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Case No: CO/3748/2021

IN THE HIGH COURT OF JUSTICE
KING'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 05/05/2023

Before :

THE HONOURABLE MR JUSTICE LINDEN

- -

Between :

THE KING

on the application of

CRUELTY FREE INTERNATIONAL

Claimant

- and -
SECRETARY OF STATE FOR THE HOME DEPARTMENT

Defendant

- -
- -

Alan Bates (instructed by **Advocates for Animals**) for the **Claimant**
Zoe Leventhal KC and Tom Tabori (instructed by **Government Legal Department**) for the **Defendant**

Hearing dates: 18 and 19 January 2023

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Approved Judgment

This judgment was handed down remotely at 10.30am on 5th May 2023 by circulation to the parties or their representatives by e-mail and by release to the National Archives.

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MR JUSTICE LINDEN

INTRODUCTION

1. Part of the Defendant's functions is the regulation of animal experimentation in Great Britain and the development of policy in relation to this issue. The regulatory aspect is carried out through the Animals in Science Regulation Unit ("ASRU"), which is responsible for determining applications for licenses pursuant to the Animals (Scientific Procedures) Act 1986 ("ASPA") and for dealing with compliance issues. Policy was also dealt with by the ASRU until April 2022 but is now dealt with by the Animals in Science Policy and Coordination Function ("the Policy Unit").

2. From 1998, government policy was that applications for licences for animal testing of cosmetics, or ingredients which are "wholly or primarily" used in such products, would be refused ("the Policy"). The Policy continued when subsequent EU legislation was enacted, ultimately in the form of Regulation (EC) No 1223/2009 ("the Cosmetics Regulation"), which aims to ensure the safety of cosmetics for the end user but, under Article 18, bans the testing on animals of cosmetics and ingredients for cosmetics, as well as the marketing of cosmetic products or ingredients, which have been tested on animals *"in order to meet the requirements of"* the Regulation. These bans were introduced over time and they became fully effective in March 2009 in the case of the testing ban, and on 11 March 2013 in the case of the marketing ban. The bans were considered to be consistent with the Policy.

3. However, there was a question at EU level as to how the bans under Article 18 of the Cosmetics Regulation interacted with the more permissive regime, at least in relation to animal testing, under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH"). This legislation imposes registration and information requirements on manufacturers and importers of chemical substances which aim to ensure the safety of chemicals from the perspective of human health and the environment. The chemical substances to which REACH applies include, in principle, substances which are or may be used in cosmetics.

4. On 24 October 2014, the European Chemicals Agency ("EChA") and the EU Commission therefore issued a Joint Statement on the "Interface between REACH and Cosmetics Regulations" ("the 2014 Joint Statement"). This document emphasised that the marketing and testing bans under the Cosmetics Regulation apply where the testing of the product or ingredient is carried out *"in order to meet the requirements of"* that Regulation. The 2014 Joint Statement took the position that, although animal testing should only ever be a last resort, registrants under REACH were in principle permitted to carry out testing on animals of substances which had various uses, including in cosmetics, in order to meet the information requirements of REACH in relation to human health. Registrants of substances which were exclusively for use in cosmetics could not use animal testing unless that testing was required in order to assess the risk to workers, involved in the manufacture or production of the substance, of exposure to that substance. Animal testing for the purposes of environmental endpoints was in principle permissible too. This view was more permissive of animal testing than the Policy.

5. In July 2017 the European Ombudsman rejected a challenge to the 2014 Joint Statement and, on 13 February 2019, the EU Commission reiterated its view in a letter to the

Claimant. On 18 August 2020, the Board of Appeal of the EChA then handed down its decisions in two appeals (Case nos A-009-2018 and 010-2018) brought by Symrise AG against requirements imposed by the EChA pursuant to REACH ("*Symrise*"). These requirements were to carry out specified tests on animals of a substance which is used exclusively in cosmetic products. Symrise's case was that it would be contrary to the bans under the Cosmetics Regulation to carry out these tests, but this argument was rejected by the Board of Appeal. It held that tests required by REACH were not tests carried out "*in order to meet the requirements of [the Cosmetics Regulation]"*: they were tests carried out in order to meet the requirements of REACH, and therefore were not subject to the bans under Article 18. The decisions in *Symrise* are being challenged by way of actions for an annulment in the EU General Court (Cases T-655/20 and T-656/20) and the case was heard in November 2022. Judgment is awaited.

6. The Claimant, formerly known as the British Union for the Abolition of Vivisection, is an organisation dedicated to the reduction and ending of the use of animals in scientific experiments in the United Kingdom and globally. Amongst its other activities, it campaigns and lobbies on this issue at a political level, including in relation to the law, and it has also conducted litigation which raises issues as to the correct interpretation of existing law on the issue of animal experimentation. The Policy was in part a response to its lobbying activities at the end of the 1990s.

7. The Claimant was concerned about the position taken by the EU Commission and the EChA in the 2014 Joint Statement and it raised the matter with the Government, including in the context of a claim for judicial review brought against the Defendant and the Secretary of State for Business Innovation and Skills ("BIS") in 2015 ("the 2015 judicial review"). This claim sought the determination of certain issues about the interpretation of the Cosmetics Regulation and REACH. The Defendant's position at that stage, as reflected in a newsletter which the ASRU issued to licence-holders on 29 July 2015, was that whatever the strict position in law, there remained "an absolute ban" on animal testing of cosmetics or substances primarily intended for use in cosmetics. The legal issues raised in the 2015 judicial review therefore did not arise for determination. The claim against the Defendant was withdrawn given that the Policy remained in place.

8. However, in the light of queries from licence holders and internal concerns about being out of step with EU law, at the end of 2017 the ASRU began to consider whether the Policy should be maintained. At the end of 2018 there were also concerns raised at EU level about the United Kingdom's position, and it was concluded within the ASRU that government policy should be brought into line with the EU interpretation of the Cosmetics Regulation so that applications for licenses to carry out animal experimentation which was required by REACH would be considered under the ASPA and could in principle be granted. Accordingly, on 14 February 2019 a licence was granted on this basis and other licences have been granted since then.

9. The Defendant accepts that this change of position "was not fully documented or widely communicated at the time". Indeed, the Claimant only became aware of what at that stage appeared to be a prospective change of policy on 2 October 2020. Both the Cosmetics Regulation and REACH are retained EU law pursuant to the European Union (Withdrawal) Act 2018 and, on 21 August 2020, the Claimant had raised questions about the United Kingdom's approach after Brexit in the light of *Symrise* and had advocated amendments to the Cosmetic Regulation and REACH, as applied in this

country, which would make clear that the United Kingdom would not interpret the law in the same way as the EU. In effect, the Claimant was told by the Department for Environment Food & Rural Affairs ("DEFRA"), which has responsibility for chemicals policy generally, that the Government agreed with the decisions in *Symrise*.

10. However, it was not until 3 August 2021 that the Defendant confirmed that she had reconsidered the Policy and had aligned her approach to that of the Board of Appeal in *Symrise.* It was only in the course of these proceedings – in the Summary Grounds of Defence - that the Claimant was told that there had in fact been a change of policy in effect since February 2019 i.e. 18 months before *Symrise*.

11. It is in these circumstances that the Claimant complains that the Government's change of policy was effected "secretly" and without consultation. It also argues that the *Symrise* decisions were wrong in law and, as a result, current government policy is based on a misunderstanding of the law and contrary to the Cosmetics Regulation.

THE PROCEEDINGS

12. The Statement of Facts and Grounds pleads four grounds of challenge. The Claimant alleges:

    i) First, that contrary to section 5B(3)(d) of the ASPA, the ASRU is not carrying out a harm/benefit analysis when determining applications for licences to test cosmetic products and ingredients on animals. Rather, licenses are automatically granted where the testing is required by the Health & Safety Executive ("HSE"), which is the regulator for REACH in this country. The Defendant's functions under the ASPA are therefore, in effect, being unlawfully delegated to the HSE. ("Ground 1").

    ii) Second, that the Defendant breached the Claimant's legitimate expectations, and/or public law principles of fairness, by failing to consult prior to abandoning (alternatively substantially modifying and weakening) the Policy. ("Ground 2").

    iii) Third, the Defendant breached the Claimant's legitimate expectations, and/or public law principles of fairness by failing to inform the Claimant and/or the public generally of the change of policy ("Ground 3").

    iv) Fourth, the Defendant's position that she will interpret and apply the Cosmetics Regulation and REACH in accordance with the decision of the Board of Appeal in *Symrise* constitutes the adoption of a legally erroneous approach which will lead to the grant of licenses to carry out animal testing on cosmetics and ingredients for cosmetics in breach of the testing ban under the Cosmetics Regulation ("Ground 4").

13. The relief sought by the Claimant is a series of declarations that the Defendant has acted, is acting, or would be acting unlawfully in the respects alleged.

14. The witness evidence relied on by the Claimant comprised statements from Dr Katy Taylor, Director of Science and Regulatory Affairs at the Claimant, dated 13 January and 28 November 2022; and a statement from Mr David Thomas, the Claimant's

solicitor, dated 26 August 2022. The Defendant relied on statements from Dr Kate Chandler, Head of the ASRU, dated 14 October and 15 December 2022, and 19 January 2023; and from Mr William Reynolds, Head of the Policy Unit, dated 17 October and 14 December 2022.

15. Permission was granted on Grounds 1 and 4 on the papers by May J on 18 July 2022. Following a renewed application, Steyn J granted permission on Grounds 2 and 3 at a hearing on 1 September 2022.

16. Each of the Grounds is contested by the Defendant on its merits and she argues, in relation to Grounds 2 and 3, that in any event relief should be refused, pursuant to section 31(3C) Senior Courts Act 1981, because it is "highly likely that the outcome for the [Claimant] would not have been substantially different" if the conduct complained of had not occurred.

17. In the Summary Grounds of Defence, the Defendant argued, somewhat surprisingly, that the entire Claim is hypothetical and/or premature, and that permission should be refused on the basis that the proceedings appeared to be a misuse of the Court's processes. The Detailed Grounds of Defence did not pursue this argument in relation to the entirety of the Claim. But in relation to Ground 4 it was argued, on the one hand, that the Claimant's position was "plainly wrong" from which it followed that Grounds 2 and 3 must fail and, on the other, that under Ground 4 the Claimant was in effect seeking an advisory opinion on a hypothetical question, and was inappropriately seeking to draw the Court into an issue as to the correctness or otherwise of *Symrise* when that issue was currently before the European Court. This remained Ms Leventhal's position in her skeleton argument.

18. At the hearing, however, Ms Leventhal agreed that I should determine Ground 4, although she asked me to bear in mind that I was not being asked to determine the issue on the basis of specific facts. Indeed, the parties agreed that the grounds of challenge would be argued in reverse order as Ground 4 was potentially dispositive or, at least, at the heart of the case. I was told that judgment was pending in *Symrise* but that both parties nevertheless invited me to determine Ground 4 because the timing of the judgment of the European Court was not known and, in any event, that judgment would not be the last word given that the matter would in all likelihood be appealed.

19. At the hearing it was agreed that the parties would put in further written submissions on points which had arisen, and detailed submissions were in due course received from the Claimant on 30 January 2023, from the Defendant on 14 February 2023 and, in reply, from the Claimant on 17 February 2023.

THE LEGISLATIVE FRAMEWORK

The Animals (Scientific Procedures) Act 1986

20. Section 3 of the ASPA prohibits, on pain of criminal sanction, the carrying out of any *"regulated procedure"* (i.e., a procedure for an experimental or other scientific purpose, or an educational purpose, which causes material pain, suffering, distress or lasting harm: section 2) on *"protected animals,"* (i.e., any living vertebrate or cephalopod: section 1) unless licensed to do so by the Defendant.

21. Three types of licence may be granted:

    i) An establishment licence, which authorises an undertaking to carry out a regulated procedure at a specified place: section 2C(1);

    ii) A personal licence, which authorises the holder of the licence personally to undertake a specified regulated procedure: section 4; and/or

    iii) A project licence, which specifies a programme of work and authorises the application, as part of that programme, of specified regulated procedures to animals of specified descriptions at a specified place(s): section 5(1).

