Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 17 March 2016[1]

Case C-592/14

European Federation for Cosmetic Ingredients
v
Secretary of State for Business, Innovation and Skills
(Request for a preliminary ruling from the

High Court of Justice of England & Wales, Queen's Bench Division (Administrative Court) (United Kingdom))

(Request for a preliminary ruling — Internal market — Regulation No 1223/2009 — Article 18(1)(b) — Cosmetic products — Cosmetic ingredients — Ban on the marketing of cosmetic ingredients having been tested on animals))

Table of contents

I – Introduction 2

II – Legal framework 3

A – EU law 3

B – National law 4

C – WTO law 4

III – Facts, procedure and questions referred 5

IV – Assessment 6

A – Preliminary considerations 6

B – Analysis of Article 18(1)(b) 7

1. Introduction 7

2. Appreciation of key elements of the parties' positions 8

1 — Original language: English.

a) EFfCI and the French Republic 8

b) Commission and the United Kingdom 10

c) Interveners and the Hellenic Republic 11

d) Conclusions on interpretations proposed by the parties 13

3. Textual, contextual and purposive analysis of Article 18(1)(b) 13

a) Textual interpretation 13

b) Context and purpose 14

i) Objectives of the Cosmetics Regulation 14

ii) Other provisions of the Cosmetics Regulation 15

iii) Legislative history 16

– Directive 93/35 17

– Directive 2003/15 18

– Conclusions on the legislative history 18

iv) Coherence with other Union legislation 19

c) On the relevance of WTO law 21

d) Conclusions on textual, contextual and purposive analysis and proposed interpretation of the marketing ban 22

V – Conclusion 23

I – Introduction

1. Regulation (EC) No 1223/2009 ('the Cosmetics Regulation')[2] lays down the conditions for the marketing of cosmetic products and ingredients in the EU. Article 18(1)(b) of the Cosmetics Regulation prohibits the placing on the EU market of cosmetics containing ingredients that have been tested on animals 'in order to meet the requirements of this Regulation' ('the marketing ban').

2. How does one determine when animal testing has been carried out 'in order to meet the requirements of [the Cosmetics Regulation]'? What factual elements are relevant to that enquiry? Those are in essence the questions raised by the present case.

2 — Regulation of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ 2009 L 342, p. 59).

II – Legal framework

A – *EU law*

3. The main piece of relevant Union legislation is the Cosmetics Regulation. The Cosmetics Regulation is a recast of the original Council Directive 76/768/EEC on cosmetic products, following amendments.[3] The Cosmetics Regulation aims at 'ensur[ing] internal market [for cosmetic products] and a high level of protection of human health' (see Article 1, see also recital 4). Its legal basis is Article 95 TEC (now Article 114 TFEU).

4. Recital 38 of the Cosmetics Regulation refers to Protocol 33 on protection and welfare of animals annexed to the TEC (now enshrined in Article 13 TFEU). Recital 39 of the Cosmetics Regulation refers to Council Directive 86/609/EEC,[4] now repealed and replaced by Directive 2010/63/EU[5] on the protection of animals used for scientific purposes ('the Animal Testing Directive').

5. In order to ensure the safety of products falling within its scope, Article 10 of the Cosmetics Regulation requires a safety assessment ('safety assessment') to be carried out and a safety report to be set up ('safety report').[6] Article 11 requires a product information file ('PIF') to be maintained on every cosmetic product marketed in the EU. The PIF must include, among other things, the safety report and also 'data on any animal testing performed by the manufacturer, his agents or suppliers …'. The latter explicitly includes 'any animal testing performed to meet the legislative or regulatory requirements of third countries'.

6. Chapter V of the Cosmetics Regulation is entitled 'Animal Testing'. Its sole article, that is, Article 18 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*;

3 — Council Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (OJ 1976 L 262, p. 169).

4 — Council Directive of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ 1986 L 358, p. 1).

5 — Directive of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ 2010 L 276, p. 33).

6 — These obligations are imposed on the 'responsible person' as defined in Article 4 of the Cosmetics Regulation (essentially, the manufacturer, importer or distributor depending on the practical situation).

(d) the performance within the Community of *animal testing* of ingredients or combinations of ingredients *in order to meet the requirements of this Regulation*, after the date on which such tests are required to be replaced by one or more validated alternative methods listed in Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or in Annex VIII to this Regulation.

…'[7]

7. Article 18(2) of the Cosmetics Regulation provides that Article 18(1)(a), (b) and (d) must be implemented by 11 March 2009. An exception is made for specific types of tests, where the deadline is fixed at 11 March 2013. These deadlines are referred to below as the 'cut-off dates'. The sixth subparagraph of Article 18(2) also permits derogation from the prohibitions contained in Article 18(1) in 'exceptional circumstances' and pursuant to strict conditions.

8. Article 20(3) of the Cosmetics Regulation lays down the conditions under which it can be claimed on product packaging or labelling that no animal testing has been conducted on a cosmetic product or its ingredients. This is the case notably where 'the manufacturer and his suppliers have not carried out or commissioned any animal tests … or used any ingredients that have been tested on animals by others for the purpose of developing new cosmetic products'.

9. Article 37 of the Cosmetics Regulation requires Member States to lay down provisions on 'effective, proportionate and dissuasive' penalties for infringement of the Cosmetics Regulation.

B – *National law*

10. The Cosmetics Regulation has been implemented in the United Kingdom via the Cosmetics Products Enforcement Regulations ('the National Regulations').[8] Regulation 12 of the National Regulations provides that it is a criminal offence for a person to contravene, among other things, Article 18 of the Cosmetics Regulation. Regulation 13 of the National Regulations (concerning penalties) provides that potential sanctions include fines and imprisonment.

C – *WTO law*

11. Article III.4 of the General Agreement on Tariffs and Trade 1994 ('GATT 1994')[9] prohibits discrimination against imported goods. Specifically, it requires contracting parties to accord to imports 'treatment no less favourable than that accorded to like products of national origin …'.

12. Article XX of the GATT 1994 sets out a number of exceptions to the Article III.4 non-discrimination rule. These include measures necessary to protect public morals (Article XX(a)) and animal health (Article XX(b)). Such measures must nonetheless not be applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries, or a disguised restriction on international trade.

7 — Emphasis added.

8 — 2013 SI 2013/1478.

9 — OJ 1994 L 336, p. 103.

III – Facts, procedure and questions referred

13. The action before the national court was brought by a trade association, the European Federation for Cosmetic Ingredients ('EFfCI'). According to the request for a preliminary ruling, three companies which are members of the EFfCI subjected certain ingredients to animal testing outside the EU and generated data as a result of that testing. The data obtained from those tests was required to enable the relevant ingredients to be used in cosmetic products to be sold in Japan or China.

14. The EFfCI was uncertain as to whether importation of those products into the United Kingdom would violate Article 18(1)(b) of the Cosmetics Regulation, potentially resulting in criminal liability and the consequent imposition of criminal sanctions in the United Kingdom. For this reason, it brought proceedings for judicial review, seeking advisory declarations as to the scope of the prohibition imposed by that provision.

15. The main defendant in the national case is the national competent authority — the Secretary of State for Business, Innovation and Skills. Two other bodies were given permission to intervene in the national case: the British Union for the Abolition of Vivisection, now Cruelty Free International ('the CFI') and the European Coalition to End Animal Experiments ('the ECEAE'), (together 'the Interveners').

