OPINION OF ADVOCATE GENERAL
KOKOTT
delivered on 12 February 2015 (1)

Case C-106/14

Fédération des entreprises du commerce et de la distribution (FCD)
and
Fédération des magasins de bricolage et de l'aménagement de la maison (FMB)
v
Ministre de l'écologie, du développement durable et de l'énergie

(Request for a preliminary ruling from the Conseil d'État (France))

(Regulation (EC) No 1907/2006 (REACH Regulation) — Registration, evaluation, authorisation and restriction of chemicals (REACH) — Concept of 'article' — Article which is composed of several articles — Duties to provide information in connection with the use of substances of very high concern — Determination of concentration — Production, import and supply)

I – Introduction

1. Where an article contains more than 0.1% of a substance of very high concern, the REACH Regulation (2) lays down certain duties to provide information to the European Chemicals Agency (ECHA) and to recipients and consumers of the article.

2. Various Member States and the European Commission disagree on how that concentration threshold is calculated where an article consists of several components which are themselves articles. In particular, the Commission, supported by the majority of the Member States, takes the view that the proportion of the substance of high concern should be calculated by reference to the assembled article. Some Member States — the majority of the parties to the present proceedings — contend that it is sufficient if the proportion is reached in the individual components. In that case the duties to provide information would arise much more frequently.

3. This dispute is obviously of considerable importance for the free movement of articles as it may result in articles being subject to different requirements in different Member States. It must therefore be settled by the Court.

II – Legislative framework

A – *EU law*

1. The REACH Regulation

4. The following recitals in the preamble to the REACH Regulation should be highlighted:

‘(1) This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation. This Regulation should also promote the development of alternative methods for the assessment of hazards of substances.

…

(3) A high level of human health and environmental protection should be ensured in the approximation of legislation on substances, with the goal of achieving sustainable development. That legislation should be applied in a non-discriminatory manner whether substances are traded on the internal market or internationally in accordance with the Community’s international commitments.

…

(29) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on substances which are intended to be released from articles and have not been registered for that use. In the case of substances of very high concern which are present in articles above tonnage and concentration thresholds, where exposure to the substance cannot be excluded and where the substance has not been registered by any person for this use, the Agency should be notified. The Agency should also be empowered to request that a registration be submitted if it has grounds for suspecting that the release of a substance from the article may present a risk to human health or the environment and the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year. The Agency should consider the need for a proposal for a restriction where it considers that the use of such substances in articles poses a risk to human health or the environment that is not adequately controlled.

…

(56) Part of the responsibility of manufacturers or importers for the management of the risks of substances is the communication of information on these substances to other professionals such as downstream users or distributors. In addition, producers or importers of articles should supply information on the safe use of articles to industrial and professional users, and consumers on request. This important responsibility should also apply throughout the supply chain to enable all actors to meet their responsibility in relation to management of risks arising from the use of substances.

…

(117) EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. …

…’

5. Article 1 of the REACH Regulation defines its aims and its scope:

‘1. The purpose of this Regulation is 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.

…

3. This 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. Its provisions are underpinned by the precautionary principle.’

6. Article 2(2) of the REACH Regulation contains a provision governing when an article is no longer regarded as such:

‘Waste … is not a substance, preparation or article within the meaning of Article 3 of this Regulation.’

7. Article 3 of the REACH Regulation defines various terms which are relevant to the present case:

‘3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

4. producer of an article: means any natural or legal person who makes or assembles an article within the Community;

…

11. importer: means any natural or legal person established within the Community who is responsible for import;

12. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. …

…

33. supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;

…’

8. Article 7 of the REACH Regulation lays down certain duties to provide information to ECHA in relation to articles:

‘2. Any producer or importer of articles shall notify the Agency …, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or

importer per year;

(b) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w).

3. Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

…

5. The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

(b) the Agency has grounds for suspecting that:

(i) the substance is released from the articles, and

(ii) the release of the substance from the articles presents a risk to human health or the environment;

(c) the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6. Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

…’

9. Article 33 of the REACH Regulation clarifies the duties to provide information to recipients and consumers in connection with articles:

‘1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0.1% weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

The relevant information shall be provided, free of charge, within 45 days of receipt of the request.’

10. The aims of the rules on substances of very high concern are laid down in Article 55 of the REACH Regulation:

‘The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.’

11. Substances of very high concern are defined in Article 57 of the REACH Regulation:

‘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.’

12. Article 59 of the REACH Regulation lays down the procedure under which ECHA can place substances having the characteristics referred to in Article 57 on the ‘candidate list’ for introduction of an authorisation requirement.

2. The European Chemicals Agency Guidance

13. The point at issue is addressed in the ECHA ‘Guidance on requirements for substances in articles (Version 2) of 1 April 2011’. (3) In section 4.4. it states that the concentration of substances of very high concern in assembled articles is to be determined by reference to the entire article:

‘A SVHC on the candidate list may be contained in different concentrations in different components of the same article, e.g. one concentration in the chassis of a laptop and another concentration in the transformer. For obligations according to Article 7(2) and 33 to apply, the concentration of this SVHC has to exceed 0.1% (w/w) in the entire article …’

B – *French law*

14. The main proceedings concern the validity of the 'Notice to economic operators on the duty to communicate information on substances contained in articles in accordance with Articles 7(2) and 33 of Regulation No 1907/2006 (REACH) — Interpretation of the 0.1% (weight by weight) threshold cited in Articles 7(2) and 33', adopted by the French Ministre de l'écologie, du développement durable, des transports et du logement (Minister for Ecology, Sustainable Development, Transport and Housing) on 8 June 2011 ('the Ministerial Notice').