22. The present case primarily concerns project licences. An application for a project licence must be accompanied by a project summary, stating the predicted harm and benefits of the programme, and demonstrating that it would be carried out in accordance with the principles of replacement, reduction and refinement ("the 3Rs"): section 5A(2). The 3Rs essentially require that, wherever possible, alternatives to animal testing should be used, such testing should be on the minimum number of protected animals, and testing should be refined so as to eliminate or reduce animal suffering: section 2A.

23. The Defendant is prohibited from granting a project licence unless she has carried out a favourable evaluation of the programme of work to be specified in the licence: section 5B(1). Under section 5B(2) a programme of work may be evaluated as favourable only if the evaluation verifies:

> *"(a) that carrying out the programme of work is justified from a scientific or educational point of view or is required by law;*
>
> *(b) that the purposes of the programme of work justify the use of protected animals; and*
>
> *(c) that the programme of work is designed so as to enable the regulated procedures applied as part of it to be applied in the most humane and environmentally sensitive manner possible."* (emphasis added)

24. In effect, the Policy took the position that animal testing of cosmetics products or ingredients was not required by law or justified for the purposes of section 5B(2)(a) or (b).

25. Section 5C(3) sets out specific purposes of a project which may be permitted, including:

> *"(b) translational or applied research with one of the following aims—*
>
> *(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality, or their effects, in man, animals or plants;*
>
> *(ii) the assessment, detection, regulation or modification of physiological conditions in man, animals or plants;…*
>
> *(c) the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs or any other substances or products, with one of the aims mentioned in paragraph (b);…"*

26. Section 5B(3) sets out the steps which the Defendant must take as part of the evaluation of a programme of work. She is required, amongst other things, to:

> *"(a) evaluate the objectives of the programme of work and its predicted scientific benefits or educational value;*
>
> *(b) assess the compliance of the programme of work with the principles of replacement, reduction and refinement;*
>
> *(c) classify as "non-recovery", "mild", "moderate" or "severe" the likely severity of each regulated procedure that would be applied as part of the programme of work;*
>
> *(d) carry out a harm-benefit analysis of the programme of work to assess whether the harm that would be caused to protected animals in terms of suffering, pain and distress is justified by the expected outcome, taking into account ethical considerations and the expected benefit to human beings, animals or the environment;*
>
> *(e) assess any scientific justification which is relevant…."* (emphasis added)

27. Section 5B(9) provides that:

> *"The Secretary of State must publish information as to the process by which he proposes to evaluate programmes of work under this section".*

28. Section 19 of the ASPA establishes the Committee for the Protection of Animals Used for Scientific Purposes (known as the Animals in Science Committee, or the ASC), and section 20(1) provides that the functions of the ASC include a duty to:

> *"…provide advice to the Secretary of State and the Animal Welfare and Ethical Review Bodies on such matters relating to the acquisition, breeding, accommodation, care and use of protected animals as the Committee may determine or as may be referred to the Committee by the Secretary of State."*

29. Section 21(1) of the ASPA provides that:

> *"The Secretary of State shall publish information to serve as guidance with respect to the manner in which he proposes to exercise his power to grant licences ... under this Act and with respect to the conditions which he proposes to include in such licences ...."*

30. And section 21(3) provides, so far as material, that:

> *"The Secretary of State shall consult the Committee for the Protection of Animals Used for Scientific Purposes before publishing or altering any information under subsection (1) above…."*

31. There is also an obligation on the Secretary of State, under section 21(5), to lay before Parliament *"copies of any information published…under subsection (1) ..above and of any alteration made by him in any such information."* which will then be subject to the negative resolution procedure.

32. Finally, section 24 of the ASPA provides that it is an offence for a person who has obtained information in the exercise of their functions under the ASPA to disclose such information otherwise than for the purposes of discharging those functions if they know or have reasonable grounds to believe that that information was given in confidence.

Regulation (EC) No 1223/2009 ("the Cosmetics Regulation")

33. The Cosmetics Regulation is a consolidation of the amendments which were made to the Cosmetics Directive (76/768/EEC), including the amendments which introduced the predecessor to Article 18 in 2003 (Directive 2003/15/EC) with a view to the testing and marketing bans being phased in over time.

34. The function of the Regulation is captured as follows in Recital (4):

> *"This Regulation comprehensively harmonises the rules in the Community in order to achieve an internal market for cosmetic products while ensuring a high level of protection of human health."*

35. In relation to testing on animals, Recital (40) states:

> *"The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, where such methods offer an equivalent level of protection to consumers."*

36. Article 1 sets out the **"Scope and objective"** of the Cosmetics Regulation as follows:

> *"This Regulation establishes rules to be complied with by any cosmetic product made available on the market, in order to ensure the functioning of the internal market and a high level of protection of human health."* (emphasis added)

37. Pursuant to this objective, Article 3 requires that, taking into account its presentation, labelling, instructions for use and disposal and any other relevant indication:

> *"A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use…"*. (emphasis added)

38. Article 4 requires that there be a responsible person designated to ensure compliance with the obligations set out in the Cosmetics Regulation. In broad terms, this is the manufacturer or their designee established within the EU where the cosmetic product is manufactured within the EU, the importer or their designee established within the EU where the product is imported into the EU, or the distributor where the product is marketed under the distributor's name.

39. Article 10 provides as follows:

> *"1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the*

> *relevant information and that a cosmetic product safety report is set up in accordance with Annex I.*
>
> *The responsible person shall ensure that:*
>
> *(a) The intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;*
>
> *(b) An appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;*
>
> *(c) The cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market. ....."* (emphasis added)

40. Annex 1 then sets out a detailed specification of categories of information which, as a minimum, must be included in the *"cosmetic product safety report"*. Part A requires categories of product safety information including, for example, *"Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints…"* (paragraph 7) and "*Without prejudice to Article 18, the toxicological profile of substance contained in the cosmetic product for all relevant toxicological standpoints…"* with a particular focus on, for example, skin and eye irritation (paragraph 8). Part B of the product safety report must set out a statement as to the safety of the product for the purposes of Article 3 and any need to give warnings or instructions for use on the label. It must also explain the reasoning which led to the relevant conclusions.

41. Under Article 11, in addition to the cosmetic product safety report, there is an obligation to maintain a *"product information file"* for any cosmetic product which is placed on the market. The product information file is required to include various categories of information including the cosmetic product safety report itself (Article 11.2(b)) and, under Article 11.2(e):

> *"data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries."*

42. The product information file is required to be readily accessible to the competent authority of the Member State in which the file is kept: Article 11.3.

43. *"Without prejudice to the general obligations deriving from Article 3"*:

    i) Articles 18.1(a) and (b) prohibit the placing on the market of cosmetic products where the final formulation or the ingredients in those products *"in order to meet the requirements of this Regulation"* have been the subject of animal testing using a method other than a validated alternative method ("the marketing ban").

ii) Articles 18(1)(c) and (d) prohibit animal testing of finished products, or the ingredients or combinations of ingredients in those products, *"in order to meet the requirements of this Regulation"*.

44. Under Article 18.2 there is then provision for derogations from Article 18.1 to be granted by the Commission in exceptional circumstances.

45. Pursuant to section 8(1) of the European Union (Withdrawal) Act 2018, the Cosmetics Regulation was subject to certain modifications under Regulation 37 and Schedule 34 to the Product Safety and Metrology (Amendment etc) (EU Exit) Regulations 2019 ("The Product Safety Regulations"). [17] of Schedule 34 substitutes the following text for Article 18:

> ***"Article 18 Animal testing***
>
> *1 Except as provided in paragraph 1A, no cosmetic product may be placed on the market –*
>
> *(a) Where the final formulation of the product has been the subject of animal testing in order to meet the requirements of this Regulation;*
>
> *(b) Where the ingredients or combinations of ingredients of the product have been the subject of animal testing in order to meet the requirements of this Regulation.*
>
> *1A Paragraph 1 does not prevent the use of historic animal testing data in order to meet the requirements of this Regulation.*
>
> *2 No animal testing of finished cosmetic products may take place in the United Kingdom in order to meet the requirements of this Regulation.*
>
> *3 No animal testing of ingredients or combinations of ingredients may take place in the United Kingdom in order to meet the requirements of this Regulation."* (emphasis added)

46. It was not suggested before me that this reformulation was intended to alter the meaning or effect of Article 18 of the Cosmetics Regulation and the focus of the discussion below will therefore be on Article 18.

47. At all material times for the purposes of this case the principal competent authority for the purposes of the Cosmetics Regulation was the Department for Business Energy and Industrial Strategy ("BEIS", formerly "BIS").

Regulation (EC) No 1907/2006 ("REACH")

48. REACH is concerned with the safety of chemicals manufactured in, or imported into, the EU. The aims of REACH include, at Recital (7):

> *"(7) To preserve the integrity of the internal market and to ensure a high level of protection for human health, especially the health of workers, and the environment, it is necessary to ensure that manufacturing of substances in the Community complies with Community law, even if those substances are exported."* (emphasis added)

49. Recitals (16)-(19) describe REACH as follows:

> *"(16) This Regulation lays down specific duties and obligations on manufacturers, importers and downstream users of substances on their own, in preparations and in articles. This Regulation is based on the principle that industry should manufacture, import or use substances or place them on the market with such responsibility and care as may be required to ensure that, under reasonably foreseeable conditions, human health and the environment are not adversely affected.*
>
> *(17) All available and relevant information on substances on their own, in preparations and in articles should be collected to assist in identifying hazardous properties, and recommendations about risk management measures should systematically be conveyed through supply chains, as reasonably necessary, to prevent adverse effects on human health and the environment. In addition, communication of technical advice to support risk management should be encouraged in the supply chain, where appropriate.*
>
> *(18) Responsibility for the management of the risks of substances should lie with the natural or legal persons that manufacture, import, place on the market or use these substances. Information on the implementation of this Regulation should be easily accessible, in particular for SMEs.*
>
> *(19) Therefore, the registration provisions should require manufacturers and importers to generate data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. To ensure that they actually meet these obligations, as well as for transparency reasons, registration should require them to submit a dossier containing all this information to the Agency. Registered substances should be allowed to circulate on the internal market."*

50. However, Recital (13) states:

> *"This Regulation should apply without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of Member States relating to cosmetic products in so far as substances are used and marketed as cosmetic ingredients and are within the scope of this Regulation. A phase-out of testing on vertebrate animals for the purpose of protecting human health as specified in Directive 76/768/EEC should take place with regard to the uses of those substances in cosmetics."*

51. Article 1 sets out the aim and scope of REACH as follows:

> *"1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.*
>
> *2. ....*

> *3. This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle."*

52. *"Substance"* is defined under Article 3 as follows:

> *"1. Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;"*

53. Under Article 2 there are then various qualifications and exemptions in respect of certain chemicals. For example, some of the requirements do not apply to the extent that a substance is used in medical products for human or veterinary use, or foods, or feeding stuffs. Certain mixtures in their final state and intended for the final user, including cosmetics (Article 2(6)(b)), are exempt from the provisions of Title IV but ingredients which will or may be used in cosmetic products fall within the scope of REACH.

54. However, Article 2.4(b) provides that REACH:

> *"shall apply without prejudice to…[the Cosmetics Directive] as regards testing involving vertebrate animals within the scope of that Directive".*

55. In broad terms, Articles 5-7 then require, as a condition of placing a chemical substance on the market in the EU, whether on its own or in mixtures or articles (i.e. goods), manufacturers or importers of that chemical in quantities of more than one tonne per year to submit a registration to the EChA.

