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CASE C-592/14

IN THE COURT OF JUSTICE OF THE EUROPEAN UNION

EUROPEAN FEDERATION FOR COSMETICS 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

WRITTEN OBSERVATIONS ON BEHALF OF THE INTERVENERS

The Interveners are represented by Mr David Thomas, Solicitor, and by Mr Alan Bates, Barrister.

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References in the format "[RB/[number]]" are references to tab numbers in the bundle of documents submitted to the Registry of the Court of Justice with the order for reference from the High Court of England and Wales

Introduction

1. These are the joint written Observations of the BUAV and ECEAE, made pursuant to the invitation of the Court of Justice dated 2 February 2015.

2. By order of the High Court of England and Wales ('**the Referring Court**') made on 24 November 2014, both organisations were given permission to intervene in the domestic proceedings and were constituted as parties to the proceedings, including for the purposes of the preliminary reference to the Court of Justice. [1] For ease of reference, they are described as '**the Interveners**' in these Observations. Their interest in the proceedings is identical, as is their position on the legal issues.

3. The following shorthand will be used:
   - **the Cosmetics Directive**: Directive 76/768/EEC (as amended)
   - **the 6th amendment**: the amendment to the Cosmetics Directive made by Directive 93/35/EEC
   - **the 7th amendment**: the amendment to the Cosmetics Directive made by Directive 2003/15/EEC
   - **the Cosmetics Regulation**: Regulation (EC) No 1223/2009, replacing the Cosmetics Directive
   - **REACH**: Regulation (EC) No 1907/2006 on the safety of chemicals
   - **cosmetic product**: products within the definition in Article 2(1) of the Cosmetics Regulation[2]
   - **the testing bans**: the prohibition on the animal testing within the EU of cosmetics products and ingredients, [3] introduced by the 7th amendment and now contained in Article 18 of the Cosmetics Regulation
   - **the marketing bans**: the prohibition, introduced by the 7th amendment and now also contained in Article 18 of the Cosmetics Regulation, on the sale in, and import into, the EU of animal tested cosmetics products and ingredients
   - **the cosmetics bans**: the testing bans and the marketing bans
   - **the three 2013 tests**: repeated-dose toxicity, reproductive toxicity and toxicokinetics tests, all of which were conditionally exempted from the ingredients marketing ban until March 2013 (at least) by the 7th amendment
   - **the 2013 deadline**: the conditional postponement of the ingredients marketing ban until March 2013 for the three 2013 tests

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[1] **[RB/17A]**.

[2] 'Product' is defined as '*any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours*'.

[3] Article 18 of the Cosmetics Regulation and the related recitals use the term '**ingredient**'. So do some other provisions. Elsewhere, the Regulation uses the term '**substance**'. Most other EU legislation, including REACH, uses the term 'substance' to describe chemicals. 'Ingredient' is not defined in the Cosmetics Regulation. 'Substance' is defined, in exactly the same way as in REACH. The terms 'ingredient' and 'substance' appear to be used interchangeably in the Cosmetics Regulation (see, for example recital (49)). They are used interchangeably in these Observations.

- **alternatives**: methods or approaches to test the safety of products or ingredients not involving the use of animals [4]
- **cruelty-free labelling**: labelling which informs consumers that there have been no animal tests in the development of a product

The Interveners

4. **The BUAV** is one of Europe's largest organisations campaigning against animal experiments. It adopts a pragmatic approach in that, wherever possible, it looks for a reduction in the number of animals used in experiments and in the suffering they endure. It also seeks to ensure that the protection which legislation is intended to give laboratory animals is indeed given.

5. **ECEAE** is Europe's leading alliance of animal protection organisations representing the many millions of people in the European Union who are concerned about the use of animals in laboratories. It has organisation members in 22 EU member states and is an accredited stakeholder organisation with the European Chemicals Agency ('**ECHA**'), having worked with it to improve its guidance to industry, in particular on the avoidance of animal testing.[5]

6. The BUAV developed, along with its ECEAE partners, an accreditation scheme (known as 'the Leaping Bunny') for cruelty-free labelling. As well as across the EU and elsewhere in Europe, it operates in Australia, the US, Canada, India, Columbia and Hong Kong. The BUAV's involvement gives it practical experience of the cosmetics industry and the requirements of regulators.

7. The BUAV's sister company, Cruelty Free International, campaigns around the world for bans on cosmetics testing on animals – for example, in the US, China, South Korea, Russia, India, Brazil, New Zealand, Israel, Argentina and Peru. The EU bans are always the benchmark in discussions and the proper interpretation of the bans, as determined by the Court of Justice, will therefore have implications far beyond the EU. India, Israel and, most recently, New Zealand, have announced bans based on the EU model and a number of other countries have signalled a modification to their regulatory practice and/or an intention to legislate.

The issue raised by the referred questions: the interpretation of Article 18(1)(b) of the Cosmetics Regulation

8. The questions asked by the Referring Court are directed at seeking from the Court of Justice a definitive interpretation of Article 18(1)(b) of the Cosmetics Regulation, which provides as follows:

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

9. The referred questions arise in the context of proceedings in which the Claimant is seeking a declaration from the Referring Court with regard to whether or not cosmetics products containing ingredients that have been tested on animals may nevertheless lawfully be marketed within the

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[4] The term is often used also to include methods or approaches which involve fewer animals or cause less suffering – the reduction and refinement limbs of the Three Rs principle – but in these Observations it is used to mean simply the replacement limb of that principle

[5] The ECHA has an important role with regard to the cosmetics bans (see paragraph 71 *et seq* below).

EU, provided that the testing was carried out in order to meet the requirements of a third country's legislation.

10. It is common ground that, for the purpose of answering the referred questions, the key phrase in Article 18(1)(b) is '*in order to meet the requirements of this Regulation*'. It is important to note that the same phrase also appears in subparagraphs (a), (c) and (d) of Article 18(1), prohibiting, respectively, the marketing of finished cosmetic products tested on animals, the testing of finished cosmetic products on animals, and the testing of ingredients used in cosmetic products on animals. The Court of Justice's definitive interpretation of the phrase '*in order to meet the requirements of this Regulation*' will therefore impact on the scope of application of *all four subparagraphs* of Article 18(1).

Summary of the Interveners' position

11. The Interveners submit that the phrase '*in order to meet the requirements of this Regulation*' refers to animal testing carried out for the purpose of demonstrating the safety for human health of cosmetics products or cosmetics ingredients (i.e. ingredients used predominantly in cosmetics). That interpretation is, for the reasons explained further below, consistent with *the purpose* of the cosmetics bans, including as discerned from their *legislative history*.

12. It is also consistent the principle of *effet utile* as relied on by Advocate General Geelhoed in Case C-244/03 *French Republic v European Parliament and Council of the European Union* [6] (**'the *French Cosmetics* case'**). As the Advocate General stated in that case:
    a. "*the ban on animal tests applies equally to tests performed for the purposes of complying with other legislation, in so far as substances that have been the subject of such tests may not be used as or in cosmetic products*" (AG's Opinion at paragraph 84); and further,
    b. "*cosmetic products and ingredients subject to animal tests outside the Community are subject to the marketing ban. Such tests would by their nature have been performed in order to meet public health requirements, thus falling within the prohibition*" (AG's Opinion at paragraph 86).

