Reports of Cases

JUDGMENT OF THE COURT (Third Chamber)

10 September 2015*

(Reference for a preliminary ruling — Environment and protection of human health — Regulation (EC) No 1907/2006 (REACH Regulation) — Articles 7(2) and 33 — Substances of very high concern present in articles — Duties to notify and provide information — Calculation of threshold of 0.1% weight by weight)

In Case C-106/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the Conseil d'État (France), made by decision of 26 February 2014, received at the Court on 6 March 2014, in the proceedings

Fédération des entreprises du commerce et de la distribution (FCD),

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,

THE COURT (Third Chamber),

composed of M. Ilešič, President of the Chamber, A. Ó Caoimh, C. Toader, E. Jarašiūnas and C.G. Fernlund (Rapporteur), Judges,

Advocate General: J. Kokott,

Registrar: V. Tourrès, Administrator,

having regard to the written procedure and further to the hearing on 8 January 2015,

after considering the observations submitted on behalf of:

— the Fédération des entreprises du commerce et de la distribution (FCD) and the Fédération des magasins de bricolage et de l'aménagement de la maison (FMB), by A. Gossement and A.-L. Vigneron, avocats,

— the French Government, by D. Colas and S. Menez and by S. Ghiandoni, acting as Agents,

— the Belgian Government, by J. Van Holm and C. Pochet and by T. Materne, acting as Agents,

— the Danish Government, by C. Thorning and M. Wolff, acting as Agents,

* Language of the case: French.

— the German Government, by T. Henze and K. Petersen, acting as Agents,

— Ireland, by E. Creedon and G. Hodge and by T. Joyce, acting as Agents, and by B. Kennedy, SC, and G. Gilmore, BL,

— the Greek Government, by K. Paraskevopoulou and V. Stroumpouli, acting as Agents,

— the Austrian Government, by C. Pesendorfer, acting as Agent,

— the Swedish Government, by A. Falk, C. Meyer-Seitz, U. Persson and N. Otte Widgren and by L. Swedenborg, E. Karlsson and F. Sjövall, acting as Agents,

— the Norwegian Government, by K.B. Moen and K.E. Bjørndal Kloster, acting as Agents,

— the European Commission, by J.-P. Keppenne and K. Talabér-Ritz, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 12 February 2015,

gives the following

Judgment

1 This reference for a preliminary ruling concerns the interpretation of Articles 7(2) and 33 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) 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 amended by Commission Regulation (EU) No 366/2011 of 14 April 2011 (OJ 2011 L 101, p. 12) ('the REACH Regulation').

2 The reference has been made in proceedings between the Fédération des entreprises du commerce et de la distribution (Federation of businesses in the trade and distribution sector, 'the FCD') and the Fédération des magasins de bricolage et de l'aménagement de la maison (Federation of DIY and home improvement shops, 'the FMB'), on the one hand, and the French Ministre de l'écologie, du développement durable, des transports et du logement (Minister for Ecology, Sustainable Development, Transport and Housing), on the other, concerning 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', (JORF of 8 June 2011, p. 9763, 'the Notice of 8 June 2011').

Legal context

EU law

3 The recitals in the preamble to the REACH Regulation state inter alia:

'(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 mixtures and in articles, while enhancing competitiveness and innovation. ...

(2) The efficient functioning of the internal market for substances can be achieved only if requirements for substances do not differ significantly from Member State to Member State.

(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.

...

(12) An important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available. ...

...

(21) Although the information yielded on substances through evaluation should be used in the first place by manufacturers and importers to manage the risks related to their substances, it may also be used to initiate the authorisation or restrictions procedures under this Regulation or risk management procedures under other Community legislation. Therefore it should be ensured that this information is available to the competent authorities and may be used by them for the purpose of such procedures.

...

(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 [European Chemicals Agency (ECHA)] should be notified. ...

...

(34) Requirements for generation of information on substances should be tiered according to the volumes of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail. To reduce the possible impact on low volume substances, new toxicological and ecotoxicological information should only be required for priority substances between 1 and 10 tonnes. For other substances in that quantity range there should be incentives to encourage manufacturers and importers to provide this information.

...

(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.

...