56. Article 10 of REACH sets out the information which must be *"submitted for general registration purposes"* when registration is required. This comprises, under Article 10(a)(i)-(xi), a *"technical dossier"* containing eleven detailed categories of information about the substance. For present purposes it is relevant to note that these categories include:

> *"(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;"*
>
> *"(vi) study summaries of the information derived from the application of Annexes VII to XI;"*
>
> *"(vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;"*

57. Annexes VII-XI set out categories of data which must be provided, the minimum requirements varying according to the tonnage of the substance which the registrant is manufacturing/importing: see Regulation 12. These Annexes specify the methods

which must be used to generate the data, including in some cases tests on animals, but they also set out *"adaptations"* or alternatives to these methods which may be available subject to various conditions set out in the provisions.

58. Under Article 10(b) a registration is also required to include:

> *"a chemical safety report when required under Article 14, in the format specified under Annex 1."*

59. Under Article 14.1:

> *"…a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant".*

60. The chemical safety report is required to document the safety assessment and to show that it has been carried out in accordance with detailed requirements specified in Article 14 and Annex 1 to the Regulation. Articles 14.3 and 14.4 set out specific steps which must be taken as part of the assessment including a *"human health hazard assessment"* (Article 14.3(a)). If, as a result of carrying out the hazard assessments required by Article 14.3, the registrant concludes that the substance fulfils the criteria for certain hazard classes which are set out in in Regulation (EC) No 1272/2008 (the Classification and Labelling Regulation) then certain additional steps are required as part of the chemical assessment. These are an *"exposure assessment"* and a *"risk characterisation"*. The exposure assessment requires the generation of exposure scenario(s) or the identification of relevant use and exposure categories if appropriate, addressing all identified uses of the registrant, as well as exposure estimation.

61. However, Article 14(5)(b) provides that:

> *"The chemical safety report need not include consideration of the risks to human health from the following end uses…*
>
> *…(b) in cosmetic products within the scope of [the Cosmetics Directive]"*

62. Annex 1 then sets out requirements as to the format of the chemical safety report including the results of any exposure assessment or risk assessment in relation to human health. In this connection the report is required to differentiate between workers, consumers and those who are indirectly exposed to the substance via the environment.

63. Article 14.6 requires that measures to control risks should be identified and Article 14.7 requires that the chemical safety report is kept up to date.

64. Articles 13(1) and 25(1) REACH emphasise that, wherever possible, alternatives to animal testing should be used to generate the required data. The latter provides, for example, that:

> *"In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests…"*

65. Under Article 41, the EChA is required to carry out compliance checks on technical dossiers for the purpose of assessing whether the information requirements under REACH have been met. The EChA has powers to direct the registrant to provide further information and to carry out further tests in order to comply with REACH and to fill in any gaps. As noted above, the counterpart of the EChA in the United Kingdom is the HSE. The Board of Appeal hears appeals from the EChA's decisions.

66. REACH was subject to various modifications made by the REACH etc (Amendment etc) (UK Exit) Regulations 2019 for the purposes of its application post Brexit. The equivalent of Art 2(4)(b) was omitted (see [2(6)] of Schedule 1 to the 2019 Regulations) but Ms Leventhal confirmed that, notwithstanding indications to the contrary in her skeleton argument, she was not contending that this has any significance from the point of view of statutory construction in the present case.

A MORE DETAILED ACCOUNT OF THE FACTS

67. It was not in dispute that in the late 1990s the government of the day introduced a number of policies which banned animal experimentation in weapons research, alcohol and tobacco, and cosmetics, as well as the use of great apes or stray animals of a domestic species in experiments. In late 1998 government policy moved from a ban on animal testing on cosmetic end products to encompass "ingredients intended primarily for" such products as well. This position was stated in a letter from George Howarth MP, the then Minister to Roger Gale MP, dated 16 November 1998, which confirmed that "we have no intention of issuing licences for such work". The letter was placed in the libraries of the House of Commons and the House of Lords.

68. In 2010 the then Home Secretary told the House of Commons, in response to a public petition seeking a statutory ban on the testing of cosmetics on animals:

> "In 1997-98, the Government secured a voluntary ban on the testing of cosmetic finished products and ingredients on animals in the United Kingdom. We did this because we believed that there was inadequate justification for using animals given the benefits of these products and the alternative tests available. …
>
> We cannot foresee any circumstances under which we would be prepared to issue licenses under the Animals (Scientific Procedures) Act 1986 for testing on cosmetic finished products and ingredients."

69. I was shown Guidance published in March 2014 pursuant to section 21 of the ASPA entitled *"Guidance on the Operation of the Animals (Scientific Procedures) Act 1986"* ("the Operational Guidance"). This included, at [5.18], the statement:

> *"Project licences will not be granted for programmes of work involving the following…testing cosmetics".*

70. It is apparent from the evidence that the same statement appeared at [5.23] of the 2000 edition of the Operational Guidance. Although the Guidance stated the position more narrowly, it is also plain that, read in the context of the evidence as a whole, the Policy applied to the testing of ingredients for use in cosmetics as well as the end product, and

this is how the Government's policy on licensing in relation to cosmetics was understood.

71. In March 2013, however, the European Commission issued COM (2013) 135 to the European Parliament and the Council "on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics". This document was principally concerned with the marketing ban under Article 18 of the Cosmetics Regulation which was to become fully effective on 11 March 2013, and it stated that in the light of progress which had been made in relation to alternatives to animal testing it was not proposing any further delay to the implementation of the ban.

72. Under the heading "Implementing the 2013 marketing ban and monitoring its effects" the EU Commission pointed out that the majority of ingredients which are used in cosmetic products are also used in other products such as pharmaceuticals, detergents, and food, which may be subject to their own legal frameworks. Such ingredients would also be subject to the requirements of REACH, and animal testing might therefore be necessary as a last resort to complete the respective data packages. It would then be for Member States to decide whether such testing for compliance with other legal frameworks fell within the scope of the 2013 marketing ban. The Commission went on to say:

> "The Commission considers that animal testing that has clearly been motivated by compliance with non-cosmetics related legislative frameworks should not be considered to have been carried out '*in order to meet the requirements of this Directive/Regulation'*. The resulting animal testing data should not trigger the marketing ban and could subsequently be relied on in the cosmetics safety assessment. Reliance on such data is subject to its relevance for the cosmetics safety assessment and its compliance with data quality requirements.
>
> Testing carried out for cosmetics relevant endpoints on ingredients that have been specifically developed for cosmetic purposes and are exclusively used in cosmetic products would in the Commission's view always be assumed to be carried out '*in order to meet the requirements of this Directive/Regulation'*.
>
> 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 assessment of cosmetics."

73. In other words, the question was as to the purpose of the testing – was it in order to comply with the Cosmetics Regulation? If the ingredient was exclusively for use in cosmetic products the answer was likely to be in the affirmative. But the marketing ban would be triggered by reliance on data from animal testing rather than the testing as such.

74. In October 2014, the Commission and the EChA then issued the 2014 Joint Statement, or "Factsheet", entitled "Interface between REACH and Cosmetics regulations. This purported to "clarify the practical meaning and implications of [COM (2013) 135] in the context of REACH."

75. Under the heading "REACH requirements for registrants that manufacture/import a substance used in cosmetic products" the following was stated:

> *"Following the Commission communication, the relationship of the testing ban enshrined in the Cosmetics Regulation and the REACH information requirements can be described as follows:*
>
> 1. *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. The exception is any testing required to assess the risks from exposure to workers;*
>
> 2. *Registrants of substances that use the substance also for non-cosmetic uses (i.e. mixed-use substances) are permitted to perform animal testing, as a last resort, for all human health endpoints;*
>
> 3. *All registrants (whether or not they only use the substance for cosmetic purposes) are permitted to perform animal testing, as a last resort, for all environmental endpoints.*
>
> *This means that the Cosmetics Regulation does not restrict testing under REACH, if:*
>
> - *This testing is required for environmental endpoints; or*
> - *The substance is also registered for non-cosmetic uses.*
>
> *Even if a substance is registered exclusively for cosmetic use, the animal testing requirements continue to apply to tests needed to assess the risks from exposure to workers in the Chemical Safety Assessment.*

76. A footnote explained that:

> *"'Workers' in this context are to be understood as persons who are actively involved in a particular activity of a production or manufacturing site, where they may be exposed directly or indirectly to chemical substances. On the other hand, professional users who use the cosmetic product as part of their professional activity (e.g. hairdressers) and consumers shall not be considered as 'workers'."*

77. The Claimant was concerned about the 2014 Joint Statement as it considered that the stated interpretation of the law was more permissive of animal experimentation than was consistent with the bans under Article 18 of the Cosmetics Regulation. In April to June 2015 Mr Thomas, on behalf of the Claimant, corresponded with BIS and the Home Office seeking clarification of their views on the interpretation of Article 18 given the 2014 Joint Statement. By letter dated 29 June 2015, Mr Thomas was told by the ASRU that the Policy remained unchanged but that it was not appropriate for the ASRU to give them legal advice.

78. On 29 July 2015, the Defendant issued a Newsletter for establishment licence holders which clarified the position as follows:

> "There has recently been some debate over the scope of the European ban on the testing of cosmetics in animals and the marketing of cosmetics which have been tested in animals…. In particular, the question has arisen about testing which may be required under other EU regulations (e.g. REACH) and whether this is permitted under the EU Cosmetics Regulation.
>
> We have therefore been asked whether testing finished cosmetics or substances primarily intended for use as ingredients in cosmetics is now permissible under ASPA. For the avoidance of any doubt, we are advising you that the current UK ban on testing cosmetics in animals is an **absolute ban**." (emphasis in the original)

79. The July 2015 Newsletter pointed to the 2000 and the 2014 editions of the Operational Guidance as making:

> "it clear that the Secretary of State will not authorise the use of protected animals for testing cosmetics products and substances primarily for use as cosmetics ingredients….The UK's policy ban remains in place even where EU legislation would appear to require or permit such testing". (emphasis added)

80. The ASRU was therefore aware that the Policy was stricter than the Commission's interpretation of the legislation, but clear that the Policy remained in place. The Newsletter added that no such licence had been issued since 1998.

81. In 2015 the Claimant and The European Coalition to End Animal Experiments ("ECEAE") issued a claim for judicial review against the Secretaries of State for BIS and the Defendant (CO/3673/2015). They sought declarations that the BIS and the Defendant were misinterpreting the law in that the bans under Article 18 of the Cosmetics Regulation mean that substances whose main or predominant use (as opposed to exclusive use) is in cosmetic products cannot be subjected to animal testing for the purposes of demonstrating their safety, and that this includes animal testing for the purposes of demonstrating their safety for workers.

82. The "Defendants' Summary Grounds for Contesting the Claim" in the 2015 judicial review set out relatively detailed reasons for disputing the claimants' analysis of the relationship between the Cosmetics Regulation and REACH. The defendants' position was that the words *"in order to meet the requirements of this Regulation"* in Article 18 refer to testing which is undertaken to ensure that cosmetic products may be safely used by end users. These words therefore require a factual assessment of the purpose of the testing of a given ingredient on animals. Testing for the purpose of assessing the safety of the ingredient for workers who deal with it as part of the production process was not contrary to Article 18(1) because they are not end users. But the Summary Grounds also reiterated that in any event there had been a ban on animal testing for cosmetic products and ingredients in place since 1998. That policy remained in place, and it applied irrespective of the purpose of the testing for which a licence was sought, i.e. whether or not the purpose was to assess worker safety. The interpretive issues in the claim therefore did not arise.

83. This position had been set out in correspondence between the parties in September 2015 and the fact that the Policy was in place had been emphasised by the Government Legal Department ("GLD") on 3 and 11 September 2015. By letter dated 16 September 2015, Mr Thomas said that the Policy did not have the same status as a judicial ruling on the

meaning of Article 18 - "The policy could be changed at any time" - but that, in the light of the explanation of the Defendant's position which had been given, the Claimant was prepared to withdraw, albeit not against BIS at that stage.

