Reports of Cases

OPINION OF ADVOCATE GENERAL
MENGOZZI
delivered on 28 September 2016[1]

Case C-323/15 P

Polynt SpA
v
European Chemicals Agency (ECHA)
and
Case C-324/15 P
Hitachi Chemical Europe GmbH
Polynt SpA
v

European Chemicals Agency (ECHA)

(Appeal — Regulation (EC) No 1907/2006 (REACH Regulation) — Article 57(f) — Substances of very high concern — Establishment of a list of substances subject to authorisation — Decision identifying cyclohexane-1,2-dicarboxylic anhydride, cis-cyclohexane-1,2-dicarboxylic anhydride, trans-cyclohexane-1,2-dicarboxylic anhydride –Decision identifying hexahydromethylphtalic anhydride, hexahydro-4-methylphthalic anhydride, hexahydro-1-methylphthalic anhydride and hexahydro-3-methlyphthalic anhydride (MHHPA) — Inclusion on the list of substances identified with a view to eventual inclusion in Annex XIV — Assessment of the hazards of the intrinsic properties of the substances — Assessment and risk management measure)

I – Introduction

1. By their appeals, (i) Polynt SpA, in Case C-323/15 P, and (ii) Hitachi Chemical Europe GmbH and Polynt SpA, in Case C-324/15 P, ask the Court to set aside, respectively, the judgments of the General Court of the European Union of 30 April 2015, *Polynt and Sitre* v *ECHA* (T-134/13, not published, EU:T:2015:254), and of 30 April 2015, *Hitachi Chemical Europe and Others* v *ECHA* (T-135/13, EU:T:2015:253) (together, 'the judgments under appeal').

2. By those judgments, the General Court dismissed the actions which those companies had brought for annulment in part of Decision ED/169/2012 of the European Chemicals Agency ('the ECHA') of 18 December 2012 concerning the inclusion of substances of very high concern in the list of candidate substances ('the decision at issue'), in accordance with Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC)

1 — Original language: French.

No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC,[2] as amended by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008[3] ('the REACH Regulation').

3. More specifically, by the decision at issue, against which the actions at first instance were dismissed, the ECHA identified (i) cyclohexane-1,2-dicarboxylic anhydride (EC No 201-604-9), cis-cyclohexane-1,2-dicarboxylic anhydride (EC No 236-086-3) and trans-cyclohexane-1,2-dicarboxylic anhydride (EC No 238-009-9) (together 'HHPA') and (ii) hexahydromethylphtalic anhydride (EC No 247-094-1), hexahydro-4-methylphthalic anhydride (EC No 243-072-0), hexahydro-1-methylphthalic anhydride (EC No 256-356-4) and hexahydro-3-methlyphthalic anhydride (EC No 260-566-1) (together 'MHHPA') as substances which meet the criteria laid down in Article 57(f) of the REACH Regulation, in accordance with Article 59 of that regulation.

4. These appeals provide the Court with the opportunity to interpret, for the first time, Article 57(f) of the REACH Regulation concerning the identification of a substance, in this instance respiratory sensitisers, as a substance of very high concern, such identification constituting the first stage in the authorisation procedure laid down in the REACH Regulation. In particular, these disputes must lead the Court to resolve the question whether, for the purposes of identification as a substance of very high concern, in application of Article 57(f) of the REACH Regulation, an assessment of the risks caused by a substance is necessary, an argument which the appellants put forward in their appeals and in respect of which they take issue with the General Court for having rejected it at first instance. In fact, it is common ground that the General Court held that only an assessment of the hazards arising from the intrinsic properties of the substances was sufficient for the purposes of the identification referred to in Article 57(f) of the REACH Regulation.

II – Legal framework

5. Title VII of the REACH Regulation, consisting of Articles 55 to 65 of that regulation, governs the authorisation procedure.

6. Article 56 of the REACH Regulation provides:

'1. A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

…

5. In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

…'

2 — OJ 2006 L 396, p. 1.

3 — OJ 2008 L 353, p. 1.

7. Article 57 of that regulation, entitled ‘Substances to be included in Annex XIV’, provides:

‘The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation (EC) No 1272/2008;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.’

8. Article 58 of the REACH Regulation, entitled ‘Inclusion of substances in Annex XIV’, provides:

‘1. Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall specify for each substance:

(a) the identity of the substance as specified in Section 2 of Annex VI;

(b) the intrinsic property (properties) of the substance referred to in Article 57;

(c) transitional arrangements:

…

(d) review periods for certain uses, if appropriate;

(e) uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

…’

9. Article 59 of the REACH Regulation, entitled ‘Identification of substances referred to in Article 57’, provides

‘1. The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).

2. The Commission may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57. …

3. Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency. …

…’

10. Article 60 of the REACH Regulation, entitled ‘Granting of authorisations’, states:

‘1. The Commission shall be responsible for taking decisions on applications for authorisations in accordance with this Title.

2. Without prejudice to paragraph 3, an authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is adequately controlled in accordance with Section 6.4 of Annex I and as documented in the applicant’s chemical safety report, taking into account the opinion of the Committee for Risk Assessment referred to in Article 64(4)(a). When granting the authorisation, and in any conditions imposed therein, the Commission shall take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision.

…

3. Paragraph 2 shall not apply to:

(a) substances meeting the criteria in Article 57(a), (b), (c) or (f) for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I;

(b) substances meeting the criteria in Article 57(d) or (e);

(c) substances identified under Article 57(f) having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties.

4. If an authorisation cannot be granted under paragraph 2 or for substances listed in paragraph 3, an authorisation may only be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. …

…’

11. Article 62 of the REACH Regulation, entitled ‘Applications for authorisations’, provides:

‘1. An application for an authorisation shall be made to the Agency.

…

4. An application for authorisation shall include the following information:

…

(d) unless already submitted as part of the registration, a chemical safety report in accordance with Annex I covering the risks to human health and/or the environment from the use of the substance(s) arising from the intrinsic properties specified in Annex XIV;

…'

III – Background to the disputes

12. It is apparent from paragraphs 1 to 3 of the judgments under appeal that HHPA and MHHPA are cyclic acid anhydrides. They are used as intermediates or monomers and also for the manufacture of articles and the manufacture of polymer resins. [4]

13. These substances have, in particular, been classified among the category 1 respiratory sensitisers, which may cause allergy or asthma symptoms or breathing difficulties if inhaled. HHPA and MHHPA have been included in Table 3.1 of Part 3 of Annex VI to Regulation No 1272/2008.