15. According to the referring court, that Notice states:

'With reference to the publication on 1 April 2011 on the website of the European Chemicals Agency … of the revised guidance concerning the application of the REACH Regulation to substances present in articles and more precisely to the executive director's note attached to that guidance which indicates that it did not find full support among all the Member States of the European Union/European Economic Area, by means of this Notice the French authorities inform economic operators of the interpretation adopted in France for the purpose of the application of Articles 7(2) and 33 of the REACH Regulation. They state that the concept of "article" is to be understood as any object meeting the definition of "article" as provided for in REACH, that is to say, any object "which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition" (Article 3(3)). Thus, an article may be composed of one or more objects which meet the definition of "article", and the provisions laid down in Articles 7(2) and 33 are therefore to apply to each of them.'

III – The main proceedings and the request for a preliminary ruling

16. In the main proceedings two French federations of trading companies are contesting the Ministerial Notice. The French Council of State (Conseil d'État), which is hearing the case, refers the following question to the Court:

Where an 'article' within the meaning of the REACH Regulation is composed of several elements which themselves meet the definition of 'article' in the regulation, are the obligations resulting from Article 7(2) and Article 33 of the regulation to apply only with regard to the assembled article or with regard to each of the elements which meet the definition of 'article'?

17. The Fédération des entreprises du commerce et de la distribution (Federation of Commerce and Distribution Undertakings) together with the Fédération des magasins de bricolage et de l'aménagement de la maison (Federation of DIY and Home Improvement Stores) (FCD and FMB), the French Republic, the Kingdom of Belgium, the Kingdom of Denmark, the Federal Republic of Germany, Ireland, the Hellenic Republic, the Republic of Austria, the Kingdom of Sweden, the Kingdom of Norway and the European Commission submitted written observations. Apart from Greece and Austria, they also took part in the hearing on 8 January 2015.

IV – Legal assessment

18. In order to gain a better understanding of the request for a preliminary ruling, the question referred must first be placed in the regulatory context of the REACH Regulation (see section A). It is then necessary to consider the concept of 'article' (see section B) and the duties of producers and importers to notify ECHA under Article 7(2) (see section C, 1 and 2) and the duties of suppliers to provide information to recipients and consumers under Article 33 (see section C, 3).

A – *The normative context of the question referred*

19. The question relates to the provisions of the REACH Regulation on ‘substances of very high concern’, whose properties are defined in Article 57. Under that provision, such substances are a hazard to health because they are carcinogenic, mutagenic or toxic to reproduction (Article 57(a) to (c)). They can also harm the environment because they are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative (Article 57(d) and (e)). In specific cases equivalent properties are also sufficient (Article 57(f)).

20. Such substances may, by a Commission decision based on a comitology procedure, be included in Annex XIV to the REACH Regulation, which, following the most recent amendment, (4) covers 31 substances. (5) Under Article 56, the use of substances included in that annex generally requires an authorisation issued by the Commission pursuant to Articles 60 to 64.

21. However, the provisions at issue concern substances on a ‘candidate list’ for inclusion in the annex. ECHA can identify such substances using a procedure laid down in Article 59 if they have the properties of substances of very high concern. From the substances on the candidate list, substances are selected whose inclusion in Annex XIV is to be examined more closely. Furthermore, in response to an enquiry at the hearing, it was common ground between the parties that after inclusion in Annex XIV these candidate substances remain on the candidate list.

22. The candidate list most recently contained 155 substances. (6) There may be other substances having those properties, (7) but as long as they are not included on the candidate list, they are not affected by the question under consideration. (8)

23. Under Article 7(2) of the REACH Regulation, any producer or importer of articles must notify ECHA where a substance on the candidate list is present in those articles in quantities totalling over one tonne per producer or importer per year and above a concentration of 0.1% weight by weight (w/w).

24. Furthermore, Article 33(1) of the REACH Regulation provides that any supplier of an article containing a candidate substance in a concentration above 0.1% weight by weight (w/w) must provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance. Under Article 33(2), the supplier must provide consumers with the same information on their request.

25. The request for a preliminary ruling concerns the application of the concentration threshold of 0.1% weight by weight (w/w) in the article. It must be clarified whether, in the case of articles which are themselves composed of articles, that threshold should be applied by reference to the entire article or to each of the component articles.

26. Several Member States illustrate this using the example of a bicycle whose plastic handlebars contain plasticisers that are on the candidate list for substances of very high concern. The threshold might possibly be reached for the handlebars as such, but presumably not for the bicycle as a whole. Other examples put forward are seats whose covers contain candidate substances or whole aircraft in which such seats are installed.

B – *The concept of ‘article’ under Article 3(3) of the REACH Regulation*

27. Most of the Member States participating in these proceedings rely on the definition in Article 3(3) of the REACH Regulation. Under that provision, an ‘article’ is an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.

