

Neutral Citation Number: [2014] EWHC 4222 (Admin)

Case No: CO/8318/2013

**IN THE HIGH COURT OF JUSTICE**  
**QUEEN'S BENCH DIVISION**  
**ADMINISTRATIVE COURT**

Royal Courts of Justice  
Strand, London, WC2A 2LL

Date: 12/12/2014

**Before :**

**MR JUSTICE LEWIS**

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**Between :**

**THE QUEEN ON THE APPLICATION OF  
EUROPEAN FEDERATION FOR COSMETIC  
INGREDIENTS**

**Claimant**

**- and -**

**(1) SECRETARY OF STATE FOR BUSINESS,  
INNOVATION AND SKILLS  
(2) ATTORNEY GENERAL**

**Defendants**

**-and-**

**(1) BRITISH UNION FOR THE ABOLITION  
OF VIVISECTION  
(2) EUROPEAN COALITION TO END  
ANIMAL EXPERIMENTS**

**Interveners**

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**Mr G Jones QC and Mr D Graham (instructed by Steptoe Johnson) for the Claimant**  
**Mr G Peretz (instructed by Treasury Solicitors) for the Defendants**  
**Mr A Bates (instructed by David Thomas, Solicitor, British Union for the Abolition of  
Vivisection) for the Interveners**

Hearing date: 24 November 2014

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**Judgment**

Mr Justice Lewis:

## INTRODUCTION

1. This is a claim for judicial review seeking declarations relating to the marketing of cosmetic ingredients which have been tested on animals. The claimant is a trade association, the European Federation for Cosmetic Ingredients. It represents the manufacturers of chemical and natural ingredients used in the cosmetics industry. The members of the association sell those ingredients to other companies and those companies then use them in the production of cosmetics.
2. In brief, the claim is concerned with Article 18(1)(b) of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council dealing with cosmetic products ("the Cosmetics Regulation"). The provision prohibits the placing on the Community market of cosmetics containing ingredients which, in order to meet the requirements of the Cosmetic Regulation, have been tested on animals. That prohibition is enforced in the United Kingdom by criminal sanctions. The claimant seeks declarations that certain types of conduct do not fall within the prohibition and so would not involve the commission of a criminal offence. In particular, the claimant contends that where ingredients are tested in third countries for the purpose of satisfying the legislative or regulatory requirements of that third country, then the use of ingredients in cosmetics placed on the market in the European Union does not involve a contravention of the prohibition.

## THE FACTS

3. The relevant facts appear from the evidence of Dr Ungeheuer. Countries outside the European Union, such as China and Japan, require cosmetic ingredients to undergo certain tests, including tests on animals, to demonstrate the safety of those ingredients. There are three companies, who are members of the claimant association, which have carried out tests on animals in countries outside the European Union and generated animal test data on cosmetic ingredients after the material provisions of the Cosmetics Regulation came into force. The data obtained from these tests was required in order to enable these ingredients to be used in cosmetic products to be sold in Japan or in China. Dr Ungeheuer has been informed by the three companies that they carried out the tests for the purpose of third country legislation relating to cosmetics and the tests were not performed to meet the requirements of the Cosmetics Regulation. There is uncertainty about whether placing cosmetic products incorporating these ingredients upon the market in the United Kingdom, or the rest of the European Union, would involve a breach of the prohibition imposed by Article 18(1)(b) of the Cosmetics Regulation. The ingredients have not, therefore, been incorporated into cosmetic products placed on the Community market.

## THE LEGAL FRAMEWORK

### *The European Union Framework*

4. The relevant European Union institutions adopted the Cosmetics Regulation on 30 November 2009. The Cosmetics Regulation replaced a Council Directive dealing

with cosmetic products, namely Council Directive 76/768/EEC which had been amended on several occasions.

5. Article 1 sets out the purpose of the Cosmetics Regulation which is to establish rules to be complied with by any cosmetic product made available on the market in order to ensure the functioning in the internal market and a high level of protection of human health.
6. Article 2 gives certain definitions. The material definitions are in Article 2.1, sub-paragraphs (g) and (h). They provide as follows:

"Making available on the market' means any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge."

