EUROPEAN COMMISSION

Brussels, 8th April 2015
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TO THE PRESIDENT AND MEMBERS

OF THE COURT OF JUSTICE OF THE EUROPEAN UNION

WRITTEN OBSERVATIONS

submitted pursuant to Article 23, second paragraph, of the Statute of the Court of Justice by the

EUROPEAN COMMISSION

represented by Mr. Leo FLYNN, Legal Adviser, and Ms. Polya MIHAYLOVA, Member of its Legal Service, acting as agents, with an address for service at the office of Merete Clausen, also a Member of its Legal Service, Bâtiment Bech, L-2721 Luxembourg, who consent to service by e-Curia,

in **Case C-592/14**,

The Queen, on the application of European Federation for Cosmetic Ingredients

v

Secretary of State for Business, Innovation and Skills and Attorney General,

and

British Union for the Abolition of Vivisection and European Coalition to End Animal Experiments, interveners,

Reference to the Court under Article 267 of the Treaty on the Functioning of the European Union from the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) – United Kingdom for a preliminary ruling on 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.

The European Commission ('the Commission') has the honour to present the following submissions and arguments to the Court:

I. BACKGROUND TO THE CASE

1. This reference 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[1] ('Regulation 1223/2009').

2. The reference has been made in proceedings between, on the one hand, the European Federation for Cosmetic Ingredients (the 'claimant before the national court') and, on the other, the Secretary of State for Business, Innovation and Skills and the Attorney General, in which the British Union for the Abolition of Vivisection and the European Coalition to End Animal Experiments have been admitted to intervene. The claimant before the national court seeks declarations[2] as to the scope of the prohibition on animal testing in relation to cosmetic ingredients imposed by Article 18(1)(b) of Regulation 1223/2009 to determine whether companies would be liable to criminal sanctions if they were to place cosmetic products on the market in the UK which included ingredients subjected to animal testing for the purposes of cosmetics legislation outside the European Union ('the Union'), in the present case in China and Japan.

3. Article 18(1)(b) of Regulation 1223/2009 provides for a marketing ban in the Union of cosmetic products containing ingredients or a combination of ingredients which, in order to meet the requirements of Regulation 1223/2009, have been subject of animal testing using a method other than an alternative method after that alternative testing method has been validated and adopted at Union level. According to Article 18(2) of that Regulation, the marketing ban is applicable since 11 March 2009, regardless of the absence of alternative methods, to all the tests covered by points (a), (b) and (d) of Article 18(1), apart from tests concerning repeated-dose toxicity,

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1 OJ L 342, 22.12.2009, p. 59.

2 Declaratory relief in the form of a declaration is a remedy which provides clarification of the rights and obligations of parties in a dispute. It is a form of preventive determination or adjudication which provides legal certainty for the parties. English courts have jurisdiction and discretion to grant declarations, both positive and negative, even when no other claim had been made. The limit on the jurisdiction is that the courts will not answer hypothetical questions. It is assumed, for present purposes that the referring court does not consider the issue before it to be hypothetical.

reproductive toxicity and toxicokinetics for which the limit date was 11 March 2013. Since 11 March 2013, the marketing ban is applicable for all the types of tests, regardless of the fact that alternative testing methods are not yet available for specific endpoints.

II. APPLICABLE LEGISLATION

4. Recital (42) of Regulation 1223/2009 reads as follows:

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 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.

5. Article 1 of Regulation 1223/2009 (*Scope and objective*) reads as follows:

This 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.

6. Article 18(1) of Regulation 1223/2009 *(Animal testing)* reads as follows:

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 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[...] or in Annex VIII to this Regulation.

7. Article 10(1) of Regulation 1223/2009 (*Safety assessment)* reads as follows:

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.

The first subparagraph shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. Those guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).

III. THE QUESTIONS REFERRED

8. The referring court asks the following two questions:

1) *Is 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 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 European 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 the first question depend on:*

a) *whether the safety assessment carried out in accordance with Article 10 of the 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 European Union;*

b) *whether the legislative or regulatory requirements of the third countries for which the animal testing was undertaken relate to the safety of cosmetic products;*

c) *whether it was reasonably foreseeable, at the time that an ingredient was subjected to animals testing outside the European 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?*

Legal analysis

9. The first question asked by the referring court pertains to the scope of the marketing ban laid down in Article 18(1)(b) of Regulation 1223/2009. In particular, it asks whether the marketing ban of cosmetic products containing ingredients tested on animals "*in order to meet the requirements of this Regulation*" also applies to cosmetic products containing ingredients tested on animals in order to meet third countries' cosmetics legislative or regulatory requirements.