28. Contrary to the suggestion made by Ireland, the function does not have to be autonomous, that is to say, belong to the object irrespective of other objects. There is absolutely no indication of this in the wording and the scope of the concept of 'article' would be restricted far too much, as the function of many objects can be realised only in combination with other objects, substances or mixtures. In addition to the abovementioned handlebars and seat covers, mention could be made of screws, for example. Nevertheless, such objects too are placed on the market so that others are able to use them to manufacture more complex articles, for example to manufacture bicycles, seats or aircraft.

29. On the other hand, bars of lead or plastic granulate (9) are not articles but substances, that is to say chemical elements and their compounds within the meaning of Article 3(1) of the REACH Regulation. Their function is not determined primarily by their shape, surface or design, but by their chemical composition. Furthermore, under Article 3(2) there are also mixtures of different substances, for example paint or varnish.

30. It should be noted for the sake of completeness that the obligations to notify ECHA (Article 7(2) of the REACH Regulation) and to provide information to recipients and consumers (Article 33), which are to be examined in the present case, do not apply to food under Article 2(5) and (6).

31. It cannot be inferred from the definition that a component article is no longer an article once it is combined with other component articles to form an entire article.

32. As Belgium and Norway state, for example, only Article 2(2) of the REACH Regulation expressly regulates when articles are no longer to be regarded as such, namely when they become waste for the purposes of EU law.

33. Contrary to the argument put forward by Ireland, a component article also does not necessarily lose its function once it is integrated into an entire article. As has already been stated, a component article will often realise its function only by being integrated into an entire article. For example, the function of the abovementioned handlebars is to be used as components of a bicycle.

34. However, on installation a component article may also be given a different shape, surface or design which modifies its function. That is possible with textiles, for example, which might be used for different articles. This functional potential is limited considerably if, as in the Belgian example, they are made into a seat cover. Nevertheless, even a component article whose function is limited in this way generally retains an independent function that distinguishes it from other component articles used for the entire article. A seat cover has a different function from the other component articles used, such as upholstery, springs or the seat frame.

35. Only if, when an article is integrated into an entire article, it loses any shape, surface or design of its own which determines its function to a greater degree than does its chemical composition is it no longer possible to identify a component article. In practice, however, such cases are probably of minor importance. And it would always have to be considered, in relation to possible examples, whether the original objects were actually articles and not substances.

36. Consequently, where, despite being integrated into an entire article, a component article retains a shape, surface or design of its own which determines its function to a greater degree than does its chemical composition, it should still be regarded as an article. The concept of 'article' as such thus suggests that in calculating the concentration of certain substances regard should be had to the component article rather than to the entire article.

C – *The connection with the duties to provide information under Articles 7(2) and 33 of the REACH Regulation*

37. However, the definition of article applies in connection with specific obligations imposed on the producer or importer (Article 7(2) of the REACH Regulation) or the supplier of an article (Article 33).

38. The Commission takes the view that these persons do not produce, import or supply the component articles, but the entire article in question. The concentration of candidate substances should therefore also be assessed by reference to the entire article.

39. According to the French Notice at issue in the main proceedings and in the view of several other Member States, on the other hand, the threshold must be calculated for the individual component articles.

40. This difference of opinion must, however, be considered separately for producers, importers and suppliers of articles.

1. The producer of articles within the meaning of Article 7(2) of the REACH Regulation

41. The duty to notify ECHA under Article 7(2) of the REACH Regulation is imposed *first* on the producer of articles. Under Article 3(4), the producer of an article is a natural or legal person who makes or assembles an article within the European Union.

42. Where a producer makes or assembles an entire article by combining component articles, this does not mean that he has also made or assembled those component articles. In an economy based on a division of labour, it is likely that the producer of an entire article acquires the necessary components in part or wholly from other producers. This is illustrated excellently by the examples cited: bicycles, seats, aircraft and cars.

43. However, it would not be compatible with the meaning of the term ‘producer’ also to attribute to the producer of an entire article the production of the component articles used by him where they were actually made or assembled by other producers. He can only be a producer of component articles if he has made them or assembled them (from other component articles) himself.

44. Accordingly, the producer of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own, but were made or assembled by other producers, is required to notify ECHA if a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) is present in the entire article above a concentration of 0.1% weight by weight (w/w).

45. Contrary to the view taken by France and Germany, for instance, it is not necessary to require the producer nevertheless to report candidate substances in the component articles used. As other parties acknowledge, ECHA obtains that information without there being any need to call on the producer of the entire article. If they are manufactured in the European Union or imported into the Union, the duty to provide information applies to the producer or, as will be shown below, the importer of the component article.

2. The importer of articles within the meaning of Article 7(2) of the REACH Regulation

46. *Secondly*, under Article 7(2) of the REACH Regulation the importer of articles is required to

notify ECHA.

47. Under Article 3(11) of the REACH Regulation, the importer is any natural or legal person established within the European Union who is responsible for import, that is to say, for the physical introduction into the customs territory of the Union (Article 3(10)).

48. According to the wording of these definitions, the importer of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own is also the importer of the component articles. Which other natural or legal person should be responsible for the physical introduction of those component articles into the customs territory of the European Union?

