Reports of Cases

JUDGMENT OF THE COURT (First Chamber)

21 September 2016*

(Reference for a preliminary ruling — Approximation of laws — Cosmetic products — Regulation (EC) No 1223/2009 — Article 18(1)(b) — Cosmetic products containing ingredients, or a combination of ingredients, which have been the subject of animal testing 'in order to meet the requirements of this Regulation' — Prohibition of marketing within the European Union — Scope)

In Case C-592/14,

REQUEST for a preliminary ruling under Article 267 TFEU from the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) (United Kingdom), made by decision of 15 December 2014, received at the Court on 19 December 2014, in the proceedings

European Federation for Cosmetic Ingredients

v

Secretary of State for Business, Innovation and Skills,

Attorney General

intervening parties:

Cruelty Free International, formerly British Union for the Abolition of Vivisection,

European Coalition to End Animal Experiments,

THE COURT (First Chamber),

composed of R. Silva de Lapuerta, President of the Chamber, A. Arabadjiev, J.-C. Bonichot, C.G. Fernlund (Rapporteur) and E. Regan, Judges,

Advocate General: M. Bobek,

Registrar: L. Hewlett, Principal Administrator,

having regard to the written procedure and further to the hearing on 9 December 2015,

after considering the observations submitted on behalf of:

— European Federation for Cosmetic Ingredients, by D. Abrahams, Barrister, and by R. Cana, and I. de Seze, avocats,

* Language of the case: English.

— Cruelty Free International, and European Coalition to End Animal Experiments, by D. Thomas, Solicitor and A. Bates, Barrister,

— the United Kingdom Government, by L. Barfoot, acting as Agent, and by G. Facenna QC, and J. Holmes, Barrister,

— the Greek Government, by S. Charitaki and A. Magrippi, acting as Agents,

— the French Government, by D. Colas and J. Traband, acting as Agents,

— the European Commission, by L. Flynn and P. Mihaylova, acting as Agents,

after hearing the Opinion of the Advocate General at the sitting on 17 March 2016,

gives the following

Judgment

1 This request for a preliminary ruling concerns the interpretation of Article 18(1)(b) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ 2009, L 342, p. 59).

2 The request has been made in proceedings between the European Federation for Cosmetic Ingredients ('EFfCI'), on the one hand, and the Secretary of State for Business, Innovation and Skills ('Secretary of State for Business') and the Attorney General, on the other, with Cruelty Free International, formerly the British Union for the Abolition of Vivisection and the European Coalition to End Animal Experiments intervening, concerning the scope of the prohibition of marketing laid down in that provision.

Legal context

EU law

3 Recitals 4, 38 to 42, and 45 and 50 of Regulation No 1223/2009 state:

'(4) This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health.

...

(38) The Protocol on protection and welfare of animals annexed to the Treaty provides that the Community and the Member States are to pay full regard to the welfare requirements of animals in the implementation of Community policies, in particular with regard to the internal market.

(39) Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes [OJ 1986 L 358, p. 1] established common rules for the use of animals for experimental purposes within the Community and laid down the conditions under which such experiments must be carried out in the territory of the Member States. In particular, Article 7 of that Directive requires that animal experiments be replaced by alternative methods, where such methods exist and are scientifically satisfactory.

(40) The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, where such methods offer an equivalent level of protection to consumers.

(41) The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products should therefore be laid down. …

(42) It will gradually become possible to ensure the safety of ingredients used in cosmetic products by using non-animal alternative methods validated at Community level, or approved as being scientifically validated, by the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the Organisation for Economic Cooperation and Development (OECD). After consulting the [Scientific Committee for Consumer Safety (SCCS)] as regards the applicability of the validated alternative methods to the field of cosmetic products, the Commission should immediately publish the validated or approved methods recognised as being applicable to such ingredients. In order to achieve the highest possible degree of animal protection, a deadline should be set for the introduction of a definitive prohibition.

…

(45) The recognition by third countries of alternative methods developed in the Community should be encouraged. In order to achieve this objective, the Commission and the Member States should take all appropriate steps to facilitate acceptance of such methods by the OECD. The Commission should also endeavour, within the framework of European Community cooperation agreements, to obtain recognition of the results of safety tests carried out in the Community using alternative methods so as to ensure that the export of cosmetic products for which such methods have been used is not hindered and to prevent or avoid third countries requiring the repetition of such tests using animals.

…

(50) In the safety assessment of a cosmetic product it should be possible to take into account results of risk assessments that have been carried out in other relevant areas. The use of such data should be duly substantiated and justified.'

4 Under Article 1 of Regulation No 1223/2009, headed 'Scope and objective', that 'Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health.'

5 Article 3 of that regulation, headed 'Safety', provides:

'A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use, …'

6 Article 10 of that regulation, headed 'Safety assessment', lays down:

'1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.