10. In its second question, the referring court asks whether the answer to the first question depends on certain factors. The Commission will examine the first and the second questions together.

11. In its Communication to the European Parliament and the Council on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics[3] of 11 March 2013 ("the Communication"), the Commission informed the European Parliament and the Council of the Commission's decision not to propose any changes in the animal testing related provisions in Directive 76/768/EEC[4] and in Regulation 1223/2009 and the reasons

3 COM(2013) 135 final.

4 Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products, OJ L 262, 27.9.1976, p. 169.

for that decision. In the Communication, the Commission explained how the phrase "*in order to meet the requirements of this Regulation*" should be applied. It stated:

> *The majority of ingredients used in cosmetic products are ingredients that are equally in use in many other consumer and industrial products, such as in pharmaceuticals, detergents and food, and animal testing may be necessary to ensure compliance with the legal frameworks applicable to these products. Ingredients used in cosmetics will generally also be subject to the horizontal REACH requirements and animal testing may be necessary as a last resort to complete the respective data packages. It therefore is for Member States to assess and decide whether such testing for compliance with other frameworks is considered to be falling in the scope of the 2013 marketing ban. Critical to this is the wording 'in order to meet the requirements of this [...]Regulation' used in [Regulation 1223/2009] in order to qualify the scope of the 2013 marketing ban.*
>
> *The Commission considers that animal testing that has clearly been motivated by compliance with non-cosmetics related legislative frameworks should not be considered to have been carried out 'in order to meet the requirements of this [...] Regulation'. The resulting animal testing data should not trigger the marketing ban and could subsequently be relied on in the cosmetics safety assessment. Reliance on such data is subject to its relevance for the cosmetics safety assessment and its compliance with data quality requirements.*
>
> *Testing carried out for cosmetics relevant endpoints on ingredients that have been specifically developed for cosmetic purposes and are exclusively used in cosmetic products would in the Commission's view always be assumed to be carried out 'in order to meet the requirements of this [...] Regulation'.*
>
> *The Commission considers that the marketing ban is triggered by the reliance on the animal data for the safety assessment under the [Regulation 1223/2009], not by the testing as such. In case animal testing was carried out for compliance with cosmetics requirements in third countries, this data cannot be relied on in the Union for the safety assessment of cosmetics.*[5]

12. As such, the Commission has already given its interpretation of Article 18(1)(b) of Regulation 1223/2009 in the Communication. The implications of that proposed interpretation are set out hereafter.

13. An interpretation of Article 18(1)(b) of Regulation 1223/2009 as not applying to animal tests performed to meet the cosmetics requirements in third countries and relied upon for the safety assessment under the Regulation, would allow suppliers of cosmetic products to circumvent the requirements of Regulation 1223/2009. In that

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5 Page 8 of the Communication. Footnotes not reproduced. The elements relating to Directive 76/768 have also not been reproduced.

situation, whenever a supplier needed to test a new ingredient, it could decide to export the tests outside the Union and market its cosmetic product in a jurisdiction where animal testing is required for cosmetics purposes, before placing the product containing the tested ingredients on the Union market.

14. Moreover, according to the Commission, Article 18(1)(b) of Regulation 1223/2009 is origin-neutral. The Commission's interpretation ensures the application of the principle of non-discrimination between cosmetic products containing ingredients tested to meet the requirements of non-cosmetics legislation within and outside the Union. Cosmetic products containing ingredients which have been subject to animal testing to meet the legislative or regulatory requirements of third countries in a field other than that of cosmetics (for example medicinal products) should be treated in the same way as cosmetic products containing ingredients which have undergone animal testing for the purposes of Union non-cosmetics legislation. In such circumstances, the animal testing should not be considered to have been carried out "*in order to meet the requirements of this Regulation*".

15. The Commission considers that the principle of non-discrimination must be equally applied on the placing on the market of cosmetic products containing ingredients tested to meet the requirements of cosmetics legislation, whether within or outside the Union. Thus, the marketing ban applies to cosmetic products containing ingredients which have been subject to animal testing for the purposes of cosmetics legislation, in case the animal testing data thus obtained has been relied upon for the safety assessment carried out in accordance with Article 10 of Regulation 1223/2009.

16. It should be noted that neither the letter nor the spirit of Regulation 1223/2009 would allow for an interpretation discriminating between animal testing performed within or outside the Union. Article 18(1)(b) of Regulation 1223/2009 provides for a ban on the 'placing on the market'[6] of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of Regulation 1223/2009 (that is to say, cosmetics legislation), have been the subject of animal testing. The text of Regulation 1223/2009 does not in any way suggest that reliance

6 'Placing on the market' is defined in Article 2(1)(h) of Regulation 1223/2009 as the first making available of a cosmetic product on the Community market.

on data from animal testing performed in third countries is exempt from the marketing ban.