14. On 6 August 2012, the Kingdom of the Netherlands sent to the ECHA a dossier proposing that HHPA and MHHPA be identified as substances of very high concern and included in Annex XIV to the REACH Regulation in accordance with Article 57 of that regulation. It is apparent from paragraph 4 of the judgments under appeal that the Kingdom of the Netherlands proposed that HHPA and MHHPA be identified as substances for which there was scientific evidence of probable serious effects on human health or the environment which gave rise to a level of concern equivalent to those of other substances listed in Article 57(a) to (e) of the REACH Regulation, in accordance with Article 57(f) of that regulation.

15. Following the appellants' comments on the dossiers relating to the identification of HHPA and MHHPA, the ECHA referred the dossiers to its Member State Committee, as referred to in Article 76(1)(e) of the REACH Regulation, which, on 13 December 2012, reached a unanimous agreement on the identification of HHPA and MHHPA as substances of very high concern meeting the criteria set out in Article 57(f) of the REACH Regulation. On the same day, the ECHA Member State Committee adopted the respective support documents for the identification of HHPA and MHHPA as substances of very high concern owing to their respiratory sensitising properties on the basis of Article 57(f) of the REACH Regulation ('the support documents').

16. On completion of the procedure laid down in Article 59 of the REACH Regulation, the ECHA adopted the decision at issue, whereby it identified HHPA and MHHPA as substances meeting the criteria set out in Article 57(f) of that regulation. In particular, the ECHA considered that those substances give rise to a level of concern equivalent to the carcinogenic substances, mutagenic substances and substances toxic for reproduction listed in Article 57(a) to (c) of the REACH Regulation.

IV – Procedure before the General Court and judgments under appeal

17. On 28 February 2013, the appellants brought their respective actions for annulment in part of the decision at issue.

4 — These substances are used, in particular, as hardeners for epoxy-resin based isolating materials. Epoxy resin is often used in the manufacturing industry of electrical equipment and systems, more particularly in the insulation of equipment subject to high voltage in the transmission and distribution of electricity, including the insulation of wind power generators and electroluminescent diodes (light emitting diodes (LEDs)).

18. The General Court granted the Commission and the Kingdom of the Netherlands leave to intervene in support of the form of order sought by the ECHA in Cases T-134/13 and T-135/13. It also granted REACh ChemAdvice GmbH and New Japan Chemical leave to intervene in support of the appellants. By order of 15 October 2014, the General Court joined the two cases for the purposes of the oral procedure

19. By the judgments under appeal, the General Court dismissed the appellants' actions in their entirety and ordered them to pay the costs.

V – Procedure before the Court of Justice and forms of order sought

20. By applications lodged at the Court Registry on 30 June 2015, the appellants brought the present appeals.

21. Each of the appellants asks the Court to set aside the judgment under appeal concerning it and to annul the decision at issue in so far as it relates to it or, in the alternative, to refer the cases back to the General Court and to order the ECHA to pay the costs.

22. The ECHA and the Commission ask the Court to dismiss the appeals and to order the appellants to pay the costs.

23. New Japan Chemical and REACh ChemAdvice GmbH lodged written observations in support of the form of order sought by the appellants. The Kingdom of the Netherlands lodged written observations in support of the form of order sought by the ECHA.

24. The Court put a series of questions to the parties, to be answered in writing. The appellants, the ECHA and the Commission answered those questions within the prescribed period.

25. The appellants, the ECHA, the Commission and Sitre Srl, which intervened in support of the forms of orders sought by the appellants before the Court,[5] presented oral argument and answered the questions put by the Court at the hearing, common to both cases, on 15 June 2016.

VI – Assessment

26. In support of their appeals, the appellants put forward four grounds of appeal. The first ground of appeal alleges contradictory reasoning and errors of law entailing an error of interpretation and application of Article 57(f) of the REACH Regulation. The second ground of appeal alleges inconsistent reasoning and errors of law leading to misinterpretation and incorrect application of Article 57(f) of the REACH Regulation. The third ground of appeal alleges a flaw in reasoning, in that the General Court incorrectly relied on Article 60(2) of the REACH Regulation. Last, the fourth ground of appeal alleges errors of law in the assessment of the arguments relating to the lack of consumer and worker exposure to the substance, leading to an incorrect application of Article 57(f) of the REACH Regulation.

5 — Sitre was an applicant in both cases before the General Court.

A – *First ground of appeal, alleging contradictory reasoning and errors of law entailing an error of interpretation and application of Article 57(f) of the REACH Regulation*

27. This ground of appeal consists of two parts. The appellants maintain that the General Court erred in law in interpreting Article 57(f) as meaning that that provision does not require a risk assessment for the purposes of identifying a substance as being of very high concern. In addition, the appellants claim that paragraphs 71 and 73 of the judgments under appeal are contradictory.

1. First part, alleging an error of law in the interpretation of Article 57(f) of the REACH Regulation

(a) Summary of the parties' arguments

28. The first part of the first ground of appeal is directed against paragraphs 71, 81 and 94 of the judgments under appeal, in that the General Court excluded the need for a risk assessment in order to identify the substances in question, in application of Article 57(f) of the REACH Regulation.

29. The appellants dispute that interpretation of Article 57(f) of the REACH Regulation.

30. They maintain that the EU legislature intended to distinguish between the substances covered by Article 57(a) to (e) of the REACH Regulation and those coming under Article 57(f) of that regulation. Substances which do not come within the cases referred to in Article 57(a) to (e) of that regulation can be regarded as being of very high concern only after further examination, on a case-by-case basis. That examination can only be a risk assessment, which must take account of the risk management measures, since respiratory sensitisers do not come within the category of carcinogenic substances, mutagenic substances or substances toxic for reproduction referred to in Article 57(a) to (c) of the REACH Regulation.

31. In answer to the written questions put by the Court, the appellants claimed that that interpretation of Article 57(f) of the REACH Regulation was confirmed by the use of the word 'utilisation' in the French version of Article 57(f) of that regulation.