84. In September 2016, the CJEU then handed down its judgment in *European Federation for Cosmetics Ingredients v Secretary of State for Business, Innovation and Skills (Cruelty Free International and European Coalition to End Animal Experiments Intervening)* Case-C-592/14 ("the *ECFI* case"), addressing preliminary questions which had been referred to it by the High Court on 15 May 2014 in the context of a claim for judicial review brought by the ECFI. The referred questions related to the position where animal testing had been carried out outside the EU in order to test the safety to human health of certain cosmetics ingredients. The data from those tests were required so that they could be used in relation to cosmetics products which were to be sold in Japan and China, and the issue was whether products which contained these ingredients could be placed on the market in the United Kingdom or whether the marketing ban under Article 18(1)(b) prohibited this.

85. The CJEU ruled that:

> *"Article 18(1)(b) [of the Cosmetic Regulation] must be interpreted as meaning that it may prohibit the placing on the European Union market of cosmetic products containing some ingredients that have been tested on animals outside the European Union, in order to market cosmetic products in third countries, if the resulting data is used to prove the safety of those products for the purpose of placing them on the EU market."* (emphasis added)

86. In other words, what is prohibited in the case of the marketing ban is the use of data derived from animal testing to prove the safety of the end product as required by Article 3 of the Cosmetic Regulation. The tests which produced the data must, for these purposes, be regarded as having been carried out *"in order to meet the requirements of this regulation"*.

87. In the light of this judgment, on 7 November 2016 Mr Thomas put the Claimant's understanding of the *ECFI* decision to the GLD. In a letter dated 30 November 2016 the GLD replied:

> "You ask my client to confirm its understanding of that judgment. That case concerned the interpretation of the marketing ban in Article 18(1)(b). It appears from paragraph 39 of the judgment that '*the fact of having relied, in the cosmetic product safety report [required under Article 10 of Regulation 1223/2009], upon the results of animal testing concerning a cosmetic ingredient in order to demonstrate the safety of that ingredient to human health must be regarded as sufficient to establish that that testing has been carried out to meet the requirements of Regulation No 1223/2009 for obtaining access to the EU market.'* Paragraph 40 and 41 indicate that it is not relevant to the application of the marketing ban where the animal testing was carried out, or whether it was required in order to market cosmetic products in third countries. On the basis of those paragraphs, it appears that the application of Art.18(1)(b) would not depend either (i) on the extent to which a cosmetic ingredient also had other uses; or (ii) on the purpose for which the testing was originally undertaken."

88. I note that this passage was very clear that it was addressing what the CJEU had decided about the marketing ban under Article 18(1)(b). Dr Taylor says, and I accept, that in the light of the Defendant's stated policy and BIS' interpretation of the *ECFI* judgment the Claimant was content to let the matter rest so far as the position in the United Kingdom is concerned and the claim for judicial review was withdrawn.

89. On 21 July 2017, the European Ombudsman gave its decision on a complaint of maladministration which had been brought in relation to the 2014 Joint Statement, apparently by an animal welfare organisation. One of the bases on which it was alleged that there had been maladministration was that the Joint Statement misinterpreted the law and was contrary to the Cosmetic Regulation and EU law more generally. Reliance was placed on the *ECFI* judgment as supporting the complainant's interpretation.

90. The position of the Commission and the EChA was that the *ECFI* case was about testing outside the EU to comply with third country regulations. The CJEU had not been concerned with the relationship between the Cosmetics Regulation and REACH. The Joint Statement was correct. At [13] the Ombudsman noted that:

> "The Commission and ECHA argued that animal testing carried out, as a last resort, to meet the requirements of the REACH Regulation could not be seen as an attempt to circumvent the prohibitions of the Cosmetics Regulation (as perhaps performing animal tests outside the EU, in accordance with third country cosmetics legislation, might be). Animal tests on ingredients of cosmetic products would thus be allowed in order to comply with other EU legislation (such as the REACH Regulation)." (underlining added)

91. At [32] the Ombudsman accepted that she did not need to take a position on the *ECFI* case given that it does not deal with the requirements of REACH, as the Joint Statement does. The complainant's overall argument was also expressly rejected at [40] of the decision. In relation to worker safety, the Ombudsman said this at [34]:

> "The first case [of the three referred to by the 2014 Joint Statement] concerns **worker exposure**. The Ombudsman agrees with the Commission and ECHA that the Cosmetics Regulation does not cover questions of safety related to the *production* of a cosmetic product. When referring to safety for human health, the Cosmetics Regulation explicitly refers to a "*cosmetic product made available on the market*". Workers may be subject to significantly different, and potentially amplified, risks during the production of a cosmetic (because, for example, they handle large amounts of undiluted ingredients) compared to consumers or even professional end-users (such as hairdressers). The potential risks from chemical ingredients during the production process are thus to be assessed **within the context of the REACH Regulation**, and any animal tests carried out in that context are subject **to the REACH Regulation's rules and limitations**." (underlining added, italics and bold in the original)

92. At [36] she said this:

> "The second case concerns chemicals used **both as ingredients in cosmetics and as ingredients in other products**. The joint statement states that **the REACH Regulation** might require animal testing for these "dual-use" chemicals (to provide, as a last resort, information under the REACH Regulation on possible

> risks to human health). Such testing **under the REACH Regulation** is not prohibited by the Cosmetics Regulation." (emboldened in the original)

93. In his witness statement Mr Reynolds says that, notwithstanding an appreciation of the position which continued to be taken at EU level, the ASRU continued to act in accordance with the Policy and did so until February 2019, albeit at the end of 2017 questions were raised internally as to whether the United Kingdom had intended to adopt a more stringent approach than was required by the Cosmetics Regulation and was consistent with REACH. An internal briefing document was prepared in December 2017 and an options paper was worked up in May 2018 although this was not taken further at that stage.

94. From the beginning of 2018, establishment licence holders also began to question the Policy. Concerns were expressed that the testing work would be conducted abroad instead, including in other EU countries whose approach was aligned with the EU position, and there were concerns raised about the lack of level playing field across Europe for contract research organisations.

95. In November 2018, the EChA contacted DEFRA to request clarity on the United Kingdom's position. When the Policy was communicated to the EChA by DEFRA, the EU Commission raised the issue as a concern at a meeting involving all Member States - the concern being that the United Kingdom was setting the bar higher than other Member States.

96. On 23 November 2018, there was a further application for a licence to carry out animal testing on a substance which could be used in cosmetics, and in December 2018 there were discussions internally about the policy position. It was reported that data were being gathered to assess the impact of the Policy in terms of work being lost to contract research organisations.

97. On 13 February 2019, the Commission replied to a letter from the Claimant. Amongst other things, the EU Commission said:

> "Regarding your request for some clarifications, we fail to agree that the testing and marketing bans in the Cosmetics Regulation would take precedence over REACH requirements. The Cosmetic Regulation does not directly aim at protecting the health and safety of workers handling the substances used in the production of cosmetics. Workers may handle such substances in greater quantities, with higher concentrations, more frequently and, consequently, with higher exposure than consumers. Therefore, to protect health of people working in that industry, animal testing may be required." (emphasis added)

98. It reiterated that the *ECFI* case was not concerned with the interaction between the Cosmetics Regulation and REACH and concluded:

> "The Commission and ECHA do not believe that animal testing carried out, as a last resort, to meet the registration requirements of REACH should be seen as an attempt to circumvent the testing and marketing bans of the Cosmetic Regulation (as perhaps performing animal testing outside the EU pursuant to third country legislation on the marketing of cosmetics might be). The testing and marketing bans in the Cosmetics Regulation should be interpreted as meaning that animal tests on

> ingredients of cosmetic products which are performed in the Union to comply with other Union legislation will not be regarded as having been performed in order to meet the requirements of the Cosmetics Regulation." (emphasis added)

99. The next day, the ASRU approved animal testing of a substance which may be used in cosmetics in order to meet the information requirements of REACH. Mr Reynolds says that "This was based upon the approach of the ECHA in respect of REACH" and that "This decision was not fully documented or widely communicated at this point, but was shared internally in ASRU and verbally by Inspectors with relevant establishments". He also refers to the "ASRU's new position now [being] aligned with the EU approach". Further approvals of similar licence applications followed in September 2019 and February 2020.

100. On 18 August 2020, the Board of Appeal of the EChA handed down its judgments in the *Symrise* cases. The key conclusion in those cases was that:

> *"The Cosmetics Regulation does not prevent registrants of a substance used, exclusively or amongst other uses, as an ingredient in cosmetic products from carrying out studies on vertebrate animals pursuant to the information requirements in the REACH Regulation"* [116/117].

101. In the light of this, on 21 August 2020 the Claimant wrote to DEFRA and BEIS urging the Government to make amendments to the Product Safety Regulations which would make clear, amongst other things, that animal testing for cosmetics ingredients and products is prohibited in the United Kingdom, irrespective of the purpose for which it is carried out or the legislation or regulatory regime under which it is carried out.

102. On 2 October 2020 Ms Rebecca Pow MP, the Minister in DEFRA responsible for chemicals policy, replied. Her letter did not directly address the question of amendments to the Product Safety Regulations but the thrust of what it said was that the Government agreed with the *Symrise* decisions. The Cosmetics Regulation did not prevent animal testing in order to comply with the information requirements of REACH. Existing EU legislation would be carried over into UK law, including the Cosmetics Regulation, REACH and the "last resort" principle under REACH. On 6 October 2020 Paul Scully MP had given a written answer to a parliamentary question to similar effect.

103. The solicitor for the Claimant therefore sent a pre-action protocol ("PAP") letter to Ms Pow MP on 19 November 2020, copied to BEIS. This letter expressed concerns that the Government apparently intended to apply the *Symrise* approach to the Product Safety Regulations when the Brexit transition period came to an end on 31 December and asked a series of questions about the Government's interpretation of Article 18. The letter stated that the Claimant would be writing separately to the Defendant to ascertain whether she still applied the Policy.

104. On 19 November 2020, the Claimant's solicitor also sent an email to the ASRU, attaching the PAP letter to DEFRA. The email asked for an answer, within 14 days, to the questions whether the Policy remained in force and, if so, whether it was still applied in the way indicated in the Summary Grounds of Defence in the 2015 judicial review proceedings.

105. The GLD replied on behalf of DEFRA and BEIS on 1 December 2020. Essentially, its answers to the questions about the law which had been posed by the Claimant reflected the decision of the CJEU in the *ECFI* case in relation to the marketing ban. It therefore agreed with some but not all of the propositions which the Claimant had put to the GLD.

106. In March 2021 a policy of regulatory testing and testing of cosmetic products and ingredients was agreed between the ASRU, BEIS and DEFRA to formalise the decision which had been taken in February 2019. However, this was not communicated more widely at this stage.

107. Despite various chasers there was no reply to the Claimant's 19 November 2020 email to the ASRU until 3 August 2021. In effect, the ASRU's letter of this date set out a new policy that where animal testing is required by other legislation/regulators it will be regarded as *"required by law"* for the purposes of section 5B(2)(a) of the ASPA. In principle, a licence could therefore be granted to carry it out. The letter said that the principle of the Policy remained in force so that animal testing of finished cosmetic products "is not required and therefore not permitted". However:

> "We can clarify that where animal testing of multi-use ingredients which may be used in cosmetics is required by legislation, and therefore by other regulators within the UK, such testing does constitute a permissible purpose under the Animals (Scientific Procedures) Act 1986 (ASPA)."

108. The letter went on to say:

> "The Home Office can confirm it has reconsidered its policy, from the approach that was stated in the 2015 Summary Grounds and has subsequently aligned its approach to the Board of Appeal of the European Chemicals Agency in the Symrise case.
>
> The Home Office aims to publicly clarify its position now with the formal publication of an updated policy and regulatory guidance on the regulation of animal testing for regulatory purposes."

109. I accept Mr Bates' submission that, apart from the unacceptably long delay in replying, this letter was misleading in that, far from admitting that the Policy had been changed 18 months earlier, the impression given was that it had been changed in response to the *Symrise* decisions.

110. Following PAP correspondence, these proceedings were then issued on 3 November 2021. It was in the Summary Grounds of Defence that the Defendant revealed that the Policy had been changed "from c. February 2019 onwards".