13. The Claimant's contrary position is that the phrase '*in order to meet the requirements of this Regulation*' refers only to animal testing carried out specifically for the purposes of satisfying the Cosmetics Regulation itself. In that regard, the Claimant considers that a distinction is to be drawn between, on the one hand, animal testing carried out specifically for the purposes of satisfying the Cosmetics Regulation, and on the other hand, *other* animal testing of cosmetics products or ingredients which is carried out in order to demonstrate their safety for humans. The Claimant contends for such an interpretation notwithstanding that the Cosmetics Regulation (and the Cosmetics Directive before it) does not mandate any particular tests, but rather requires that cosmetics products and ingredients are placed on the EU market only where the "responsible person" referred to in Article 4 of the Cosmetics Regulation (usually the manufacturer, importer or distributor) is satisfied that they are safe within the meaning of Article 3 of the Cosmetics Regulation ('*safe for human health when used under normal or reasonably foreseeable conditions of use*').[7] Pursuant to Articles 10 and 11 of the Cosmetics Regulation, the 'responsible person' is responsible for assessing the safety of the product or ingredient, and must also produce a 'product safety report' to be maintained within a 'product information file'.

14. The Claimant contends, on the basis of its preferred interpretation, that animal testing performed in order to meet public health requirements falls outside Article 18(1) whenever it can be said to have been done for any reason other than to satisfy a requirement directly imposed by the Cosmetics Regulation. Such other reasons for testing cosmetic products or ingredients on animals could, for example, include generating evidence to demonstrate the safety of the ingredients or

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[6] Case C-244/03 *French Republic v European Parliament and Council of the European Union* [2005] ECR I 4021, ECLI:EU:C:2005:178 (Advocate General's opinion), ECLI:EU:C:2005:299 (judgment).

[7] The fact that it is the "responsible person" who has the responsibility for ensuring that the product or ingredient is safe within the meaning of Article 3 is confirmed in Article 5(1) of the Cosmetics Regulation.

finished cosmetic products with a view to marketing cosmetics products in third countries, or demonstrating the safety of chemical substances under REACH. [8]

15. In the Interveners' submission, the interpretation contended for by the Claimant cannot be right, since it would, if adopted, render the prohibitions in Article 18(1) of the Cosmetics Regulation of practically no substantive effect. In particular, cosmetics products and ingredients that have been tested on animals after the relevant dates in Article 18(1) (see paragraph 23) could be freely marketed in the EU, provided that the person placing those products or ingredients on the EU market could point to some product safety requirement imposed by a third country for the purposes of which the animal testing could be said to have been carried out. Indeed, if the Claimant's interpretation were correct, it would be lawful even for such animal testing to be carried out *within the EU territory* provided that such testing was said to be being carried out to satisfy legislative or regulatory requirements other than the Cosmetics Regulation.

16. While the majority of third countries do not yet impose similar bans, very few third countries mandate the use of animal tests for confirming safety of cosmetics products and ingredients. The cosmetics bans in the EU serve to incentivise the development and use of alternatives to animal testing across the world. That was part of the purpose of the marketing ban. The ban should not be rendered ineffective in achieving that purpose by an interpretation that permits the placing on the EU market of cosmetic products and ingredients that have been tested on animals after the relevant dates, simply because the testing is said to have been carried out with a view to marketing the products or ingredients in third countries (and/or to confirm safety for workers or for other reasons). Nor would the effectiveness of the cosmetics bans in achieving that purpose be saved by interpreting them as permitting the Claimant's members to choose to use animal testing for verifying the safety of new cosmetics ingredients intended for sale worldwide, thereby satisfying themselves as to the safety of those ingredients, provided only that the member then omits to refer to the results of that animal testing when completing the product safety report form.

17. Further, as explained at paragraphs 71-82, the Claimant's interpretation would also permit the conduct of animal testing of cosmetics products and ingredients within the EU wherever it could be asserted that the testing was for the purpose of demonstrating the safety of those products/ingredients for workers involved in their production. Since those tests would be directed at demonstrating the safety of the products or ingredients for humans coming into contact with them, such testing cannot be meaningfully distinguished from safety testing of cosmetics and cosmetic ingredients for use as such: the tests in each case are identical. Again, an interpretation of Article 18(1) that allowed for such an exception would allow animal tests to be carried out for cosmetics purposes, and the marketing of animal tested cosmetics, within the EU, thus substantially depriving the cosmetics bans of their *effet utile* and also frustrating the result that the EU legislature intended the bans to achieve.

18. Article 18(1) reflects a moral position on the part of the EU legislature that the infliction of suffering on animals cannot be justified for the purpose of developing, and demonstrating the safety of, cosmetics products and ingredients. In prohibiting, within the EU, not only the testing on animals of cosmetics products and ingredients, but also the marketing of products and ingredients tested on animals after the relevant dates, the EU is not seeking to legislate extraterritorially, but rather to exercise its entitlement to regulate the marketing of products in the EU territory consistently with that moral judgement. It cannot have been intended by the EU legislature that animals be subjected to experiments for the purposes of cosmetics provided only that such testing could be said to have been carried out to confirm safety for workers involved in manufacturing the cosmetics, or with a view to placing the products on the market in third countries.

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[8] Although the referred questions make reference to only a sub-category of the latter reason – namely testing carried out in connection with *requirements imposed by third countries* – the logic of the Claimant's interpretation of Article 18 would apply to <u>any</u> situation where testing could be said to be being done for a purpose other than satisfying a requirement imposed by the Cosmetics Regulation.

The legislative history

19. The cosmetics bans had a lengthy gestation. The legislative history is as follows:

- **June 1993**: the 6th amendment prohibited the marketing of cosmetics containing ingredients (or combinations of ingredients) tested on animals after 1 January 1998. The ban was to be extended for at least two years if insufficient progress had been made with developing alternatives
- **April 1997**: Commission Directive 97/18 postponed the marketing ban until 30 June 2000, on the basis that insufficient progress had been made with developing alternatives
- **June 2000**: Commission Directive 2000/41 postponed the marketing ban a second and last time to 30 June 2002
- **February 2003:** the 7th amendment was introduced, incorporating both a testing ban and a marketing ban.
- **November 2009**: the Cosmetics Regulation replaced the Cosmetics Directive, incorporating the cosmetics bans.

20. It is also instructive to consider the process leading to the 7th amendment

- **5 April 2000**: the Commission made a proposal to amend the Cosmetics Directive. [9] The proposal replaced the marketing ban included in the 6th amendment with a ban on the performance in the EU of animal tests for cosmetics purposes (a testing ban).
- **3 April 2001**: the Parliament at first reading reinstated the marketing ban, whilst retaining the testing ban proposed by the Commission. The marketing ban was not conditional on alternatives being available.
- **22 November 2001**: the Commission issued an amended proposal, [10] accepting some of the Parliament's first reading amendments and rejecting others. In particular, it rejected a marketing ban which was not conditional on alternatives being available, citing World Trade Organisation (**'WTO'**) concerns and the Community's preference for pursuing animal welfare trade issues on a multilateral basis.
- **14 February 2002**: the Council adopted its Common Position on the Commission's proposal.[11] It retained the testing ban but included a marketing ban. Each ban was conditional on alternatives being available.
- **26 February 2002**: the Commission issued a Communication to the Parliament indicating its broad agreement with the Common Position. [12]
- **11 June 2002**: the Parliament amended the Common Position on second reading. It introduced, for the first time, exceptions to the marketing ban in respect of the three 2013 tests - for up to 10 years - but otherwise maintained its position that the marketing bans, as well as the testing bans, should be unconditional when they came into effect.
- **26 July 2002**: the Commission, in its opinion on the Parliament's second reading,[13] strongly rejected unconditional testing and marketing bans.
- **26 August 2002**: the Council indicated it could not accept all of the Parliament's amendments. The proposal was subsequently referred to Conciliation.
- **8 January 2003**: an agreement was reached at Conciliation, reflected in the 7th amendment. This contained both testing and marketing bans. Both were to come fully into force by March 2009 at the latest, irrespective of the availability of alternatives, except that the ingredients

[9] COM(2000) 189 final, OJ 2000/C 311 E/06.
[10] COM(2001) 697 final, OJ 2002/C 51 E/32.
[11] (EC) No 29/2002.
[12] SEC/2002/225/final.
[13] Com(2002) 435 final.

marketing ban was partially postponed until March 2013 in respect of the three 2013 tests (with a further postponement if necessary).