32. At the hearing, the appellants stated that the risk assessment to which they referred in their appeal corresponded to a risk assessment within the meaning of Annex I to the REACH Regulation.

33. The ECHA contends that the appellants have misunderstood the words of the judgments under appeal. It claims that the General Court correctly applied the *Etimine* case-law (judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504) by distinguishing between hazards and risks. In its submission, the General Court was correct to hold that, as in the case of the substances referred to in Article 57(a) to (e), Article 57(f) of the REACH Regulation does not require a risk assessment. The identification of a substance as being of very high concern can result simply from the assessment of the hazards of the intrinsic properties of that substance. In addition, the ECHA observes that, in the absence of an exposure threshold, as is the position in this instance for respiratory sensitisiers, a normal risk assessment is not possible.

34. At the hearing, the ECHA stated that the procedure involving the taking into account of the data on human exposure that enable an assessment of the hazards arising from the intrinsic properties of the substances and the procedure involving the exposure assessment and the risk assessment are completely different procedures.

35. The Commission also maintains that the General Court was correct to find that Article 57(f) of the REACH Regulation does not require a risk assessment in order to identify substances which do not come within the other points in that article. That is clear from the wording and the structure of that regulation.

(b) Assessment

36. In paragraph 69 of the judgments under appeal, the General Court pointed out that the Court of Justice had already held in the judgment of 21 July 2011, *Etimine* (C-15/10, EU:C:2011:504, paragraphs 74 and 75), that a distinction must be made between hazards and risks. Hazard assessment constitutes the first stage of the process of risk assessment, which is a more specific concept. Thus, an assessment of the hazards linked to the intrinsic properties of a substance must not be limited in light of specific circumstances of use, as in the case of a risk assessment, and may be properly carried out regardless of the place where the substance is used, the route by which contact with the substance might arise and the possible levels of exposure to the substance.

37. Although the title of the appellants' first ground of appeal refers to paragraph 69 of the judgments under appeal, the appellants do not dispute the General Court's assessment in that paragraph, or the distinction which it drew between hazard assessment and risk assessment, a point which should be noted.

38. In that regard, and in order to have a better understanding of the distinction between hazard assessment and risk assessment, especially in the present cases, I would add that the purpose of the assessment of hazards to human health is to establish the maximum level of exposure to the substance to which humans may be subjected without that exposure having harmful effects. That level of exposure, called the Derived No-Effect Level ('the DNEL'), is based on the assessment of human and non-human information. [6]

39. The objective of the exposure assessment is to establish the levels of known or reasonably foreseeable human exposure to that substance. [7] That assessment takes account of the operational conditions and the risk management measures. The risk characterisation consists of a comparison between the levels of known or reasonably foreseeable human exposure to that substance and the relevant DNEL. The risk may be considered to be adequately controlled if the levels of known or reasonably foreseeable human exposure to that substance do not exceed the DNEL. [8]

40. Those initial points having been made, it is apparent from paragraph 70 of the judgments under appeal, which, too, is not called in question by the appellants, that the classification and labelling of hazardous substances at EU level, as now laid down in Regulation No 1272/2008, are based on the assessment of the hazards linked to the substances' intrinsic properties.

41. In paragraph 71 of the judgments under appeal, the General Court inferred that 'since classification among category 1 carcinogenic substances, mutagenic substances and substances toxic for reproduction is sufficient for a substance to be identified as being of very high concern pursuant to Article 57(a) to (c) of [the REACH Regulation], it cannot be concluded that, in order for a substance to be identified in accordance with Article 57(f) of [the REACH Regulation], the ECHA must take a risk assessment into consideration'.

6 — See Section 1 of Annex I to the REACH Regulation.

7 — See Section 5 of Annex I to the REACH Regulation.

8 — See Section 6 of Annex I to the REACH Regulation.

42. In paragraph 81 of the judgments under appeal, the General Court likewise rejected the appellants' argument concerning the failure to take into account the risk management measures, controls and conditions relating to the protection of workers, on the ground that it is '[sufficient] to point out that the hazards arising from the intrinsic properties of HHPA and MHHPA have not changed, and the fact that the negative effects associated with the use of a substance can be controlled adequately does not preclude its identification as a substance of very high concern'.

43. The General Court thus considered that the hazards arising from the intrinsic properties of HHPA and MHHPA are sufficient to justify their being identified as substances of very high concern.

44. That appraisal was confirmed in paragraph 95 of the judgment under appeal in Case T-134/13 and paragraph 94 of the judgment under appeal in Case T-135/13.

45. The General Court thus held that, for the purpose of identifying substances under Article 57(f) of the REACH Regulation, no risk assessment was necessary and that only an assessment of the hazards linked with intrinsic properties of those substances was required.

46. The appellants dispute that interpretation of Article 57(f) of the REACH Regulation and maintain that that provision *requires* that a risk assessment be taken into account.

47. In spite of the rather concise reasoning in the judgments under appeal, I do not share that view.

48. It should be observed, at the outset, that the REACH Regulation introduces an integrated system for monitoring chemical substances, including registration, evaluation and authorisation, together with possible restrictions on their use. [9]

49. The REACH Regulation devotes particular attention to substances regarded as being of very high concern, as is apparent, in particular, from recitals 63, 69 and 70 of that regulation, [10] to which the authorisation procedure laid down in Title VII of that regulation, consisting of Articles 55 to 66 of the REACH Regulation, applies.

50. The authorisation procedure makes the use and placing on the market of the substances in Annex XIV subject to authorisation. That procedure consists of three stages.

51. Briefly, the first stage consists in identifying the substances of very high concern pursuant to Article 57 of the REACH Regulation and including them in the list of candidate substances for *eventual* inclusion in Annex XIV, entitled 'List of substances subject to authorisation'. I shall, of course, return later to this first stage, which is central to these appeals. The second stage of the procedure consists in including certain candidate substances in Annex XIV, in accordance with Article 58 of the REACH Regulation. The third stage of the authorisation procedure consists in the granting of authorisation for the substances included in Annex XIV to the REACH Regulation. In principle, without authorisation, the substance can be neither used nor placed on the market.

