

**IN THE COURT OF JUSTICE OF THE EUROPEAN UNION**

**CASE C-592/14**

**THE EUROPEAN FEDERATION FOR COSMETIC INGREDIENTS**

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**WRITTEN OBSERVATIONS OF THE UNITED KINGDOM**

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The United Kingdom is represented by Mr. Luke Barfoot of the European Law Group, Government Legal Department, acting as Agent, and by Mr. Josh Holmes, Barrister.

Submitted by:

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## A. INTRODUCTION

1. Pursuant to Article 23 of the Protocol on the Statute of the Court of Justice of the European Union, the United Kingdom (**‘the UK’**) submits these Written Observations to the Court.
2. The case arises out of a reference for preliminary ruling made by the High Court of England and Wales (**‘the Referring Court’**) on 12 December 2014, regarding 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 Regulation’**).
3. That provision prohibits the placing on the market within the European Union (**‘the EU’**) of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of the Regulation, have been the subject of animal testing.
4. The Claimant is a trade association representing manufacturers within the EU of ingredients for use in cosmetic products. Its members, or their customers, wishing to market cosmetic products in certain third countries, including China, must subject the products to tests on animals in order to demonstrate their safety for human health. It has brought proceedings before the Referring Court to determine whether such persons may lawfully place products that have been tested in this way on the market in the EU, relying upon the data obtained from the animal testing in order to show that they are safe for the purposes of the Regulation.
5. The Referring Court considers that the proper interpretation of Article 18(1)(b) of the Regulation is not free from doubt. It has therefore decided to stay the national proceedings in order to obtain guidance from the Court of Justice.

6. The Referring Court has referred two questions for preliminary ruling, which are set out at §24 of the order for reference. In summary, the Court seeks:
  - a. To ascertain whether the prohibition in Article 18(1)(b) applies in the case of cosmetic products containing ingredients, or combinations of ingredients, which have been tested on animals outside the EU in order to meet the legislative or regulatory requirements imposed by third countries on those wishing to market cosmetic products containing those ingredients in those countries; and
  - b. To establish the relevance of various factors in answering that question, including in particular:
    - i. whether the data obtained from such testing are used in order to demonstrate, for the purposes of the safety assessment required by Article 10 of the Regulation, that the cosmetic product is safe for human health; and
    - ii. whether the third country requirements relate to the safety of cosmetic products.
7. The United Kingdom sets out below its interpretation of the prohibition contained in Article 18(1)(b) of the Regulation by reference to those factors. In summary, the xxxxxxxxxxxxxxxx submits that:
  - a. **Point 1:** Article 18(1)(b) prohibits the placing on the market in the EU of a cosmetic product containing ingredients, or combinations of ingredients, which have been tested on animals outside the EU in order to satisfy the requirements of a third country, in circumstances where:

- i. the data obtained from the animal testing are used in order to demonstrate that the cosmetic product is safe for human health for the purposes of the Regulation and
  - ii. the third country requirements are intended to ensure the safety of cosmetic products.
- b. **Point 2:** Article 18(1)(b) does not prohibit the placing of such a product on the market in the EU in circumstances where the data obtained from the animal testing are not used in order to demonstrate that the cosmetic product is safe for human health for the purposes of the Regulation
- c. **Point 3:** Article 18(1)(b) does not prohibit the placing of such a product on the market in the EU in circumstances where:
  - i. the data obtained from the animal testing are used in order to demonstrate that the cosmetic product is safe for human health for the purposes of the Regulation; but
  - ii. the third country requirements are intended to ensure a purpose other than the safety of the cosmetic product, for which animal testing remains lawful in the EU.

## **B. ANALYSIS**

### **The United Kingdom's proposed interpretation of Article 18(1)(b) of the Regulation**

#### **Point 1**

8. In the United Kingdom's submission, the prohibition in Article 18(1)(b) of the Regulation applies to products containing ingredients, or combinations of ingredients, which have been tested on animals

outside the EU in order to satisfy the requirements of a third country, in circumstances where:

- a. the results of such testing are used in order to demonstrate that the cosmetic product is safe for human health for the purposes of the Regulation; and
  - b. the testing is required to be undertaken by the third country concerned in order to achieve the same purpose as is pursued by the Regulation, namely ensuring the safety of cosmetic products.
9. Such an interpretation accords with the purpose of Article 18(1)(b) as it emerges from the recitals in the preamble of the Regulation:
- a. Recital (38) underlines the need *‘to pay full regard to the welfare requirements of animals in the implementation of [EU] policies, in particular with regard to the internal market’*. Recital (42) likewise identifies the objective of achieving *‘the highest possible degree of animal protection’*.
  - b. Recital (39) refers to the requirement under Directive 86/609/EEC that *‘animal experiments be replaced by alternative methods, where such methods exist and are scientifically satisfactory’*.
  - c. Recital (40) records that *‘the safety of cosmetic products and their ingredients may be ensured through the use of alternative methods’* to animal testing, and that *‘the use of such methods by the whole cosmetic industry should be promoted and their adoption at [EU] level ensured, where such methods offer an equivalent level of protection to consumers’*.