7. Then 'placing on the market' is defined as:

"The first making available of a cosmetic product on the Community market."

8. Article 3 of the Cosmetics Regulations provides that a cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use. The responsible person, as defined in Article 4 of the Cosmetics Regulation, must ensure compliance with the obligations imposed by the Cosmetics Regulation.
9. Article 10 of the Cosmetic Regulations provides that, in order to demonstrate that a cosmetic product complied with Article 3, the responsible person shall ensure that the cosmetic product has undergone a safety assessment on the basis of relevant information.
10. Article 11 of the Cosmetic Regulations requires the responsible person to maintain what is called a "product information file" containing certain information. Article 11(2)(e) says that the information to be included within this file includes data on any animal testing performed by the manufacturers' 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.
11. The central provision in this case is Article 18 of the Cosmetics Regulations. Article 18(1) provides 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 placed by one or more validated alternative methods listed in Commission Regulation (EC) No. 4402008 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) or in Annex VIII to this Regulation”.

12. The material provision, so far as the facts of this case is concerned is Article 18(1)(b), as this case concerns the scope of the prohibition on the placing on the Community market of cosmetic products containing ingredients.
13. Article 37 requires Member States to provide penalties for infringement of the Cosmetics Regulation. Within the United Kingdom, that is done by making it a criminal offence to breach the Cosmetics Regulations.

#### *The Domestic Legislation*

14. The relevant domestic regulations are the Cosmetics Products Enforcement Regulations 2013 (“the domestic Regulations”). Regulation 12 of the domestic Regulations provides that it is an offence for a person to contravene, amongst other provisions, the prohibitions imposed by Article 18 of the Cosmetics Regulation. Regulation 6 of the domestic Regulations provides that it is the duty of an enforcement authority to enforce the Cosmetics Regulations and an enforcement authority is empowered to investigate and prosecute an alleged contravention of the obligations imposed by the Cosmetics Regulations. The enforcement authorities within England and Wales are the Secretary of State and local weights and measures authorities.

#### THE ISSUES

15. Against that background, two issues arise. First, as a matter of domestic law, is this case an appropriate case in which to consider granting declaratory relief? Secondly, if so, should this court refer questions on the interpretation of Article 18(1)(b) of the Cosmetics Regulation to the Court of Justice of the European Union for a preliminary ruling pursuant to Article 267(2) of the Treaty on the Functioning of the European Union (“the TFEU”)?

#### THE FIRST ISSUE – THE APPROPRIATENESS OF DECLARATORY RELIEF

16. The first issue is whether it is appropriate for proceedings for a declaration to be brought for judicial review as a matter of domestic law. First, courts generally only entertain claims for declaratory relief where there is a genuine issue as between the parties that needs to be determined. There are a number of reasons why no genuine dispute may be considered to have arisen. The parties may be in agreement as to the relevant law. There may as yet not be any concrete set of facts in existence to provide the appropriate context or basis for considering or granting declaratory relief. The courts have accepted in the context of public law claims that they have jurisdiction to grant a declaration if there is a need to rule on a point of law of general importance. The discretion to do so, however, is to be exercised with caution and there needs to be a good reason in the public interest for the courts to take that course of action. In general, the courts have been reluctant to grant declarations, often referred to as advisory declarations, giving general rulings on points of law divorced from the facts of a current live dispute.
17. Secondly, the courts have been reluctant to grant declarations in civil proceedings as to whether or not particular conduct would be contrary to the criminal law. The reluctance to grant such declaratory relief is particularly great where a case is fact sensitive in that the outcome depends significantly on the particular facts of the case. Where the issue relates to matters of law, however, and where “there is a genuine, cogent public or individual interest” for granting a declaration, the courts may be prepared to entertain a claim (see *R (Haynes) v Stafford Borough Council* [2007] 1 W.L.R. 1365 at para. 16).
18. Thirdly, the claimant here is primarily seeking a reference to the Court of Justice of the European Union. It is important to bear in mind the circumstances in which the Court of Justice considers such rulings. Article 267 of the TFEU confers jurisdiction on the Court of Justice to give preliminary rulings concerning the validity and interpretation of acts of the European Union institutions. Where such a question is raised before any court or tribunal of a Member State, that court or tribunal may, if it considers that a decision on the question is necessary to enable it to give judgment, request the Court of Justice to give a ruling. The Court of Justice has consistently emphasised that the purpose of the preliminary ruling procedure is to assist in the administration of justice and to that end to provide rulings which are of use to the national court in dealing with a dispute before it and not to provide advisory opinions on general or hypothetical questions.
19. I am satisfied that a genuine issue of law, concerning the proper interpretation of Article 18(1)(b) of the Cosmetics Regulation, does arise in the present case and that it is necessary to resolve that issue in order to give judgment. This case concerns the question of whether, and if so in what circumstances, that Article