111. In March 2022, the policies agreed in March 2021 were formally approved by Ministers and communication of the new policy was agreed across relevant government departments.

112. On 22 July 2022, Mr Reynolds wrote to all Establishment Licence Holders enclosing two policy documents in relation to animal testing, one general and one applicable

specifically to cosmetics and ingredients which may be used in cosmetics. The latter set out the position as follows:

> "The Animals in Science Regulation Unit (ASRU) will not authorise the testing on animals of cosmetic ingredients or finished cosmetic products for meeting the requirements of the Cosmetics Regulations themselves, but will allow the testing of cosmetic ingredients and products to meet the requirements of other UK Regulations for example UK REACH provided all other requirements under ASPA are met."

113. Mr Reynolds' covering letter explained:

> "The 'testing' and 'manufacturing' bans under the Cosmetics Regulations remain. This means that no testing in the UK of cosmetic products or ingredients in order to meet the terms of the Cosmetics Regulations is permitted and no cosmetics may be marketed in the UK which have undergone animal testing after the ban came into force in 1998 for the purpose of meeting the Cosmetics Regulations.
>
> However, where a chemical that has multiple uses, including use in cosmetics manufacture, or where a chemical is only used in cosmetics manufacture, it may require animal testing under other legislation including REACH. This is usually to ensure a high level of protection of workers at manufacturing plants, animal or human health or the environment. Such testing will only be permitted where there are no other alternative ways to meet requirements of REACH. In these limited circumstances only will animal testing be deemed as lawful in the UK and not in conflict with the bans under the Cosmetics regulations."

114. On 13 September 2022, the Policy Unit also emailed the 22 July 2022 letter to the members of its Protection and Welfare and its Regulated Sector Stakeholder Groups including the Claimant.

GROUND 4: "The Defendant's position that she will interpret and apply the Cosmetic Regulation.. and ….REACH in accordance with the legal view reached by the EChA Board of Appeal in its Symrise decisions constitutes the adoption of a legally erroneous approach"

Preliminary observation

115. Mr Bates' argument was that *Symrise* was wrongly decided and that a licensing policy which adopts the approach taken by the Board of Appeal is therefore based on a misunderstanding of the law and, indeed, would lead to the licensing of animal experimentation which was prohibited by the Cosmetics Regulation.

116. I had misgivings about whether I should enter into the debate between the parties about the correctness of *Symrise*. Quite apart from the fact that the *Symrise* cases are subject to actions for annulment, as I have noted, the policy position of the Defendant stated in her letter of 3 August 2021 and the communications of 22 July 2022 was and is merely that the ASRU may now grant licences for animal testing which is required by legislation other than the Cosmetics Regulation, such as REACH. On one view, such a policy can hardly be regarded as legally erroneous in itself: it would merely require that the ASRU decided, in the case of each application for a licence, whether it was required

by law. Rather than in the abstract, arguably the appropriate context in which to consider the correctness or otherwise of *Symrise* would be where a licence had been granted and it was contended that this was not required by REACH and/or was prohibited by the Cosmetics Regulation.

117. Conversely, I did not accept Ms Leventhal's submission that, in effect, the Policy was contrary to REACH and that, in the light of *Symrise*, the Defendant could only take the approach which she has now taken. This was part of her answer to Grounds 2 and 3 in that she submitted that the Claimant could not have a legitimate expectation that the Defendant would maintain a policy which was contrary to REACH and the court should not grant relief which would require her to do so. I accept Mr Bates' submission that it would in principle be open to the Defendant to adopt a policy that, whether or not animal testing of ingredients for use in cosmetics is required if they are to be placed on the market and/or is permissible in law, applications for licences to test them on animals will generally not be granted under the ASPA. The consequence would be that where, for example, REACH required animal testing of such ingredients they could not be registered and placed on the market here, but it would be open to the Defendant to take this position as a matter of policy, for example in relation to the question whether, under section 5B(2)(b) *"the purposes of the programme of work justify the use of protected animals"*. The reality is that the Defendant has modified her policy position for pragmatic reasons rather than being driven to do so by *Symrise* or any legal requirement.

118. However, ultimately both parties urged me to determine the correctness of *Symrise* on the basis that the practical effect of the Defendant's revised policy is that the ASRU will take the view that the granting of a licence to carry out testing required by REACH is not contrary to the Cosmetics Regulation. Ms Leventhal also accepted that, in effect, Mr Bates' argument is that the Defendant's policy will therefore "permit or encourage" (*R (A) v Secretary of State for the Home Department* [2021] UKSC 37, [2021] 1 WLR 3931) unlawful decision making i.e. the granting of licences to carry out testing which is contrary to the Cosmetics Regulation.

Summary of the *Symrise* decisions

119. Taking decision A-009-2018 for the purposes of this summary, in November 2016 the EChA initiated a compliance check of the technical dossier submitted by Symrise AG for the purposes of REACH in relation to a product called homosalate, which is an ultraviolet radiation filter used exclusively in cosmetics. The case was therefore concerned with the basic or standard information about a substance required by Article 10(a) on registration, rather than the contents of the Article 14 safety report required by Article 10(b) in cases involving the importation of more than 10 tonnes of the substance. The EChA found that Symrise had not submitted data resulting from tests required by sections 8.6.2, 8.7.2 and 8.7.3 of Annex IX to REACH and had, instead, incorrectly submitted adaptations. It therefore required Symrise to submit information on sub-chronic toxicity, pre-natal developmental toxicity and extended one-generation reproductive toxicity for human beings based on tests carried out on animals, as specified by the relevant sections of Annex IX.

120. The view of the EChA was that this decision was required by REACH and that the tests were not prohibited by the Cosmetics Regulation notwithstanding that homosalate was exclusively for use in cosmetics. Such testing was not *"in order to meet the requirements of"* the Cosmetics Regulation; it was in order to meet the requirements of

REACH to assess the risks to workers from exposure. The tests therefore would not trigger the marketing ban, nor the testing ban, under Article 18 of the Cosmetics Regulation. Reliance was placed on the 2014 Joint Statement and COM (2013) 135.

121. Symrise appealed this decision on grounds which included an argument that the EChA had erred in requiring tests which would be contrary to the testing ban and would trigger the marketing ban under the Cosmetics Regulation. It was also argued that there was an error of assessment in stating that the tests were justified by the fact that workers may be exposed to the substance.

122. At [55]-[56] the Board of Appeal said this:

> "55. Both regulations can apply – as is the case for homosalate – to the same substance. Neither regulation contains a provision expressly giving it primacy over the other.
>
> 56. The REACH Regulation and the Cosmetics Regulation must therefore be interpreted and applied so that each is compatible and coherent with the other (see, by analogy, judgment of 28 June 2012, *Commission v Éditions Odile Jacob*, C-404/10 P, EU:C:2012:393, paragraph 110; see also Case A-013-2016, *BASF Personal Care and Nutrition*, Decision of the Board of Appeal of 12 December 2017, paragraphs 47 to 54)." (emphasis added)

123. The Board first examined the relevant provisions of REACH with a view to deciding whether there was any exemption from the requirements of Annexes VII-X and XI in respect of ingredients for use in cosmetic products. These requirements included the provision of "information on the intrinsic properties" of the substance.

124. The Board noted Article 2(4)(b) of REACH and said:

> "65. In interpreting a provision of European Union law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (judgment of 19 September 2019, *Gesamtverband Autoteile-Handel,* C-527/18, EU:C:2019:762, paragraph 30).
>
> 66. First, as regards the wording, the words '*without prejudice'* (in other language versions of the REACH Regulation: '*unbeschadet', 'sans préjudice', 'fatte salve'*) are not indicative of an exemption. They indicate that the REACH Regulation and the Cosmetics Regulation should be interpreted and applied so that they are compatible with each other.
>
> 67. Second, as regards the context, the registrants of a substance are required in principle to provide information on the intrinsic properties of a substance independently from the uses of that substance." (emphasis added)

125. The Board went on to note that there are exemptions, under Article 2, from certain requirements of REACH depending on the uses to which the substance is put:

> "69. Those exemptions, however, have all been made explicit by the legislature. There is no provision in the REACH Regulation stating that there is a general exemption for registrants of a substance used as an ingredient in cosmetic products

> from providing information on the intrinsic properties of a substance in accordance with Annexes VII to X.
>
> 70. Interpreting Article 2(4)(b) as exempting registrants of substances used as ingredients in cosmetic products from the information requirements set out in Annexes VII to X would, therefore, be inconsistent with the context of that provision."

126. The Board of Appeal then noted the human health objectives of REACH and held that:

> "74. Interpreting Article 2(4)(b) as exempting registrants of substances used as ingredients in cosmetic products from the information requirements set out in Annexes VII to X would, therefore, mean that risks due to exposure arising – for example – from the manufacture of that substance or the formulation of cosmetic products containing that substance as an ingredient would not be addressed." (emphasis added)

127. The Board's conclusion in relation to Article 2(4)(b) was that:

> "76. Consequently, in light of its wording, context and objectives, Article 2(4)(b) cannot be interpreted as exempting registrants of substances used as ingredients in cosmetic products from the requirement to provide information on the intrinsic properties of their substances in accordance with Annexes VII to X." (emphasis added)

128. The Board then examined Article 14(5)(b) of REACH and held that:

> "79. Article 14(5)(b) therefore exempts registrants and downstream users from carrying out an exposure assessment and risk characterisation for their substance with regard to risks to human health posed by exposure arising from end uses of a substance as an ingredient in cosmetic products. This provision does not exempt registrants of a substance from the obligation to assess the intrinsic properties of their substance in accordance with Annexes VII to X." (emphasis added)

129. The Board then examined Section 3 of Annex XI which allows registrants to submit a general adaptation instead of data from certain of the tests required by Annex IX and held that:

> "89. Section 3.2.(a) of Annex XI, in conjunction with Article 14(5)(b), must therefore be understood as exempting registrants from carrying out certain studies – including the 90-day subchronic toxicity study, the PDNT study and EOGRTS at issue in this case – on condition that there is no, or no significant, relevant exposure to a substance other than the exposure arising from the use, by the end user, of a cosmetic product containing that substance as an ingredient. The remaining conditions of the relevant provisions must also be fulfilled." (emphasis added)

130. In other words, Article 14(5)(b) could operate in conjunction with Section 3 of Annex XI to exempt the registrant from the requirements to provide the specified data as to the intrinsic properties of the substance if there was no significant exposure other than to end users. Implicitly, in such a case the question of safety would be addressed under the Cosmetics Regulation, which applies to protect end users of the cosmetic product.

Similarly, in cases where more than 10 tonnes of the substance are involved, and a chemical safety report is therefore required under Articles 10(b) and 14, the effect of the exemption under Article 14(5)(b) is that the safety of the end user is addressed under the Cosmetics Regulation rather than REACH. Where, however, there would be significant human exposure in the course of the manufacturing and production process, REACH requires the risks to workers involved in those processes to be assessed and specifies the tests which have to be carried out for this purpose.

131. The interim conclusion of the Board at [93] was as follows:

> "The REACH Regulation contains no provision that exempts registrants from the requirement to carry out studies on vertebrate animals only because the substance is used as an ingredient in cosmetic products. In order to benefit from an exemption, registrants of a substance used as an ingredient in cosmetic products must establish that the conditions for an adaption under Section 3 of Annex XI in conjunction with Article 14(5)(b) are fulfilled."

132. The Board of Appeal then analysed the relevant provisions of the Cosmetics Regulation and considered the testing and the marketing bans with particular reference to ingredients for cosmetic products. As far as the testing ban is concerned, at [102]-[104] it said:

> "102. The words '*in order to meet the requirements of [the Cosmetics Regulation]'* demonstrate that Article 18(1)(d) and (2) of the Cosmetics Regulation does not prohibit the performance of studies on vertebrate animals *per se*.
>
> 103. Furthermore, in the absence of any specific provision, Article 18(1)(d) and (2) of the Cosmetics Regulation cannot be interpreted as prohibiting the performance of tests required by the REACH Regulation. Such an interpretation would not ensure that the two regulations are consistently and coherently interpreted and applied (see paragraph 56 above; see also, on this point, the Opinion of Advocate General Bobek in *European Federation for Cosmetic Ingredients*, C-592/14, EU:C: 2016:179, paragraphs 65 and 66).
>
> 104. Article 18(1)(d) and (2) of the Cosmetics Regulation does not, therefore, prohibit the performance of studies on vertebrate animals carried out pursuant to the information requirements set out in the REACH Regulation."