52. Article 57 of the REACH Regulation, which, as stated above, forms part of the first stage of the authorisation procedure, lays down the criteria for the identification of substances of very high concern which may be included in Annex XIV. Article 57 sets out, in points (a) to (c), the substances meeting the criteria for classification as carcinogenic substances, mutagenous substances or substances toxic for reproduction, in category 1A or 1B, in accordance with Annex I to Regulation No 1272/2008

9 — See judgments of 10 September 2015, *FCD and FMB* (C-106/14, EU:C:2015:576, paragraph 32), and of 17 March 2016, *Canadian Oil Company Sweden and Rantén* (C-472/14, EU:C:2016:171, paragraph 25).

10 — See judgment of 10 September 2015, *FCD and FMB* (C-106/14, EU:C:2015:576, paragraph 34).

('the CMR substances') and, in points (d) and (e), the substances which are persistent, bioacumulative and toxic (PBT) and the substances which are very persistent and very bioaccumulative (vPvB), in accordance with the criteria set out in Annex XIII to the REACH Regulation [11] ('the PBT and vPvB substances').

53. Point (f) of Article 57 of the REACH Regulation refers to 'substances — such as those having endocrine disrupting properties or those having [PBT] properties or [vPvB] properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59 [of the REACH Regulation]'.

54. It is common ground that HHPA and MHHPA are classified as respiratory sensitisers in accordance with Section 3.4 of Annex I to Regulation No 1272/2008.

55. Furthermore, as was more fully explained at the hearing before the Court, the appellants do not dispute, in their respective appeals, the findings of the General Court set out in paragraphs 45 to 48 of the judgments under appeal, according to which respiratory sensitisers do indeed come within the scope of Article 57(f) of the REACH Regulation, as the list of substances set out in that provision is not exhaustive.

56. Nor is it disputed that the CMR, PBT and vPvB substances come within the category of substances of very high concern on the sole basis of their classification under Regulation No 1272/2008, which is itself based solely on the assessment of the hazards arising from their intrinsic properties.

57. In the appellants' submission, and contrary to the General Court's finding in paragraph 71 of the judgments under appeal, the position is different for the substances referred to in Article 57(f) of the REACH Regulation. In support of their argument that Article 57(f) of the REACH Regulation requires, at the stage of the identification of substances of very high concern, not only a hazard assessment but also a risk assessment, the appellants rely on the notion that substances not coming within Article 57(a) to (e) of the REACH Regulation can be identified as substances of very high concern only following an additional examination which, in their submission, could only be a risk assessment. According to the appellants, such a risk assessment includes an exposure assessment taking into account the risk management measures, as provided for in Annex I, Sections 5 and 6, of the REACH Regulation. In their answers to the written questions put by the Court, and at the hearing, the appellants also submitted that the use of the word 'utilisation' in the French version of the REACH Regulation confirms their argument that a risk assessment is necessary at the identification stage provided for in Article 57(f) of that regulation.

58. It is appropriate to reject at the outset the appellants' argument based on the reference to the word 'utilisation' in the French version of Article 57(f) of the REACH Regulation. As the Commission has emphasised, none of the other language versions of that article contains that word and it reflects an 'unfortunate mistake' in the French version. In any event, it has consistently been held that the need for a uniform interpretation of EU law makes it impossible for the text of a provision to be considered, in case of doubt, in isolation but requires that it be interpreted and applied in the light of the versions existing in the other official languages. [12]

11 — Annex XIII lists the criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances.

12 — See, in particular, judgments of 2 April 1998, *EMU Tabac and Others* (C-296/95, EU:C:1998:152, paragraph 36), and of 11 June 2015, *Pfeifer & Langen* (C-51/14, EU:C:2015:380, paragraph 34).

59. In fact, it is clear from those versions [13] that the 'equivalent level of concern' referred to in Article 57(f) of the REACH Regulation relates to the substances listed in points (a) to (e) of that article as such and not to their use.

60. That said, it is true that the identification of the CMR substances as substances of very high concern is based solely on the class of hazard as defined in Regulation No 1272/2008 and that the identification of the PBT and vPvB substances is based solely on the criteria set out in Annex XIII to the REACH Regulation.

61. It is equally true that inclusion in a particular hazard class under Regulation No 1272/2008 is not an essential condition in order for specific substances to fall within the scope of Article 57(f) of the REACH Regulation. [14] Although, in the present case, HHPA and MHHPA do indeed come within the hazard class relating to respiratory sensitisers in Annex I to Regulation No 1272/2008, endocrine disruptors do not thus far come within any hazard class even though they are mentioned in the list of substances in Article 57(f) of the REACH Regulation as substances that may be identified as substances of very high concern.

62. In order for a substance to be classified as being of very high concern, Article 57(f) of the REACH Regulation requires that two conditions be fulfilled: there must be 'scientific evidence of probable serious effects to human health or the environment' and those effects must give rise to 'an equivalent level of concern' to those of other substances listed in points (a) to (e) of that article.

63. As the ECHA and the Commission have acknowledged, in a case where, as here, substances do indeed come within a hazard class under Annex I to Regulation No 1272/2008, that classification is a first stage, which is taken into consideration for the purposes of determining whether the first condition set out in the preceding point of this Opinion is satisfied. However, that classification it is not sufficient for the substances in question to be regarded as substances of very high concern within the meaning of Article 57(f) of the REACH Regulation.

64. That does not mean, however, that scientific proof that the substances in question give rise to serious effects for health or the environment *requires* that a risk assessment be carried out in the case of those substances. Of course, as stated in Sections 1 to 4 of Annex I to the REACH Regulation, historical data relating to human exposure to the substances may be taken into consideration for the purposes of assessing the hazards linked with the properties of those substances. Neither the ECHA nor the Commission disputes that. Nor did the General Court state the contrary. In fact, as regards respiratory sensitisers used in industry, those data and their analysis enable the level of the intrinsically hazardous nature of those substances to be better identified and make it possible to verify, on a case-by-case basis, whether those substances give rise to serious effects for human health.

65. However, that examination is not equivalent to an exposure assessment or to a risk assessment either; nor, a fortiori, does it mean that the risk management measures are to be taken into account, as the General Court correctly held in the judgments under appeal.