would prohibit the marketing of products which incorporate ingredients which have undergone testing on animals in third countries outside the European Union.

20. The claimant contends that the prohibition only applies to cosmetic products incorporating ingredients tested “in order to meet the requirements of this Regulation”. It contends that the prohibition in Article 18(1)(b) of the Cosmetics Regulation therefore only applies where the testing has been undertaken for the purpose of meeting one or more of the requirements of the Cosmetics Regulation, such as the need to obtain data to demonstrate that the product is safe for human health in accordance with Articles 3 and 10 of the Cosmetic Regulation. It submits that where ingredients are subject to animal testing outside the European Union, in order to meet the legislative or regulatory requirements of a third country, the ingredients have not been the subject of testing “in order to meet the requirements of” the Cosmetics Regulation and placing cosmetics products which include such ingredients on the Community market is not, therefore, prohibited. The claimant further submits that that interpretation is supported by the legislative context and the legislative history of the Cosmetics Regulation.
21. The Defendants contend that the prohibition in Article 18(1)(b) should be interpreted so that it prohibits the placing on the market of cosmetic products including ingredients which have been tested in order to meet the requirements of the Cosmetics Regulation and equivalent third country legislation. The Defendants contend that this interpretation is consistent with the purpose underlying the Cosmetics Regulation and with the view of the Commission expressed in a communication from the Commission to the European Parliament and the Council dated 11 March 2013. In that communication, the Commission expressed the view that:

"The Commission considers that the marketing ban is triggered by the reliance on the animal data for the safety assessment under the Cosmetics Directive/Regulation, not by the testing as such. In case animal testing was carried out for compliance with cosmetic requirements in third countries, this data can not be relied on in the Union for the safety assessment of cosmetics."
22. The interveners take the view that the purpose of the prohibition in Article 18(1)(b) is to prohibit the placing on the market of cosmetic products which include any ingredients which have undergone any animal testing. They consider that the marketing of cosmetic products including such ingredients is prohibited whether or not it is necessary to use the data obtained from testing in third countries to demonstrate that the product is safe for human health under Articles 3 and 10 of the Cosmetics Regulation. They rely on what they say is the purpose of the prohibition, and on Article 18(1) of the Cosmetics Regulation read as a whole, and on observations in the opinion of Advocate General Geelhoed, at paragraphs 84 and 86 in particular, in Case C-244/03 *France v Council and Parliament* [2005] ECR I-4012.
23. In my judgment, there is a real issue of law that needs to be resolved in this case as to the meaning of Article 18(1)(b) of the Cosmetics Regulation and, in particular, the words “in order to meet the requirements of this Regulation”.