133. I note that, at [103], the Board drew support for its conclusion from the Opinion of the Advocate General in *ECFI*.

134. In relation to the marketing ban, the Board noted the ruling of the CJEU in *ECFI* and said:

> "107 Therefore, the marketing ban is triggered only if the results of a study on vertebrate animals, required pursuant to the information requirements set out in the REACH Regulation, are relied on in the cosmetic product safety report in order to demonstrate the safety for the end user of products containing the registered substance. (emphasis added)

> 108. The results of a study on vertebrate animals, carried out pursuant to the information requirements set out in the REACH Regulation, might confirm the safety of cosmetic products containing the registered substance, as already demonstrated in the cosmetic product safety report under Article 10 of the Cosmetics Regulation.
>
> 109. In this case, the results of the study will not need to be relied on in order to demonstrate the safety for the end user of products containing that substance and the marketing ban will not be triggered. The relevant study will however be available to the authorities for scrutiny in the cosmetic product information file under Article 11 of the Cosmetics Regulation, and in the registration dossiers under the REACH Regulation for possible other purposes covering the entire life-cycle of the substance.
>
> 110. The results of a study on vertebrate animals carried out pursuant to the information requirements set out in the REACH Regulation might however call into question the safety of cosmetic products containing a registered substance, contradicting the cosmetic product safety report under Article 10 of the Cosmetics Regulation.
>
> 111. In this case, if the safety of cosmetics products containing the substance can no longer be established, then it is possible that cosmetic products containing the substance in question as an ingredient can no longer be placed on the market. This is not, however, an automatic consequence of carrying out a study on vertebrate animals pursuant to the information requirements set out in the REACH Regulation. It is a consequence of the results of that study, in conjunction with the legislature's choice – set out in Articles 3 and 18 of the Cosmetics Regulation – that cosmetic products must be safe for the end user whilst no vertebrate animals should be sacrificed for the purpose of establishing their safety."

135. In other words, applying the approach in *ECFI*, the data generated by animal testing required by REACH to assess the safety for workers of exposure to the substance could not be relied on to prove the safety of the cosmetic product for the end user for the purposes of the Cosmetics Regulation. If the REACH tests supported the safety assessment for the purposes of the Cosmetics Regulation, they were not required to be included in the product safety report. They would be included in the product information file. If, on the other hand, they called the safety of the product into question, the product may have to be withdrawn.

136. The arguments of Symrise AG were therefore rejected. The essential reasoning of the Board was that the tests to which Symrise objected were required by the terms of REACH. There were no relevant exemptions spelt out in REACH and Article 2(4)(b) could not be interpreted as an exemption. There might have been an adaptation available under Section 3 of Annex XI of REACH had there been no significant exposure to homosalate on the part of workers but, as there was, it was necessary to test the risks to them from such exposure.

The Claimant's argument

137. Mr Bates pointed out, and Ms Leventhal accepted, that decisions of the Board of Appeal are not *"retained case law"* under sections 6(3) and (7) of the 2018 EU Withdrawal

Act. It was also common ground that I could have regard to decisions of EU entities such as the Board, albeit the parties reached that position by different routes, but that it was for me to decide the correct interpretation of the phrase *"in order to meet the requirements of this Regulation"* in Article 18 *"in accordance with …retained case law and…retained principles of EU law"*: section 6(3) of the 2018 Act.

138. Mr Bates relied on the approach of the CJEU in the *ECFI* case insofar as it rejected an ordinary language interpretation of Article 18 and adopted a purposive approach on the basis that the purpose of the Article was to bring about the phasing out of the use of animal testing in the cosmetics sector. His submission was that although *ECFI* was concerned with the marketing ban, rather than the testing ban, the phrase *"in order to meet the requirements of this Regulation"* must have the same meaning wherever it appears in Article 18.

139. Mr Bates therefore argued for an approach in relation to the testing ban which adapted the *ECFI* approach. He acknowledged that, at [37], the CJEU stated that the fact of animal testing for the purpose of third-party regulatory requirements did not trigger the marketing ban. But he argued that this has to be seen in the light of the requirements in Article 10(1) of the Cosmetics Regulation to adopt a weight of evidence approach and to keep the cosmetic product safety report up to date taking account of *"relevant information generated subsequent to placing the product on the market"*. Mr Bates' argument was that in the case of the testing ban, as opposed to the marketing ban, the question whether the testing is banned has to be decided at the point at which it is proposed to be carried out, and therefore prospectively, by asking whether the resulting data would be likely to be included in a cosmetic product safety report given the requirements of Article 10(1). Such an approach would enable businesses to determine whether to carry out the proposed testing and to avoid inadvertently triggering the marketing ban as a result of carrying out tests which they were then obliged to include in the cosmetic product safety report. Moreover, he argued, an animal study for assessing a human toxicity end point of a cosmetic ingredient for the purposes of a United Kingdom or EU regulatory regime is intrinsically liable to constitute a significant part of the evidence base to be considered when assessing the safety of a product in the product safety report, especially where the testing has been required in order to fill in gaps in the information required for REACH purposes. Manufacturers and importers were not permitted to pick and choose, and would therefore be highly likely to be bound to include the resulting data in their report.

140. Mr Bates also relied on the "effet utile" principle. He said that his approach would mean that the testing ban precluded animal testing of ingredients for cosmetics for REACH related purposes and furthered the aim of the Cosmetics Regulation to phase out animal testing in this sector. On the other hand, since all cosmetic ingredients have to be registered under REACH, that purpose would be largely undermined if *Symrise* were right because the animal studies required for generating data required by REACH are essentially the same as the studies which were previously in use for the purposes of generating data for product safety reports under the Cosmetics Regulation. In this connection he relied on *Re Cosmetic Products Directive: France v Parliament* EU: C:2005 [2005] 3 CMLR 6 where the Advocate General said this at [84] of his Opinion:

> "*84. First, 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."*

141. Mr Bates also relied on Article 2(4)(b) of REACH which, as noted above, provides that REACH applies "*without prejudice to…[the Cosmetic Directive] as regards testing involving vertebrate animals within the scope of that Directive".* He argued that this provision effectively gives priority to the bans in the Cosmetics Regulation and would be otiose if those bans were of no application to animal testing for REACH purposes. The bans under the Cosmetics Directive preceded the REACH Regulation and Article 2(4)(b) was therefore inserted to ensure that REACH did not override those bans. He relied on the Manual of Precedents for Acts Established within the Council of the European Union which states that *"'without prejudice to'* means *'without affecting'…'independently of'…'leaving intact'*".

142. Mr Bates added that this approach was consistent with the principle that the provisions of a lex specialis, such as the Cosmetics Regulation, take precedence over a lex generalis such as REACH, and in this connection he relied on [121] of the Opinion of the Advocate General in *ECFI* where he said:

> *"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."*

143. Finally, Mr Bates argued that *Symrise* is inconsistent with the 2014 Joint Statement in that the Joint Statement, at least, stated as a general rule that substances used exclusively in cosmetics could not be tested on animals for REACH purposes, the only exception being where the tests were to generate data relating to the risk to workers i.e. there was a general ban on animal testing of cosmetic products and ingredients to generate human health endpoint data for the purposes of REACH.

144. He submitted that the *Symrise* cases were therefore wrongly decided. Animal testing on cosmetic products and ingredients required by REACH was contrary to Article 18 of the Cosmetics Regulation.

The Defendant's argument

145. Ms Leventhal argued that *Symrise* reflects the consistent position of the EU Commission, the EChA and the EU Ombudsman referred to above and is correctly decided.

146. She submitted that the *France* case does not assist. The Opinion of the Advocate General in that case was not adopted by the Court. The decision also preceded REACH and did not consider the how Article 18 interacted with REACH.

147. She pointed out that *ECFI* was not concerned with testing which was required by another EU Regulation and there was no finding or implication that this would be prohibited. The decision was essentially a pragmatic one which was intended to prevent

the circumvention of Article 18 of the Cosmetics Regulation by the carrying out of animal testing in third countries under more permissive animal testing regimes. No such issue arises in a case where the testing in question is required under EU legislation which includes principles and requirements which minimise the use of animal testing.

148. In relation to Article 2(4)(b) of REACH, Ms Leventhal argued that the Board of Appeal was right to hold that this provision indicated that the two sets of provisions should be interpreted so that they are compatible with each other. The Cosmetics Regulation and REACH have different purposes; the former is concerned with safety for the end user of the cosmetic product, whereas the latter may require animal testing to ensure the safety of workers engaged in the manufacture of the ingredient itself or goods containing the substance. Given the aims of the testing in each case, the testing required is likely to be different since workers are likely to be exposed to the substance in greater quantities and in different circumstances. It is therefore unlikely that the results of animal testing for REACH purposes would find its way into a cosmetic product safety report required by the Cosmetic Regulation. The Board of Appeal was also right to draw attention to Article 14(5)(b) of REACH as indicating the boundary between the two Regulations. and to take the view that there was no conflict between the two Regulations.

149. She argued that the lex specialis arguments "go nowhere". REACH is its own lex specialis and, in any event, the Advocate General went on to reject the Claimant's argument in the *ECFI* case.

Discussion and conclusion on Ground 4

150. I agree with the Board of Appeal in *Symrise* that animal testing which is required by REACH is not carried out in order to meet the requirements of the Cosmetics Regulation. This is so even where the ingredient in question is exclusively for use in cosmetics. And I agree with the reasoning of the Board of Appeal which led it to this conclusion.

151. The aims and requirements of REACH are different to, and broader than, those of the Cosmetics Regulation. The former is concerned with the safety of the substance itself from human and environmental standpoints and it seeks to ensure that all those who come into contact with the substance do so safely. To this end it sets out a detailed and comprehensive testing regime which is required to be complied with if a chemical substance is to be placed on the market, as well as detailed requirements for the documenting of the results. The prescribed testing regime includes specific requirements as to the data which are required to be generated and the tests and methods by which they are to be generated.

152. The Cosmetics Regulation is concerned with the safety of the cosmetic product for the end user. Testing *"in order to meet the requirements of"* that Regulation is testing in order to comply with the requirement under Article 3 that: *"A cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use…"* and as part of the safety assessment required by Article 10 *"In order to demonstrate that a cosmetic product complies with Article 3*". That the focus of the Cosmetics Regulation is on the safety of the end product, rather than on setting out a testing regime for each ingredient included in a given product, is further confirmed by the fact that Article 10 requires a safety

assessment *"on the basis of the relevant information"* but the Regulation it is not prescriptive as to the methods by which the data which inform this assessment are to be generated in the way that REACH is.

153. It is therefore perfectly coherent to take the view that the two legislative regimes can be read compatibly with each other. Testing required by REACH has a different and broader focus, namely the safety of the substance in all of the contexts in which human beings will come into contact with it, whereas the testing referred to in Article 18 of the Cosmetics Regulation is testing with a particular focus on the effect on human beings who use a cosmetic product containing that substance. On the other hand, Mr Bates' analysis creates a degree of incoherence between the two legislative regimes in that it has the consequence that testing on animals of ingredients which are exclusively for use in cosmetics is not permitted even if such testing is considered necessary for human safety, at least in the sense that REACH requires it. As the EU Commission, the EChA and the EU Ombudsman and the Board of Appeal have implicitly pointed out, that would mean that the substance could not be tested for the purposes of assessing the safety of workers who were exposed to it, and therefore could not be placed on the market at all.