(58) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if those uses are not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks. For the same reason, downstream users should manage the risks arising from their uses of substances. In addition, it is appropriate that any producer or importer of an article containing a substance of very high concern should provide sufficient information to allow safe use of such an article.

...

(63) It is also necessary to ensure that generation of information is tailored to real information needs. … In cooperation with Member States, the Agency should give priority to certain substances, for instance those which may be of very high concern.

...

(69) To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention. Authorisation should be granted where natural or legal persons applying for an authorisation demonstrate to the granting authority that the risks to human health and the environment arising from the use of the substance are adequately controlled. Otherwise, uses may still be authorised if it can be shown that the socio-economic benefits from the use of the substance outweigh the risks connected with its use and there are no suitable alternative substances or technologies that are economically and technically viable. Taking into account the good functioning of the internal market it is appropriate that the Commission should be the granting authority.

(70) Adverse effects on human health and the environment from substances of very high concern should be prevented through the application of appropriate risk management measures to ensure that any risks from the uses of a substance are adequately controlled, and with a view to progressively substituting these substances with a suitable safer substance. Risk management measures should be applied to ensure, when substances are manufactured, placed on the market and used, that exposure to these substances including discharges, emissions and losses, throughout the whole life-cycle is below the threshold level beyond which adverse effects may occur. ...

...

(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. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures. ...

...

(130) Since the objectives of this Regulation, namely laying down rules for substances and establishing a European Chemicals Agency, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Community level, the Community may adopt measures, in

accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this regulation does not go beyond what is necessary in order to achieve those objectives.'

4 Paragraph 1 of Article 1 of the REACH Regulation, entitled 'Aim and scope', provides:

'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.'

5 Paragraph 2 of Article 2 of that regulation, entitled 'Application', provides:

'Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council [of 5 April 2006 on waste (OJ 2006 L 114, p. 9)] is not a substance or article within the meaning of Article 3 of this Regulation.'

6 Article 3 of that regulation, entitled 'Definitions', contains the following definitions:

'For the purposes of this Regulation:

'1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

2. mixture: means a mixture or solution composed of two or more substances;

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;

...

7. registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

...

10. import: means the physical introduction into the customs territory of 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. Import shall be deemed to be placing on the market;

...

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;

...

35. recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;

...'

7 Article 6 of the REACH Regulation, entitled 'General obligation to register substances on their own or in mixtures', provides in paragraph 1:

'Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency.'

8 Article 7 of that regulation, entitled 'Registration and notification of substances in articles', is worded as follows:

'1. Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

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

(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

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

2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, 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 one 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.

...

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

...'

9 Article 10 of that regulation lists the information to be submitted for general registration purposes.

10 According to Article 33 of the REACH Regulation, entitled 'Duty to communicate information on substances in 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.'

11 Article 55 of that regulation, entitled 'Aim of authorisation and considerations for substitution', provides:

'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.'

12 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 [of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1)];

(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 … 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 … No 1272/2008;

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

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII [to] 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.'

13 Article 59 of that regulation provides for a procedure for the identification of substances referred to in Article 57.

14 Article 77 of the REACH Regulation, entitled 'Tasks', provides:

'1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2.

The Secretariat shall undertake the following tasks:

...

(g) providing technical and scientific guidance and tools where providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;

(h) providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States under Title XIII;

(i) providing guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances, on their own, in mixtures or in articles;

...

(k) preparing explanatory information on this Regulation for other stakeholders;

...

(m) keeping a Manual of Decisions and Opinions based on conclusions from the Member State Committee regarding interpretation and implementation of this Regulation;

...'

Commission Note of 4 February 2011

15 Document CA/26/2011 of the European Commission dated 4 February 2011, entitled 'Update of Commission opinion — Substances in articles', addressed to the competent national authorities, states that: '... the Commission has come to the conclusion that objects which at a certain step in their life-cycle meet the definition of article under REACH cease to be individual articles and become

components once they are assembled into another article. For this reason, the obligations in Article 7(2) and 33 apply only with respect to such assembled article, and not with respect to its individual components'.

ECHA Guidance document

16 The 'Guidance on requirements for substances in articles', published by the European Chemicals Agency (ECHA) on 1 April 2011 ('the ECHA Guidance document'), contains information in chapter 4 for determining the concentration of a substance of very high concern included on the candidate list in articles with different components.