The responsible person shall ensure that:

(a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;

(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;

(c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market.

...'

7 Article 11 of Regulation No 1223/2009, headed 'Product information file', provides that '[w]hen a cosmetic product is placed on the market, the responsible person shall keep a product information file for it' and that that file is to contain inter alia 'the cosmetic product safety report referred to in Article 10(1)' and 'data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries'.

8 Article 18 of that regulation, headed 'Animal testing', reads as follows:

'1. Without prejudice to the general obligations deriving from Article 3, the following shall be prohibited:

(a) the placing on the market of cosmetic products where the final formulation, in order to meet the requirements of this Regulation, has been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

(b) the placing on the market of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Regulation, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;

(c) the performance within the Community of animal testing of finished cosmetic products in order to meet the requirements of this Regulation;

(d) the performance within the Community of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Regulation, after the date on which such tests are required to be replaced by one or more validated alternative methods listed in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No. 1907/2206 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [OJ 2008 L 142, p. 1] or in Annex VIII to this Regulation.

2. The Commission, after consulting the [Scientific Committee for Consumer Safety (SCCS)] and the European Centre for the Validation of Alternative Methods (ECVAM) and with due regard to the development of validation within the OECD, has established timetables for the implementation of the provisions under points (a), (b) and (d) of paragraph 1, including deadlines for the phasing-out of the various tests. The timetables were made available to the public on 1 October 2004 and sent to the European Parliament and the Council. The period for implementation was limited to 11 March 2009 in relation to points (a), (b) and (d) of paragraph 1.

In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to 11 March 2013.

...

In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredient, a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consulting the [Scientific Committee for Consumer Safety (SCCS)] and by means of a reasoned decision, authorise the derogation. That authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.

A derogation shall only be granted if:

(a) the ingredient is in wide use and cannot be replaced by another ingredient able to perform a similar function;

(b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.

...'

9 Annex I to that regulation lists the items which must appear in the cosmetic product safety report and paragraph 8 thereof, which is included in Part A of that annex, entitled, 'Cosmetic product safety information', provides:

'Without prejudice to Article 18, the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints. …'

UK law

10 Regulation 12 of the Cosmetic Products Enforcement Regulations 2013 (SI 2013/1478) provides, inter alia, that it is a criminal offence for a person to contravene the prohibitions of Article 18 of Regulation No 1223/2009.

11 Regulation 6 of the 2013 Regulations provides that it is the duty of the enforcement authority, in the present case the Secretary of State for Business, to enforce Regulation No 1223/2009 and provides that authority with powers to investigate and prosecute an alleged contravention of the obligations imposed by Regulation No 1223/2009.

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

12 The EFfCI is a trade association representing the manufacturers within the European Union of ingredients for use in cosmetic products.

13 Members of that association have conducted animal testing outside the EU in order to test the safety to human health of certain cosmetic ingredients. The data from those tests was required for the use of those ingredients in cosmetic products intended to be sold in Japan and China.

14 Those ingredients have not yet been incorporated in the cosmetic products placed on the EU market, since the scope of the prohibition on animal testing laid down in Article 18(l)(b) of Regulation No 1223/2009 was uncertain.

15 Therefore, the EFfCI brought an action for judicial review before the referring court on the scope of that prohibition in order to determine the possible exposure of the three companies concerned to criminal penalties if they were to place on the UK market cosmetic products containing ingredients that have been the subject of animal testing outside the Union.

16 Before that court, the EFfCI claimed that the prohibition set out in Article 18(1)(b) of Regulation No 1223/2009 applies only where the animal testing at issue was carried out in order to meet one or more of the requirements of that regulation. Accordingly, where those tests have been performed outside the EU in order to meet the legislative or regulatory requirements of a third country, it cannot be considered that the ingredients have been tested 'in order to meet the requirements of [Regulation No 1223/2009].'

17 In contrast, the Secretary of State for Business and the Attorney General contended that Article 18(1)(b) of Regulation No 1223/2009 must be interpreted as being a prohibition of placing on the market also cosmetic products containing ingredients that have been tested on animals outside the EU in order to meet the requirements of legislation of a third country where the latter is analogous to Regulation No 1223/2009.

18 Cruelty Free International and the European Coalition to End Animal Experiments maintained, referring in particular to points 84 to 86 of Advocate General Geelhoed's Opinion in *France* v *Parliament and Council* (C-244/03, EU:C:2005:178), that that provision is intended to prohibit the marketing of cosmetic products containing any ingredient that has been the subject of animal testing, regardless of whether or not it is necessary to use the data obtained from that testing in third countries in order to prove that the product is safe for human health in accordance with Regulation No 1223/2009.

19 The referring court considers that the scope of Article 18(1)(b) of Regulation No 1223/2009, and in particular of the words 'in order to meet the requirements of this Regulation', raises a real issue of law.