16. By order of 12 December 2014, received at the Court Registry on 22 December 2014, the High Court of Justice decided to stay the proceedings and to refer the following questions to the Court of Justice for a preliminary ruling:

'(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 by Article 10 of that regulation to demonstrate that the cosmetic product is safe for human health prior to it being made available on the Community market would involve the use of data resulting from the animal testing performed outside the European Union;

(b) whether the legislative or regulatory requirements of the third countries relate to the safety of cosmetic products;

(c) whether it was reasonably foreseeable, at the time that the testing of on [sic] an ingredient on animals was performed outside the EU, 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?' [10]

10 — There are slight differences between the wording of questions 2(b) and (c) in the request for a preliminary ruling and in the order for reference. The version used in the request has been used here. However, these minor differences in wording do not alter the analysis carried out in this Opinion.

17. The parties and interveners in the main case — EFfCI, the United Kingdom Secretary of State for Business, Innovation and Skills, CFI and ECEAE — as well as the Hellenic Republic and the European Commission of the EU submitted written observations in this case and presented oral arguments at the hearing on 9 December 2015. The French Republic also requested leave to intervene at the hearing and presented oral arguments at the hearing.

IV – Assessment

A – *Preliminary considerations*

18. The national court's questions aim at clarifying the scope of the marketing ban on cosmetic products containing ingredients tested on animals.

19. The questions raise a number of sensitive issues. Two issues in particular stand out: Union policy on animal testing and the requirement of legal certainty in the sense of clarity and comprehensibility of the law. These issues form an important part of the backdrop to this Opinion. For that reason, I will comment briefly on each issue before embarking on the detailed substantive assessment.

20. First, on *EU animal testing policy*, the EU recognises the significance of animal welfare. Animal testing should be limited. This position is clearly reflected in the Treaty itself (Article 13 TFEU) and in secondary law (for example, the Animal Testing Directive and the Cosmetics Regulation).

21. Thus, there is a manifest value statement on the part of the Union, at both primary and secondary levels of EU law, which can be seen as providing interpretative guidance. Nonetheless, as with other values, animal welfare is not absolute. The legislator has not chosen to impose a complete ban on animal testing in the EU. Instead it balances animal welfare against other objectives, in particular the protection of human health. The marketing ban is just one example of that balance being struck in the field of cosmetics.

22. Second, there is the requirement of *legal certainty*. On the level of legislative drafting, that principle amounts to a requirement of a minimal degree of clarity and comprehensibility of the law.[11] One aspect of legal certainty is foreseeability: advised operators and individuals must be able to understand and to a reasonable degree predict what the law allows and what it does not.[12]

23. The requirement of legal certainty becomes even stronger once sanctions, in particular criminal sanctions, are involved. Read in conjunction with the principle of legality, it results in the maxim *nullum crimen, nulla poena sine lege (certa)*, which is enshrined (among others) in Article 49 of the Charter of Fundamental Rights of the European Union as well as in Article 7 of the European Convention on Human Rights. That maxim commands a very careful and a rather restrictive interpretative approach in cases where sanctions or fines are envisaged for violations of provisions with unclear scope or meaning.[13] In other words, a legislator is to a great extent free to enact prohibitions or sanctions. But it must do so clearly and explicitly.

11 — See, for example, judgments in *Afton Chemical*, C-343/09, EU:C:2010:419, paragraph 79; *IATA and ELFAA*, C-344/04, EU:C:2006:10, paragraph 68; and *Gondrand and Garancini*, 169/80, EU:C:1981:171, paragraphs 17 and 18. In general see, for example, Schwarze, J., *Droit administrative européen*, second edition, Bruylant, Brussels, 2009, p. 996; Tridimas, T., *The General Principles of EU Law*, second edition, Oxford University Press, Oxford, 2007, p. 244.

12 — A concern shared by a number of national legal systems — see for example the various contributions in the second part of Conseil d'État, *Rapport public 2006. Jurisprudence et avis de 2005. Sécurité juridique et complexité du droit*. Études & documents No 57. La documentation française, 2006, p. 229 et seq.

13 — At least until such time as the scope of the prohibition has been clarified. See, for example, judgments in X, C-74/95 and C-129/95, EU:C:1996:491, paragraph 25; *Dansk Rørindustri and Others* v *Commission*, C-189/02 P, C-202/02 P, C-205/02 P to C-208/02 P and C-213/02 P, EU:C:2005:408, paragraphs 215 to 219; *Advocaten voor de Wereld*, C-303/05, EU:C:2007:261, paragraph 49; and *The International Association of Independent Tanker Owners and Others*, C-308/06, EU:C:2008:312, paragraph 70.

24. As far as the interpretation of the Cosmetics Regulation is concerned, it is clear that the adoption of the marketing ban was a slow and controversial process. The resulting text is not a paragon of clarity.

25. This is particularly unfortunate as a breach of the marketing ban entails serious consequences. Article 37 of the Cosmetics Regulation requires Member States to impose sanctions in the case of such a breach. The United Kingdom has chosen to impose criminal sanctions, which may include imprisonment (see above, point 10). Even if, in other Member States, the particular national enforcement regime might be different, it is bound to involve at least administrative sanctions and fines. After all, Article 37 requires the sanctions to be 'effective, proportionate and dissuasive'.

26. The compatibility of the Article 18(1)(b) marketing ban with the principle of legal certainty has already twice been the subject of litigation before this Court.[14] However, both cases were dismissed as inadmissible with no judgment on substance.[15]

27. In this case, the national court has not asked any questions on the *validity* of Article 18(1)(b). However, principles of legal certainty and legality are not just yardsticks for judicial review. They also play a role in the *interpretation* of that provision. That role is all the more important in light of the potential imposition of sanctions in case of breach.

28. Having introduced these broader issues, I set out my more detailed legal assessment in the following sections.

B – *Analysis of Article 18(1)(b)*

1. Introduction

29. Article 18(1)(b) of the Cosmetics Regulation prohibits the placing on the market of cosmetic ingredients that 'in order to meet the requirements of this Regulation, have been the subject of animal testing …'.

30. On a purely textual and isolated reading, the relevant words of Article 18(1)(b) could reasonably be interpreted as meaning that one must investigate the specific subjective purpose behind the conduct of animal testing.

31. I do not agree with this reading. The basic problem is that it gives rise to irreconcilable incoherencies with other areas of EU law (cross-sectoral issues) as well as with other systems and jurisdictions (cross-jurisdictional issues). It also leads to intractable problems of proof and evidence. True, such questions of proof and evidence are for national authorities and courts dealing with concrete cases to solve, in accordance with the principle of national procedural autonomy. However, the job of interpreting EU law ultimately falls to the Court. In my opinion, not imposing on Member States interpretations that are in practice unworkable is part of that job.

14 — More precisely, Article 4a of Directive 76/768, which was the substantively identical predecessor of Article 18(1) of the Cosmetics Regulation (see below at point 110).

15 — An action for annulment was brought by EFfCI (the applicant before the national court in the present case), which was dismissed for lack of standing of the applicant (order in *EFfCI* v *Parliament and Council*, T-196/03, EU:T:2004:355 upheld on appeal in *EFfCI* v *Parliament and Council*, C-113/05 P, EU:C:2006:222). The French Republic also brought an action for annulment of the equivalent of Article 18(1), which was dismissed due to lack of severability of that provision (judgment in *France* v *Parliament and Council*, C-244/03, EU:C:2005:299). The substantive arguments were therefore not addressed in the judgment. However, Advocate General Geelhoed's Opinion considered some of the points raised by the present case.