154. It is also hard to see a principled reason why, if the Cosmetics Regulation does not prohibit animal testing required by REACH on substances which have mixed uses, including as ingredients for cosmetics, it prohibits animal testing required by REACH on substances which are exclusively for such use. Whilst the distinction is superficially attractive, there is nothing in the words *"to meet the requirements of this Regulation"* which explains why the same tests on the former are *"to meet the requirements of"* REACH whereas they are to meet the requirements of the Cosmetics Regulation in the case of the latter. In both cases they are required by REACH and therefore to meet the requirements of that Regulation.

155. On the other hand, there is a principled basis for the *Symrise* approach, namely that the overriding imperative under both Regulations is human safety, and therefore all substances should be tested to ensure that they are safe for all purposes. This is the point which the Board of Appeal made when it said this at [71] to [73]:

> "71. Third, as regards the objectives, the main objective of the registration provisions in the REACH Regulation is to ensure a high level of protection of human health and the environment (see, to this effect, judgment of 7 July 2009, *S.P.C.M. and Others,* C-558/07, EU:C:2009:430, paragraph 45).
>
> 72. The REACH Regulation pursues that objective by requiring registrants to generate, collect, assess and submit information on the risks posed by substances during their entire life-cycle.
>
> 73. The use of substance as an ingredient in cosmetic products does not constitute the entire life-cycle of that substance. " (emphasis added)

156. As the EU Commission and the EU Ombudsman have also pointed out, that life-cycle includes the manufacture and production of the substance and of the mixtures and goods of which it forms part, in the course of which workers will be exposed to the substance, and exposed in a way which is different to the exposure of the end user of a cosmetic product: see the passages cited at [91] and [97] above.

157. I agree with Ms Leventhal's submission that the *ECFI* case was not specifically concerned with the relationship between the Cosmetics Regulation and the requirements of REACH, and is therefore not directly on point: see, in particular, [21] of the Judgment. But I regard the decisions in *Symrise* as more consistent with the *ECFI* decision than inconsistent with it.

158. The essential approach of the CJEU was to prevent the use of animal testing to prove the safety of a cosmetic product so as to be able to place it on the market. As the EU Commission and the EU Ombudsman say in the passages which I have quoted at [90] and [98] above, this was a pragmatic decision which was considered to be the best way to prevent the circumvention of Article 18 and to fulfil its purposes. The concern was that if a manufacturer or importer could argue that the testing was carried out in a third country or to meet the legal requirements of a third country, and therefore not to meet the requirement of the Cosmetics Regulation, Article 18 could be circumvented easily: see [42] of the judgment in *ECFI* where this point is explicitly made. But as the EU Commission pointed out in its 13 February 2019 letter (see [98] above) that concern does not arise where the testing is required by other EU legislation.

159. Mr Bates rightly points out that the Advocate General and the CJEU rejected a literal and subjective construction of the words *"in order to meet the requirements of this Regulation"*. This was because of the practical difficulties in applying such a test given, for example, the difficulties in proving or disproving the motivation of the person carrying out the testing: see [30]-[31] of the Judgment and [30]-[31] of the Advocate General's Opinion in *ECFI*. But an approach which asks whether the testing is required by other EU legislation is not an inherently subjective approach. It requires an objective determination of whether the particular animal testing is indeed required by that legislation. It is therefore eminently workable given that a person who applies for a licence to carry out such testing will be required to show that this is the case. In the case of a cosmetic product or ingredient, an applicant who was not able to show that this was so would almost inevitably be held to be carrying out the testing for the purposes of the Cosmetic Regulation and the application therefore refused.

160. I note that the CJEU's analysis in *ECFI* did not prevent animal testing or the use of ingredients which have been tested on animals, but it did further the aims of Article 18 by rendering animal testing for the purposes of the Cosmetics Regulation pointless, as the results of such testing could not be used to demonstrate the safety of the end product. The *Symrise* decision does not undermine the *ECFI* approach given that the Board confirmed, at [107] (quoted at [134] above), that reliance on the results of animal testing to demonstrate the safety of a cosmetic product will continue to be prohibited; data produced from animal testing required by REACH will continue to be unusable for Cosmetics Regulation purposes. I appreciate that the Commission said otherwise in COM (2013) 135, but that was before the decision in *ECFI*.

161. As far as Mr Bates' argument that the results of animal testing required by REACH would be highly likely to be included in the product safety report, and therefore to trigger the marketing ban, this is not how I read *ECFI*. The CJEU held that the trigger for the marketing ban was reliance on animal testing to prove the safety of the product. Unless there was an attempt to use the data for this purpose, the problem would not arise, and there would be no requirement to include the data in the product safety report: either the product could be assessed as safe without these data or it could not. I note that this accords with the view of the Advocate General in *ECFI* who drew a distinction

between using animal testing to demonstrate the safety of the cosmetic products pursuant to Article 10 of the Cosmetics Regulation and simply being required, under Article 11(2)(e), to include it in the product information file. This distinction was approved by the CJEU. At [38] the Court said this:

> *"It should also be stated that, as the Advocate General noted in points 94, 95 and 98 of his Opinion, the mere inclusion in the cosmetic product information file of data resulting from animal testing is insufficient to trigger the prohibition laid down in Article 18(1)(b).. In fact, it follows from Article 11 of that regulation that the data on any animal testing performed inter alia by the manufacturer to meet the legislative or regulatory requirements of third countries must be included in that file."*

162. The Advocate General had said this:

> "94. In addition, the wording and structure of the above mentioned 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 [product information file]. (emphasis added)
>
> 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.
>
> 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."

163. The Advocate General concluded at [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." (emphasis added)

164. I note that in *Symrise* the Board of Appeal drew essentially the same distinction at [107]-[111], cited above at [134].

165. In any event, Mr Bates' test based on predicting the outcome of tests which have yet to be carried out and, on this basis, whether the resulting data are likely to be placed in the cosmetic product safety report does not seem to me to be workable. Mr Bates' argument also proves too much: on his approach any human health related data generated by tests required by REACH which was relevant to the Article 10 cosmetic safety assessment

would be likely to have to be included in the product safety report and would trigger the marketing ban. But there is no principled reason why this approach should be confined to data relating to substances which were exclusively for use in cosmetics. Article 18 would therefore have potentially far-reaching effects in relation to testing on mixed use products i.e. potentially significant cross-sectoral effects. I agree with the view of the Board of Appeal that if the data produced by REACH testing confirms a prior assessment that the product is safe it need not be included in the product safety report – they can be included in the product information file. If the animal testing calls the safety of the product into question, it may need to be withdrawn.

166. As for Mr Bates' reliance on Article 2(4)(b) of REACH, in my view the Board of Appeal was right to say that this does not create an exemption for ingredients which are exclusively used in cosmetics which, in effect, is his argument. Where there is an exemption, this is stated in terms in REACH. Nor did Mr Bates take me to, or question the Board's reliance on, the cases to which it referred in holding that it was required to interpret the two Regulations compatibly with each other.

167. This aspect of Mr Bates' argument also assumes what he needs to prove. The *"without prejudice"* provision applies to *"testing involving vertebrate animals within the scope of"* the Cosmetics Regulation. Clearly, the Cosmetics Regulation does not purport to ban all animal testing of cosmetics products or ingredients. The terms of Article 18 limit the ban to testing *"in order to meet the requirements of this Regulation"*. If the testing is not carried out for this purpose it is not *"within the scope of"* the Cosmetics Regulation and the testing does not *"prejudice"* that Regulation. It is therefore necessary to determine the meaning of Article 18 in order to come to a conclusion about whether testing required by other legislation would "prejudice" the Cosmetics Regulation.

168. In relation to the lex specialis/lex generalis argument, it is true that, at [121] and [122] of his Opinion in *ECFI* the Advocate General said:

> "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.
>
> 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….."

169. I agree that one reading of this passage is that REACH defers to the Cosmetics Regulation where the ingredient is exclusively for use in cosmetics. But these passages were part of a general discussion of why, in the view of the Advocate General, the best approach to the marketing ban was to prohibit reliance on the results of animal testing in order to satisfy the Cosmetics Regulation, and the Advocate General was addressing the issue of 'dual use' [119] substances rather than substances used exclusively for use

in cosmetics. Nor was he addressing the point at issue in the present case, and it might be said that REACH defers to the Cosmetics Regulation through Article 14(5)(b) on its own or in conjunction with Section 3 of Appendix XI depending on the quantity of the substance involved. These provisions recognise that, subject to various conditions, there may be an adaptation or an exemption which leaves the question of the safety of ingredients for end users of cosmetics to the Cosmetics Regulation.

170. I also note that, as part of the same discussion, at [129] and [130] the Advocate General considered a possible rule that "substances cannot be animal tested under REACH where they are used exclusively for cosmetics". At [130] he rejected this approach:

> "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."

171. At [132] his conclusion was:

> "Animal testing may be carried out as a last resort under REACH. <u>There is no special rule that applies where a substance happens also to be used in cosmetics</u>. *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. However, they cannot be used to demonstrate the safety of the ingredient." (underlining added)

172. Referring to an argument that any testing on animals to demonstrate safety for human health would trigger the marketing ban, at [65] and [66] the Advocate General had also said, in a passage relied on by Board of Appeal in *Symrise* as I have noted at [133] above*:*

> "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).
>
> 66. This would be the case even if the testing in the EU were being proposed in the context of another (non-cosmetic 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') would be prohibited by the simple fact that the relevant substance is also used in cosmetic products. <u>Nothing suggests that such a broad, cross-sectoral prohibition on animal testing was envisaged in the sector-specific Cosmetics Regulation.</u>" (emphasis added)

173. As for Mr Bates' effet utile argument, I agree with Ms Leventhal that what the Advocate General said in the *France* case is not of particular assistance given that the issues in that case were so far removed from the issues in the present case. Moreover, as the Advocate General said in *ECFI,* one cannot "simply ignore the text and set sail on the foggy sea of effet util" [78]. I accept that data produced by tests required by REACH might well inform the question of the safety of the end product for human use for the purposes of the Cosmetics Regulation. There was a dearth of evidence before me on this point but I note that the EU Commission and the EU Ombudsman have pointed out not only that there is a need to ensure the safety of those who work in the manufacture and production of the substances which are within the scope of REACH, but also that the nature of their exposure to the substance is different to that of the end user of a cosmetic product containing the substances (see [91] and [97] above). This tends to support Ms Leventhal's submission that the tests and data required for REACH purposes will not necessarily be identical to the tests and data which would show that the end-product is safe for Cosmetics Regulation purposes. Indeed, it appears from *Symrise* that cosmetics containing homosalate were already on the market, their safety having been demonstrated without reliance on data generated by animal testing.

174. But even if this is wrong it does not mean that the Cosmetics Regulation, and in particular Article 18, has no practical effect. The fact remains that animal testing for the purposes of proving the safety of a cosmetic product will not serve any useful purpose for those who wish to place that product on the market. They will therefore be obliged to find alternatives, even if they have been required to carry out animal testing under the terms of REACH, or otherwise will be unable to place the product on the market. Moreover, animal testing of ingredients for cosmetics which is not required by REACH or any other regulation will be prohibited by Article 18.

175. For all of these reasons, then, I reject Ground 4.

GROUND 2: breach of legitimate expectation and/or breach of public law fairness by failing to consult prior to abandoning/weakening the Policy

The Claimant's argument

176. Mr Bates submitted that the withdrawal of the Policy was unfair given that:

i) The Policy was announced in response to campaigning and lobbying by the Claimant and it followed close engagement with the Home Office. It represented a significant victory for the Claimant and other organisations campaigning to end animal testing of cosmetic ingredients.

ii) The Policy remained in place and had been repeatedly confirmed and restated by the Home Office, under successive Home Secretaries, over the past 23 years, including directly to the Claimant.

iii) The Defendant relied on the existence of the Policy in response to the 2015 judicial review claim, on which basis the Claimant agreed to withdraw the claim.

iv) The Claimant had given wide publicity to its victory in securing the Policy.

v) The announcement of the Policy, and the subsequent understanding on the parts of the Claimant and the public that it remained in force was, he argued, also politically advantageous to the Home Office given that it enabled Home Office Ministers to avoid public criticism and scrutiny with respect to licensing animal testing of cosmetic ingredients.

vi) The announcement of the Policy, and the subsequent reiterations that it remained in force were, he argued, always intended to provide assurance to the Claimant, and to the public at large, as to the approach that was, and would be, taken for determining applications for project licences. Providing such assurance was part of the Policy's raison d'être.