17 Section 4.4. of the ECHA Guidance document, entitled 'Determination of the concentration of a [substance of very high concern] included on the candidate list in articles with different components', is worded as follows:

'A [substance of very high concern] 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 [substance of very high concern] has to exceed 0.1% (w/w) in the entire article as identified according to chapter 2. In order to check this condition firstly it needs to be known for each component whether it contains above 0.1% (w/w) of the SVHC or not (if not yet available, this information can be obtained by different means as described in chapter 5).'

French law

18 According to the Notice of 8 June 2011:

'With reference to the publication of 1 April 2011 on the site of the [ECHA] (http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf) … of the revised guide concerning the application of the REACH Regulation to substances contained in articles and more precisely to the executive director's memorandum attached to that guide which indicates that it was not the subject of consensus 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 each object meeting the definition of "article" as provided for in REACH, that is to say, each 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 several 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.

…

It is on the basis of those factors that the French authorities will apply Articles 7.2 and 33. Control measures will gradually be implemented to verify compliance with those provisions, using an approach which is pragmatic and proportionate to the health and environmental matters at stake.'

The dispute in the main proceedings and the question referred for a preliminary ruling

19 By application of 5 December 2011, FCD and FMB brought proceedings before the Conseil d'État (Council of State, acting in a judicial capacity) against the Notice of 8 June 2011. They argued that that notice was based on an interpretation of the concept of article which does not adhere to either the Commission Note of 4 February 2011 or the ECHA Guidance document. The Conseil d'État considers that the answer to the pleas in law put forward by FCD and FMB turns on the question whether, in the case of an article made up of more than one component, each coming within the definition of article laid down in the REACH Regulation, the obligations arising under Articles 7(2) and 33 of that regulation apply only in respect of the assembled article or in respect of each of those components.

20 It is on that basis that the Conseil d'État decided to stay proceedings and to refer the following question to the Court for a preliminary ruling:

'Where an "article" within the meaning of [the REACH Regulation] is composed of several elements which themselves meet the definition of "article" given by 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 meets the definition of "article"?'

Preliminary observations

The subject-matter of the present proceedings

21 FCD and FMB submit that the dispute in the main proceedings has arisen from the diverging interpretation of the REACH Regulation adopted by the French Republic in the Notice of 8 June 2011. Following the publication of that notice, the Commission looked into whether there was a possible infringement by the French Republic. At the end of its analysis, on 21 June 2012 the Commission sent a letter of formal notice to the French Republic in the procedure 2012/2109.

22 In July 2013, the French, Belgian, Danish, German, Swedish and Norwegian Governments published a guide for suppliers of articles. That guide indicates that the same piece of information about the presence of substances on the candidate list for authorisation must be provided, irrespective of whether that article is sold separately or as part of an article assembled from more than one article. The guide states (note 3, p. 6) that the co-authoring States and the Republic of Austria do not accept the interpretation of that regulation given by the ECHA in its guide.

23 FCD and FMB take the view that the interpretation contained in the Notice of 8 June 2011 is clearly contrary to the one put forward as early as 2007 by the Commission and the ECHA. The rules introduced in the REACH Regulation need to be defined and implemented at EU level. That regulation specifically entrusted the Commission and the ECHA with the mission of acting to implement effectively the provisions it introduces. FCD and FMB observe in that regard that Article 77 of the REACH Regulation provides expressly that the ECHA may provide technical and scientific guidance to producers and importers of articles for the application of Article 7 of that regulation and draw up explanatory information about the article for interested parties. The French authorities' divergent interpretation hinders the uniform implementation of the REACH Regulation and undermines legal certainty as well as the proper functioning of the internal market and fair competition between economic operators.

24 The Commission submits that the divergences in the interpretation and application of the REACH Regulation by the French Republic and certain other Member States jeopardise the indivisibility of the EU legal order and undermine the principles of legal certainty and of the protection of legitimate

expectations, as well as the proper functioning of the internal market. The Commission observes that Article 33 of the REACH Regulation effects an exhaustive harmonisation at EU level of the obligation to provide information on the substances contained in articles. If the French authorities wish to depart from that provision, they must provide proof of the existence of valid grounds relating to the protection of public health and/or the environment, as required under Article 114(4) to (9) TFEU.