32. That is why I suggest that the Court take a more nuanced approach. In substance, the provision of Article 18(1)(b) should be read as precluding access to the EU market for cosmetic products that *seek to rely* on animal testing in order to demonstrate their compliance with the Cosmetics Regulation. The marketing ban should be understood in the sense that for a given cosmetic ingredient (i) access to the EU market requires demonstration of its safety in accordance with the procedure laid down in the Cosmetics Regulation and (ii) that demonstration cannot rely on the results of animal testing, conducted after the relevant cut-off dates imposed in the Cosmetics Regulation (see point 7 above).

33. The determining factor is therefore *reliance* on the results of the animal testing in order to gain access to the EU market. It is thus irrelevant:

— where the testing was conducted;

— whether or not the testing was carried out with other (EU or non-EU) legislation in the 'mind' of the relevant corporate entity, as well as whether any such other legislation is cosmetics related or not; or

— at what point marketing of cosmetics (in the EU) was foreseen.

34. I set out below the reasons why I consider that key elements of the various interpretations proposed by the parties present serious problems, and therefore cannot be maintained (Section 2). I go on to conduct a textual, contextual and purposive analysis of the marketing ban (Section 3).

2. Appreciation of key elements of the parties' positions

a) EFfCI and the French Republic

35. EFfCI considers, in substance, that the marketing ban is triggered where the specific purpose behind the animal testing was to comply with the Cosmetics Regulation. Where there is another purpose, such as compliance with legislation of a third country or with other EU legislation (such as pharmaceutical or chemical legislation), the marketing ban would not be triggered. A similar interpretation was also supported by the French Republic during the oral hearing.

36. Interpretation of EU law provisions is based first and foremost on the text. What is the literal meaning of the words on the page? This approach reflects the core principles of predictability and legal certainty — principles which ultimately contribute to the strength of the rule of law in the EU legal order.[16] What you see should be what you get.

37. However, if the text is ambiguous,[17] or the literal meaning would lead to a nonsensical result,[18] that meaning may be reappraised after being 'placed in its context and interpreted in the light of the provision of [EU] law as a whole, regard being had to the objectives thereof and to its state of evolution at the date on which the provision in question is to be applied'.[19]

38. On a purely textual, isolated reading of Article 18(1)(b), the interpretation proposed by EFfCI and the French Republic does seem at first sight reasonable.

16 — See, for example, judgments in *Belgium* v *Commission*, C-110/03, EU:C:2005:223, paragraph 30; and *Glaxosmithkline and Laboratoires Glaxosmithkline*, C-462/06, EU:C:2008:299, paragraph 33.

17 — Judgments in *ECB* v *Germany*, C-220/03, EU:C:2005:748, paragraph 31; and *Carboni e derivati*, C-263/06, EU:C:2008:128, paragraph 48.

18 — Opinion of Advocate General Jääskinen in *Commission* v *United Kingdom*, C-582/08, EU:C:2010:286, point 27, citing Opinion of Advocate General Mayras in *Fellinger*, 67/79, EU:C:1980:23, p. 550.

19 — Judgment in *Cilfit and Others*, 283/81, EU:C:1982:335, paragraph 20.

39. However, in my view, that interpretation would pose major challenges for national administrative authorities and courts, both in terms of *identifying* purpose and also from the point of view of *evidence and proof* of such purpose. Indeed, for the reasons set out below, I consider that such an approach would lead to fundamental incoherencies and would be unworkable in practice.

40. As regards *identification of purpose*, establishing the purpose or intent of a corporate entity creates its own challenges. However, assuming those challenges could be overcome, it is not even clear the purpose or intent of *which entity* would be relevant. Possible choices include not just the producer of the cosmetic product itself, but also the lab conducting the testing, the entity initially mandating the testing and any entity to which the data is subsequently licensed or transferred, be it within or outside the same corporate group.

41. The situation is rendered even more complex when one considers possible mixed purposes in both dimensions: geographical as well as sectoral.

42. For example, the testing might be carried out mainly with the Chinese market in mind, but also with Europe as a potential future market. Such scenarios appear possible and indeed highly likely. In developing and testing a new cosmetic ingredient, any cosmetics company with global reach is unlikely to completely disregard Europe, which is a major market. Such issues are implicit in the national court's question 2(c).

43. Similarly, substances often have 'dual uses'. They may be used in both cosmetics and non-cosmetics. Examples in the latter category include pharmaceuticals or chemicals. Animal testing results might be useful for demonstrating the safety for human health of the substance for cosmetic and non-cosmetic uses. This again shows the potential for mixed or multiple purposes for generating animal testing data. Such issues are implicit in the national court's question 2(b).

44. Because of this potential for mixed purposes, attaching the determination of the legality of the use of such data to the specific intention held when that data was originally generated appears quite artificial. It disregards the fact that similar sets of data-sets may circulate, to be sold or resold between companies, crossing both geographical and sectoral borders.

45. Furthermore, the logical consequence of the interpretation proposed by EFfCI and the French Republic would be that data 'free from original sin' (in the sense that even if subject to animal testing, the data was not specifically generated with the EU cosmetics market in mind), could subsequently circulate completely freely and could be sold for inclusion in safety assessments and safety reports on cosmetic products. It is obvious that the potential for circumvention created by such a reading of the provision of Article 18(1)(b) is significant.

46. At what point does a recognised potential for marketing in the EU crystallise into a specific purpose to conduct testing 'in order to meet the requirements of [the Cosmetics] Regulation'? This question presents yet another dimension of complexity. For example, the company generating the data may have been originally specifically targeting a non-cosmetics market in China, but might have also given some thought to subsequent use for cosmetics in the Union. How serious does the prospect of future marketing in the EU need to be before it transforms into specific intent and 'taints' the data? A brief discussion in the marketing department? A board paper?

47. Let us nonetheless suppose that one can establish whose intent is concerned and the degree of consideration of the EU market necessary to establish specific purpose. A further difficulty is raised by the question of *proof* of purpose. This requires evidence which meets a given burden and standard of proof. At the hearing, different suggestions were put forward in this regard. Reference was made, among others, to self-declarations, terms of reference for laboratories carrying out the testing, the compulsory nature of animal testing abroad, and consideration of the chronology of events.

48. There is no doubt that national courts, in particular national courts of first instance, are used to and skilled in dealing with questions of facts and proof on daily basis. Thus, the concern that it would be in practice unrealistic to expect national administrative authorities and/or courts to engage in such an exercise is not an issue of competence, but one of feasibility and appropriateness. Asking national authorities to ascertain subjective corporate intent of potentially a number of undertakings active in different sectors and/or jurisdictions in the recent or distant past might perhaps be called for in criminal trials, but hardly within a system of essentially administrative registration of products wishing to enter the EU internal market.

49. In light of these observations, I do not consider that the interpretation proposed by EFfCI would be enforceable. The words 'in order to meet the requirements of this Regulation' cannot be interpreted as referring to a specific purpose or intention at the moment animal testing is conducted.

b) Commission and the United Kingdom

50. The Commission and the United Kingdom also consider that the purpose of the testing is decisive. However, they read the marketing ban as being broader. In their view, the ban would be triggered if the testing was conducted with the purpose of complying with the Cosmetics Regulation *or analogous third country legislation*.

51. I see two fundamental problems in that approach.

52. First, Article 18(1)(b) explicitly and precisely refers to requirements of the Union Cosmetics Regulation, not to the requirements of other EU legislation or non-EU legislation. Any other reading of this in my view clearly expands in a rather selective way the natural meaning of the words.