49. The interpretation of the concept of 'producer' outlined above also suggests that the importer of an entire article is to be regarded as the importer of the component articles contained therein. On that interpretation, the concepts of 'producer' and 'importer' are complementary and ensure that comprehensive information is provided to ECHA. It would obtain the necessary information on the use of substances on the candidate list in component articles either from the actual producers of the component articles in the European Union or from importers, whether it be the importers of component articles or the importers of entire articles containing component articles.

50. The objections raised by the Commission, FCD and FMB, Ireland and Greece cannot be upheld, on the other hand.

a) The absence of clearer rules

51. The Commission takes the view that if the legislature had intended to impose a duty of notification on the importer in respect of component articles, it would have laid down that duty more clearly than in Article 7(2) of the REACH Regulation. This is apparent, for example, from the restrictions under point 23(5) to (7) of Annex XVII and point 61 of Annex XVII, which also provide for concentration thresholds applying expressly to articles 'or any parts' thereof. It submits that in the legislative procedure there were even various proposals for a wording to that effect, (10) and they were not adopted.

52. Denmark and Germany correctly show, however, that the parallel with Annex XVII is not compelling. Restrictions at least for cadmium under point 23 were incorporated from Directive 76/769/EEC, (11) in which the term 'article' was not used. The inclusion of components therefore required express provision to be made. The fact that, when making later additions to Annex XVII such as the restrictions for dimethylfumarate in point 61, the legislature followed this regulatory practice is of no particular importance for the interpretation of provisions of the REACH Regulation that are not directly connected with that annex.

53. It must be conceded, with regard to the references to the suggestions made in the legislative procedure, that clearer rules could have been laid down on the inclusion of component articles in Article 7(2) of the REACH Regulation. At the same time, such inclusion was not excluded. Consequently, the absence of more precise rules may also mean that the suggestions for more precise provisions were considered superfluous or that it was not possible to reach agreement on either of the two alternative interpretations. Accordingly, this argument also does not require the concept of 'importer' to be interpreted as strictly as the Commission proposes.

b) Legal certainty

54. This is also not affected by Ireland's reliance on legal certainty. Under the general principle of legal certainty, which is a fundamental principle of EU law, rules should in particular be clear and precise, so that individuals may ascertain unequivocally what their rights and obligations are and may take steps accordingly. (12)

55. However, the principle of legal certainty does not require a rule to exclude all doubt as to its interpretation. What matters is rather whether the legal measure in question displays such ambiguity as to make it difficult to resolve with sufficient certainty any doubts as to the scope or meaning of the provision. (13) That can be done, however, in the present case, and that is not called into question by Ireland.

56. On the other hand, it is not evident why, according to the principle of legal certainty, one of the two alternative interpretations of Article 7(2) of the REACH Regulation should be given preference in relation to importers.

57. I understand this argument to the effect that the difficulties in interpreting Article 7(2) of the REACH Regulation would be resolved if the ECHA Guidance had binding effect. This will be examined immediately below.

c) The ECHA Guidance

58. The French Notice at issue in the main proceedings and the view of most of the Member States that are party to the proceedings conflict with the Guidance which ECHA has published with the approval of the majority of Member States. (14) According to that Guidance, reference should be had to the concentration in the entire article.

59. Like other ECHA guidance, this document is helpful for understanding the relevant provisions, in particular in so far as it records the view shared by the Commission and the Member States. The ECHA Secretariat also has the task, under Article 77(2)(g), of providing technical and scientific guidance for the application of Article 7 by producers and importers of articles. Furthermore, Article 77(2)(k) provides for preparing explanatory information on the regulation. Nevertheless, a guide cannot give a binding interpretation of the provisions of EU law. (15)

60. Nor is this affected by the broad discretion enjoyed by the European Union authorities in the assessment of highly complex scientific and technical facts, which is underlined by Greece. That discretion is also accorded to ECHA, for example in connection with the inclusion of substances in the candidate list under Article 59 of the REACH Regulation. (16) However, the point at issue is not an assessment of facts, but the interpretation of EU law. This is reserved for the Court even in the case of complex legal matters.

61. This is also made clear by a note on the imprint page of the Guidance: 'However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice.'

62. The ECHA Guidance is not therefore binding.

d) The internal market

63. In connection with the ECHA Guidance the Commission also refers to an impairment of the internal market. This is conceivable if the Member States interpret the duty of notification under Article 7(2) of the REACH Regulation differently and some of them question the marketability of articles under Article 5 in the absence of notification.

64. Such risks to the internal market do underline the need to answer the question raised in the request for a preliminary ruling, but they are not an argument for a particular interpretation of Article 7(2) of the REACH Regulation.

e) Proportionality

65. Nevertheless, the Commission considers a duty of notification for the candidate substances present in component articles to be disproportionate.

66. The principle of proportionality is binding on the European Union under the second sentence of Article 5(1) and (4) TEU and is one of the general principles of EU law. According to that principle, measures adopted by EU institutions must not exceed the limits of what is appropriate and necessary in order to attain the legitimate objectives pursued by the legislation in question, and where there is a choice between several appropriate measures, recourse must be had to the least onerous, and the disadvantages caused must not be disproportionate to the aims pursued. (17)

67. An obligation on importers to notify ECHA of candidate substances which are present in the relevant quantities in component articles contained in imported entire articles is appropriate in order to attain the objectives of the duty of notification. Notification enables ECHA to take into consideration the relevant quantities of substances and their use in the selection to be made under Article 58(3) of the REACH Regulation of substances for which the Commission introduces an authorisation requirement. Reporting the substances also allows ECHA to demand a registration for those substances under Article 7(5) or to consider a proposal for a restriction under Article 69, as is envisaged in recital 29 in the preamble.