21. It is clear from this account where the areas of disagreement lay between the three institutions. The Commission wanted a testing ban but initially opposed implementation of the marketing ban contained in the 6th amendment; the Council wanted both a testing ban and a marketing ban, but each conditional on alternatives being available (a position with which the Commission then agreed); and the Parliament wanted both a testing ban and a marketing ban, in neither case conditional on alternatives being available. The Parliament prevailed, albeit that the bans would be introduced progressively over an extended period and be subject to an exceptional circumstances derogation.

22. As far as the cosmetics bans are concerned, the Regulation was not intended to effect any change in policy from the Cosmetics Directive. The wording of the relevant provisions is almost identical.

The timeline for the cosmetics bans

23. The timeline for the cosmetics bans in the 7th amendment (and now in the Cosmetics Regulation) coming into force was as follows:

- **March 2004**: testing and marketing bans for finished cosmetics products
- **March 2009**: testing ban for cosmetics ingredients (earlier if there was a validated alternative for the test in question)
- **March 2009**: marketing ban for ingredients (earlier if there was a validated alternative for the test in question), with an exception for the three 2013 tests
- **March 2013**: marketing ban for the three 2013 tests for ingredients (earlier if there was a validated alternative for the test in question). The Commission was given the power to make a legislative proposal, by March 2011, to extend the 2013 deadline if alternatives had not been developed but in the event chose not to do so.

24. The cosmetics bans do not apply to testing on animals carried out before each of the relevant dates.

25. Persistently in the proceedings before the Referring Court, the Claimant has referred to March 2013 as being the relevant date for all the bans. Indeed, the Referring Court fell into the same error when granting the Claimant permission to proceed with two of its grounds of challenge (this was prior to the Interveners' intervention). [14] This is plainly wrong. March 2013 was simply the date when the ingredients marketing ban was completed (the three 2013 tests could no longer be an exception); the testing bans had already fully come into force in March 2009 and so had most of the marketing bans. [15]

A political compromise

26. The cosmetics bans represent a political compromise. Animal welfare organisations (including BUAV and ECEAE) were far from happy with the outcome. They were unhappy, for example, about the long lead-in time for most of the bans (at least 10 years in respect of the three 2013 tests for the marketing bans), and about the fact that, because of the restrictive definition of 'cosmetic product' (now in Article 2 of the Cosmetics Regulation), botulinum toxins (botox) are excluded.[16] However, the animal welfare movement accepted that a political compromise had been wrought.

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[14] See paragraphs 35-40 of the Referring Court's judgment given on 15 May 2014 **[RB/15A]**.
[15] The testing and marketing bans for finished cosmetic products had come into force in March 2004.
[16] Botox is used extensively for cosmetics purposes. Because it is injected (subcutaneously), it falls outside the definition of 'cosmetics product' in the Cosmetics Regulation.

27. The Claimant, by contrast, appears unwilling to accept the compromise. As the Defendants (the relevant UK government departments) noted in their submissions to the Referring Court, [17] the Claimant disagrees with the political and ethical judgement of the EU institutions; it has attempted to frame that disagreement in a series of legal arguments. Its primary objective has been to have the cosmetics bans declared invalid. Its first attempt to do that was in the case it brought at the Court of First Instance.[18] The Claimant sought an order that Article 1 of the 7th amendment be annulled insofar as it inserted into the Cosmetics Directive Article 4a(2) and (2.1) and Article 4b (the cosmetic bans) and Article 6.3 (dealing with cruelty-free labelling).

28. In the event, both the Court of First instance and the Court of Justice held that the Claimant did not have standing to bring the case. The Claimant has subsequently sought to establish invalidity in the proceedings before the Referring Court, if its highly restrictive interpretation of Article 18 of the Cosmetics Regulation does not prevail. It has persisted in the attempt despite the Referring Court refusing permission to pursue the validity issue. [19] It will be shown further below just how restrictive the Claimant's interpretation is. In short: there is every indication that the Claimant's objective, if it cannot establish formal invalidity, is to secure an interpretation which would render the cosmetics bans of virtually no practical effect.[20]

Key features of the cosmetics bans

29. The testing bans in the Cosmetics Regulation are inward-looking: they prohibit the testing on animals for cosmetic purposes on the territory of Member States (after the relevant dates). Clearly, the EU cannot legislate for what happens in third countries.

30. The **marketing bans** are also inward-looking: they prohibit the marketing in the EU of cosmetics products where the products or their ingredients have been tested on animals (after the relevant dates). However, they are also outward-looking in the sense that what happens in third countries can determine whether cosmetics products may be marketed in the EU. This is why the Commission raised WTO concerns when proposing replacement of the marketing ban in the 6th amendment with a testing ban for the 7th amendment. (Both the Council and the Parliament rejected the Commission's concerns in their Observations in the *French Cosmetics* case, [21] as did the Advocate-General in his Opinion, [22] and no WTO challenge has been brought, but the Commission was correct in identifying that the marketing bans have an extra-territorial aspect).

31. This feature of the marketing bans is of crucial importance when resolving the referred questions. The EU legislators intended that the cosmetics bans would impact on conduct in third countries. In its Communication to the Parliament and the Council on 11 March 2013 (the Commission's 2013 Communication), [23] the Commission noted: [24]

> '*Past experience demonstrates clearly that animal testing provisions in the cosmetics legislation have been a key accelerator in relation to the development of alternative methods and have sent a strong signal far beyond the cosmetics sector and far beyond Europe. Methods developed in the cosmetics sector, such as reconstructed human skin models, are*

[17] Defendants' skeleton argument for the permission hearing on 15 May 2015 **[RB/8]**, paragraph 16.
[18] T-196/03 *European Federation for Cosmetics Ingredients v European Parliament and Council of the European Union*, reasoned order of 10 December 2004 (ECLI:EU:T:2004:355); on appeal Case C-113/05 P, reasoned order of 30 March 2006 (ECLI:EU:C:2006:222).
[19] See, for example, paragraph 58 *et seq* of the Claimant's consolidated skeleton argument for the substantive hearing before the Referring Court on 24 November 2014 **[RB/9]**.
[20] In similar vein, in *French Cosmetics* (note 6, *supra*), the Parliament suggested that the true objective of the French Government might have been to obtain a restrictive interpretation of the Cosmetics Directive by means of an action for annulment (France is home to many of the major animal-testing cosmetics companies, including, no doubt, many of the Claimant's members): Advocate General's Opinion, paragraph 56.
[21] See *French Cosmetics* (note 6, *supra*), Advocate General's Opinion, paragraphs 51 and 58.
[22] *French Cosmetics* (note 6, *supra*), Advocate General's Opinion, paragraph 114 *et seq*.
[23] COM(2013) 135 final
http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/com_at_2013_en.pdf, p3
[24] Paragraph 2.4, p6.

now used in other sectors as well and the interest in alternative methods for cosmetics has grown in many countries outside the Union.