53. A systemic argument supports my reservation. Article 11(2)(e) of the Cosmetics Regulation, in contrast with Article 18(1), explicitly refers to testing performed 'to meet the legislative or regulatory requirements of third countries'. Article 18(1) clearly does not make such a reference. Such wording would have been nonetheless easy to add also to the marketing ban, if the legislator ever intended it.[20]

54. Therefore, contrary to the position supported by the Commission and the United Kingdom, 'the requirements of this Regulation' cannot be read naturally as 'the requirements of this Regulation *and analogous cosmetics regulations in non-Member States*'. These expressions have very different meanings and scope.

55. Second, the Commission and the United Kingdom's approach also relies on identifying the purpose of the testing. It therefore presents the same type of problems as that of the EFfCI identified above (see point 40 et seq.), relating both to multi-purpose uses and proof and evidence. Other than that, the Commission and the United Kingdom's proposal potentially adds a further layer of complexity to an already problematic approach. National authorities would not only have to peer into the corporate mind to establish intent. In addition to that, they would then have to conduct an analysis of foreign laws and regulations in order to determine whether they are 'analogous' to the Cosmetics Regulation.

56. Thus, for the same reasons, I also disagree with the interpretation of the marketing ban proposed by the Commission and the United Kingdom.

20 — It is not without interest that the addition of wording having similar effects was proposed by the European Parliament in 1993, but rejected by the Council — see points 105 to 108 below.

c) Interveners and the Hellenic Republic

57. The Interveners and the Hellenic Republic contend in substance that the marketing ban is triggered whenever animal testing is conducted *to demonstrate that an ingredient is safe for human health*. This is the case irrespective of where or why the testing is done, as long as the ingredient that is tested is used in cosmetic products. [21]

58. This reading cannot be correct.

59. As a preliminary remark, interpretation of EU law often requires us to look beyond the natural meaning of the words on the page (see point 37 above). However, the interpretation proposed by the Interveners appears difficult to relate back to those words at all. It seems to ignore the words 'in order to' by stating in fact that both the purpose of the testing and the use of the results are irrelevant. Instead, it is the testing event that is in itself decisive. Similarly, the words 'requirements of this Regulation' are all but ignored by interpreting them as referring to the broad objective of protecting human health. As observed by the French Republic at the oral hearing, animal testing is in the vast majority of cases carried out in pursuit of that objective, be it in the context of cosmetics, pharmaceuticals, chemicals, plant protection products, etc.

60. More importantly, the approach proposed by the Interveners would lead to very peculiar and, in my view, extreme results.

61. Let us take the example of a substance that is tested on animals (a) outside the Union, (b) in order to demonstrate that it is safe for humans when used in detergents and (c) where the testing on animals is required under the legislation of a third country.

62. According to the Interveners, because this testing was conducted in order to show it is safe for human health, the marketing ban would be triggered. The tested substance could not be used as a cosmetic ingredient in the EU. If the ingredient is already being used in cosmetics in the EU, it should logically be withdrawn from the market.

63. In other words, according to the Interveners' interpretation, the marketing ban could be triggered by apparently unconnected events (temporally, territorially and sectorally). Such events might be entirely out of the control of the person marketing the relevant cosmetics ingredients. [22] I do not see any credible justification for such a broad reading of the marketing ban. [23]

64. Another problem with the Interveners' broad reading of the marketing ban is revealed by a systemic reading of Article 18(1).

65. While Article 18(1)(b) contains a marketing ban, Article 18(1)(d) prohibits all animal *testing* of ingredients in the EU 'in order to meet the requirements of this Regulation' ('the testing ban'). If the Interveners' interpretation were favoured, Article 18(1)(d) would logically prohibit all animal testing in the EU of all substances from the moment they are used in cosmetic products, *unless such testing does not seek to demonstrate safety for human health* (for example, in relation to environmental end-points).

21 — The Interveners do propose a caveat to this. The marketing ban would *not* apply, if the predominant use of the ingredient were *not* in cosmetic products (the 'minor use exception'). I discuss this in more detail below at point 67 et seq.

22 — The Parliament generally sought a broad marketing ban during the legislative process. However, even the Parliament acknowledged that the ban should not be triggered in cases of testing outside the manufacturers' control (or at least supply chain). See Report of the Parliament of 21 March 2001, A5-0095/2001, final, justifications on amendments 14 and 25, pp.12 and 21.

23 — See also below, points 90 to 92 on Article 11(2)(e) and recital 45 of the Cosmetics Regulation.

66. This would be the case even if the testing in the EU were being proposed in the context of another (non-cosmetics related) piece of EU legislation and the results were never relied on in the context of the Cosmetics Regulation. For example, all human health-related animal testing under Regulation (EC) 1907/2006 ('REACH') [24] would be prohibited by the simple fact that the relevant substance is also used in cosmetic products. [25] Nothing suggests that such a broad, cross-sectoral prohibition on animal testing was envisaged in the sector-specific Cosmetics Regulation. [26]

67. The Interveners do try to address some of these issues by acknowledging that animal testing could be carried out under REACH in the EU in order to demonstrate that a substance is safe for human health. This would be allowed if the predominant use of the substance is *not* in cosmetic products ('the minor use exception').

68. The minor use exception postulated by the Interveners would eliminate some of the unexpected and far-reaching effects referred to above. However, it would not eliminate all of them.

69. Notably, cross-sectoral effects of the ban would also exist in relation to substances predominantly used in cosmetics but also having important uses in non-cosmetic products.

70. The scope of the minor use exception is also very unclear. For example, is predominant use identified in terms of the volume of the ingredient being used for cosmetic products? Is it related to the monetary value of that ingredient? Assuming volume were the key, does predominant use mean that more than 50% of the volume [27] of that ingredient is used in cosmetic products, or does it simply mean the most important among several uses (even if the cosmetics use remains minor in terms of volume)? Is the assessment of predominant use to be carried out at a global level, within the EU or on the basis of some other territory?

71. Perhaps more fundamentally, the basis of the minor use exception is unclear. Where does it come from? No basis for it is proposed other than that the relevant legislation is cosmetics related and that allegedly the exception 'would accord with what the public understands by the bans'. I do not doubt the inventiveness of manufacturers and enforcement authorities to find practical answers to some of the questions in the preceding paragraph. However, I consider that by respecting the text of the Cosmetics Regulation more closely, these sorts of questions might be avoided entirely. I also underline that violation of those 'newly discovered' and very detailed rules is sanctioned. In the case of the United Kingdom, imprisonment is an option. In such circumstances, I find the Interveners' proposed approach impossible to reconcile with the maxim *nullum crimen, nulla poena sine lege certa*.

72. Finally, it is stated that in some extra-EU jurisdictions animal testing of cosmetics ingredients is mandatory. To the extent that this is the case, the interpretation proposed by the Interveners would in practice require producers to choose between marketing an ingredient in the EU or that other jurisdiction which mandates animal testing. In other words it would create de facto export or import bans.

24 — Regulation of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ 2006 L 396, p. 1).

25 — See also points 118 to 120 below on the interaction between REACH and the Cosmetics Regulation.

26 — Moreover, recital 40 of the Cosmetics Regulation also explicitly envisages situations where the safety of a given ingredient is demonstrated using alternative methods for use in cosmetics and using animal testing in case of other uses. No mention is made of an automatic prohibition on the testing of the ingredient for non-cosmetic uses as a result of its parallel use in cosmetics (or of an automatic ban on the marketing of the ingredient in cosmetics, as a result of its testing on animals, by application of Article 18(1)(b)).