68. The duty of notification is also necessary in order to attain those objectives. Without reporting there would be a danger that ECHA would not be informed of the use of substantial quantities of substances of very high concern in articles — more than one tonne per importer per year.

69. In this connection, the argument put forward by the Commission and by FCD and FMB that it is not necessary to include component articles because restrictions, the authorisation requirement or protective measures by the Member States in accordance with Article 129 of the REACH Regulation would sufficiently ensure the protection of the environment and health must be rejected. Notification of ECHA is specifically intended to help to clarify the need for restrictions or an authorisation requirement. It likewise does not appear to be ruled out that protective measures by the Member States could be triggered by notification of ECHA.

70. However, the Commission's argument alleges that the disadvantages of the duty of notification in respect of component articles are disproportionate to the objectives pursued.

71. It relies in this regard upon the difficulties experienced by importers in obtaining the necessary information from their suppliers in third countries. They would often be unaware whether candidate substances are present in articles because the relevant information would not be passed along their supply chain in third countries. In some cases, the relevant information would also be treated as a trade secret.

72. FCD and FMB correspondingly emphasise the cost of investigating articles in order to ascertain the presence and the concentration of candidate substances. Examining a shoe would cost from EUR 2 200 to EUR 2 400. If, on the other hand, the component articles contained in the shoe had to be investigated, the cost would be EUR 22 800.

73. However, as Germany, for example, explains, it is unclear whether restricting the duties of notification to entire articles actually has the desired effect of easing the burden. Each entire article would still have to be investigated in order to establish the concentration of candidate substances. ECHA, supported by the majority of the Member States, proposes that the importer should first determine the concentration in all component articles contained and then calculate the concentration in the entire article from those values. (18)

74. If, however, the concentration in the component articles is to be determined in any event, it is not evident why it should entail excessive disadvantages to report that available information to ECHA. On the contrary, as some Member States submit, if the notification relates to component articles, the burden is actually smaller because the concentration does not have to be determined precisely. It is sufficient to establish whether the concentration threshold and the total quantity of one tonne per importer per year have been exceeded. Furthermore, for notification under Article 7(4)(f) of the REACH Regulation it is necessary to determine the quantitative range of the substance, such as 1 to 10 tonnes or 10 to 100 tonnes (per year).

75. The positions taken by FCD and FMB, Ireland and the Commission can only be understood if importers do not closely follow the ECHA Guidance, but rely on more or less precise estimates in order to rule out notification. During the hearing the Commission even expressly proposed such an approach, which has no basis in the ECHA Guidance, for clear cases.

76. However, the burdens entailed by a duty of notification under Article 7(2) of the REACH Regulation can be properly assessed only in their regulatory context.

77. It should be noted, first of all, that at least certain double burdens are avoided as, under Article 7(6) of the REACH Regulation, the duty of notification does not apply if the candidate substance in question has already been registered by the importer itself or by others for the relevant use. (19)

78. If there has been no registration, notification under Article 7(2)(a) of the REACH Regulation is necessary only if the substance is present in the articles concerned in quantities totalling over one tonne per importer per year. Consequently, substantial quantities of candidate substances having the properties of substances of very high concern are at issue. It must also be assumed that the importers concerned import relatively large quantities of articles with that substance or fewer articles with a relatively high concentration.

79. Furthermore, the duty of notification under Article 7(3) of the REACH Regulation does *not* apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. Under that provision, in such cases the producer or importer must supply appropriate instructions to the recipient of the article.

80. Accordingly, also if the concentration is calculated by reference to the relevant component articles, the duty of notification exists only where exposure to humans or the environment cannot be excluded in respect of substantial quantities of substances having the properties of substances of very high concern.

81. In this situation the objective of a high level of protection of human health and the environment and the precautionary principle *require* notification of ECHA so that it can, if appropriate, take the necessary precautions under the REACH Regulation. Reference is made to these objectives in Article 1(1) and (3) of and recitals 1, 3, 9 and 69 in the preamble to the REACH

Regulation; they are however also apparent from Articles 9, 11 and 191(2) TFEU and Articles 35 and 37 of the Charter of Fundamental Rights.

82. This is in keeping with the obligation of importers under Article 1(3) of the REACH Regulation to ensure that they place on the market or use such substances that do not adversely affect human health or the environment. Consequently, in the light of the risks described above and in view of the restriction of notification to the import of relatively large quantities of those substances, importers can be expected to obtain the necessary information and to notify ECHA.

83. It must be assumed that manufacturers in third countries wishing to produce substantial quantities of articles for the European market will communicate to importers the necessary information on the presence of candidate substances in component articles. In so far as those manufacturers had to use information from their own supply chain in third countries for that purpose, the duty of notification would even disseminate the standards established by the REACH Regulation outside the European Union.