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The Commission considers that the possible risks from the 2013 marketing ban can be turned into an opportunity for the Union to set an example of responsible innovation in cosmetics with positive impact beyond Europe' (emphasis added).

32. Importantly, the cosmetics bans have no impact whatsoever on the **safety** of cosmetics products. Cosmetics companies retain an overriding duty of safety, under Article 3 of the Cosmetics Regulation: '*A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use ...*'. Article 18(1) opens with the words, '*Without prejudice to the general obligations from Article 3*', making it clear that the overriding safety obligation remains despite the cosmetics bans.

33. Given that the EU has decided that animal tests for cosmetics, and the marketing of animal-tested cosmetics, should be prohibited but that cosmetics still have to be safe, the legal position is as follows: if and to the extent that an animal test, now banned, is *scientifically* thought important to ensure the safety of a particular cosmetics ingredient, the legal bar on using that test would mean that the ingredient could not be used, not that it could be used with a question mark over its safety. In any event, companies remain perfectly free to rely on the wealth of animal test data generated prior to the dates the relevant bans came into effect. Similarly, the marketing bans do not prevent the import and sale of cosmetics tested on animals prior to the relevant dates. This is a forward-looking measure. (The Interveners note in passing that the reliability of animal tests in determining the safety of cosmetics (or other) products is, in fact, strongly contested. They believe that alternative methods are often more reliable). [25]

34. The corollary of the potential inability to use an ingredient is that the EU legislators accepted that there might be a negative impact on **innovation** (although the extent of any impact is again strongly contested[26]). It is a truism that any regulation on the development and sale of a product could have an impact on innovation. The Claimant's attempts to rely in the domestic proceedings on Article 173 TFEU [27] and Articles 15 and 16 of the Charter of Fundamental Rights, [28] encouraging competitiveness, are therefore without merit. Those provisions are not intended to trump all other concerns, such as safety and animal welfare.

Purpose of the cosmetics bans

35. The Court of Justice, of course, adopts a purposive approach to interpretation of EU legislation. [29]

36. There is nothing in any of the *travaux préparatoires* – prior to the 6th amendment, the 7th amendment or the Cosmetics Regulation – spelling out precisely what is meant by the phrase '*in order to meet the requirements of this [Directive/Regulation]*'. Similarly, little assistance can be derived from a detailed textual analysis of the various proposals and counter-proposals put forward by the three EU institutions for the 6th and 7th amendments, because they approached

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[25] As long ago as 1992, an Explanatory Note by the Parliament noted that animal tests are often unreliable (paragraph 24)

[26] In the *French cosmetics* case, the Parliament 'reject[ed] the contention that the Directive would give rise to a disaster for the European cosmetics industry, pointing to the considerable number of cosmetic companies that had already implemented policies complaint with the Directive prior to its adoption' (paragraph 57 of the Advocate-General's Opinion). The Commission, in its 2013 Communication, saw an opportunity for a new risk assessment paradigm (p6).

[27] See, for example, paragraph 63 of the Combined Statement of Facts and Grounds **[RB/2]**

[28] See, for example, paragraphs 69 and 70 of the Combined Statement of Facts and Grounds **[RB/2]**

[29] See, for example, Case C-174/08 *NCC Construction Danmark A/S v Skatteministeriet* [2009] ECR I-10567 (ECLI:EU:C:2009:669), paragraph 23; Case C-162/91 *Tenuta il Bosco* [1992] ECR I-5279 (ECLI:EU:C:1992:392), paragraph 11; Case C-315/00 *Maierhofer* [2003] ECR I-563 (ECLI:EU:C:2003:23), paragraph 27; and Case C-280/04 *Jyske Finans* [2005] ECR I-10683 (ECLI:EU:C:2005:753), paragraph 34.

matters from such different, and evolving, policy standpoints. There are, nevertheless, overwhelming indications that, as one would expect, the legislators intended that the cosmetics bans should make a real impact.

Animal welfare as the objective of the cosmetics bans

37. The objective of the cosmetics bans is to further animal welfare and thereby to meet the ethical position of the EU public regarding the causing of animal suffering for cosmetics purposes. The **Commission** proposal for the 7th amendment acknowledged the ethical imperative: [30]

> '*In accordance with Directive 76/768/EEC, it is essential that the aim of abolishing animal experiments be pursued and that the prohibition of such experiments becomes effective on the territory of the Member States*' (emphasis supplied).

38. In its 2013 Communication, the Commission described animal welfare as an 'European value', [31] echoing recital (2) of Directive 2010/63/EC ('**the Animal Experiments Directive**').

39. Article 13 of the TFEU, referred to in recital (38) to the Cosmetics Regulation, [32] requires EU institutions to have full regard to animal welfare in the development and implementation of policy in specified areas, including, relevantly, the internal market.[33]

40. The Court of Justice has recognised the importance of animal welfare in the context of EU policy-making. For example, in *Agrarproduktion Staebelow GmbH*, [34] it said that, even when pursuing the objective of the protection of human health, other interests, including animal welfare, had to be fully taken into account. Similarly, in his opinion in the *French Cosmetics* case, the Advocate-General said there was no doubt that the elimination of animal suffering was a valid EU objective and that this was supported, not undermined (as France had argued), by the judgment of the Court of Justice in *Jippes*. [35] He referred [36] to the final sentence of what is now recital (42) of the Cosmetics Regulation: '*In order to achieve the highest possible degree of animal protection, a deadline should be set for the introduction of a definitive prohibition [on animal tests]*'.

41. Many of the animal tests traditionally used for cosmetics cause significant suffering – for example, the notorious Draize eye test which involves the dripping into rabbits' eyes of a substance (rabbits have no tear ducts and so cannot wash away the substance). [37]

42. The **Parliament** has been consistent in its opposition to animal testing for cosmetics throughout. At the second reading of the Commission's proposal to amend the Directive for a 7th time on 11 June 2002, Dagmar Roth-Behrendt MEP, the rapporteur from the Environment Committee,