20 In those circumstances, the High Court of Justice (England and Wales), Queen's Bench Division (Administrative Court) (United Kingdom), decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(1) Is Article 18(l)(b) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products to be interpreted as prohibiting the placing on the Community market of cosmetic products containing ingredients, or a combination of ingredients, which have been the subject of animal testing where that testing was performed outside the Union to meet the legislative or regulatory requirements of third countries in order to market cosmetic products containing those ingredients in those countries?

(2) Does the answer to question (1) depend on:
   (a) whether the safety assessment carried out by Article 10 of that Regulation to demonstrate that the cosmetic product is safe for human health prior to it being made available on the Community market would involve the use of data resulting from the animal testing performed outside the Union;
   (b) whether the legislative or regulatory requirements of the third countries relate to the safety of cosmetic products;

(c) whether it was reasonably foreseeable, at the time that the testing of an ingredient on animals was performed outside the Union, that any person might seek to place a cosmetic product including that ingredient at some stage on the Community market; and/or
(d) any other factor, and if so, what factor?'

The requests to reopen the oral procedure

21 By letters received at the Court Registry on 28 April and 6 June 2016, respectively, the EFfCI and the French Government requested the reopening of the oral procedure, on the grounds that the Advocate General's Opinion is based on considerations that have not been debated between the parties. In addition, the Opinion went beyond the scope of the questions referred, given that the referring court had expressly held that the animal testing carried out for the purposes 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), did not warrant a reference for a preliminary ruling.

22 It should be borne in mind that the Statute of the Court of Justice of the European Union and the Rules of Procedure of the Court of Justice make no provision for the interested parties referred to in Article 23 of that Statute to submit observations in response to the Advocate General's Opinion (see, inter alia, judgment of 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 24).

23 Under the second paragraph of Article 252 TFEU, it is to be the duty of the Advocate-General, acting with complete impartiality and independence, to make reasoned submissions on cases which, in accordance with the Statute of the Court of Justice of the European Union, require his involvement. The Court is not bound either by the Advocate General's Opinion or by the reasoning on which it is based (judgment of 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 24).

24 Consequently, a party's disagreement with the Opinion of the Advocate General, irrespective of the questions which he examines in his Opinion, cannot in itself constitute a ground justifying the reopening of the oral procedure (judgment of 9 June 2016, *Pesce and Others*, C-78/16 and C-79/16, EU:C:2016:428, paragraph 24).

25 That said, it should be recalled that the Court, in accordance with Article 83 of its Rules of Procedure, may at any time, after hearing the Advocate General, order the reopening of the oral procedure, in particular if it considers that it lacks sufficient information or where the case must be decided on the basis of an argument that has not been debated between the parties or the interested persons referred to in Article 23 of the Statute of the Court of Justice of the European Union.

26 In the present case, the Court, having heard the Advocate General, takes the view that it has all the information necessary to answer the questions referred and that that information has been debated between the parties, in particular during the hearing on 9 December 2015.

27 Therefore, the Court refuses the requests to reopen the oral procedure.

Consideration of the questions referred

28 By its two questions, which should be examined together, the referring court asks, in essence, whether and, if so, in what circumstances Article 18(1)(b) of Regulation No 1223/2009 must be interpreted as prohibiting the placing on the EU market of cosmetic products containing some ingredients that have been tested on animals outside the EU in order to market cosmetic products in third countries.

29 In order to answer those questions, it is appropriate, in particular, to examine whether the words 'in order to meet the requirements of [Regulation No 1223/2009]', appearing in Article 18(1)(b) of that regulation, may cover such animal testing as that at issue in the main proceedings.

30 In that regard, it should be noted that, according to their usual meaning in everyday language, those words suggest a reference to the intention of complying with the requirements of Regulation No 1223/2009, which would have been a reason for the testing at issue. From a purely literal point of view, those words may accordingly be interpreted as requiring evidence to be established that the person responsible for that testing, during the period when it was carried out, was motivated by the intention of meeting the requirements of that regulation. According to such an interpretation, animal testing allegedly motivated by a desire to comply with the regulatory requirements of third countries concerning the safety of cosmetic products, such as those at issue in the main proceedings, does not bring into play the prohibition set out in that provision.

31 However, it is settled case-law that, when a provision of EU law is interpreted, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (see, inter alia, judgment of 10 July 2014, *D. and G.*, C-358/13 and C-181/14, EU:C:2014:2060, paragraph 32 and the case-law cited).

32 In that regard, it should be recalled that, according to recital 4 of Regulation No 1223/2009, the latter is intended comprehensively to harmonise the rules in the European Union in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health. Accordingly, it follows from Article 1 of that regulation that it establishes rules that must be met by any cosmetic product placed on the EU market.