66. In other words, the reference to the 'serious effects' to which the substances in question give rise does not mean that a risk assessment has to be carried out. The 'serious effects' refer to the level or degree of hazard linked with the properties of the substances. Thus, according to Section 1 of Annex I to the REACH Regulation, the human health hazard assessment is to consider not only the toxicokinetic profile (that is to say, absorption, metabolism, distribution and elimination) of the

13 — See, in particular, the Spanish ('… que suscitan un grado di preocupación equivalente al que suscitan otras sustancias enumeradas en las letras a) a e) …'), German ('… die ebenso besorgniserregend sind wie diejenigen anderer in den Buchstaben a bis e aufgeführter Stoffe …'), English ('which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e)'), Italian ('… che danno adito ad un livello di preoccupazione a quella suscitata dalle altre sostanze di cui alle lettere da a) a e) …') and Finnish ('… jotka antavat aihetta samantasoiseen huoleen kuin muiden a-e alakohdassa lueteltujen aineiden vaikutukset …') language versions.

14 — See also Section 1.3.1 of Annex I to the REACH Regulation.

substance being examined but also the 'groups of effects' listed, including sensitisation, without any requirement that the conditions of use of the substance being examined be taken into account. Recital 115 of the REACH Regulation also confirms that the concept of 'effects' refers to the properties of the substances and that the determination of those effects does not include a risk assessment. [15]

67. However, according to Article 57(f) of the REACH Regulation, the condition relating to the serious effects to which the substances in question give rise is not sufficient for the substances in question to be identified as substances of very high concern. There must also be scientific evidence that those serious effects give rise to an equivalent level of concern to those of other substances listed in Article 57(a) to (e) of the REACH Regulation.

68. In referring to an 'equivalent level of concern' to those of the substances listed in points (a) to (e) of Article 57 of the REACH Regulation, that is to say, to a level of concern based exclusively on the hazards linked with the intrinsic properties of those substances, Article 57(f) of the REACH Regulation requires a comparison of the hazard levels linked with the properties of the substances and not of the risk levels. Thus, as is apparent from the support documents adopted on 13 December 2012, the ECHA developed a number of criteria on the basis of which it may be determined, by reference to the hazardous nature of the substances examined, whether they may be regarded as giving rise to an 'equivalent level of concern' to those of the CMR substances. [16] Those criteria and their assessment are not the subject of these appeals.

69. The literal interpretation of Article 57(f) of the REACH Regulation defended here is borne out by a number of other provisions of that regulation.

70. Thus, Article 58(1)(b) of the REACH Regulation states that the decision to include substances in Annex XIV is to specify, in particular, 'the intrinsic property (properties) of the substance referred to in Article 57', and makes no distinction between points (a) to (f) of Article 57. The first column of Annex XIV to that regulation confirms that the information requested consists solely in an indication of the 'intrinsic property(ies) referred to in Article 57', therefore including the substances coming under point (f) of that article.

71. In addition, Annex XV to the REACH Regulation states, as regards the dossier relating in particular to the identification of a substance of equivalent concern in accordance with Article 59 of that regulation, that it is necessary to carry out 'an *assessment of the hazards* and a comparison [of the available information concerning that substance] with Article 57(f), according to the relevant parts of Sections 1 to 4 of Annex I'. [17]

15 — Recital 115 of the REACH Regulation states that 'resources should be focused on substances of the highest concern. A substance should therefore be added … if it meets the criteria for classification as [CMR], as a respiratory sensitiser, or in respect of other effects on a case-by-case basis'.

16 — It should be observed, in that respect, that the ECHA Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern sets out the scientific and technical elements that may be used in order to demonstrate that a substance raises concerns equivalent to CMR substances. In accordance with that guide, the 'concerns for substances which exhibit carcinogenicity, mutagenicity and reproductive toxicity arise from a number of factors — the seriousness of the effects, the often irreversible nature of the effects, the consequences for society and the difficulty in performing concentration-based risk assessments — should be taken into account when considering whether a substance shows an equivalent level of concern to CMR (category 1 or 2) substances'. Also, as the ECHA states in its replies to the questions put by the Court, these factors are linked to the assessment of the hazards as provided for in Sections 1 to 4 of Annex I to the REACH Regulation.

17 — Emphasis added.

72. In addition, Article 56(5), Article 60(2) and Article 62(d) of the REACH Regulation refer to the identification of the substances referred to in Article 57(f) of that regulation according solely to the 'hazards which those substances represent or their 'intrinsic properties', without ever mentioning a risk assessment or, a fortiori, indicating that risk management measures should be taken into account. [18]

73. The interpretation according to which only the examination of the hazardous nature of the substances is required under Article 57(f) of the REACH Regulation is also supported by the general structure of the authorisation system introduced by Title VII of that regulation.

74. In fact, as stated in point 51 of this Opinion, the authorisation system consists of three stages, namely the identification of the substances of very high concern and the inclusion of those substances in the list of candidate substances for eventual inclusion on the list of substances subject to authorisation (Articles 57 and 59 of the REACH Regulation), inclusion on the list of substances subject to authorisation (Article 58 of the REACH Regulation) and the granting of the authorisations requested (Articles 60 to 64 of the REACH Regulation).

75. It is clear from that system that a risk assessment is required only at the stage of the granting of the authorisations.

76. According to Article 60(2) of the REACH Regulation, an authorisation is to be granted if the *risk* to human health or the environment from the *use* of a substance arising from its intrinsic properties, specified in Annex XIV, is adequately controlled as shown by the risk assessment provided for in Section 6 of Annex I to the REACH Regulation.

77. Furthermore, in cases where an authorisation cannot be granted under Article 60(2) of the REACH Regulation, or for substances for which it is not possible to determine the maximum level of exposure to a substance to which humans can be exposed (DNEL), as is the case for HHPA and MHHPA, Article 60(4) of that regulation provides that authorisation may be granted only if it is shown that socio-economic benefits outweigh *the risk to human health or the environment arising from the use* of the substance and if there are not suitable alternative substances. That decision must take into account, in particular, the *risk* posed by uses of the substance and the appropriateness and effectiveness of the *risk management* measures proposed.