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[30] Note 11 *supra*, recital (2).
[31] Commission's 2013 Communication, p6.
[32] What became Article 13 TFEU was at that time a Protocol to the EC Treaty.
[33] The legislative basis of the Cosmetics Regulation was Article 95 of the EC Treaty.
[34] [2006] ECR I-679 (ECLI:EU:C:2006:30), paragraph 37. See also Joined Cases C-96/03 and C-97/03 *Tempelman and van Schaijk* [2005] ECR I-1895 (ECLI:EU:C:2005:145), paragraph 48.
[35] Case C-189/01 *Jippes and Others* [2000] ECR I-5689 an unsuccessful challenge to a requirement to slaughter the applicant's animals following an outbreak of foot and mouth disease
[36] *French Cosmetics* (note 6, *supra*), Advocate General's Opinion, paragraph 96.
[37] The Claimant demonstrates a worrying lack of understanding of the effect the animal tests it wants to facilitate. In its consolidated skeleton argument for the substantive hearing in the domestic proceedings **[RB/9]**, it suggests: '... much of which experimentation would not harm the animals unnecessarily because the cosmetics manufacturers are not intentionally developing harmful products' (paragraph 68). However, substances are not applied to animals in the manner or in the quantity that consumers use their cosmetics; rather, the substances are force-fed into animals' stomachs via the throat, and applied to other sensitive parts of their bodies, in quantities far in excess, relative to body weight, of those a consumer would ever use. The doses used are designed to induce a carcinogenic or reproductive toxic effect, or other toxic effect, for some of the animals. The studies can last for up to two years. The Claimant lists some of the common tests in paragraph 104 of its Combined Statement of Facts and Grounds **[RB/2]**, by reference to the REACH testing Annexes.

captured the mood of members: '*So let there be a stop to animal experiments in the field of cosmetics*'. A petition with 4 million signatures had been presented to the EU. [38]

The purpose of the marketing bans

43. The **Parliament's** amendments, reinstating the marketing bans alongside a testing bans, were passed with a majority of nearly 500 votes. [39] The Environment Committee had passed them 44:0 on second reading, with just 2 abstentions. [40] During the second reading debate, Chris Davies MEP noted that a testing ban was ineffective without a marketing ban, a point Ms Roth-Behrendt herself noted, during the post-Conciliation debate on 15 January 2003, that the Parliament had stressed time and again – animal testing would otherwise simply be exported.

44. In its submissions to the Referring Court, the **Claimant** acknowledged: [41]

> '*The Claimant does accept that it is arguable that the banning the marketing of products which have been tested on animals, for any purpose, would tend to advance the legislative purpose or reducing the use of animals in experimentation. This is particularly the case where the product is an existing product on sale in the EU but proposed to be exported and marketed to a third country that requires animal testing. That was the view taken by the Advocate-General [in the French Cosmetics case]...*'

Banning animal-tested cosmetics products and ingredients from sale would act as a disincentive to testing them on animals in the first place. That is an important purpose of the marketing ban, as acknowledged by the Commission in its 2013 Communication (see extract at paragraph 31 above).

45. The Claimant has confirmed that most animal testing for cosmetics happens outside the EU. [42] The EU legislators recognised that the bans therefore had to have a global dimension. EU companies could otherwise carry out or commission animal tests outside the EU and sell the resultant cosmetics products in the EU, with no animal welfare gain.

The Interveners' submissions on the phrase 'in order to meet the requirements of this Regulation'

46. Article 18(1) of the Cosmetics Regulation prohibits animal tests, or the marketing of products or ingredients tested on animals, where the tests have been carried out 'in order to meet the requirements' of the Regulation. One therefore has to discern what are the requirements of the Regulation.

47. Article 1 identifies the objectives of the Regulation: '*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*' (emphasis added). Article 3 requires that cosmetics products placed on the EU market are safe.

48. The safety of cosmetics products has to be assessed and demonstrated by manufacturers and importers. Under Article 10(1), the 'responsible person' which each manufacturer and importer has to nominate [43] must, in order to demonstrate compliance with Article 3, ensure that a product has undergone a safety assessment on the basis of relevant information and that a cosmetic safety

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[38] See the speech of Marilies Flemming MEP at 2nd reading.
[39] See the second speech of Ms Roth-Behrendt during the debate on 24 September 2012.
[40] See the first speech of Ms Roth-Behrendt during the second reading debate on 11 June 2002.
[41] Claimant's skeleton argument for the permission hearing on 15 May 2014 **[RB/7]**, para 45.
[42] *Ibid*, paragraph 63.
[43] See Article 4(1) of the Cosmetics Regulation.

report is compiled in accordance with Annex I. Under Article 11, the responsible person must keep a product information file for cosmetic products placed on the market. [44]

49. It follows from all this that an animal test is carried out to meet the requirements of the Cosmetics Regulation if it is designed to ensure the safety of the ingredient or product – the protection of human health. In the *French Cosmetics* case, the **Council** agreed: [45]

> '*... the Council maintains that the expression "in order to meet the requirements of this Directive" in the contested provision refers simply to the objective of Directive 76/768, namely, the protection of public health. In the Council's contention, the contested provision clearly means that only alternative methods that do not resort to animal testing may be used as evidence that a cosmetic ingredient or product is safe for public health.*
> ...
> *The marketing prohibition extends to cosmetic products for which animal tests have been used outside the Community for the purpose of compliance with third country legislation ... the prohibition on marketing extends not only to those products for which animal tests have been carried out within the Community, but also for which animal tests have been carried out outwith the Community*'.

50. The **Parliament** echoed [46] many of the arguments expounded by the Council, unsurprisingly given the strong views expressed by Members during debates.

51. In the same case, the Advocate-General advised:

> '*81. As observed by the Council, the phrase 'in order to meet the requirements of this Directive' must be read in the context of the overriding objective of Directive 76/768 to which Article 4a is expressly subject, namely, the protection of public health. As noted above, this principle is expressed in Article 2 of the Directive: "Cosmetic products put on the market within the Community must not be liable to cause damage to human health when they are applied under normal conditions of use".*
>
> *82. It is to my mind clear that the phrase at issue thus expresses the legislature's intention that animal tests to which the prohibitions apply must be aimed at achieving the public health requirements for cosmetics set out in Directive 76/768. Furthermore, it seems to me reasonable to suppose that, in the cosmetics sector, practically all animal tests would be performed for this purpose, and this has not been denied by the French Government.*
>
> ...
>
> *86. ... it follows equally from this wording that cosmetic products and ingredients subject to animal tests outside the Community are subject to the marketing ban. Such tests would by their nature have been performed in order to meet public health requirements, thus falling within the prohibition*'.

The Interveners respectfully agree with the positions of the Council and the Advocate-General as set out above.

52. It is quite unnecessary to ask, as the Claimant urges, which particular regulatory regime, EU or third country, the manufacturer had in mind when carrying out an animal test. That is not the question Article 18(1) wants answered. Article 18 covers testing carried out for the protection of

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[44] The file must include animal data relating to the development or safety assessment of a product or its ingredients, including any animal testing preformed to meet the legislative or regulatory requirements of third countries: Article 11(2)(e). This refers principally to data generated prior to the entry into force of the relevant cosmetics bans. As explained above, there is nothing to prevent companies relying on historic animal data, and it is clear that they will continue to do so for many years.

[45] *French Cosmetics* (note 6, *supra*), Advocate General's Opinion, paragraphs 46-47.

[46] *French Cosmetics* (note 6, *supra*), Advocate General's Opinion, paragraph 52.

human health, because that is what the Regulation is designed to achieve. It is irrelevant whether particular tests are required by separate legislation or in practice mandated by separate regulatory requirements. As explained above, the Cosmetics Regulation does not mandate any particular test or data, or require prior approval of products, and any programme of safety testing for cosmetics will therefore in practice be done under some other legislative or regulatory regime, whether EU or third country (see further paragraph 61 below).