17. The Commission in its Communication confirmed the application of the general principle of non-discrimination on the basis of origin:

> *The 2013 marketing ban applies to all cosmetic products placed on the Union's market, thus to those produced in the Union and to imported cosmetic products alike. Competent authorities should ensure a level playing field between the different products on the market.*[7]

18. Furthermore, the Commission's interpretation is in line with the teleological interpretation of Article 18(1)(b) of Regulation 1223/2009 which should be read in accordance with the purpose of Regulation 1223/2009 as set out in its Article 1, namely, to ensure a high level of protection of human health. The prohibition on relying on animal testing data used to meet third countries' cosmetics legislative or regulatory requirements does not compromise human health. As long as it cannot be demonstrated, through non-animal alternative methods or through data generated before 11 March 2009 or 11 March 2013 in compliance with the marketing ban's regime, that a cosmetic product is safe, that product will not be allowed on the European market and will thus not endanger the health of consumers.

19. The Commission's interpretation is equally in line with the objective set out in the last sentence of recital (42) of Regulation 1223/2009, i.e. the achievement of 'the highest possible degree of animal protection'.

20. The Commission explained that objective in its Communication:

> *Animal welfare considerations were at the origin when the first provisions on a marketing ban of cosmetics tested on animals were introduced 20 years ago. The marketing ban, first introduced in 1993 with a deadline for 1998, was introduced with the clear political objective to end animal testing for cosmetics without being based on a scientific estimation when a full set of alternative methods would be available. Similarly, the European Parliament and the Council imposed the testing ban and the 2009 marketing ban in full knowledge that by that time a complete replacement of the relevant animal tests would not be possible. The European Parliament and the Council did not make the 2013 marketing ban dependent on the availability of a full set of replacement methods. In the meantime animal welfare*

7 Page 9 of the Communication. Footnotes not reproduced.

has been enshrined in Article 13 of the Treaty on the Functioning of the European Union (TFEU) as a European value to be taken into account in Union policies.[8]

21. The interpretation suggested by the Commission in the Communication also reflects the legislative context and the legislative history of Regulation 1223/2009. The substance of Article 18(1)(b) of Regulation 1223/2009 has not changed since the 7th amendment to Directive 76/768 by Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003.[9] The content of Article 4 bis (1)(b) as introduced by Directive 2003/15 (which corresponds in substance to Article 18(1)(b) of Regulation 1223/2009) was the result of a compromise between the co-legislators. Their aim was to avoid circumvention of the ban on animal testing by exporting the tests outside the Union, while ensuring compliance with the principle of non-discrimination. The Commission's interpretation as expressed in the Communication ensures that requirement is met.

22. In the first part of the second question, the referring court asks if the answer to the first question depends on whether the safety assessment carried out in accordance with Article 10 of Regulation 1223/2009 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.

23. The Commission's understanding is that where data resulting from the animal testing performed for the purposes of cosmetics legislation outside the Union is used for the safety assessment carried out in accordance with Article 10 of Regulation 1223/2009 to demonstrate that the cosmetic product is safe for human health prior to it being made available on the Union market, the placing on the market of that product is prohibited. Thus, where an ingredient has been subject to animal testing for the specific purposes of third countries' cosmetics legislative or regulatory requirements, the data from those tests may not be used to prove the safety of the cosmetic product as set out in Article 10 of Regulation 1223/2009, or else the placing on the market of that product is prohibited.

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8 Pages 5 and 6 of the Communication.

9 Directive 2003/15/EC of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products. OJ L 66, 11.3.2003, p. 26.

24. In line with that understanding and in order to allow effective market surveillance, the legislator has set out in Article 11(2)(e) of Regulation 1223/2009 the obligation of the responsible person[10] to include in the product information file 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. Therefore, responsible persons must ensure that for any animal testing data relied on in the product information file, including animal testing performed in third countries, relevant data (such as the date and place of the test) are clearly documented.

25. It is the task and responsibility of the Member States' competent authorities to monitor compliance with Regulation 1223/2009 by means of in-market controls of cosmetic products made available on the market and to ensure compliance with the animal testing provisions laid down by that Regulation.[11] It is then up to the national court to decide in each individual case of dispute, based on the information submitted to it, whether the data relied upon by the responsible persons constitutes data from animal testing performed for the purposes of third countries' cosmetics legislative or regulatory requirements. If the data is from animal testing performed for the purposes of cosmetics legislation, then the marketing ban on the products concerned would be triggered.