25 It is apparent from those observations that FCD and FMB and the Commission are asking the Court to rule on the compatibility of the Notice of 8 June 2011 with EU law. It is settled case-law, however, that it is not for the Court, in the context of a reference for a preliminary ruling under Article 267 TFEU, to give a ruling on the compatibility of provisions of national law with EU law or to interpret national legislative or regulatory provisions (see, to that effect, inter alia, judgment in *Vueling Airlines*, C-487/12, EU:C:2014:2232, paragraph 26 and the case-law cited). The Court has jurisdiction to give the national court full guidance on the interpretation of EU law in order to enable it to determine the issue of compatibility for the purposes of the case before it (judgment in *Transportes Urbanos y Servicios Generales*, C-118/08, EU:C:2010:39, paragraph 23 and the case-law cited).

26 In the present case, the Court is being called on not to rule on the compatibility of national law with EU law, but to provide the referring court with guidance as to the interpretation of the REACH Regulation, in order to enable it to determine whether EU law requires it to disapply national rules governing the interpretation of that regulation. The question before the Court is therefore not whether, in adopting the Notice of 8 June 2011, the French authorities infringed their obligations under EU law.

27 Moreover, the fact that the interpretation the REACH Regulation given by the French authorities in the Notice of 8 June 2011 is contrary to the one adopted by the ECHA in its Guidance document of 1 April 2011 and the one issued by the Commission to the Member States once in 2007 and then a second time in 2011, is not relevant for the purposes of the present proceedings under Article 267 TFEU.

28 It is true that Article 77(2) of the REACH Regulation confers on the Secretariat of the ECHA the task, inter alia, of 'providing technical and scientific guidance and tools where appropriate for the operation [of that regulation] in particular ... technical and scientific guidance for the application of Article 7 by producers and importers of articles' and 'preparing explanatory information on [that regulation] for other stakeholders'. Given the legislature's intention, a document such as the ECHA Guidance document may be one of the factors to be taken into consideration in interpreting the REACH Regulation. However, despite the scientific and technical nature of the aspects relating to the chemical substances regulated by the REACH Regulation, a document of that nature remains purely explanatory. The interpretation it gives of that regulation's provisions is of no legislative effect whatsoever. It is a document drawn up by the ECHA and is not among the legal acts of the European Union referred to in Article 288 TFEU; accordingly it cannot be of a legally binding nature (see, by analogy, judgment in *Chemische Fabrik Kreussler*, C-308/11, EU:C:2012:548, paragraph 23).

29 That lack of legally binding nature is, moreover, set out expressly in a preliminary section in the ECHA Guidance document, entitled 'Legal notice', which states that 'the text of the REACH Regulation constitutes the sole authentic legal reference; the information contained in the present document has no legal value' and that '[ECHA] declines all liability in respect of content'. It is also apparent from a 'Note to reader' that the guidance document 'has not been fully supported by the national authorities of the Member States ... consulted at the final consultation stage [and that] consequently, undertakings may encounter divergent implementation practices with regards to some of the aspects of this document'.

30 Against that background, it is for the Court, as part of the judicial cooperation established by Article 267 TFEU, to respond to the request for a preliminary ruling in order to ensure a uniform interpretation and application of the relevant provisions of the REACH Regulation.

The REACH Regulation

31 Before examining the provisions the interpretation of which has been sought by the referring court, it must be remembered that it is apparent from Article 1(1) of the REACH Regulation that it aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

32 To that end, the REACH Regulation introduces an integrated system for monitoring chemical substances, including registration, evaluation and authorisation, together with possible restrictions on their use. The cardinal principles governing those aspects were presented by the Commission in the introduction to its regulation proposal in COM(2003) 644 final of 29 October 2003, which describes 'the REACH system' as comprising, first of all, registration, which requires 'industry to obtain relevant information on their substances and to use that data to manage them safely', next, '[e]valuation[, which] provides confidence that industry is meeting its obligations' and authorisation for substances of very high concern whose '[r]isks associated with uses … are adequately controlled, … if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies …'. Lastly, '[t]he restrictions procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system'.

33 In accordance with those objectives, the REACH Regulation places the responsibility for the analysis of chemical substances with industry, instituting, for that purpose, a number of information-related mechanisms aimed at contributing, all along the supply chain, to the identification of their dangerous properties and risk management in order to ensure that human health and the environment are not adversely affected.