84. Accordingly, it is not disproportionate but necessary to assess the duty of notification imposed on importers by Article 7(2) of the REACH Regulation by reference to the concentration of candidate substances in component articles.

f) Alleged discrimination against importers

85. In this connection the alleged unequal treatment of importers and European Union producers is also claimed, as producers can obtain the necessary information much more easily from suppliers from the European Union.

86. However, restricting the duty of notification to entire articles in which the concentration threshold is reached does not eliminate this unequal treatment, but at most reduces the number of cases in which it exists.

87. Furthermore, restricting the duties of notification under Article 7(2) of the REACH Regulation to entire articles would place European Union producers at a disadvantage. Under that provision, producers and importers of component articles would be required to give notification and would pass on the associated costs to their recipients, namely producers of entire articles. It would therefore be less attractive to produce the entire article within the European Union than to import it.

88. Furthermore, the Court has already held that importers must be subject to the same obligations as those to which manufacturers in the European Union are subject, or (at least) to similar obligations which lead to an approximation of costs, in order to ensure genuine competition within the European Union. (20) In addition, protecting European Union producers against competitive disadvantages which might result from a different situation for importers is a permissible objective of the EU legislature. (21)

89. Therefore, the effects on importers and producers in the European Union do not militate against a duty of notification on the basis of the concentration of candidate substances in component articles.

g) Interim conclusion

90. Consequently, the importer of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own is

required to notify ECHA if a substance meeting the criteria in Article 57(e) of the REACH Regulation and identified in accordance with Article 59(1) is present in a component article above a concentration of 0.1% weight by weight (w/w).

3. The supplier of articles within the meaning of Article 33 of the REACH Regulation

91. Under Article 33 of the REACH Regulation, any supplier of an article containing a candidate substance in a concentration above 0.1% weight by weight (w/w) must provide the recipient of the article, and the consumer on his request, with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

92. Article 3(33) of the REACH Regulation provides a very broad definition of the term 'supplier of an article'. Under that provision, it covers any producer or importer, as well as distributors or other actors in the supply chain, placing an article on the market. Article 3(12) provides a similarly broad definition of 'placing on the market'; it encompasses supplying or making available, whether in return for payment or free of charge, to a third party.

93. These broad definitions suggest an interpretation under which the supplier of an entire article is also the supplier of the component articles contained in it which, despite being integrated into an entire article, retain a shape, surface or design of their own. The definitions would instead have to be given a restrictive interpretation for the duties of suppliers to be assessed only by reference to the concentration of candidate substances in the entire article.

94. The above interpretation of Article 7(2) of the REACH Regulation in respect of importers also suggests, in principle, that the duties to provide information imposed on suppliers should be assessed by reference to the concentration of candidate substances in component articles.

a) The differences between Article 33 and Article 7(2) of the REACH Regulation

95. Nevertheless, the duty to provide information under Article 33 of the REACH Regulation differs in certain important respects from the duty of notification under Article 7(2).

96. A key difference is that information on candidate substances is not notified to ECHA, but to recipients or consumers of articles. It is therefore possible that they will decide not to purchase the article because of the presence of a substance of very high concern. In the case of consumers in particular, it cannot be ruled out that such a decision is based on a misconception of the risk associated with the substance.

97. Providing information to consumers does not, however, constitute a disadvantage of the duty to provide information that would make it appear disproportionate. Rather, it is consistent with the high level of consumer protection to be pursued under Article 38 of the Charter of Fundamental Rights and Article 169(1) TFEU, which, under the latter provision in particular, includes the right of consumers to information. This is expressly recognised in recitals 56 and 117 in the preamble to the REACH Regulation. Suppliers must address any misconceptions on the part of consumers by providing appropriate clarification on the risks of the substances present.

98. Furthermore, Germany rightly states that the incentive to avoid substances of very high concern where possible created by the duty to provide information is in keeping with the aims of the rules on those substances. Article 55 of the REACH Regulation expressly provides that the aim of those rules is for these substances to be progressively replaced by suitable alternative substances or technologies where these are economically and technically viable.

99. Provision of information to recipients must be subject to the same considerations as provision of information to consumers, as consumers can only receive information if it has previously been passed along the supply chain.

100. As various Member States argue, it would be unsatisfactory to stop passing on that information along the supply chain simply because a component article is incorporated into an entire article and the concentration threshold of 0.1% weight by weight (w/w) is now no longer reached in the entire article. This would also not significantly reduce the burden on suppliers.

101. There are nevertheless also differences from the duty of notification under Article 7(2) of the REACH Regulation that may significantly increase the burdens associated with the duty to provide information under Article 33.

102. First of all, the threshold of one tonne per supplier per year laid down in Article 7(2)(a) of the REACH Regulation is not present. Consequently, a duty to provide information may arise even with much smaller sales volumes. This is particularly important in the case of the import of articles. While it seems altogether likely that producers or suppliers in third countries will provide the necessary information in the case of larger quantities, this would appear to be increasingly doubtful the smaller the imported quantities are.

103. Furthermore, the duty to provide information does not lapse where the supplier can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal, as is provided for in Article 7(3) of the REACH Regulation in respect of notification to ECHA. Accordingly, the burden created by the duty to provide information could arise even though exposure is not to be expected.