78. Last, to subscribe to the interpretation defended by the appellants, according to which a risk assessment, consisting of risk management measures, must be taken into account at the stage to the identification of a substance, would have the consequence of removing a large number of potentially highly hazardous substances from all stages of the authorisation procedure laid down in the REACH Regulation. In particular, if risk management measures were taken into account at the stage of the identification of substances for which authorisation may be granted only if it were shown that there are no appropriate alternative substances, [19] as is the case here, the industry would be allowed to avoid any need to ascertain whether such alternative substances actually exist. That consequence would run counter to one of the main objectives of the REACH Regulation, which is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances where suitable alternatives are available. [20]

18 — This argument is also supported by the fact that, unlike the dossier for the identification of a substance giving rise to an equivalent level of concern, the dossier for a restrictions proposal must, according to Annex XV, contain both an assessment of the hazards and an assessment of the risks of the substance concerned.

19 — In accordance with Article 60(4) of the REACH Regulation.

20 — See recital 12 and Article 55 of the REACH Regulation.

79. In the light of those considerations, I consider that the General Court did not err in law in holding that the identification of substances as substances of very high concern, provided for in Article 57(f) of the REACH Regulation, did not require that a risk assessment be taken into account.

2. Second part, alleging a contradiction in the reasoning between paragraphs 71 and 73 of the judgments under appeal

(a) Summary of the parties' arguments

80. The appellants maintain that paragraphs 71 and 73 of the judgments under appeal are vitiated by a contradiction in the reasoning. Whereas, in paragraph 71 of the judgments under appeal, the General Court confirmed that, in order to be identified as a substance of very high concern pursuant to Article 57(f) of the REACH Regulation, a substance is not required to be the subject of a risk assessment, it stated the contrary in paragraph 73 of those judgments.

81. The ECHA and the Commission propose that this part of the plea should be rejected. They contend that the appellants' interpretation of paragraph 73 of the judgments under appeal is incorrect. In particular, the ECHA and the Commission claim that the ECHA Guidance does not require a risk assessment, but requires that it be determined whether a normal risk assessment makes it possible to act adequately against the risk. A normal risk assessment cannot be carried out for substances for which, as in this case, it is not possible to define a DNEL, that is to say, the maximum level of exposure to which humans may be exposed without serious effects being produced.

(b) Assessment

82. Primarily, I consider that the second part of the first plea must be rejected as ineffective. Since, as was examined above, the General Court's interpretation of Article 57(f) of the REACH Regulation in paragraph 71 of the judgments under appeal is to my mind well founded, the fact that it stated the contrary in paragraph 73 of those judgments has no consequence for the operative part of those judgments and cannot therefore entail their annulment. [21]

83. If the Court should nonetheless consider that the part of the plea alleging a contradiction in the reasoning must be examined, I consider, in any event, that it must be rejected.

84. It should be borne in mind, above all, that in paragraph 73 of the judgments under appeal, the General Court stated that, 'as regards the fact that section 6.3 of the support document, which refers to the [ECHA] guidance for the identification of substances of very high concern in this connection, mentions a normal risk assessment, it should be pointed out that, according to that section, whether it is possible to prevent the effects of a substance within the framework of a normal risk assessment is but one of the considerations that ought to be taken into account by the ECHA in the context of the procedure for the identification of a substance as being of very high concern under Article 57(f) of [the REACH Regulation] …'.

85. Section 6.3 of each of the two relevant support documents, to which the General Court refers, reproduces word for word Section 3.3.3.2 of the ECHA Guidance on the preparation of an Annex XV dossier for the identification of substances of very high concern ('the ECHA Guidance').

21 — See, to that effect, orders of 26 January 2007, *Righini* v *Commission* (C-57/06 P, EU:C:2007:65, paragraphs 62 and 63), and of 13 March 2007, *Arizona Chemical and Others* v *Commission* (C-150/06 P, not published, EU:C:2007:164, paragraph 47 and the case-law cited).

86. Section 3.3.3.2 of the ECHA Guidance, which sets out the circumstances that the ECHA must take into account, in particular, when it examines a substance under Article 57(f) of the REACH Regulation, does not require that a risk assessment be carried out, but requires that it be determined *whether a normal risk assessment makes it possible to take adequate action against the risk*.

87. In that respect, it should be made clear that the normal risk assessment referred to by the ECHA Guidance and by the General Court in paragraph 73 of the judgments under appeal corresponds to the risk assessment as laid down in Section 6.4 of Annex I to the REACH Regulation, which is based on a comparison between the estimated exposure level and the appropriate DNEL (the maximum exposure level to which humans can be exposed without such exposure having harmful effects).

88. As I have already emphasised in points 38 and 39 of this Opinion, a normal risk assessment cannot be carried out for substances for which a DNEL cannot be defined, which is the case for HHPA and MHHPA.

89. Thus, it is quite apparent that the object of paragraph 73 of the judgments under appeal was solely to recall the conclusion of the ECHA Member State Committee, contained in the respective support documents, that a normal risk assessment was not adequate for HHPA and MHHPA, and not to require that the ECHA take a risk assessment into account at the stage of identifying a substance under Article 57(f) of the REACH Regulation.

90. In such circumstances, it cannot be concluded, contrary to the appellants' contention, that the General Court intended, in paragraph 73 of the judgments under appeal, to assert that the ECHA was required to take a risk assessment into account in order to determine whether a substance may be identified as being of very high concern pursuant to Article 57(f) of the REACH Regulation. It follows, in my view, that paragraphs 71 and 73 of the judgments under appeal are not contradictory.

91. Accordingly, if it is not ineffective, the second part of the first plea is in my view unfounded.

92. I therefore propose that the Court reject the first ground of appeal.

B – *Second ground of appeal, alleging inconsistent reasoning and errors of law leading to an error in the interpretation and application of Article 57(f) of the REACH Regulation*

1. Summary of the parties' arguments

93. The appellants point out that, in paragraph 49 of the judgments under appeal, the General Court stated that the guides to interpretation, such as the ECHA Guidance, did not constitute legal advice. In the appellants' submission, however, it is clear from the case-law that such rules of general conduct are not without legal effect, since by those instruments the institutions which adopt them impose a limit on the exercise of their discretion.[22] Quite apart from the contradiction between the reasoning set out in paragraph 49 and in paragraph 73 of the judgments under appeal, the General Court departed from that consistent case-law.