34 It is apparent from regulation proposal COM(2003) 644 final that in 1981 there were over 100 000 substances and that almost 3 000 new substances were subsequently placed on the market. Of all those substances, the REACH Regulation focuses particular attention on those considered to be of very high concern, as evidenced by inter alia recitals 63, 69 and 70 in the preamble thereto.

35 The substances of very high concern are those listed in either Article 57(a) to (e) of the REACH Regulation due to their carcinogenic, mutagenic or reproductive toxic properties, or because they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, or in Article 57(f), which includes all other substances '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)'.

36 Article 59 of the REACH Regulation introduces a procedure for identifying substances of very high concern which provides for the establishment of a list of so-called 'candidate' substances intended to eventually be included in Annex XIV thereto containing the list of substances subject to authorisation. As observed by the Advocate General in point 22 of her Opinion, on 16 June 2014 155 substances were on the candidate list.

37 Under Article 7(2) of the REACH Regulation, any producer or importer of articles must notify the 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).

38 Under Article 7(3) of the REACH Regulation, Article 7(2) of that 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 Article 7(6) of that regulation, nor does the latter provision apply 'to substances that have already been registered for that use'.

39 It follows from the foregoing that the duty of notification provided for in Article 7(2) of the REACH Regulation requires that four cumulative conditions be met:

— the use of the substance of very high concern has not been previously registered;

— the possibility of risk of exposure for humans and the environment cannot be ruled out;

— the quantity of the substance in question exceeds one tonne per year per producer or importer; and

— the concentration of that substance exceeds the threshold of 0.1% weight by weight in the article in question.

40 Article 33 of the REACH Regulation is found under Title IV of that regulation, entitled 'Information in the supply chain'. It introduces a duty to communicate information on substances in articles. Thus, Article 33(1) provides that '[a]ny supplier of an article containing [a substance of very high concern] 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'. Article 33(2) imposes a similar duty to communicate information on any supplier of an article containing a substance meeting the same criteria, when requested to do so by a consumer.

The question referred for a preliminary ruling

41 By its question, the referring court asks, in essence, whether, in the case of a product composed of one or more articles within the meaning of Article 3(3) of the REACH Regulation, Articles 7(2) and 33 of that regulation must be interpreted as meaning that the concentration threshold for a substance of very high concern of 0.1% weight by weight referred to in those provisions must be established in relation to the total weight of that product.

42 FCD and FMB, Ireland, the Greek Government and the Commission submit that that question should be answered in the affirmative. The French, Belgian, Danish, German, Austrian, Swedish and Norwegian Governments take the view that the question should be answered in the negative.

43 In order to answer the question, it is necessary to examine the term 'article' as defined in Article 3(3) of the REACH Regulation and then the duties to notify and communicate information provided for in Articles 7(2) and 33 respectively of that regulation.

Concept of 'article' within the meaning of Article 3(3) of the REACH Regulation

44 FCD and FMB submit that the classification as 'article' within the meaning of Article 3(3) of the REACH Regulation applies only to the final product the composition of which includes articles. An interpretation to the contrary would involve considerable burdens, in particular:

— an obligation for suppliers and importers to determine the concentration of substances of very high concern in the final product manufactured, imported or placed on the market, using tests or on the basis of information provided by their own suppliers, entailing a complex and costly process;

— substantial difficulties for importers in obtaining detailed information on substances of very high concern present in each of the components making up complex products from producers established outside the European Union.

45 The French Government submits that Article 3(3) of the REACH Regulation defines an article as a manufactured object the shape of which is more important than the chemical composition for determining its function. No object is outside the scope of that definition once it is given a special shape, surface or design during production, which — more than its chemical composition — determines its function. Articles 7(2) and 33 of that regulation do not provide that the term 'article' must be interpreted more restrictively than under Article 3(3) thereof.

46 It should be observed in that regard that Article 3(3) defines 'article' as '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'.

47 It is clear from that definition that the classification of an object as an article within the meaning of the REACH Regulation turns on three factors. Firstly, the term 'article' refers only to objects which have undergone 'production'. It therefore pertains only to manufactured objects, in contrast to objects in their natural state. Secondly, the production process must give the object in question 'a special shape, surface or design', except for inter alia physical or chemical properties. Thirdly, that shape, surface or design resulting from the manufacturing process must be more decisive for the function of the object in question than its chemical composition.