104. Lastly, the duty to provide information under Article 33 of the REACH Regulation also does not depend on whether the candidate substance in question has already been registered for the relevant use. There may be cases in which it is not necessary, for the purposes of Article 7(2), to clarify whether an article actually contains a candidate substance, as the possibility of use in such articles has already been registered in principle. Nevertheless, Article 33 would require such a determination to be made.

105. These aspects are addressed only indirectly by a restriction of the duty to provide information to cases in which the concentration threshold is reached in the entire article.

106. On the one hand, with regard to the duty to provide information under Article 33 of the REACH Regulation, the ECHA Guidance requires in principle the concentration in the entire article to be calculated on the basis of the concentration in the component articles contained in it. If the supplier follows this approach, providing the recipient with information on candidate substances in the component articles would not really create undue burdens.

107. On the other hand, it is also possible that entire articles which reach the concentration threshold are imported only in small quantities or that a risk of exposure can be excluded in the case of those articles. It is not clear why in these cases the duty to provide information should be more reasonable than for component articles.

108. The main effect of the interpretation advocated by the Commission and Ireland is that the abovementioned disadvantages occur in fewer cases. However, it may happen that the same component article gives rise to duties to provide information where it is supplied as a separate article, whereas information no longer has to be provided once it has been incorporated into an

entire article. This would be particularly unsatisfactory where the supplier of the entire article has obtained the necessary information from the supplier of the component article and it would therefore be reasonable to pass it on to the recipients or the consumers of the entire article.

b) The interpretation of Article 33 of the REACH Regulation in the light of the principle of proportionality

109. It is nevertheless possible to interpret Article 33 of the REACH Regulation, in accordance with the principle that information should be provided along the supply chain, in such a way that unreasonable duties to provide information are avoided.

110. Under Article 33 of the REACH Regulation, the supplier must provide both recipients and consumers with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.

111. At first sight, that provision seems to mean — at least on the basis of some language versions, such as the German or the English version — that the supplier must in any case — even if that information is not available to him — notify, as a minimum, the name of the candidate substance in question. If the supplier cannot obtain sufficient information on the substance from its supplier, he would therefore in principle have to examine the article to ascertain whether candidate substances are present in the relevant concentration.

112. Such a duty of examination appears problematical above all where exposure can be excluded, but also in the case of particularly small quantities of supplied articles.

113. Nevertheless, all the parties adhered to this interpretation in principle when an enquiry was made to that effect. They based their view on the idea that a supplier must have the necessary information to comply with Article 33 of the REACH Regulation, and must obtain it if necessary.

114. Unreasonable burdens on suppliers would be avoided, however, if notification of the name of the substance was also subject to that information being available to the supplier. This interpretation is not precluded by the wording of Article 33 of the REACH Regulation. Rather, indicating the name can be understood as a subset of providing information to allow safe use of the article. Yet that information has to be passed on only if it is available. On the basis of the French version of Article 33 this interpretation is actually more plausible than requiring the name of the substance to be notified even where information is not available.

115. If Articles 7(2) and 33 of the REACH Regulation were complied with in the supply chain, the name of the substance would be available to a supplier of articles if ECHA has been notified of the presence of the substance.

116. If Article 7(2) of the REACH Regulation were not applicable, information on candidate substances should also be available to the supplier in the case of articles, provided they are made in the European Union. The producer ought to be aware whether candidate substances are present in the necessary concentration. That information could therefore easily be passed on to recipients and consumers.

117. On the other hand, it must be assumed that importers of smaller quantities of articles often do not have available any information on candidate substances.

118. In addition, that information would not necessarily be available where, under Article 7(3) or (6) of the REACH Regulation, notification of ECHA in connection with import was omitted

because the importer could exclude exposure or the candidate substance had already been registered for use in such articles. In these cases it is not absolutely necessary, for the application of Article 7(2), to clarify whether the substance is actually present in the article.

119. At first sight there would appear to be grounds for concern that this interpretation of Article 33 of the REACH Regulation would significantly undermine the practical effectiveness of that provision. It is correct that suppliers of imported articles would be exempted, perhaps to a considerable extent, from the duties to provide information on the presence of candidate substances.

120. However, that exemption could not extend so far that suppliers that were unaware of the presence of candidate substances could claim that the articles were free from such substances. They would have to acknowledge at least that they had not received any information on the presence of candidate substances.

121. Furthermore, a lack of information on candidate substances does not mean that suppliers could ignore any risks. As the Commission, for example, explains, there are other rules on safety of articles, such as Directive 2001/95/EC on general product safety in the case of consumer products. (22) As part of quality assurance under these other rules, suppliers should minimise risks resulting from the presence of candidate substances and, if necessary, obtain relevant information which they must pass on in the supply chain. If, on the other hand, the possible presence of candidate substances has no risk relevance, it is acceptable to refrain from providing clarification. The inclusion of these other product safety rules thus creates a focus on possible risks, which — as various parties argue — is not present in the conditions for the duty to provide information.

122. According to this interpretation, the duty to provide information under Article 33 of the REACH Regulation would therefore extend further than the duty of notification under Article 7(2), but undue burdens would not arise because the relevant information would not have to be gathered specifically for the purposes of the duty to provide information, but would already be available.

c) Interim conclusion

123. Consequently, the supplier of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own is required to provide information to recipients and, on request, consumers under Article 33 of the REACH Regulation on a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) if it is present in a component article above a concentration of 0.1% weight by weight (w/w) and relevant information is available to the supplier.