53. It would, in any event, place an intolerable burden on Member States, were they required to identify which particular legislative or regulatory regime (or regimes) a manufacturer had in mind when carrying out or commissioning an animal test. Given the global nature of the cosmetics market, the reality is that a manufacturer will almost certainly have multiple markets, and therefore multiple regulatory regimes, in mind. It would be impossible to determine which regime was at the mental forefront, if that were the legal test. Indeed, as the UK Government pointed out in its submissions to the Referring Court, [47] different employees within the same company may see different purposes: whose is to prevail? What if the intended market changes over time, as is perfectly possible?

54. In any event, given that what is at issue are cosmetics products which a company wishes to market in the EU, it is almost inevitable that demonstrating safety for the purposes of the Cosmetics Regulation will form at least part of the motivation for carrying out a test – a point made by the UK Government in its Detailed Grounds of Resistance of 11 July 2014. [48]

The relevance of Article 2(4) of REACH

55. The relationship between the cosmetics bans and REACH has an important bearing on this case. REACH requires companies manufacturing or importing substances (over one tonne a year) to register them with the ECHA and hold data establishing their safety. Substances (ingredients) used in cosmetics are often used in other types of product, too. The EU legislators therefore had to make provision for the relationship between the cosmetics bans and the new regime under REACH then under consideration. Substances used in cosmetics are just as much subject to the REACH regime as any other substances.[49] The outcome of the legislators' deliberations was Article 2(4) of REACH:

> '*This Regulation shall apply without prejudice to:*
> ...
> *(b) Directive 76/768 [the Cosmetics Directive] as regards testing involving vertebrate animals within the scope of that Directive*' [50] (emphasis supplied.)

In other words, the cosmetics bans take precedence over the requirements of REACH, where those requirements would lead to animal testing. That which is prohibited under the Cosmetics Regulation cannot take place under REACH. There is, therefore, no question of a cosmetics company being required to carry out an animal test under REACH on an existing ingredient and then find itself unable to use it in future. Cosmetics ingredients have to be *registered* under REACH, and data has to be supplied for them. But they cannot be *tested on animals*. Since the primary objective of both REACH [51] and the Cosmetics Regulation is the protection of human health, the position is entirely consistent with the Interveners' submission that '*in order to meet the requirements of this Regulation*' simply means '*for the protection of human health*'.

56. By contrast, on the Claimant's narrow construction, Article 2(4) would not have been needed at all. Tests carried under REACH would have not been tests carried out '*in order to meet the*

[47] Defendants' detailed grounds of resistance dated 11 July 2014 **[RB/6]**, paragraph 10.
[48] *Ibid*, paragraph 12.
[49] The only relevant exceptions are those in Article 2(7)(a) and Annex IV, and Article 2(7)(b) and Annex V, of REACH: substances for which there is sufficient information to demonstrate minimal risk and substances for which registration is deemed inappropriate, respectively.
[50] Article 2(6)(b) of REACH disapplies Title IV (information in the supply chain) for cosmetics products. Article 14(5) says that a chemical safety report need not include consideration of risks from such products.
[51] See Article 1(1) of REACH.

requirements of this Regulation' if the phrase meant only tests carried out with the Cosmetics Regulation specifically in mind. There would have been no legislative clash to make provision for. Thus, the fact that the EU legislators thought it necessary to delineate the relationship between the two pieces of legislation shows that they did not intend 'in order to meet the requirements of this Regulation' to have the narrow meaning for which the Claimant contends.

The Claimant's interpretation of 'in order to satisfy the requirements of this Regulation' would deprive the cosmetics bans of their effet utile

57. It is instructive to understand more about the Claimant's position in the proceedings before the Referring Court, because this casts important light on the answers to the referred questions. When it initiated the proceedings, the Claimant asserted a number of propositions, in each case framed in terms of reliance on data generated by animal tests:

i. The cosmetics bans do not prohibit reliance on animal data generated before the bans came into effect (this has, in fact, always been common ground between all the parties and the EU institutions)

ii. They do not prohibit reliance on data from animal tests conducted to comply with other EU legislation such as REACH (even where the ingredient is used exclusively in cosmetics products). [52] This includes testing for both existing and new ingredients.[53] It is clear from the Claimant's letter to the UK Department for Business Innovation & Skills on 20 June 2013 [54] that it was the relationship between the Cosmetics Regulation and REACH that most concerned the Claimant and its members, not third country legislation

iii. The cosmetics bans do not prohibit reliance on data from animal tests conducted to comply with third country legislation. As the case developed, it became clear that the Claimant contended that it could even rely on data from animal tests conducted within the EU if the tests were carried out with a view to the products being exported. [55]

58. On 15 May 2014, the Referring Court granted the Claimant permission to proceed with the two parts of proposition (iii). [56] At the substantive hearing on 24 November 2014, the Claimant abandoned its request for a declaration that it was permissible to rely on data generated within the EU, where the testing was done to comply with third country legislation (i.e. for export). However, it is important to understand that that proposition is entirely consistent with the Claimant's contention that it is permissible to rely on animal data generated outside the EU to comply with third country legislation. It argues that what matters is the narrow purpose for which an animal test is carried out. If the purpose is to comply with legislation other than the Cosmetics Regulation, the animal test, it says, falls outside the scope of Article 18 – it would not have been carried out '*in order to meet the requirements of this Regulation*'. Since that phrase must have the same meaning in each of the subparagraphs of Article 18(1), the result must be that it is permissible, on the Claimant's construction, to carry out animal tests within the EU, if the objective is to comply with the requirements of third country legislation.

59. The consequence is this: were the Court to answer referred question 1 in the way the Claimant urges, the effect would not only be that the relevant products could be marketed in the EU, but also testing on animals could take place within the EU. That would emasculate not only the marketing bans but also the testing bans.

60. The Claimant goes further. In its Combined Statement of Facts and Grounds [57] in the proceedings before the Referring Court, it refers [58] to '*tests permitted or required by other legislation*'

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[52] See paragraph 24 of Mr Ungeheuer's first witness statement made on 16 July 2013 **[RB/18]**.
[53] See paragraph 5(b) of the Claimant's Reply to the Defendants' Summary Grounds of Resistance, dated 23 September 2013 **[RB/4]**.
[54] **[RB/2A]**.
[55] See, for example, paragraph 51 of the Claimant's skeleton argument for the permission hearing on 15 May 2014 **[RB/7]**.
[56] Order of the Referring Court dated 15 May 2014 **[RB/16]**.
[57] **[RB/2]**.

(emphasis added). Where third countries have laws governing animal experiments, they are usually extremely permissive; many have no laws at all. Contrary to the impression given by the Claimant, [59] third country legislation only very rarely *requires* cosmetics ingredients or products to be tested on animals. The position is generally that it is for a manufacturer to demonstrate safety, and how it does so is a matter for it, subject to oversight by the regulator. On the Claimant's approach, the fact that a company was permitted to satisfy a given country's requirements by relying on animal testing data – even though not required to do so – would mean that it was then free to sell the resultant cosmetic product in the EU, and thereby sidestep the marketing bans. Moreover, it could sell the product here after animal tests in a third country even though there were alternatives for those tests recognised by EU legislation. [60]

61. As already noted, the Claimant also argued that companies can rely on animal data generated under REACH – even substances which are solely used in cosmetics. The argument, to recap, is that such data has not been generated '*in order to meet the requirements of [the Cosmetics] Regulation*', but rather to meet the requirements of a separate piece of legislation. This ignores Article 2(4) of REACH, discussed above, but more importantly it ignores the reality that animal testing will almost always take place, or be permitted by, some other legislation, whether EU or third country. The Cosmetics Regulation, unusually for EU safety legislation, does not mandate any particular test or data and does not require prior authorisation or registration before a cosmetic can be marketed. In that respect, it may be contrasted with, for example, the Medicines Directive, [61] the Veterinary Medicines Directive, [62] the Biocides Regulation [63] and the Pesticides Regulation, [64] as well as with REACH. Cosmetics companies must carry out a safety assessment, and the results must be available in the product information file, but no prior regulatory approval is needed and no testing regime is mandated.