48 The situation referred to by the referring court concerns a so-called 'complex' product because it is made up of a number of manufactured objects meeting the criteria laid down in Article 3(3) of the REACH Regulation. Such a situation raises the question whether the classification as an article must be applied both to the product as a whole and simultaneously to each of the articles forming part of its composition.

49 It should be noted that the REACH Regulation does not contain any provisions governing specifically the situation of a complex product containing more than one article. That legislative silence must be construed in the light of the principal objective pursued by the regulation, which is not to regulate all manufactured products, but to monitor the chemical substances present by themselves or in a mixture as well as, in certain cases, particularly those listed restrictively in Article 7 thereof, when they are contained in articles.

50 Consequently, in the absence of any specific provision, there is no need to draw a distinction not provided for by the REACH Regulation between the situation of articles incorporated as a component of a complex product and that of articles present in an isolated manner. The question whether a complex product itself may be classified as an article therefore turns solely on a determination according to the criteria laid down in Article 3(3) of that regulation.

51 It is therefore only if the production of an object using a combination of more than one article gives that object a special shape, surface or design which is more decisive for its function than its chemical composition that that object may be classified as an article. Accordingly, unlike a simple assembly process, that production process must alter the shape, surface or design of the articles used as components.

52 That does not necessarily mean, however, that the articles used in that production process thereby cease to be articles. It should be noted in that regard that Article 2(2) of the REACH Regulation provides that '[w]aste as defined in [Directive 2006/12] is not a substance or article within the meaning of Article 3 [of that regulation]'. It follows that an object meeting the criteria laid down in Article 2(2) of that same regulation ceases to be an 'article' for the purposes of the REACH Regulation when it becomes waste as defined in EU law (judgment in *Commune de Mesquer*, C-188/07, EU:C:2008:359, paragraph 40). Apart from that provision, the REACH Regulation does not contain any provision under which an object meeting the definition of article within the meaning of Article 3(3) thereof is liable subsequently to cease being an article.

53 It is clear from the foregoing and from point 31 of the Advocate General's Opinion that a manufactured object meeting the criteria laid down in Article 3(3) of the REACH Regulation does not cease to be an article when it is assembled or joined with other objects in order to form with them a complex product. In such a situation, that manufactured object remains an 'article' within the meaning of that provision. It remains so as long as it retains a special shape, surface or design which is more decisive for its function than its chemical composition or as long as it does not become waste within the meaning of Directive 2006/12.

54 Consequently, the classification as an article remains applicable to any object meeting the criteria in Article 3(3) of the REACH Regulation and forming part of the composition of a complex product unless, following a production process, that object becomes waste or ceases to have the shape, surface or design which is more decisive in determining its function than its chemical composition.

Article 7(2) of the REACH Regulation

55 The duty of notification provided for in Article 7(2) of the REACH Regulation applies equally to importers and producers of articles, the latter being defined in Article 3(4) thereof as 'any natural or legal person who makes or assembles an article within the [Union]'. It follows from that definition that the term 'producer of an article' refers solely to natural or legal persons who themselves make or assemble an article on the territory of the Union. It is therefore only if a person makes or assembles, on the territory of the Union, an object meeting the definition of article within the meaning of Article 3(3) of that regulation that that person will, in their capacity as producer, be subject to the requirements of Article 7(2) thereof. It thus becomes clear from a combined reading of Articles 3(4) and 7(2) of the REACH Regulation that the producers' duty of notification concerns only those articles which they make or assemble themselves.

56 This interpretation is supported by recital 29 in the preamble to the REACH Regulation, which states that '[s]ince 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', and adds that '[i]n 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 ECHA] should be notified'. In using the possessive adjective 'their', the legislature showed its intention to restrict the scope of the duties to register and notify provided for in Article 7(1) and Article 7(2) respectively of the REACH Regulation to those articles which the producers personally make or assemble.

57 It follows from the foregoing that the producer's duty to notify articles under Article 7(2) of the REACH Regulation is not applicable to an article which, although used by that producer as input, was made by a third party.