V – Conclusion

124. I therefore propose that the Court answer the request for a preliminary ruling as follows:

(1) If the other conditions laid down in Article 7(2) of the REACH Regulation are satisfied,

(a) the producer of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own, but were made or assembled by other producers, is required to notify ECHA if a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) is present in the entire article above a concentration of 0.1% weight by weight (w/w); and

(b) the importer of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own is required to notify ECHA if a substance meeting the criteria laid down in Article 57 and identified in accordance with Article 59(1) is present in a component article above a concentration of 0.1% weight by weight (w/w).

(2) The supplier of an entire article consisting of component articles which, despite being integrated into an entire article, retain a shape, surface or design of their own is required to provide information to recipients and, on request, consumers under Article 33 of the REACH Regulation on a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) if it is present in a component article above a concentration of 0.1% weight by weight (w/w) and relevant information is available to the supplier.

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1 – Original language: German.

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2 – 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) 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 (OJ 2006 L 396, p. 1), as last amended by Commission Regulation (EU) No 895/2014 of 14 August 2014 (OJ 2006 L 244, p. 6).

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3 – echa.europa.eu/documents/10162/13632/articles_en.pdf.

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4 – Commission Regulation (EU) No 895/2014 of 14 August 2014 amending Annex XIV to Regulation (EC) No 1907/2006 (OJ 2014 L 244, p. 6).

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5 – On 1 September 2014 the European Chemicals Agency published a draft recommendation for inclusion of a further 22 substances in Annex XIV to Regulation No 1907/2006 (Draft results of the 6th prioritisation of the SVHCs on the candidate list with the objective to recommend priority substances for inclusion in Annex XIV, http://echa.europa.eu/documents/10162/13640/prioritisation_results_6th_rec_en.pdf, consulted on 27 November 2014).

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6 – http://echa.europa.eu/candidate-list-table, as at 16 June 2014, consulted on 27 November 2014.

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7 – Various NGOs maintain lists of other substances of high concern which could in future be included on the candidate list. For example, the International Chemical Secretariat's 'SIN List' contains 830 substances (sinlist.chemsec.org, consulted on 1 December 2014); a list produced by the European Trade Union Confederation in 2010 included 334 substances (http://www.etuc.org/press/reach-etuc-updates-its-priority-list-authorisation, consulted on 1 December 2014).

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8 – See judgment in *Rütgers Germany and Others* v *ECHA* (T-96/10, EU:T:2013:109, paragraph 34).

9 – de.wikipedia.org/wiki/Kunststoffgranulat.

10 – The Commission apparently refers to the suggestion by the Netherlands documented in footnote 39 of Council document 13788/2/04 REV 2, the suggestion by Sweden documented in footnote 57 of Council document 5579/2/05 REV 2, and the proposed Amendment 38 of the Recommendation for second reading of the Parliament, document A6-0352/2006 of 13 October 2006.

11 – Council Directive of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (OJ 1976 L 262, p. 201).

12 – Judgments in *IATA and ELFAA* (C-344/04, EU:C:2006:10, paragraph 68) and *International Association of Independent Tanker Owners and Others* (C-308/06, EU:C:2008:312, paragraph 69).

13 – Judgment in *Belgium* v *Commission* (C-110/03, EU:C:2005:223, paragraph 31).

14 – See above, point 13.

15 – See, for example, judgments in *Rohm Semiconductor* (C-666/13, EU:C:2014:2388, paragraph 25 and the case-law cited) with regard to the Explanatory Notes drawn up by the Commission for the Combined Nomenclature; *Fish Legal and Shirley* (C-279/12, EU:C:2013:853, paragraph 38) with regard to the Aarhus Convention Implementation Guide; and *Expedia* (C-226/11, EU:C:2012:795, paragraph 23 et seq.) with regard to the Commission Notice on agreements of minor importance which do not appreciably restrict competition under Article 81(1) [EC].

16 – Orders in *Rütgers Germany and Others* v *ECHA* (C-290/13 P, EU:C:2014:2174); *Cindu Chemicals and Others* v *ECHA* (C-289/13 P, EU:C:2014:2175); and *Rütgers Germany and Others* v *ECHA* (C-288/13 P, EU:C:2014:2176) (paragraph 25 in each case).

17 – Judgments in *Jippes and Others* (C-189/01, EU:C:2001:420, paragraph 81); *S.P.C.M.and Others* (C-558/07, EU:C:2009:430, paragraph 41); *Afton Chemical* (C-343/09, EU:C:2010:419, paragraph 45); and *Schaible* (C-101/12, EU:C:2013:661, paragraph 29).

18 – See the Guidance cited in point 13, section 4.4.

19 – See the Guidance cited in point 13, section 6.4.

20 – Judgment in *S.P.C.M. and Others* (C-558/07, EU:C:2009:430, paragraph 60).

21 – Judgment in *S.P.C.M. and Others* (C-558/07, EU:C:2009:430, paragraph 57).

22 – Directive of the European Parliament and of the Council of 3 December 2001 (OJ 2002 L 11, p. 4).