26. Based on the above, the Commission proposed that the first question and the first part of the second question of the referring court should be answered as follows:

Article 18(1)(b) of Regulation 1223/2009 must be interpreted as prohibiting the placing on the Union 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 European Union to meet the cosmetics legislative or regulatory requirements of third countries in order to market cosmetic products containing those ingredients in those countries, to the extent that the

10 Within the meaning of Article 4 of Regulation 1223/2009.

11 Article 25(1)(g) of Regulation 1223/2009.

animal testing data thus obtained has been relied upon for the safety assessment carried out in accordance with Article 10 of Regulation 1223/2009.

27. The referring court then asks if the answer to the first question depends on whether the legislative or regulatory requirements of the third countries for which the animal testing was undertaken relate to the safety of cosmetic products.

28. As explained above, the principle of non-discrimination should be respected in the interpretation to be given to Article 18(1)(b) of Regulation 1223/2009. In order to fall under the marketing ban foreseen in that provision, the ingredients or combination of ingredients would have to be subject to animal testing to meet third country legislative or regulatory requirements in the field of cosmetic products, as is the case for cosmetic products tested for the purposes of the Union's cosmetics legislation.

29. Therefore, point b) of the second question should be answered in the affirmative.

30. The referring court next asks if the answer to first question depends on whether it was reasonably foreseeable, at the time that an ingredient was subjected to animals testing outside the Union, that any person might seek to place a cosmetic product including that ingredient at some stage on the Community market.

31. The issue of the potential marketing ban arises when a person seeks to place a cosmetic product containing ingredients tested on animals for cosmetics purposes on the Union market. To place the product on the market, the safety of that product must be demonstrated based on alternative, non-animal methods or on data generated before the ban. Therefore, the intention at the time that an ingredient was subjected to animal testing outside the Union is irrelevant.

32. Point c) of the second question should thus be answered in the negative.

33. Finally, the referring court asks if the answer to the first question depends on any other factor, and if so, what factor.

34. In the view of the Commission, the other factor to take into account for the answer is the date when the animal testing was performed. It is still possible to rely on data from animal testing carried out for cosmetics purposes, in the absence of alternative methods before 11 March 2009 for all tests, except for tests concerning repeated-

dose toxicity, reproductive toxicity and toxicokinetics, and before 11 March 2013 for those three categories of tests. By contrast, reliance on animal testing data carried out after those dates for the purposes of cosmetics legislation triggers the marketing ban of Article 18(1)(b) of Regulation 1223/2009.

35. Therefore, the Commission proposes to reply to point d) of the second question that the other factor to take into account is the date when the animal testing for cosmetics purposes was performed.

36. Based on the above, the Commission proposed that the remainder of the second question of the referring court should be answered as follows:

It is relevant for the purposes of Article 18(1)(b) of Regulation 1223/2009 that the legislative or regulatory requirements of the third countries for which the animal testing was undertaken relate to the safety of cosmetic products.

It is not relevant for the purposes of Article 18(1)(b) of Regulation 1223/2009 that at the time that an ingredient was subjected to animals testing outside the Union that any person might seek to place a cosmetic product including that ingredient at some stage on the Community market.

For the purposes of Article 18(1)(b) of Regulation 1223/2009 the date when the animal testing for cosmetics purposes was performed is also relevant.

IV. CONCLUSION

37. In conclusion, the Commission has the honour to propose to the Court the following answers to the questions posed by the High Court of Justice (England & Wales), Queen's Bench Division (Administrative Court) – United Kingdom:

Article 18(1)(b) of Regulation 1223/2009 must be interpreted as prohibiting the placing on the Union 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 European Union to meet the cosmetics legislative or regulatory requirements of third countries in order to market cosmetic products containing those ingredients in those countries, to the extent that the animal testing data thus obtained has been relied upon for the safety assessment carried out in accordance with Article 10 of Regulation 1223/2009.

It is relevant for the purposes of Article 18(1)(b) of Regulation 1223/2009 that the legislative or regulatory requirements of the third countries for which the animal testing was undertaken relate to the safety of cosmetic products.

It is not relevant for the purposes of Article 18(1)(b) of Regulation 1223/2009 that at the time that an ingredient was subjected to animals testing outside the Union that any person might seek to place a cosmetic product including that ingredient at some stage on the Community market.

For the purposes of Article 18(1)(b) of Regulation 1223/2009 the date when the animal testing for cosmetics purposes was performed is also relevant.

[redacted]

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