 8.4.2.2 of the Guidance according to which '*[i]f there are ecotoxicity data showing effects in aquatic organisms, but the substance is not classified as dangerous to the aquatic environment, an aquatic PNEC can nevertheless be derived thus indicating a hazard to the aquatic environment*'. In the Appellant's view, the mere possibility of deriving a PNEC gives no indication as to whether the REACH Regulation requires exposure assessment and risk characterisation as subsequent steps.

75. The Board of Appeal recalls, however, that the hazard to the environment posed by the substance in the present case, as identified by the Appellant during the first step of hazard assessment, is acute toxicity for aquatic organisms (fish mortality). It is the identification of that hazard, not the derivation of a PNEC, which 'triggered' the obligation to perform the additional steps of chemical risk assessment, namely exposure assessment and associated risk characterisation. That fact was recognised in the Contested Decision, which states that '*[i]t is clear from the dossier that the Registrant has identified a hazard for the environment: effects (mortality) are seen in the short term fish test at concentrations as low as 8 mg/L (LC50 fish=8.27 mg/L with fish being the most sensitive species). Therefore, the Registrant is required to carry out the exposure assessment and subsequent risk characterisation also for the environment in order to address the hazard identified for the environment*.' The Appellant's argument is therefore unfounded.

76. In addition, the argument raised by the Appellant is directed against a subsidiary ground of the Contested Decision, as evidenced by the use of the word '*moreover*' in the Contested Decision (cited at paragraph 8 above). It must therefore also be rejected as ineffective since it cannot call into question the primary justification for requesting an environmental exposure assessment and risk characterisation.

c. The allegation relating to the extensive application of the precautionary principle

77. Finally, the Appellant argues that the precautionary principle is not an appropriate legal basis for the Contested Decision and cannot be used to extend the scope of the legal obligations under the REACH Regulation.

78. The Board of Appeal notes, in this regard, that the Contested Decision is based on *'Articles 41(1)(c), 41(3), 10(b), 14 and Annex I of the REACH Regulation*'. The part of the Contested Decision entitled '*Statement of reasons*' provides inter alia that '*ECHA therefore considers the additional steps of exposure assessment and risk characterisation for any identified hazard irrespective of classification [to be] a measure in line with the precautionary principle that is underpinning the REACH Regulation'.*

79. The fact that a measure is '*in line*' with the precautionary principle does not mean that the measure in question has its legal basis in that principle.

80. Moreover, the fact that the Agency reasoned that its interpretation of the REACH Regulation was '*in line*' with the precautionary principle does not mean that it used that principle unlawfully to extend the scope of the relevant legal provisions. While the precautionary principle may support the interpretation according to which exposure assessment and risk characterisation are required for all hazards identified under Article 14(3), the fact remains that the requirement stems directly from the REACH Regulation (see paragraph 60 above). The Appellant's argument in this regard must therefore be rejected.

81. For all those reasons, the Board of Appeal finds that the Contested Decision does not lack a legal basis. Accordingly, the Appellant's first plea is rejected.

The second plea, alleging a breach of the principle of legal certainty

Arguments of the Parties

82. By its second plea, the Appellant alleges that the Contested Decision violates the principle of legal certainty.

83. In support of that plea, the Appellant argues that the Agency breached the principle of legal certainty by extending the concept of '*hazard*' within the meaning of Article 14 to all observed adverse effects. The Appellant argues that, as there is no clear and unequivocal basis for this approach in the REACH Regulation, and as there is no definition of which observed adverse effects constitute a hazard within the meaning of Article 14, it was not in a position to ascertain unequivocally its rights and obligations.

84. The Appellant adds that the Guidance, which is not a binding rule of law, is not an adequate means in order to satisfy legal certainty in this regard. The Appellant alleges that the Guidance is not sufficiently clear either.

85. The Agency disputes the merits of the Appellant's arguments. It argues that the obligation, incumbent on the Appellant, to perform an environmental exposure assessment and risk characterisation for the Substance derives directly from the REACH Regulation, which is sufficiently clear in itself. Moreover, the Agency argues that it has communicated its interpretation of the rules in question to the public in a clear and consistent manner.

Findings of the Board of Appeal

86. In accordance with settled case-law, the principle of legal certainty requires that rules of law be clear and precise and predictable in their effect, so that interested parties can ascertain their position in situations and legal relationships governed by EU law (see Case C–147/13, *Spain* v *Council*, EU:C:2015:299, paragraph 79).

87. With regard to the Appellant's argument that the Agency breached the principle of legal certainty by extending the concept of '*hazard*' within the meaning of Article 14 to all possible adverse effects without a clear and unequivocal basis for doing so, the Board of Appeal has already found that the Appellant's obligation to perform an environmental exposure assessment and associated risk characterisation for all identified hazards stems directly from the REACH Regulation (see paragraph 60 above). Insofar as the plea relating to the principle of legal certainty overlaps in part with the first plea raised in this appeal, alleging the lack of a legal basis, it must be rejected as unfounded for the same reasons as the first plea.

88. Moreover, as regards the absence of a precise definition of what constitutes a '*hazard*' for the purposes of Article 14, as has been explained at paragraph 39 above, the identification of the hazards posed by a substance is based on all the information available to the registrant for the purpose of fulfilling the information requirements laid down in Annexes VII to XI in order to comply with Articles 10 and 12.

89. In the present case, the Appellant could and did identify an environmental hazard (fish mortality) itself during the course of the chemical safety assessment.

90. It has already been found that the scope of the exposure assessment and associated risk characterisation provided for by Article 14(4) is not limited to hazards which lead to classification under the CLP Regulation, and that this interpretation of Article 14 is correctly reflected in Section B.8.1 of the Guidance (see paragraphs 60 and 73 above).

91. As a consequence, in the present case, the Appellant was in a position to ascertain with precision its obligations under Article 14. The Board of Appeal considers therefore that the Agency did not breach the principle of legal certainty when, on the basis of the information provided by the Appellant in its registration dossier, it held that the Substance poses a hazard to the environment necessitating an environmental exposure assessment and associated risk characterisation.

92. Finally, as regards the Appellant's argument that the Guidance is unclear, the Board of Appeal observes that Section B.8.1 of the Guidance, quoted in paragraph 73 above, is clear and could not have left the Appellant in any doubt as regards the Agency's interpretation of the scope and meaning of Article 14(4). The argument must therefore be rejected.

93. In these circumstances, the Appellant could resolve with sufficient certainty any doubts as to the scope of its obligations. Accordingly, the Appellant's argument must be rejected.

94. For these reasons, the second plea is unfounded and the appeal in its entirety is dismissed.

Refund of the appeal fee

95. 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.

96. As the appeal has been dismissed, the appeal fee shall not be refunded.

Effects of the Contested Decision

97. According to Article 91(2), an appeal before the Board of Appeal shall have suspensive effect.

98. The Contested Decision, upheld in the present appeal proceedings, required the registrant, now the Appellant, to submit the required information by 24 March 2015, which is 188 calendar days from the adoption of the Contested Decision. The Board of Appeal considers however that, because of the duration of the present appeal proceedings, the deadline set in the Contested Decision should be interpreted, in the light of the principle of suspensive effect laid down in Article 91(2), as if it referred to 188 calendar days from the date of notification of the final decision of the Board of Appeal.

99. Consequently, the information required by the Contested Decision shall be submitted within 188 calendar days from the date of notification of the Board of Appeal's decision in present case.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the information required by the Contested Decision shall be submitted by 2 January 2017.**
3. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO

Chairman of the Board of Appeal

Alen MOČILNIKAR

Registrar of the Board of Appeal