62. One may ask, rhetorically: when, on the Claimant's approach, would animal testing *ever* take place to meet the requirements of the Cosmetics Regulation? Even if the Claimant was able to identify a small subset of cases, it is inconceivable that this is all the EU legislators had in mind when negotiating the political settlement over so many years.

The UK Government's position

63. According to the judgment given by the Referring Court, the UK Government's position is that Article 18(1)(b) 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 analogous third country legislation (i.e. cosmetics legislation). [65]

64. This suffers from the same defect as the Claimant's position: it seeks to discern which regulatory regime a manufacturer had in mind when carrying out an animal test, rather than simply ask whether it was for the purposes of protecting human health. The interpretation is slightly less restrictive than the Claimant's but it still represents fundamentally the wrong approach, as demonstrated by the gloss on the wording of Article 18(1)(b) which the UK Government feels compelled to add to breathe a little more life into the provision. It would also lead to uncertainty: by what criteria would it be decided whether third country legislation was 'analogous to' the Cosmetics Regulation?

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[58] Claimant's the Combined Statement of Facts and Grounds **[RB/2]**, paragraph 127(b).
[59] See, for example, paragraph 109 *et seq* of the Combined Statement of Facts and Grounds **[RB/2]**.
[60] Such as Commission Regulation 440/2008. Made under REACH. The UK Government departments have recognised this point in their submissions to the Referring Court: Defendants' skeleton argument for the substantive hearing on 24 November 2014 **[RB/10]**, paragraph 29.
[61] Directive 2003/83/EC.
[62] Directive 2003/82/EC.
[63] Regulation (EU) No 528/2012.
[64] Regulation (EC) No 396/2005.
[65] See paragraph 30 of the Defendants' skeleton argument for the substantive hearing on 24 November 2014 **[RB/10]**.

Reliance on data or prohibition on marketing?

65. In its 2013 Communication, the Commission said: [66]

> '*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 cosmetics requirements in third countries, this data cannot be relied on in the Union for the safety of assessment of cosmetics*'.

66. The Claimant appears to agree. But this again represents an unwarranted gloss on what Article 18(1)(b) actually says, if the suggestion is that a company could *market* in the EU cosmetics products containing ingredients tested on animals (after the relevant date), provided that no reliance was placed on the data in the safety assessment. The provision, by its express terms, prohibits 'the placing on the market' of cosmetics products containing ingredients tested on animals. 'Placing on the market' is defined by Article 2(1)(h) as '*the first making available of a cosmetic product on the Community market*', and 'making available on the market' is in turn defined, by Article 2(1)(g), as '*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*'. The prohibition is on marketing, not on reliance on data.

67. The interpretation is also unrealistic in that it assumes that, where the safety of a product or ingredient has been verified by means of animal testing data, that knowledge can then somehow be shut out of the mind of the 'responsible person' when considering whether or not the product or ingredient is safe within the meaning of Article 3. But evidence in the form of animal testing data which supports a conclusion that a product or ingredient is safe will inevitably be within the institutional knowledge of the responsible person when deciding whether or not it can vouch for the safety of that product or ingredient. That knowledge, and therefore the use of animal testing for verifying the safety of the product or ingredient, cannot be vanished away simply by the responsible person avoiding mention of that data in the product safety report required by Article 10. It would be too easy for a manufacturer to sidestep the prohibition in Article 18(1)(b) by claiming that it relied in its safety assessment not on particular data but on the absence of any adverse effects from use of an ingredient.

68. In the *French Cosmetics* case, the Advocate-General said: [67]

> '*... it seems clear that the ban on animal tests applies equally to tests performed for the purposes of complying with other legislation, in so far as substances that have been the subject of such tests may not be used as or in cosmetic products. This interpretation seems necessary for the effet utile of the Directive and is consistent with the intention expressed in the preparatory documents leading up to its adoption*' (emphasis added).

The Interveners respectfully agree with this analysis. The Advocate-General correctly identified that the consequence of breach of Article 18(1)(b) was that the ingredient in question (or, therefore, a product containing it) could not be marketed in the EU. (He did not spell it out, but the Interveners would accept that the sanction only applies to ingredients which are *predominantly* used in cosmetics (see paragraphs 71-75 below).

69. The **Parliament's** press service said on 24 March 2009:

> *'The last time this topic came before Parliament, MEPs fought hard and successfully for a ban on sales of any animal-tested cosmetics products and ingredients, including those from outside the EU ...*' (emphasis added)

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[66] Paragraph 3.1, p8

[67] *French Cosmetics* (note 6, *supra*), Advocate General's Opinion, paragraph 84.

Conclusion on the Interveners' interpretative approach

70. The Interveners' interpretation of the phrase '*in order to meet the requirements of this Regulation*' is the natural meaning, in context. It also has the merit of ease of application by Member States. It is entirely consistent with the purpose of the testing and marketing bans, as identified above.

Worker safety and exclusive use

71. There are further aspects to the meaning of the phrase '*in order to meet the requirements of this Regulation*'. These relate to whether the cosmetics bans extend to ingredients which are not exclusively used in cosmetics (but are predominantly so used) and to worker safety testing. These are not issues explicitly raised by the referred questions but they are directly relevant to the proper interpretation of the phrase.

72. ECHA and the Commission have recently given their opinion on these aspects, in the context of the relationship between the Cosmetics Regulation and REACH. On 27 October 2014, ECHA posted this note on its website: [68]

> '*To meet the requirements of the new Cosmetics Regulation (Regulation (EC) 1223/2009) cosmetic products are prohibited to be placed on the market where the final formulation, ingredients in a final formulation or a finished product, have been subject to animal testing. Those same chemical ingredients may, however, also need to be registered under REACH. This has created some uncertainty about whether testing on animals can take place in order to comply with REACH, or whether it should not, in order to comply with the Cosmetics Regulation.*
>
> *The European Commission, in cooperation with ECHA, has now clarified the relationship between the marketing ban and the REACH information requirements as follows:*
>
> - *Registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints, with the exception of tests that are done to assess the risks to workers exposed to the substance. Workers in this context, refers to those involved in the production or handling of chemicals on an industrial site, not professional users using cosmetic products as part of their business (e.g. hairdressers).*
> - *Registrants of substances that are used for a number of purposes, and not solely in cosmetics, are permitted to perform animal testing, as a last resort, for all human health endpoints.*
> - *Registrants are permitted to perform animal testing, as a last resort, for all environmental endpoints.*
>
> *Therefore, the testing and marketing bans in the Cosmetics Regulation do not apply to testing required for environmental endpoints, exposure of workers and non-cosmetic uses of substances under REACH.*
> *Registrants of substances registered exclusively for cosmetic use will still have to provide the required information under REACH wherever possible, by using alternatives to animal testing)such as computer modelling, read-across, weight of evidence etc.)*'.