94. The appellants maintain that, in failing to take the ECHA Guidance into consideration when interpreting Article 57(f) of the REACH Regulation, the General Court did not properly take the risk assessment into account. Consequently, in applying the reasoning set out in paragraphs 65 to 91 of the judgments under appeal, the General Court misinterpreted and misapplied Article 57(f) of the REACH Regulation.

22 — The appellants refer in that regard to the judgment of 28 June 2005, *Dansk Rørindustri and Others* v *Commission* (C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraphs 209 to 212).

95. The ECHA and the Commission contend that this ground of appeal is based on a misreading of paragraphs 49 and 73 of the judgments under appeal and propose that it be rejected.

2. Assessment

96. I consider that this ground of appeal is based on a misreading of the import of paragraph 49 of the judgments under appeal.

97. In order to fully understand the General Court's assessment, it is necessary to bear in mind that, in paragraphs 45 to 48 of the judgments under appeal, the General Court rejected the first part of the first plea raised before it, whereby the appellants claimed that respiratory sensitisers did not come within Article 57(f) of the REACH Regulation. As I have already stated in point 55 of this Opinion, the appellants do not dispute, in the appeal, the assessment set out in paragraphs 45 to 48 of the judgments under appeal.

98. In paragraph 49 of those judgments, which is introduced by the word 'moreover', the General Court also rejected the appellants' argument, still in support of the first part of the first plea put forward at first instance, that the ECHA Guidance confirmed that Article 57(f) of the REACH Regulation did not apply to respiratory sensitisers. The General Court rejected that argument on the ground that 'that document constitutes a working tool produced by the ECHA *in order to facilitate the implementation* of [the REACH Regulation]. As the guidance correctly states, the text of [the REACH Regulation] is the only authentic legal reference and the information contained in that guidance does not constitute legal advice'. [23]

99. The assessment set out in paragraph 49 of the judgments under appeal was therefore made for the sake of completeness. It follows, in my view, that the criticism directed against paragraph 49 may be regarded as ineffective. [24]

100. Nonetheless, the appellants also take issue with the General Court for having failed to take the ECHA Guidance into consideration when examining the second part of the first plea put forward at first instance, alleging the absence of a level of concern equivalent to those of the CMR substances.

101. As the appellants themselves note, however, the General Court did indeed take that document into account in paragraph 73 of the judgments under appeal, which forms part of the General Court's response to the second part of the first plea raised before it. The fact that the General Court did not support the interpretation of that guidance defended by the appellants is another matter, which, moreover, I have already addressed when examining the first ground of appeal.

102. Contrary to the appellants' contention, the fact that the General Court took the ECHA Guidance into account in paragraph 73 of the judgments under appeal does not contradict the assessment made in paragraph 49 of those judgments. To my mind, it is quite correct to refuse to take that guidance into consideration for the purpose of *interpreting* Article 57(f) of the REACH Regulation, just as it is entirely proper, as the General Court did in paragraph 73 of the judgments under appeal, to take that guidance into account when reviewing the way in which the provisions of the REACH Regulation are *applied* to specific substances, in particular for the purpose of ascertaining whether those substances have an 'equivalent level of concern' to those of the CMR substances.

23 — Emphasis added.

24 — According to settled case-law, complaints directed against grounds included purely for the sake of completeness are considered ineffective: see, in particular, judgment of 13 February 2014, *Hungary* v *Commission* (C-31/13 P, EU:C:2014:70, paragraph 82).

103. Accordingly, there is in my view no need to examine the complaint relating to the binding or non-binding nature of the ECHA Guidance, since the General Court did not make a general determination of that question. In fact, paragraph 49 of the judgments under appeal does not have the general application which the appellants ascribe to it, in that the General Court solely (and correctly) determined in that paragraph of those judgments that the Courts of the European Union were not bound by the interpretation of Article 57(f) of the REACH Regulation set out in the ECHA Guidance. In other words, the General Court (correctly) did not rely on the reasoning set out in paragraph 49 of the judgments under appeal to find that the risk assessment was not required for the purposes of identifying a substance as being of very high concern pursuant to Article 57(f) of the REACH Regulation.

104. Consequently, I suggest that the second ground of appeal be rejected as ineffective in part and unfounded in part.

C – *Third ground of appeal, alleging a flaw in reasoning, in that the General Court incorrectly relied on Article 60(2) of the REACH Regulation*

1. Summary of the parties' arguments

105. The appellants take issue with the General Court, in essence, for having relied, in paragraphs 61 and 68 of the judgments under appeal, on Article 60(2) of the REACH Regulation to confirm its view that a risk assessment is not required in the context of the identification of a substance pursuant to Article 57(f) of that regulation. In the appellants' submission, the General Court itself acknowledged, in paragraph 73 of the judgments under appeal, that Article 60(2) of the REACH Regulation does not apply to HHPA and MHHPA. Furthermore, although the appellants acknowledge that there may be a link between the substance identification procedure and the authorisation procedure, the fact that authorisation may be granted does not inform the decision whether or not to identify a substance as being of very high concern.

106. The ECHA and the Commission contend that the appellants have misread the relevant paragraphs of the judgments under appeal. In particular, the ECHA claims that, far from having erred in referring to Article 60(2) of the REACH Regulation, the General Court correctly used that provision in order to illustrate the fact that if substances the uses of which can be controlled could not be identified as being of very high concern and placed in Annex XIV, Article 60(2) of the REACH Regulation would be deprived of any meaning.

2. Assessment

107. It is common ground that, in paragraph 61 of the judgments under appeal, the General Court held that 'it is apparent from Article 60(2) of [the REACH Regulation] that the fact that the negative effects associated with the use of a substance can be controlled adequately does not preclude its identification as a substance of very high concern. If this were not so, the possibility, pursuant to the provision in question, of authorising a substance the risks of which can be adequately controlled, would be rendered meaningless, as the ECHA states'.