27 — Furthermore, would that be volume produced, imported or used (or some other figure)?

73. I do not consider it necessary to delve in detail into international trade law to dismiss the Interveners' proposed interpretation. However, it is obvious that export and import prohibitions constitute serious impediments on international trade. Regardless of whether or not they can be defended under WTO law,[28] if the legislator had really sought such effects, one could legitimately have expected it to have chosen clearer wording to express that intent.

d) Conclusions on interpretations proposed by the parties

74. I sympathise with the plight of anyone trying to make sense of Article 18(1)(b) of the Cosmetics Regulation. It is not well drafted. Moreover, the legitimate doubts expressed by the national court's questions had apparently been envisaged by the legislator over 20 years ago during the initial legislative process.[29] This makes it all the more unfortunate that these issues have to be addressed at this late stage.

75. That said, I remain unconvinced by fundamental aspects of the interpretations proposed by the parties.

76. I set out in the following section my own analysis of the marketing ban in light of its text, context and purpose. The main conclusion from that analysis is that 'in order to meet the requirements of this Regulation' should be interpreted as precluding reliance on results of animal testing for the purposes of marketing cosmetic products in the EU.

3. Textual, contextual and purposive analysis of Article 18(1)(b)

a) Textual interpretation

77. The first port of call in any interpretative exercise is the text of the provision.[30] The most obvious natural meaning of 'in order to meet the requirements of [the Cosmetics Regulation]' is that the testing was carried out with the (primary) purpose of complying with that legislation. For the reasons set out above, I consider that such a reading poses intractable problems in terms of identifying and proving purpose, as well as the systemic coherence of the Cosmetics Regulation with other areas of EU law.

78. That does not, however, mean that one can simply ignore the text and set sail on the foggy sea of *effet utile*. This is all the more so given that that notion seems to be understood very differently by the various actors, as was evident from the written and oral observations of the parties in this case. Even if, for the reasons set out above, it appears impossible to rely on the text alone, interpretation ought to stick as closely as possible to the text and the notions therein, while at the same time respecting the legislative intent and value choices expressed by the legislator, as far as those can be comprehensibly discerned.

79. In my view, the text of the marketing ban implies a necessary link between (a) the animal testing and (b) compliance with the specific requirements of the Cosmetics Regulation. Such a link is fundamental in light of the words of Article 18(1)(b): '[an ingredient,] *in order to* meet the requirements of [the Cosmetics Regulation], has been the subject of animal testing'.[31]

28 — On interpretation of the marketing ban in the light of WTO law, see below, point 134 et seq.

29 — See points 105 to 108 below.

30 — See points 36 and 37 above.

31 — Emphasis added.

80. Article 1 of the Cosmetics Regulation clearly states that the Regulation establishes rules which all cosmetic products that are to be made available on the internal market must comply with. Why then would any undertaking wish to comply with the requirements of the Cosmetics Regulation other than to gain access to the internal market?

81. Given that necessary link, I consider that *reliance on the results of animal testing* in order to gain access to the EU market with a cosmetic product *is a condition sine qua non* to trigger the marketing ban. That is the point raised by the national court in its question 2(a).

82. For the reasons set out below, this conclusion is confirmed by a contextual and purposive analysis. Moreover, that analysis does not in my view reveal any additional conditions necessary for triggering the marketing ban.

b) Context and purpose

83. There are various elements of context and purpose of the marketing ban that I consider worth exploring in this case, namely:

— the objectives of the Cosmetics Regulation;

— other provisions of the Cosmetics Regulation;

— the legislative history of the Cosmetics Regulation;

— coherence with other Union legislation.

i) Objectives of the Cosmetics Regulation

84. As provided in Article 1 of the Cosmetics Regulation, its main objectives are 'to ensure the functioning of the internal market [for cosmetic products] and a high level of protection of human health'.[32] In pursuing these objectives, recital 38 et seq. of the Cosmetics Regulation also underlines the importance of animal welfare. These recitals and objectives translate into the marketing and testing bans found in Article 18(1).

85. It is clear, however, that the Cosmetics Regulation is first and foremost a sector-specific internal market measure. The Cosmetics Regulation sets out the conditions under which the EU will allow cosmetic products and ingredients to enter the internal market. The main condition is that they must be safe for humans. This is confirmed by the choice of legal basis, namely Article 95 TEC (now Article 114 TFEU).

86. Animal welfare is a very important consideration. However, it is not the main purpose of the legislation. Moreover, regardless of the precise limits animal welfare imposes, it is clear that the legislation does not create a total prohibition on animal testing or on marketing of animal-tested cosmetics (ingredients).[33]

32 — Article 1 of the Cosmetics Regulation. See also recital 4.

33 — Article 18(2) of the Cosmetics Regulation does foresee potential exceptions to the marketing and testing bans. The Cosmetics Regulation also does not seek to impose a marketing ban on cosmetic products or ingredients in relation to which testing has occurred in the past (before the cut-off dates). More importantly, had the intention been to impose absolute bans, the wording of the legislation could have been significantly more straightforward.

87. Thus, seen in the context of the Cosmetics Regulation as a whole, a producer will wish to 'meet the requirements of this Regulation' in order to gain access to the internal market. The meaning of Article 18(1)(b) would therefore be more accurately captured as: 'animal testing should not be used in order to gain access to the internal market for cosmetics'.

88. This confirms the interpretation suggested above that *reliance* on the *results* of animal testing is the key condition for triggering the marketing ban.

ii) Other provisions of the Cosmetics Regulation

89. Although not decisive in themselves, certain other provisions of the Cosmetics Regulation are also noteworthy as far as contextual-systemic arguments are concerned. In particular, those provisions shed light on some of the situations that were seen by the legislator as being compatible with the testing and marketing bans. As such, they help when trying to understand the scope of those bans.

90. Article 11(2)(e) of the Cosmetics Regulation requires submission in the PIF of any animal testing data generated for compliance with non-EU requirements. Thus, animal testing of a cosmetic ingredient in third countries clearly *can* be compatible with marketing of that ingredient in the EU.[34]

91. It is also interesting that the explicit reference to third country requirements in Article 11(2)(e) stands in contrast to Article 18(1)(b), which fails to make any such reference. This could be read as implying that testing to meet the requirements of third country legislation was purposefully excluded as a trigger for the marketing ban.

92. As mentioned above,[35] recital 40 of the Cosmetics Regulation also apparently foresees situations where animal testing could be conducted *in the EU* under, for example, REACH, and the tested ingredients can also be used in cosmetic products.

93. The abovementioned provisions and recitals support the view I already expressed that animal testing of ingredients that are used in cosmetics is not *in itself* the issue. It underlines that there must be a link between the testing and marketing on the internal market. As already stated, I consider that link to be established by *reliance* on the animal testing data for the purpose of demonstrating safety for human health, in the context of the Cosmetics Regulation.

94. In addition, the wording and structure of the abovementioned provisions also highlight a particular distinction under the Cosmetics Regulation that is material to this case, and warrants discussion here. This distinction is between, on the one hand, *reliance* on animal testing data to demonstrate safety and, on the other hand, 'mere' *inclusion* of animal testing data in the PIF.

95. Article 10 of the Cosmetics Regulation requires that the safety of a cosmetic ingredient be demonstrated by a safety assessment and recorded in a safety report. In order to demonstrate safety, *reliance* must be placed on scientific evidence. Article 11 of the Cosmetics Regulation sets out the information that must be *included* in the PIF.