58 This literal interpretation of Article 7(2) of the REACH Regulation is in keeping with the objective pursued by the duty of notification and, more generally, the overall scheme of the regulation of which it forms a part. It must be remembered that it is, in essence, apparent from recital 21 in the preamble to the regulation that registration and assessment aim to yield information on substances and may also be used 'to initiate the authorisation or restrictions procedures under [that regulation] or risk management procedures under other Community legislation'.

59 In keeping with that general objective, the duty of notification provided for in Article 7(2) of the REACH Regulation is aimed at informing the ECHA about certain substances of very high concern which have not been registered. When they are contained in articles, such substances do not come

within the general duty to register substances per se or substances contained in mixtures as provided for in Article 6 of the REACH Regulation and the correlative duty to provide, for general registration purposes, the information listed in Article 10 of that regulation.

60 It is therefore in order to avoid an information deficit about the use of substances of very high concern in articles that Article 7(2) of the REACH Regulation requires producers and importers of those articles to notify the ECHA of certain information. Under Article 7(4)(e) of the REACH Regulation, that notification is to include 'a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s)'.

61 Thus, in the scenarios provided for in Article 7(2) of the REACH Regulation, the producer is required to notify the ECHA of the presence of substances of very high concern in the article that producer is making or assembling. If that article is subsequently used downstream by a second producer as input in the production of a complex product, that second producer is not then required also to notify the ECHA of the presence of the substance in question in that article. Such a notification would duplicate the one effected by the producer of that article. Such a redundant and needless burden is difficult to reconcile with the principle of proportionality observance of which is referred to in recital 130 in the preamble to the REACH Regulation.

62 It follows that, for the purposes of application of Article 7(2) of the REACH Regulation, it is for the producer to determine whether a substance of very high concern is present in a concentration over 0.1% weight by weight in any article produced by that producer.

63 The foregoing considerations are applicable, mutatis mutandis, to the duty of notification importers have under Article 7(2) of the REACH Regulation.

64 The term 'importer' is defined in Article 3(11) of the REACH Regulation as 'any natural or legal person established within the Community who is responsible for import', with 'import' being defined in Article 3(10) as 'the physical introduction into the customs territory of [the Union]'.

65 Given that definition, the importer of a product the composition of which comprises one or more of the objects coming within the definition of the term 'article' within the meaning of Article 3(3) of the REACH Regulation, must also be considered to be the importer of that article or those articles for the purposes of applying Article 7(2) of that regulation.

66 It should be borne in mind, as observed by the Advocate General in point 49 of her Opinion, that the duty of notification laid down in Article 7(2) of the REACH Regulation for producers and importers is aimed at ensuring that comprehensive information is provided to the ECHA on the use of substances of very high concern in articles. The duty importers have to notify also enables the ECHA to be informed of the quantities in which substances of very high concern are placed on the market. Thus, as evidenced by recital 34 in the preamble to that regulation, 'these [quantities] provide an indication of the potential for exposure of man and the environment to the substances'.

67 As observed by the Advocate General in point 68 of her Opinion, a different interpretation would give rise to a danger that the ECHA would not be informed of the use of substantial quantities of substances of very high concern placed on the internal market. Such a situation would not be in keeping with the regulation's objective of ensuring a high level of protection of human health and the environment.

68 In its observations, the Commission stated that it can be difficult for importers to obtain the required information from their suppliers established in non-EU countries. Difficulties of that nature do not, however, affect the interpretation of Article 7(2) of the REACH Regulation.

69 It follows that, for the purposes of applying Article 7(2) of the REACH Regulation, it is for the importer of a product made of up of more than one article to determine, for each article, whether a substance of very high concern is present in a concentration over 0.1% weight by weight of that article.

Article 33 of the REACH Regulation

70 Article 33(1) of the REACH Regulation states that '[a]ny supplier of an article containing a substance meeting the criteria in Article 57 and identified [as being of very high concern] 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'. Article 33(2) of that regulation imposes a similar duty on any supplier of an article meeting the same criteria, when requested to do so by a consumer.

71 The term 'supplier of an article' is defined in Article 3(33) of the REACH Regulation as 'any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market'.

72 The expression 'placing on the market' is defined in Article 3(12) of the same regulation in the following terms: 'supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market'.