33 As regards the rules ensuring a high level of protection of human health, it is clear from Articles 3, 10 and 11 of that regulation that such a product is to be safe for human health, that its safety must be assessed on the basis of the relevant information and that the safety report must be drafted and included in the cosmetic product information file.

34 Regulation No 1223/2009 also contains rules which intend to establish a level of animal protection in the cosmetics sector exceeding that applicable to other sectors. In fact, it follows from an overall reading of recitals 38 to 42, and 45 and 50 thereof that the EU legislature sought to take into account the welfare requirements of animals under that regulation, in particular by actively promoting use of non-animal alternative methods to ensure the safety of products in the cosmetics sector, which is more extensive than in other sectors. In particular, it follows from recital 42 to that regulation that it will gradually become possible to ensure the safety of ingredients used in cosmetic products by using such methods, and that, '[i]n order to achieve the highest possible degree of animal protection, a deadline should be set for the introduction of a definitive prohibition' of other methods.

35 Accordingly, Regulation No 1223/2009 having the objective of establishing the conditions for access to the EU market for cosmetics products and ensuring a high level of protection of human health, whilst ensuring the well-being of animals by prohibiting animal testing in the sector of those products, Article 18(1)(b) of that regulation must be understood to make that access conditional upon compliance with the prohibition of animal testing.

36 In that regard, it should be noted, first, that it is in the context of the safety assessment of a cosmetic product required by Article 10 of Regulation No 1223/2009 that animal testing may be considered. Under Article 10(1)(b), the safety assessment of a cosmetic product is to be ensured using an appropriate weight-of-evidence approach for reviewing data from all existing sources. However, paragraph 8 of Annex I to that regulation provides that the toxicological profile, integral to the cosmetic product safety report, must be established without prejudice to Article 18 of that regulation.

37 The results of animal tests that are not included in that report cannot, therefore, be regarded as having been carried out 'in order to meet the requirements of [Regulation No 1223/2009]', within the meaning of Article 18(1)(b) of that regulation. In fact, where the cosmetic product safety assessment can be ensured without those results, access to EU market for that product is not dependent on such testing.

38 It should also be stated that, as the Advocate General noted in points 94, 95 and 98 of his Opinion, the mere inclusion in the cosmetic product information file of data resulting from animal testing is insufficient to trigger the prohibition laid down in Article 18(1)(b) of Regulation No 1223/2009. In fact, it follows from Article 11 of that regulation that the data on any animal testing performed inter alia by the manufacturer to meet the legislative or regulatory requirements of third countries must be included in that file.

39 By contrast, the fact of having relied, in the cosmetic product safety report, upon the results of animal testing concerning a cosmetic ingredient in order to demonstrate the safety of that ingredient to human health must be regarded as sufficient to establish that that testing had been carried out to meet the requirements of Regulation No 1223/2009 for obtaining access to the EU market.

40 It is irrelevant in that regard that the animal testing was required in order to market cosmetic products in third countries.

41 Second, it should be noted that Article 18(1)(b) of Regulation No 1223/2009 makes no distinction depending on where the animal testing at issue was carried out. The introduction, by interpretation, of such a distinction would be contrary to the objective relating to animal protection pursued by Regulation No 1223/2009 in general and by Article 18 thereof in particular.

42 In fact, as has been noted in paragraph 34 of the present judgment, that regulation seeks actively to promote the use of non-animal alternative methods to ensure the safety of products in the cosmetics sector, which is broader than in other sectors, in particular by phasing out animal testing in the cosmetics sector. In that regard, it should be noted that the attainment of that objective would be seriously compromised if it were possible to circumvent the prohibitions laid down in Article 18(1) of Regulation No 1223/2009, by carrying out the prohibited animal testing outside the European Union.

43 Therefore, read in the light of its context and objectives, that provision must be interpreted as meaning the results of animal tests, carried out outside the European Union in order to market cosmetic products in third countries, the results of which are used to prove the safety of those products for the purpose of their being placed on the EU market, must be regarded as having been carried out 'in order to meet the requirements [of that regulation]'.

44 The prohibition of marketing laid down in Article 18(1)(b) of Regulation No 1223/2009 may thus apply, provided that the animal testing at issue in the main proceedings has been carried out after the deadlines for the phasing out of the various tests, provided for in Article 18(2) of that regulation, which it is for the referring court to determine.

45 It follows from all the foregoing considerations that the answer to the questions referred is that Article 18(1)(b) of Regulation No 1223/2009 must be interpreted as meaning that it may prohibit the placing on the EU market of cosmetic products containing some ingredients that have been tested on animals outside the EU, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market.

Costs

46 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 (First Chamber) hereby rules:

Article 18(1)(b) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products must be interpreted as meaning that it may prohibit the placing on the European Union market of cosmetic products containing some ingredients that have been tested on animals outside the European Union, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purposes of placing them on the EU market.

[Signatures]