34 — The Interveners submit that this refers 'principally' to testing data generated before the relevant cut-off dates. However, no such restriction appears in the provision. Moreover, recital 45 of the Cosmetics Regulation explicitly envisages situations where the safety of a given ingredient is demonstrated in the EU using alternative methods and *subsequently* animal tested outside the EU for use in cosmetics. Although not conclusive, this tends to confirm the reading that non-animal tested and animal tested ingredients can be marketed in parallel inside and outside the EU respectively.

35 — Footnote 26.

96. In its written submissions and at the oral hearing the Interveners argued in substance that from the moment testing results are *included* in the PIF, they necessarily form part of the body of evidence *relied on* to demonstrate safety. In support of this, they cite Article 10(1)(b) of the Cosmetics Regulation, which states in relation to the safety assessment that 'an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from *all existing sources*'.[36] Such sources must include any animal testing results. This raises the prospect that animal testing will continue to be used to help support conclusions on the safety of cosmetic products. In order to avoid this, the only solution, according to the Interveners, is to prohibit the placing on the market in the EU of cosmetic ingredients from the moment any animal testing has been carried out on them (wherever and for whatever reason).[37]

97. I disagree with this interpretation, in particular for the following reasons.

98. First, Article 11(2)(e) acknowledges the existence of situations where animal testing on cosmetic ingredients has been conducted to meet third country requirements. Such data must be included in the PIF if it refers to the '*development or safety assessment*' of the ingredient. Those words imply that not all animal testing data included in the PIF must necessarily be *used* to support the conclusions in the safety assessment.

99. Second, the Cosmetics Regulation requires that the safety of cosmetic ingredients and products be positively demonstrated using alternative testing methods. As confirmed in the oral hearing, among others by the United Kingdom and the Commission, it is simply insufficient to refer to absence of proof of harm to justify the conclusion that an ingredient is safe.

100. Third, as noted above at point 60, the Interveners' reading leads to very peculiar and extreme results. If such results were really the intention, one could legitimately expect them to be spelt out more clearly in the legislation. That is not the case. Indeed, many other elements as set out in this section confirm the opposite.

101. Finally, Article 10(1)(b) of the Cosmetics Regulation cannot be read in isolation. To the extent that Article 18(1)(b) reduces the scope of evidence that can be relied upon to meet the requirements of the Cosmetics Regulation, it must also be understood as limiting the type of test results that can form part of the weight-of-evidence assessment referred to under Article 10(1)(b).

102. In conclusion on this point, I do not consider that Article 10(1)(b) of the Cosmetics Regulation brings into question the interpretation proposed above that the trigger for the marketing ban is reliance on animal testing data, not the testing event itself. Moreover, there is an important distinction to be drawn between *reliance* on testing data and mere *inclusion* in the PIF.

iii) Legislative history

103. There is significant debate on the marketing ban in the legislative history. Unfortunately, that debate generates more heat than light. Nonetheless, it is worth setting out the main elements.

36 — Emphasis added.

37 — Subject to the 'minor use exception'.

– Directive 93/35

104. The original Cosmetics Directive 76/768 contained no marketing ban or reference to animal testing. The marketing ban was first introduced by Directive 93/35/EEC,[38] using essentially the same relevant wording as that seen today in the Cosmetics Regulation ('in order to meet the requirements of this Directive').[39]

105. The insertion of these words was controversial. The original Commission proposal contained no marketing ban.[40] This was inserted by the European Parliament at first reading. The marketing ban proposed by the Parliament initially extended explicitly to 'ingredients or combination of ingredients tested on animals after January 1998 *in order to assess their safety or efficacy for use in cosmetic products, or to comply with the requirements of this Directive*'.[41]

106. In my view, this wording sought to distinguish animal testing carried out to comply (i) with the Directive and (ii) with other cosmetics-related rules (EU or non-EU).[42]The Parliament sought to cover both of those scenarios with the marketing ban ('the broad formula').[43]

107. The Commission reduced the scope of the Parliament's proposed marketing ban to cover testing 'in order to meet the requirements of this Directive' that is, the first of the scenarios outlined at point 106 of this Opinion ('the narrow formula').[44] The Parliament insisted and sought to have the broad formula introduced again in its second reading.[45] The Commission accepted this the second time round. In its own words, it was 'introducing an explicit ban on tests on animals for purposes other than compliance with the requirements of the Directive'.[46] However, the Council again reduced the scope of the marketing ban to the narrow formula,[47] which was ultimately adopted in Directive 93/35.

108. I infer from this institutional ping pong that the difference between the narrow and broad scope of the marketing ban was clearly recognised and considered to be material by all three institutions.

109. Full entry into force of the marketing ban was subsequently postponed on two occasions.[48]

38 — Council Directive of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ 1993 L 151, p. 32).

39 — Article 1(3) of Directive 93/35, inserting Article 4(1)(i) in the Cosmetics Directive.

40 — Proposal for a Council Directive amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, COM(90) 488 final (OJ 1991 C 52, p. 6).

41 — OJ 1992 C 176 p. 91. Emphasis added.

42 — 'To assess their safety and efficacy for use in cosmetic products.'

43 — The existence and relevance of these distinctions are in my view confirmed by two other amendments to the draft text of Directive 93/35 proposed by the Parliament 'Ingredients which have been tested on animals exclusively for purposes other than for use in cosmetic products may be permitted, provided that no additional animal testing is carried out in order to meet the requirements of this Directive' and, in relation to labelling, '[…] all claims concerning animal experiments must clearly indicate to what extent the tests concern the finished product or the ingredients composing it, specifying for the latter whether they are used exclusively in cosmetics or whether they were previously used in another category of products' (OJ 1992 C 176/91 and 92). These proposed additions were not included in the final text.

44 — Amended proposal for a Council Directive amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products, COM(92) 364 final (OJ 1992 C 249, p. 5).

45 — OJ 1993 C 150, p. 124.

46 — COM(93) 293 final, p. 1.

47 — Common Position 9816/92.

48 — First until 30 June 2000 by Commission Directive 97/18/EC of 17 April 1997 postponing the date after which animal tests are prohibited for ingredients or combinations of ingredients of cosmetic products (OJ 1997 L 114, p. 43). Subsequently until 30 June 2002 by Commission Directive 2000/41/EC of 19 June 2000 postponing for a second time the date after which animal tests are prohibited for ingredients or combinations of ingredients of cosmetic products (OJ 2000 L 145, p. 25).

– Directive 2003/15

110. In 2003, Directive 2003/15/EC[49] inserted the wording of the marketing and testing bans that appears in Article 18(1) of the Cosmetics Regulation today.[50] That wording included, unchanged, the narrow formula 'in order to meet the requirements of this Directive'.

111. The legislative procedure leading to the adoption of Directive 2003/15 involved significant discussion on the marketing ban. Much of that discussion was dedicated to concerns with compatibility of the marketing ban with WTO law.[51] To respond to those concerns, the Council and the Commission had initially sought to tie any introduction of the marketing ban to the introduction of alternative testing methods at OECD level.[52] This was resisted strongly by the Parliament, which insisted on a final cut-off date for introduction of the bans.[53] Cut-off dates were ultimately included in the final text (see above, point 7).