108. In paragraph 68 of the judgments under appeal, the General Court confirmed that assessment.

109. It follows from the judgments under appeal that that assessment was carried out with the aim of explaining the structure of the authorisation procedure, including the first stage, which, as already stated, consists in identifying the substances of very high concern, in particular pursuant to Article 57(f) of the REACH Regulation.

110. While it is true that Article 60(2) of the REACH Regulation does not apply to substances for which a DNEL cannot be determined, which is the case for HHPA and MHHPA, paragraphs 61 and 68 of the judgments under appeal do not refer specifically to the substances at issue, but are intended to explain, in general terms, the interaction between the first stage, which consists in identifying the substances, and the third stage, concerning the granting of authorisations. It is therefore quite correct, irrespective of whether Article 60(2) of the REACH Regulation does in fact apply to the substances at issue in the present case, to assert, as the General Court did, that the adoption of risk management measures does not preclude the identification of a substance as a substance of very high concern, in application of Article 57(f) of the REACH Regulation. It is possible, moreover, to my mind, to be more categorical and to assert that the stage consisting in identifying those substances is an essential precondition of the stage consisting in checking and assessing the risks posed by those substances.

111. In addition, contrary to the appellants' suggestion, the fact that it is not possible to determine a DNEL for a particular substance does not mean that it is necessary to carry out a risk assessment or that risk management measures must be taken into consideration before or at the time of the identification of that substance pursuant to Article 57(f) of the REACH Regulation.

112. I therefore propose that the appellants' third ground of appeal should be rejected as unfounded.

D – *Fourth ground of appeal, alleging errors of law in the assessment of the arguments relating to the lack of consumer or worker exposure to HHPA and MHHPA, leading to an incorrect application of Article 57(f) of the REACH Regulation*

1. Summary of the parties' arguments

113. The appellants point out that, in paragraph 67 of the judgments under appeal, the General Court rejected their arguments, relating to the absence of risk arising from HHPA and MHHPA owing to the low degree of workers' and consumers' exposure to those substances, stating that any exposure to HHPA and MHHPA cannot be excluded for consumers and workers. In the appellants' submission, that analysis departs from the settled case-law that 'zero risk' does not exist in the context of a risk assessment which applies the precautionary principle.[25] The General Court therefore relied on an incorrect legal test in order to reject their arguments relating to the absence of consumer or worker exposure to HHPA and MHHPA.

114. According to the ECHA, the General Court did not mention a 'zero risk'. Nor do the judgments under appeal suggest that the appellants were required to prove that there was zero risk.

115. The Commission contends, in particular, that the assessment of worker and consumer exposure is part of the risk assessment. Since such an assessment is not required at the stage of the identification of a substance as a substance of very high concern, a lack of exposure by consumers or workers is also irrelevant for the purposes of that identification.

25 — The appellants refer in that regard to the judgment of 11 September 2002, *Pfizer Animal Health* v *Council* (T-13/99, EU:T:2002:209, paragraph 145).

2. Assessment

116. It should be borne in mind that, before the General Court, the appellants claimed, in particular, that, in accordance with the programmes for the monitoring of products and the applicable legal requirements, HHPA and MHHPA are used in closed systems which prevent exposure and ensure a very limited to near zero risk of exposure.[26]

117. In paragraph 67 of the judgments under appeal, the General Court rejected that argument, pointing out, in the first place, that 'even according to the [appellants'] arguments, it is not possible completely to exclude consumers' and workers' exposure' to HHPA and MHHPA'.

118. It is apparent from paragraph 68 of the judgments under appeal and from paragraphs 69 to 73 of those judgments that the General Court, in the second place, rejected the taking into account of the risk management measures invoked by the appellants on the basis of arguments which I have examined in the context of the first and third grounds of appeal and which I propose should also be rejected. In fact, paragraph 68 of the judgments under appeal is introduced by the expression 'even if all users of [HHPA and MHHPA] do implement effective risk management', which means, by implication but necessarily, that the assessments carried out in paragraph 67 of the judgments under appeal are 'absorbed' or, in other words, have become ancillary to those carried out in paragraphs 68 to 73 of those judgments.

119. Consequently, in taking issue with paragraph 67 of the judgments under appeal, the appellants are putting forward a ground of appeal against a subsidiary assessment of the General Court. Such criticisms are ineffective, since even if they were well founded, they would have no effect on the operative parts of the judgments under appeal and could therefore not entail their annulment.

120. In any event, the General Court did not require the appellants to demonstrate a 'zero risk', since the risk assessment and the taking into consideration of risk management measures are not required in the identification of substances, in application of Article 57(f) of the REACH Regulation, as the General Court correctly held, in essence, in paragraphs 68 to 73 of the judgments under appeal.

121. Accordingly, I suggest that the fourth ground of appeal should be rejected.

122. For all of the foregoing considerations, I propose that the appeals should be dismissed.

VII – Costs

123. Under Article 184(2) of the Rules of Procedure of the Court of Justice, where the appeal is unfounded, the Court is to make a decision as to costs.

124. Under Article 138(1) of those rules, which is to apply to the procedure on appeal by virtue of Article 184(1) of those rules, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

125. As the ECHA has claimed that the appellants should be ordered to pay the costs in both cases, the appellants should be ordered, in addition to bearing their own costs, to pay the costs incurred by the ECHA.

26 — See the summary of their arguments in paragraph 65 of the judgments under appeal.

126. Under Article 140(1) of the Rules of Procedure, the Member States and the institutions which have intervened in the case are to bear their own costs. Under Article 140(3) of the Rules of Procedure, the Court may order an intervener other than those referred to in Article 140(1) of those rules to bear his own costs.

127. The Commission and the Kingdom of the Netherlands, which have intervened in the proceedings, must bear their own costs. I also propose that New Japan Chemical, REACh ChemAdvice GmbH and Sitre, which have intervened in support of the appellants in the proceedings before the Court of Justice, should bear their own costs.

VIII – Conclusion

128. In the light of the foregoing considerations, I propose that the Court should:

— dismiss the appeals;

— order Polynt SpA, in Case C-323/15 P, and Hitachi Chemical Europe GmbH and Polynt SpA, in Case C-324/15 P, to pay the costs;

— order the European Commission, the Kingdom of the Netherlands, New Japan Chemical, REACh ChemAdvice GmbH and Sitre Srl to bear their own costs.