10. It would be inconsistent with those objectives if the Regulation were construed as allowing cosmetic manufacturers to rely on data obtained from animal testing performed in third countries for the same purpose (of ensuring the safety of cosmetic products) as is pursued by the Regulation itself.
11. The proposed interpretation also accords with the view expressed by the Commission in its communication on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics (COM/2013/0135 final), at §3.1.
12. Such an interpretation would enable manufacturers easily to circumvent the requirements of Article 18(1)(b) of the Regulation, by purporting to place a product containing a given ingredient on the market in a third country where animal testing is required, carrying out animal tests and using the data resulting from such tests in order to meet the requirements of the Regulation.

## **Point 2**

13. However, on its proper construction, Article 18(1)(b) of the Regulation does not go so far as to preclude the placing on the market of a product containing ingredients which have been the subject of animal testing pursuant to the requirements of a third country, but where data obtained from such testing are not relied upon in order to demonstrate that the cosmetic product is safe for human health for the purposes of the Regulation.
14. In that case, it cannot be said that the tests are in any sense being used '*in order to meet the requirements of the Regulation*'.
15. It would be disproportionately onerous to require manufacturers to choose between marketing products containing particular ingredients in the EU and in third countries where animal testing is required.

16. Recital (45) in the preamble of the Regulation shows that this was not the intention of the EU legislature. That recital exhorts the Commission and the Member States to encourage the recognition by third countries of alternative methods to animal testing '*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*'. The recital therefore records the view of the legislature that unnecessary animal testing in third countries should be prevented or avoided. It does not indicate any intention that the effect of such testing should be to block the marketing of the products in question within the EU.

### **Point 3**

17. Equally, on its proper construction, Article 18(1)(b) of the Regulation does not prohibit a manufacturer from placing a product on the market in the EU which contains ingredients that have been tested on animals outside the EU in order to meet a third country's requirements where the purpose of those requirements is not to ensure the safety of cosmetic products but to achieve some other objective (e.g. the safety testing of a medicinal product), for which animal testing remains permissible within the EU.
18. In such a case, the testing is not undertaken in order to meet the same underlying purpose as the Regulation – namely to ensure the safety of cosmetic products – but rather to meet other objectives that are recognised as legitimate reasons to undertake animal testing within the EU legal order.
19. Such testing therefore cannot be said to have been undertaken '*in order to meet the requirements of the Regulation*', even where the data are subsequently used to meet those requirements.

**Arguments as to the construction of Article 18(1)(b) of the Regulation advanced by the Claimant in the national proceedings**

20. In the national proceedings, the Claimant contends that the Regulation permits manufacturers to meet the requirements of the Regulation by reference to data obtained from animal testing undertaken outside the EU to meet the requirements of a third country, whatever the purpose underlying those requirements.
21. The Claimant has advanced three principal arguments in support of that contention. For the reasons set out below, those arguments are incorrect.
22. First, the Claimant cites Articles 11(2)(e) and 20(3) of the Regulation, which both refer to animal testing in connection with products that are (lawfully) marketed in the EU, in support of a contextual interpretation of Article 18(1)(b) of the Regulation as permitting reliance on data obtained from animal testing.
23. Those provisions do not support the Claimant's case: under the interpretation of the United Kingdom, advanced above, a product may lawfully be marketed notwithstanding the fact that such animal testing has been undertaken in a third country. This may occur, for example:
  - a. where the testing was undertaken for a purpose other than to ensure the safety of cosmetic products; or
  - b. where the results of the testing are not relied on to show the safety of the products for the purposes of the Regulation; or
  - c. where the testing was undertaken before the deadline for validation and adoption of alternative methods at EU level.



24. Secondly, the Claimant refers to various recitals in the preamble of the Regulation, which show that the Regulation has as one of its purposes to achieve a functioning internal market in cosmetics.
25. However, it is also clear from the recitals that the Regulation was intended to achieve a high level of human health and respect for the welfare of animals. The United Kingdom submits that its interpretation of Article 18(1)(b) of the Regulation best achieves the purposes of the Regulation, considered together.
26. Thirdly, the Claimant identifies certain aspects of the legislative history of (what is now) Article 18(1)(b) of the Regulation, which are said to support its interpretation. In particular, it says that when the European Parliament first introduced an amendment providing for the prohibition now contained in that provision, the amendment referred to ingredients tested on animals '*in order to assess their safety or efficacy*', but the prohibition as adopted omitted the reference to '*safety or efficacy*'. This is said to support a narrow interpretation of '*the requirements of the Regulation*', excluding safety testing originally undertaken to comply with third country requirements.
27. However, the deletion of the reference to safety and efficacy could equally have been made because the legislature thought that the deleted words were otiose. The legislative history therefore does not provide any support for the Claimant's position.

## C. CONCLUSION

28. For the reasons set out above, the UK respectfully submits that the Court should answer the questions referred as follows:

**'Article 18(1)(b) of the Regulation prohibits the placing on the market of cosmetic products containing ingredients or combinations of ingredients the safety of which is proved, for the purposes of the Regulation, by means of data obtained from animal tests carried out in order to satisfy the legislative and**

**regulatory requirements of third countries, where those requirements are intended to ensure the safety of cosmetic products but not where they are intended to ensure other purposes, for which animal testing remains lawful in the EU.'**



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