112. By contrast, the debate on the marketing ban did not include any detailed discussion on the distinction between animal testing carried out to comply (i) with the Directive and (ii) with other cosmetics-related rules (EU or non-EU) (see points 106 to 108 above). The narrower formula approved in the 1993 version of the marketing ban — 'in order to meet the requirements of this Directive' — was reused without change. The Parliament briefly mentioned that it had lost the battle to have its broad formula used, which would have covered other cosmetics-related rules (EU and non-EU). The Parliament did not set out in detail the consequences of the narrow formula. It nonetheless concluded that, as a result, the marketing ban contained a 'substantial loophole, particularly with regard to cosmetics imported from third countries'.[54] This appears to reflect a concern, also expressed elsewhere,[55] that a non-comprehensive marketing ban would simply lead to circumvention by animal testing moving out of the EU.

– Conclusions on the legislative history

113. Despite considerable ambiguity, I consider that at least some conclusions from the legislative history can be drawn.

49 — Directive of the European Parliament and of the Council of 27 February 2003 amending Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ 2003 L 66, p. 26).

50 — 'This Directive' now replaced by 'this Regulation'.

51 — The Commission in particular repeatedly raised its concerns. See first Commission proposal (Proposal for a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768 on the approximation of the laws of the Member States relating to cosmetic products, COM(2000) 189 final, at point 1.2.3 (OJ 2000 C 311 E, p. 134)); second Commission proposal (Amended proposal for a Directive of the European Parliament and of the Council amending for the seventh time Council Directive 76/768 on the approximation of the laws of the Member States relating to cosmetic products, COM(2001) 697 final, (OJ 2002 C 51 E, pp. 385 to 388)); Communication from the Commission to the European Parliament pursuant to the second paragraph of Article 251(2) of the EC Treaty concerning the common position of the Council on the adoption of a European Parliament and Council Directive amending for the seventh time Council Directive 76/768 on the approximation of the laws of the Member States relating to cosmetic products, SEC(2002) 225 final, at points 3.2 and 3.4 ('Commission Communication').

52 — See, for example, Common Position (EC) No 29/2002 of 14 February 2002 (OJ 2002 C 113 E, p. 109), statement of reasons at point III.1; Commission Communication, at point 3.3.

53 — See, for example, Recommendation of 24 May 2002 for second reading on the Council common position for adopting a European Parliament and Council directive amending Council Directive 76/768, PE 232.072/DEF, amendment 13 ('Second Reading Report').

54 — Report on the proposal for a European Parliament and Council directive amending for the seventh time Council Directive 76/768 on the approximation of the laws of the Member States relating to cosmetic products, PE 297.227, p. 28.

55 — Ibid., p. 31; Second Reading Report, p. 34; Report on the joint text approved by the Conciliation Committee for a European Parliament and Council directive amending for the seventh time Council Directive 76/768 on the approximation of the laws of the Member States relating to cosmetic products, PE 287.617, p. 7.

114. First, there is no clear and explicit statement endorsed by all three institutions that the marketing ban was intended to be absolute, in the sense that it would be triggered by a mere testing event (irrespective of where, why or by whom the tests were conducted). On the contrary the importance of a link between the testing and the Cosmetics Directive/Regulation *specifically* (not just the cosmetics sector generally), was in my view repeatedly confirmed during the adoption of Directive 93/35. This further supports a rejection of the Interveners and the Hellenic Republic's proposed broad reading of the marketing ban, which they contend is triggered by the testing event itself. [56]

115. Second, all three institutions apparently viewed the cut-off dates as a watershed. The Parliament was unwilling to push back the marketing ban indefinitely to wait for the introduction of alternative methods. After the cut-off dates, the marketing and testing bans would apply regardless of the existence of alternative methods. Notwithstanding this strong stance, no proposal was made by any of the institutions to remove the qualifying words in the text — 'in order to meet the requirements of this Regulation'.

116. Third, the risk of circumvention was mentioned on a number of occasions during the legislative procedure. The main focus of this was concern about delocalisation. [57] Concern was also voiced about circumvention through testing allegedly carried out specifically in non-cosmetics sectors being carried across to the cosmetics sector. [58]

117. In my view, the presentation of the cut-off dates as a watershed and the concerns about circumvention support the conclusion that, wherever it is carried out, animal testing should not be used to gain access to the EU market. These elements also provide further support for the idea that *reliance* on animal testing data is the trigger for marketing ban.

iv) Coherence with other Union legislation

118. The most comprehensive piece of EU legislation seeking to ensure the safety of substances is REACH. [59] REACH requires substances imported into or manufactured in the Union in quantities over one tonne to be registered. Registration involves submission of a scientific dossier, which must show, among other things, that the substance is safe for human health. Cosmetic ingredients are also subject to REACH.

119. That raises the question of how 'dual use' substances that are used in both cosmetic and non-cosmetic products are to be treated under REACH. The answer will help clarify the scope of the marketing ban under the Cosmetics Regulation.

120. Recital 13 of REACH states that it applies 'without prejudice' to the Cosmetics Regulation. REACH also contains a number of explicit derogations for substances to the extent that they are used in cosmetic products. In particular, REACH applies 'without prejudice' to the Cosmetics Regulation 'as regards testing involving vertebrate animals *within the scope of that [Regulation*]'. [60]

56 — Subject to the 'minor use exception'.

57 — See point 112 above.

58 — See Council common position of 17 December 1992, pages 3 and 4.

59 — Footnote 24.

60 — Articles 2(6)(b), 14(5)(b) and 56(5)(a) REACH also contain a number of explicit derogations from specified REACH requirements to the extent that the relevant substance is used in cosmetic products. Emphasis added.

121. In my view the aim here is clear. REACH creates a general framework for the registration, evaluation and authorisation of substances. Where a substance is used in a specific sector and sector-specific legislation exists, REACH can apply without prejudice and (partially) defer to that specific sectoral legislation. That has been done in the case of cosmetics, and also in a number of other areas, such as medicinal products, medical devices, food and feedstuffs, etc. [61]

122. However, contrary to the position defended by the Interveners in particular, that does not mean that, when a substance is employed in cosmetics, rules contained in the Cosmetics Regulation can extend to it in relation to all uses (cosmetic and non-cosmetic). It does not mean that, for example, a substance included in a detergent cannot be tested on animals in the EU by virtue of the mere fact that it is also contained in cosmetics. [62] Nor does it mean that as soon as any animal testing is carried out by the detergent manufacturer outside the EU, that prevents any (further) marketing of the substance in cosmetics in the EU.

123. As pointed out by EFfCI, the almost absolute prohibition on animal testing that exists in the cosmetics sector is very specific. The more common situation under EU legislation is that animal testing is to be avoided wherever possible but reluctantly tolerated wherever no alternative is available. [63]

124. In those circumstances, the legislator cannot have intended the type of cross-sectoral effects of the Cosmetics Regulation argued by the Interveners. Moreover, I recall that the very wording of the marketing ban in the Cosmetics Regulation is on its face, sector specific ('in order to meet the requirements of *this Regulation*').

125. Once again, the foregoing confirms the need for a link between the animal testing and the Cosmetics Regulation *specifically* before the marketing ban can be triggered. The testing event in itself is not enough.

126. Nonetheless, I understand the concerns voiced by the Interveners in relation to the effectiveness of the Cosmetics Regulation bans and the risk of circumvention. In that regard, the Interveners argue in substance that a company could too easily carry out tests in order to register a cosmetic ingredient under REACH and subsequently use those results in a safety assessment under the Cosmetics Regulation. This would be possible because the results were not generated 'in order to meet the requirement of the [Cosmetics] Regulation' but rather 'in order to register under REACH'.