Furthermore, there is a proper and genuine factual basis for consideration of that issue. The evidence is that three companies have subjected ingredients to animal testing outside the European Union to meet the regulatory requirements of third countries on the use of such ingredients in cosmetic products intended to be sold in third countries. The evidence is that there is uncertainty as to whether placing cosmetic products on the market in the United Kingdom which include such ingredients would involve a contravention of the prohibition and the commission of a criminal offence under the domestic Regulations. Further, there is a cogent individual interest on the part of the claimant in bringing these proceedings for judicial review as to the meaning of Article 18(1)(b) of the Cosmetics Regulations. There is no mechanism by which they could seek or obtain a ruling from the Defendants as to the scope of the prohibition imposed by Article 18(1)(b) of the Cosmetics Regulation. The only method, apart from the present proceedings, by which the interpretation of Article 18(1)(b) could be considered by the courts would be if a manufacturer of a cosmetic product were prepared to incorporate ingredients subjected to animal testing in third countries in a cosmetics product and then place that product on the market in the United Kingdom and run the risk of prosecution. It could then seek to raise the defence that, on a proper interpretation of the Cosmetics Regulations, its actions were not unlawful. It would not, in my judgment, be appropriate to compel the manufacturer of a cosmetic product to run that risk in order to enable this issue to be resolved. There is a cogent, individual interest in allowing a claim for a declaration to be brought notwithstanding that the case involves consideration of whether certain conduct would involve a criminal offence. This is a case where a genuine issue of law arises, on a proper factual basis. Furthermore, the court has before it three sets of parties putting forward the differing, and competing, arguments as to the proper scope of the prohibition in Article 18(1)(b) of the Cosmetics Regulations. In those circumstances, there is a real issue of interpretation raised which this court needs to resolve in order to give judgment.

THE SECOND ISSUE – IS A REFERENCE TO THE COURT OF JUSTICE APPROPRIATE?

24. The next issue is whether it is appropriate to refer questions of interpretation to the Court of Justice for a preliminary ruling as a matter of discretion pursuant to Article 267(2) of the TFEU. In my judgment, this is an appropriate case for a reference.
25. First, this case depends on the proper interpretation of European Union legislation. The Cosmetics Regulation was intended to harmonise the rules within the European Union in order to achieve an internal market for cosmetic products (as appears from the fourth recital to the Cosmetics Regulation). It is sensible and preferable for the Court of Justice to give a definitive interpretation of the relevant provision of the EU legislation, which will be applicable within all the Member States of the European Union.
26. Secondly, it is appropriate to bear in mind the guidance given by the Court of Justice in *CILFIT Srl v Ministero dello Sanita* [1982] ECR 3415. European Union legislation is drafted in several languages and the different language versions are all equally authentic. An interpretation of a provision of European Union law may involve a comparison of the different language versions. Even where the different

language versions are in accord with one another, European Union law uses terminology which is peculiar to it. Further, legal concepts do not necessarily have the same meaning in European Union law as in the law of the various Member States. More importantly here, every provision of European Union law must be placed in its context and interpreted in the light of the provisions of EU law as a whole, with regard being had to its objectives and to its state of evolution at the date on which the provision in question is to be applied. These factors all point in favour of making a reference in the present case.

27. Thirdly, the Court of Justice is able to consider submissions from the European Union institutions, and the Member States. Given the legislative history, there is a real possibility that different views may well emerge as to the purpose and scope of the Cosmetics Regulation.
28. For those principal reasons, this is an appropriate case in which to refer questions on the interpretation of Article 18(1)(b) of the Cosmetic Regulations to the Court of Justice. I have considered carefully the need not to overburden that Court, given its increasing workload. However, in this case, a ruling on the proper interpretation of Article 18(1)(b) of the Cosmetics Regulation is necessary to enable judgment to be given in this case and a reference to, and preliminary ruling by, the Court in this case is appropriate.
29. The parties have made submissions as to the questions that are appropriate for a reference. The form of the questions is, ultimately, a matter for the court itself to determine. The questions that, in my judgment, should be referred are these:
  - “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 question (1) depend on: -
    - (a) whether the safety assessment carried out in accordance with 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 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?"

## CONCLUSION

30. This claim involves a real issue, arising out of particular facts, as to the proper interpretation of Article 18(1)(b) of the Cosmetics Regulation and the prohibition on the placing on the Community market of cosmetic products containing ingredients which have been tested on animals outside the European Union to meet the legislative or regulatory requirements of third countries. A ruling on the questions of interpretation that arise is necessary to enable this court to give judgment in relation to the claim for a declaration. Given the nature of the issue that arises, and the advantages enjoyed by the Court of Justice of the European Union, it is appropriate to refer the questions to that Court pursuant to Article 267 (2) of the TFEU.