73 It is apparent from the foregoing that the obligation provided for in Article 33 of the REACH Regulation is applicable to any person in the supply chain once that person makes an article available to a third party.

74 That obligation is distinct in a number of respects from the duty to notify provided for in Article 7(2) thereof.

75 First of all, its scope ratione personae is much broader than that of Article 7(2). Whilst Article 7(2) covers only producers and importers, Article 33 imposes an obligation to provide information on all operators along the supply chain. Whilst the ECHA is the sole recipient of the mandatory notification provided for in Article 7(2) of the REACH Regulation, there are many recipients of the information mandatorily provided pursuant to Article 33 thereof. Thus, under Article 33(1), the information must be provided to any 'recipient of [an] article', that is to say, as provided for in Article 3(35), to any person who is 'an industrial or professional user, or a distributor, being supplied with an article but does not include consumers'. The information referred to in Article 33(2) thereof must be provided to any consumer who requests it.

76 Next, the obligation provided for in Article 33 of the REACH Regulation is distinct from that provided for in Article 7(2) in terms of its conditions of applicability. As observed in paragraph 39 of this judgment, in order for the duty of notification to apply, four cumulative conditions must be met, including the condition of a concentration threshold for a substance of very high concern of 0.1% weight by weight. By contrast, that is the only condition required under Article 33.

77 Lastly, the mechanisms for notification and information differ in purpose. The purpose of the duty of notification is to inform the ECHA of the use of substances of very high concern in articles in order to lay the groundwork for the adoption, by the competent authorities, of potential risk management measures in accordance with the authorisation and restriction procedures put in place by the REACH Regulation. The duty to provide information provided for in Article 33 of the REACH Regulation, whilst contributing towards the attainment of the general objective of ensuring that human health and the environment are not adversely affected, is, as evidenced, in essence, by recitals 56 and 58 in the

preamble to that regulation, aimed at enabling all operators in the supply chain to take, at their stage, those risk management measures which follow from the presence of substances of very high concern in articles in order to guarantee their completely safe use.

78 The duty to provide information is aimed indirectly at allowing those operators and consumers to make a supply choice in full knowledge of the properties of the products, including those of articles forming part of their composition. It must be borne in mind in that regard that recital 12 in the preamble to the REACH Regulation states that an 'important objective of the new system to be established by this Regulation is to encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies where suitable economically and technically viable alternatives are available', which objective is reflected in Article 55 thereof, which provides expressly that substances of very high concern 'are [to be] progressively replaced by suitable alternative substances or technologies where these are economically and technically viable'.

79 The conjunction of these various factors therefore weighs in favour of an interpretation which guarantees the effectiveness of the duty to provide information provided for in Article 33 of the REACH Regulation, all along the supply chain through to the final consumer. The duty to provide information imposed on successive operators all along the supply chain is therefore intended to follow the article to which it relates through to the final consumer.

80 It would be incompatible with such a duty to take the position that the inclusion of an article as input in a complex product can interrupt the transmission of that duty to provide information to each of the operators along the supply chain, given that that duty relates directly to the presence of a substance of very high concern in that article.

81 As regards the fears expressed by certain parties who have submitted observations to the Court about the compatibility of such a system with the principle of proportionality, it should be noted that the duty to provide information follows from the duty of notification provided for in Article 7(2) of the REACH Regulation whilst completing it by organising, for the benefit of all operators along the supply chain through to the final consumer, the transmission of vital information about the presence of a substance of very high concern. Its scope, however, is limited by Article 33 thereof, which states that 'sufficient information, available to the supplier, to allow safe use of the article [in question]' must include, as a minimum, the name of that substance. That requirement, which is minimal in nature, cannot be regarded as being an excessive burden.

82 It follows that Article 33 of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.

83 It follows from all the foregoing considerations that the answer to the question referred is as follows:

— Article 7(2) of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a substance of very high concern identified in accordance with Article 59(1) of that regulation is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.

— Article 33 of the REACH Regulation must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.

Costs

84 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.

On those grounds, the Court (Third Chamber) hereby rules:

Article 7(2) 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) 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, as amended by Commission Regulation (EU) No 366/2011 of 14 April 2011, must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a substance of very high concern identified in accordance with Article 59(1) of that regulation, as amended, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.

Article 33 of Regulation No 1907/2006, as amended, must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.

[Signatures]