127. What interpretation of the marketing ban would avoid this risk of circumvention, whilst respecting the wording of Article 18(1)(b)?

128. One response to this could be that circumvention would be avoided by looking at what the 'true' purpose of the testing was. Was it 'really' in order to register under REACH register? Or, deep down, was it 'really' to comply with the Cosmetics Regulation? This is in essence the proposal made by EFfCI and the French Republic. I have set out above [64] my grave concerns with the practicality of such an approach.

61 — See Article 2(4), (5) and (6) of REACH.

62 — In relation to the 'minor use exception' postulated by the Interveners, see points 67 to 71 above.

63 — See, for example, Article 25(1) REACH, animal testing is a 'last resort'; Article 7(1) CLP Regulation, 'only where no other alternatives are […] possible' (Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ 2008 L 353, p. 1)).

64 — See point 35 et seq.

129. Another response, proposed by the Commission (and the European Chemicals Agency), is basically that substances cannot be animal tested under REACH where they are used *exclusively* in cosmetics. [65]

130. Such an approach is attractive. If there is no non-cosmetic use for a substance, then why would it be tested under REACH other than in order to market it in a cosmetic product? However, what if the testing were carried out for a potential future non-cosmetic use? On what grounds would the testing be prevented? The prohibition would therefore only apply to substances with an actual or potential use *exclusively* in cosmetics. The Interveners submit that substances are only very rarely used *exclusively* in cosmetics. Such a reading would therefore have little practical effect. I agree with these concerns.

131. How, then, does one tackle the circumvention concern, whilst respecting the wording of Article 18(1)(b) and reading the Cosmetics Regulation and REACH coherently? In my opinion, there is only one plausible solution that does so. Once again, *reliance* on the animal testing results is key.

132. Animal testing may be carried out as a last resort under REACH. There is no special rule that applies where a substance happens also to be used in cosmetics. *However, it should not be possible to rely on the results of those tests in the context of the Cosmetics Regulation*. They will of course have to be reported in the PIF. [66] However, they cannot be used to demonstrate the safety of the ingredient.

133. This is the only reasonable interpretation that I see which reconciles these two pieces of legislation and avoids circumvention while at the same time (a) respecting the sectoral nature of the Cosmetics Regulation, (b) maintaining the link between the animal testing and sale of the tested ingredient in cosmetics as required by the wording of the legislation and (c) avoiding impossible enquiries into specific purpose/subjective intent.

c) On the relevance of WTO law

134. Both EFfCI and the French Republic stressed the importance of interpretation in conformity with Article III.4 of GATT 1994. Moreover, the Commission voiced serious concerns about the compatibility of the marketing ban with that provision during the legislative process leading to the adoption of Directive 2003/15.

135. Consequently, it is necessary to say a few words about WTO law before concluding on my interpretation of Article 18(1)(b) of the Cosmetics Regulation.

136. Assessment of the marketing ban in the light of WTO law clearly raises sensitive issues and requires resolution of complex legal questions. Ultimately, those questions would have to be assessed by the competent bodies within the WTO dispute settlement system.

137. As already observed above (see point 73), the interpretations proposed by the Interveners and the Hellenic Republic do create considerable barriers to international trade. As such they arguably have the potential to raise (more significant) issues under WTO law. However, since the proposed interpretations of all parties have been dismissed on other grounds, it is not necessary to consider their interpretation in conformity with WTO law in any detail here.

65 — ECHA/NA/14/14/46, '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.

66 — To the extent performed by the manufacturer, his agents or suppliers in accordance with Article 11(2)(e) of the Cosmetics Regulation.

138. For the reasons set out above, I have proposed the interpretation of the marketing ban that I consider sticks as closely to the text of the Cosmetics Regulation as possible, whilst respecting context and purpose. In my view, that interpretation of the marketing ban also ensures to the greatest extent possible conformity with the relevant provisions of GATT.

d) Conclusions on textual, contextual and purposive analysis and proposed interpretation of the marketing ban

139. In light of the foregoing, I consider that the marketing ban must be understood as preventing *reliance* on the results of animal testing for the purpose of meeting the requirements of the Cosmetics Regulation (subject to the relevant cut-off dates). *Reliance* on animal testing results must, moreover, be distinguished from mere *inclusion* of those results in the PIF.

140. From this key suggestion follow the answers to the specific questions posed by the referring court. Those questions correctly highlight a number of potential problematic points to which reliance on subjective corporate intent might lead in a world characterised by trans-sectoral and trans-jurisdictional complexity, in which data-sets freely circulate. Should the Court decide to follow the interpretative approach outlined in this Opinion, the answers to those questions become relatively straightforward. They can be outlined in the following way:

141. It is irrelevant to the application of the marketing ban where the testing was conducted. The testing may have been conducted in the EU (for example, to comply with REACH), or outside the EU (for example, because it is required by relevant foreign legislation).

142. The subjective intent or specific purpose behind the testing is also irrelevant (whether that be the specific purpose of the lab conducting the tests, the entity commissioning them or some other entity). In particular, it makes no difference if the exclusive purpose, the main purpose or just one of the multiple purposes was to conduct testing with a view to satisfying the requirements of a given piece of legislation (EU or non-EU).

143. It is equally irrelevant whether that piece of legislation is cosmetics or non-cosmetics related.

144. It is irrelevant whether and at what point in time marketing of cosmetics (in the EU) was foreseen.

145. Finally, in accordance with the clear wording of Article 18(2) of the Cosmetics Regulation, the marketing ban can only be triggered by animal testing that was carried out after the relevant cut-off dates.

146. This is the reading which I consider best fits with the wording of the Cosmetics Regulation, whilst maintaining coherency with the remainder of that regulation and other EU law provisions, upholding the legislative intent and ensuring enforceability. At the same time, it maintains a reasonable balance amongst the various interests involved while respecting the fundamental principles of the rule of law: legal certainty and legality.

V – Conclusion

147. On the basis of the analysis set out above I propose that the Court answers the questions referred by the High Court of Justice of England & Wales, Queen's Bench Division (Administrative Court) as follows:

Question 1: Article 18(1)(b) of Regulation (EC) No 1223/2009 of the European Parliament and the Council of 30 November 2009 on cosmetic products should not be interpreted as prohibiting the placing on the EU market of cosmetic products containing ingredients, or a combination of ingredients, by the mere fact that such ingredients 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. The same provision, however, prevents reliance on the results of animal testing for the purpose of meeting the requirements of the Cosmetics Regulation, subject to the relevant cut off-dates.

Question 2(a): The marketing ban contained in Article 18(1)(b) of the Cosmetics Regulation may be triggered if the safety assessment carried out under Article 10 of the Cosmetics Regulation to demonstrate that the cosmetic product is safe for human health prior to it being made available on the EU market involves the reliance on data resulting from the animal testing performed outside the European Union. This depends on the other conditions for the marketing ban being met, in particular that the testing is carried out after the relevant cut-off date. The reliance on data in the safety assessment must, moreover be distinguished from mere inclusion in the product information file.

Question 2(b): It is irrelevant whether or not the legislative or regulatory requirements of the third countries relate to the safety of cosmetic products.

Question 2(c): It is irrelevant whether or not it was reasonably foreseeable, at the time that the animal testing was performed outside the Union, that any person might seek to place a cosmetic product including that ingredient at some stage on the EU market.

Question 2(d): The date on which the animal testing was conducted is relevant in light of the entry into force of the marketing ban. Only the reliance on the results of animal testing conducted after the relevant cut-off dates will trigger the ban.