73. The Interveners disagree with ECHA and the Commission on their approach to exclusive use and worker safety.

Exclusive use

74. The Interveners submit that ECHA and the Commission are wrong to say that the cosmetics bans only apply to ingredients used exclusively in cosmetic products. As noted above, most ingredients used in cosmetics are also used in other products. To limit the cosmetics bans to ingredients

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[68] "ECHA/NA/14/46, 'Clarity on interface between REACH and the Cosmetics Regulation', available at http://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation

exclusively used in cosmetics would therefore severely curtail their scope. The Interveners maintain that the correct position is that the bans extend to ingredients mainly, even if not exclusively, used in cosmetics. Such ingredients are recognisably cosmetics ingredients. That would accord with what the public understands by the bans. It would be for Member States to determine whether an ingredient was recognisably a cosmetic ingredient.

75. On the ECHA/Commission approach, an ingredient would fall outside the scope of the cosmetics bans even if it was used 99.9% in cosmetics products. Indeed, it would, presumably, be sufficient to take an ingredient out of scope if, at the time of testing, the manufacturer foresaw a possible non-cosmetics use, albeit one not then identified and even though the manufacturer was commissioned to develop the ingredient by a company dealing exclusively in cosmetics. At the time of testing, it is always foreseeable that an ingredient may in time find a non-cosmetics use.

Worker safety

76. By 'workers', ECHA and the Commission mean people involved in the manufacture, formulating and packaging of a substance. [69]

77. The Interveners submit that the EU legislators cannot possibly have intended that tests carried out for worker safety should fall outside the scope of the cosmetics bans. That would, once again, deprive the bans of virtually any *effet utile*. Worker safety data is required under REACH: it has to be addressed in the chemical safety report required for most substances under Article 14 and Annex I. Importantly, the tests deployed for worker safety are identical to those required for consumer safety. There are no separate testing requirements for worker safety.

78. The ECHA/Commission note gives two examples where worker safety testing would not be required in the context of REACH: (i) where a substance is imported into the EU already incorporated into an article: and (ii) where it is used under such strictly controlled conditions that there is no worker exposure. In fact, example (i) is unlikely to obviate animal tests because the substance will probably have been tested on animals before incorporation into an article and export to the EU. The scope of the cosmetics ban would in practice be limited to the extremely narrow second example.

79. Workers, to state the obvious, are human beings. As already noted, Article 1 of the Cosmetics Regulation explains that its objective is to achieve a high level of protection of human health. The Regulation does not impose obligations simply on retailers but also to those further down the supply chain. For example, Article 6(4) states: '*Distributors shall ensure that, while a product is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in this Regulation*'. In any event, tests done for worker safety will directly benefit consumers (because the tests are identical).

80. Commissioner Vella sought to justify why tests for worker safety fell outside the scope of the cosmetics bans in a written answer to the Parliament on 24 February 2015: [70]

> '*...Worker exposure to ingredients during the manufacturing of cosmetics can be very different to consumer exposure to the final cosmetic product. Workers may handle substances in greater quantities, with higher concentrations and more frequently than consumers. Therefore animal testing may be required to protect people working in that industry even for substances that have no other uses than in cosmetics ...*'

With respect, this entirely misses the point. The political settlement, as explained above, is that the suffering of animals is not justified for the development of cosmetics ingredients. The degree of risk which a particular ingredient may represent in a particular situation is irrelevant. If the

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[69] The ECHA notice (*ibid.*) states: '*Workers in this context, refers to those involved in the production or handling of chemicals on an industrial site, not professional users using cosmetic products as part of their business (e.g. hairdressers)*'.

[70] P-000498/2015, available at http://www.europarl.europa.eu/sides/getAllAnswers.do?reference=P-2015-000498&language=EN

risk can only be assessed by causing suffering to animals, society must forego the ingredient: that is what the Parliament and the Council decided in 2003.

Conclusion on worker safety and exclusive use

81. The ECHA/Commission note addresses animal testing under REACH. However, the principles it puts forward would apply to any other legislation, including third country legislation. On the ECHA/Commission approach, an ingredient tested on animals for worker safety in China, or an ingredient with a minor non-cosmetics use so tested there, could be marketed in the EU. The note includes a diagram showing when the cosmetics bans would and would not apply. It demonstrates that, if the approach were right, the cosmetics bans could hardly ever apply. Only ingredients exclusively used in cosmetics, in the rare case where no worker safety testing would take place, would be within scope.

82. Importantly, the public statements which the Commission has made give no hint of the highly restrictive interpretation of the cosmetics bans it now advances. Rather, its statements describe bans on *any* animal tests for cosmetics products and ingredients, regardless of the specific purpose of the test. For example:

- in its press statement of 15 January 2003 [71] on the introduction of the 7th amendment, it said: '*It will thus no longer be possible for the ingredients used in cosmetics products to be tested on animals once alternative tests have been validated at European level, and in any event the final deadline for ending these tests will be in six years' time*'. There was no qualification such as 'unless they have been tested for worker safety' or 'provided the ingredients are exclusively used in cosmetics'

- In its Q&A issued on 11 March 2003, [72] the Commission said, in answer to the question *With the full ban in place – can consumers be sure that cosmetics and cosmetic ingredients purchased in Europe were not subject to animal testing?*:

  > '*With the testing and marketing ban in force there can be no new animal testing for cosmetics purposes in the Union – be it for cosmetics products or ingredients thereof – and it is no longer possible to simply carry out testing for these purposes outside the Union and then use data here to substantiate the safety of cosmetics. Consumers can therefore be sure that the cosmetic use of an ingredient in Europe cannot be the reason for any new animal testing*' (emphasis added).

  Again, there is no qualification.

- Similarly, in a statement issued on 11 March 2014, to mark the first anniversary of full implementation of the ingredients marketing ban, Commissioner Mimica referred to '[the] complete prohibition of animal testing for cosmetics in the EU' and said '... *the Union has taken global leadership to demonstrate that safe and innovative cosmetics are possible without new animal tests*'.

Those statements simply cannot be reconciled with the ECHA/Commission note.

Answers to the referred questions

83. The Interveners respectfully submit that the referred questions should be answered as follows:

1. **Yes. The words '*in order to meet the requirements of this Regulation*', as used in Article 18(1) of the Cosmetics Regulation, refer to animal tests carried out for the purpose of verifying the safety for human health of a cosmetics product or ingredient. Accordingly,**

[71] Commission Press Release IP/03/55, available at http://europa.eu/rapid/press-release_IP-03-55_en.htm .
[72] http://europa.eu/rapid/press-release_MEMO-13-188_en.htm

Article 18(1)(b) of the Cosmetics Regulation prohibits the placing on the EU market cosmetic products containing ingredients, or a combination of ingredients, which have been tested on animals for the protection of human health (including that of workers). It is irrelevant whether the testing nominally takes place for compliance with separate legislative or regulatory requirements, in the EU territory or in a third country. The prohibition applies to ingredients predominantly used in cosmetics products, which is for Member States to assess.

2. **The only relevant factors are (i) whether the animal test was for the protection of human health (including that of workers); and (ii) whether the ingredient is predominantly used in cosmetic product. The prohibition relates to the placing on the market of relevant cosmetics products, not to the reliance on data.**

[redacted]

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[redacted]

ALAN BATES
Barrister

13 April 2015