177. Give these circumstances, Mr Bates argued that the Claimant had a substantive legitimate expectation that the Defendant would decide applications for licences for projects which involved animal testing in accordance with the Policy and in this regard he relied on *R (Davies) v Revenue and Customs Commissioners* [2011] 1 WLR 2625. Whilst he accepted that a substantive legitimate expectation may be terminated by the withdrawal of the representation on which it was based, that expectation may give rise to a procedural legitimate expectation of being consulted about its proposed withdrawal. In this connection he relies on Laws LJ in *R (Bhatt Murphy) v Independent Assessor* [2008] EWCA Civ 755 at [41]-[42].

178. Mr Bates also submitted that it was conspicuously unfair not to consult the Claimant given that the Defendant did consult some stakeholders. In this regard he relies, as a further factor supporting this conclusion, on evidence that there were conversations between the Defendant and certain establishment licence holders but not with the Claimant or other animal protection organisations. These conversations were, he argues, in substance consultations (see *R (FDA, PCSU and Prospect) v Minister for the Cabinet Office* [2018] EWHC 2746 (Admin) at [99]) and it was conspicuously unfair and/or irrational to exclude the Claimant from this process given its close interest and involvement in the policy on animal testing. He cites Pill LJ in *R (Milton Keynes Council) v Secretary of State for Communities and Local Government* [2011] EWCA Civ 1575 at [32]: a decision maker cannot *"routinely pick and choose whom he will consult. A fair consultation requires fairness in deciding whom to consult as well as fairness in deciding the subject matter of the consultation and its timing"*.

179. Mr Bates also raised an unpleaded complaint that the ASC was not consulted pursuant to section 21(3) of the ASPA.

Relevant legal principles

180. As far as the law is concerned, it is uncontroversial that a statement of policy may generate a substantive legitimate expectation as to how a public body will act in exercising a discretionary power. However, that expectation will only last for as long as the policy is operative: see *Davies* at [27]. The question under Ground 2 is whether there was a procedural legitimate expectation that, before withdrawing the Policy, the Defendant would consult, and that the consultation would include the Claimant.

181. In the well known passages from *Bhatt Murphy* relied on by Mr Bates, Laws LJ said:

> *"41….a public authority will not often be held bound…to maintain in being a policy which on reasonable grounds it has chosen to alter or abandon. Nor will the law often require such a body to involve a section of the public in its decision-making process by notice or consultation if there has been no promise or practice to that effect.*
>
> *42 But the court will (subject to the overriding public interest) insist on such a requirement, and enforce such an obligation, where the decision-maker's proposed action would otherwise be so unfair as to amount to an abuse of power, by reason of the way in which it has earlier conducted itself. In the paradigm case of procedural expectations it will generally be unfair and abusive for the decision-maker to break its express promise or established practice of notice or consultation. In such a case the decision-maker's right and duty to formulate and re-formulate policy for itself and by its chosen procedures is not affronted, for it must itself have concluded that that interest is consistent with its proffered promise or practice. In other situations … something no less concrete must be found. The cases demonstrate as much… What is fair or unfair is of course notoriously sensitive to factual nuance…"* (emphasis added)

182. In explaining the sorts of *"other situations"* in which a legitimate expectation might be established, at [49] Laws LJ said:

> *"Accordingly for this secondary case of procedural expectation to run, the impact of the authority's past conduct on potentially affected persons must, again, be pressing and focussed. One would expect at least to find an individual or group who in reason have substantial grounds to expect that the substance of the relevant policy will continue to enure for their particular benefit: not necessarily for ever, but at least for a reasonable period, to provide a cushion against the change. In such a case the change cannot lawfully be made, certainly not made abruptly, unless the authority notify and consult."* (emphasis added)

183. At [58] Laws LJ said:

> *"The secondary class of procedural expectation denotes an exceptional case. It runs, as I have said, where the impact of the authority's past conduct on potentially affected persons is pressing and focussed, and in reason such person or persons have substantial grounds to expect that the substance of the relevant policy will continue to enure for their particular benefit. There is nothing of the kind here."*

184. *Bhatt Murphy* was a case in which the claimant law firms relied on income from preparing and presenting applications under a compensation scheme for miscarriages of justice which was withdrawn without notice or consultation. Yet this was held not to fall within the exceptional category of procedural expectation, and nor was it unfair nor an abuse of power to fail to give them notice of this or to consult them about it. No legitimate expectation of notice or consultation had arisen. At most, there was a factual expectation that the scheme would continue until rational grounds for cessation arose.

185. In *R (Plantagenet Alliance) v Secretary of State for Justice* [2014] EWHC 1662, [2015] 3 All ER 261 Hallett LJ said this at [98(2)]:

> *"There are four main circumstances where a duty to consult may arise. First, where there is a statutory duty to consult. Second, where there has been a promise to consult. Third, where there has been an established practice of consultation. Fourth, where, in exceptional cases, a failure to consult would lead to conspicuous unfairness. Absent these factors, there will be no obligation on a public body to consult…"*

186. In *R (Article 39) v Secretary of State for Education* [2020] EWCA Civ 1577, [2021] PTSR 696 at [31] Baker LJ recognised that the *"paradigm case"* and the *"secondary case"* of procedural expectation described by Laws LJ in *Bhatt Murphy* in effect corresponded to Hallett LJ's third and fourth categories.

187. I agree with the submission of Ms Leventhal that the reference to conspicuous unfairness in the Hallett LJ's fourth category was not intended to create a free standing public law principle. Rather, it was intended to emphasise the extreme nature of the conduct required to amount to a breach of duty i.e. irrationality or breach of a legitimate expectation established in accordance with recognised principles: see *R (Gallagher) v Competition and Markets Authority* [2018] UKSC 25, [2019] AC 96 at [40]-[41].

The application of these principles

188. In the present case Mr Bates does not point to any statutory duty to consult with the Claimant, nor any promise to do so, nor any practice of doing so. He therefore relies on the Laws LJ's residual category of secondary or exceptional case.

189. However, I do not see anything in the evidence, whether "concrete" or otherwise, which gave rise to a legitimate expectation of consultation about any change in the Policy. Whilst the exceptional category is in principle fact sensitive, this is not a case where the Claimant or anyone else "*in reason have substantial grounds to expect that the substance of the relevant policy will continue to enure for their particular benefit"*. It is a case where a policy based on political and ethical considerations, which accorded with the views of the Claimant and others, was in place for a number of years. Like all such policies, there could be no substantial grounds to expect that the Policy would continue, particularly when, from 2015 at the latest, it was considered by the Defendant to go further than the law required. No assurances were given to the Claimant that it would continue for any particular length of time, nor that the Claimant or anyone else would be consulted in respect of any proposed changes.

190. The nature of the Claimant's involvement in this issue over the years has been to campaign for a particular policy position in relation to animal testing, and government policy has reflected or accepted some of its arguments. But that, of itself, did not give rise to an expectation that it would be consulted in advance about any proposed change in the Policy any more than any other member of the public or organisation with an interest in the issue of animal experimentation. Similarly, nor do I accept that the fact that over the years the Claimant has corresponded with the Government and EU institutions about the law, has lobbied and campaigned on this issue, and has been involved in litigation about animal testing means that it would be an abuse of power to fail to consult them about any proposed change. Moreover, the effect of these activities was that the views of the Claimant were well known in any event.

191. Particular emphasis was placed by Mr Bates on the 2015 judicial review, but no representation was made, or indication given, by the ASRU that the Policy would never change or that any proposed changes would be subject to prior consultation. The claim was withdrawn because the pleaded issues did not arise. In his letter of 16 September 2015 stating that the claim would be withdrawn, Mr Thomas rightly observed, in effect, that no commitment was being made by the defendants when he said: "The policy could be changed at any time".

192. As far as the argument based on consultation with others is concerned, it was common ground that the question whether there was such consultation was one of substance rather than form. I accept Ms Leventhal's submission that, for this aspect of Mr Bates' argument to run, there needed to be evidence that the Defendant engaged in a process of seeking views on a proposal to alter the Policy so as to bring it into line with the position of the EU Commission, the EChA and the Board of Appeal in *Symrise* on the relationship between the Cosmetics Regulation and REACH. If she did, then the question would be whether it was fair and/or rational not to involve the Claimant in the consultation.

193. The evidence of Mr Reynolds is that there were two meetings with establishment licence holders, in August 2018 and January 2019, to understand the businesses of these establishments, to update them on proposed ASRU operational procedures and to assist the ASRU in developing policy in areas which may impact on their business. The establishments highlighted problems arising from the fact that animal testing which was required by REACH was nevertheless prohibited, including the effect on the ability to compete with other European contract research organisations. They also asked for clarity on the Policy and how it linked to REACH and the EU approach.

194. I accept Ms Leventhal's submission that this did not amount to more than an "exchange of information on some issues" rather than there being a consultation exercise with two establishments from which others were excluded (compare the approach of Simler J (as she then was) in the *FDA* case at [102]). That being so, I do not consider that these meetings gave rise to a duty to consult more widely or to consult the Claimant in particular.

195. Looking at the matter more broadly, it was neither unfair nor irrational to hold these two meetings without holding similar meetings with the Claimant or consulting with them. The establishment licence holders which met with the ASRU were in a materially different position viz a viz the ASRU to that of the Claimant and the nature of the meetings reflected the fact that they had a direct interest in the Policy which was of a different nature to that of the Claimant.

196. As far as Mr Bates' reliance on section 21(3) of ASPA is concerned, the duty is to consult the ASC before publishing or altering the Operational Guidance published pursuant to section 21(1). At the time of writing there has been no alteration of the Operational Guidance and there has therefore not been any breach of section 21(3).

197. I therefore dismiss Ground 2.

GROUND 3: breach of legitimate expectation and/or breach of public law fairness by failing to inform the Claimant and/or the public generally, that the Home Department would cease applying the Policy

The Claimant's argument

198. Mr Bates submits that in this case there was a duty on the Defendant to inform the Claimant and the public generally of her change of policy. He argues that this duty is a necessary corollary of the duty of a public body to act in accordance with published policy and, in this regard, he places particular reliance on *R (Save Britain's Heritage) v Secretary of State for Communities and Local Government* [2018] EWCA Civ 2137, [2019] 1 WLR 928. He submits that the Claimant and the public had a legitimate expectation that existing policy would be applied until such time as they were told otherwise.

199. Mr Bates also relies on *R (Nadarajah) v Secretary of State for the Home Department* [2003] EWCA Civ 1768; [2004] INLR 139 at [68] to argue that the existence of a duty to inform in this case is consistent with the principle that a public body cannot rely on an unpublished policy to render lawful something which is inconsistent with its published policy. And he submits that his argument is reinforced by the fact that the Defendant is under an obligation, under sections 5B(9) and 21 ASPA, to publish information and guidance relating to the exercise of her licensing function.

200. It was unlawful, Mr Bates submits, for the Defendant to change her policy "secretly", misleading the Claimant and the public as a result. He points out that the December 2017 "Briefing document on animal testing for cosmetics", the May 2018 "Options for cosmetic policy strategy" document and email correspondence in July 2018, referred to by Mr Reynolds, show that the perception of officials in the ASRU was that the public were aware of the testing ban and that watering it down would be unpopular. For example, in the Briefing document it was considered that any "clarification" of the Policy:

> "would be viewed by the public as a reduction in the protection offered to animals and would be publicly and politically highly undesirable. Thus any communications in this area are likely to be highly sensitive"

201. The implication is that officials were aware of the expectations of the public but chose not to publicise the change of policy because the change would be politically unpopular.

202. Mr Bates also points out that, as late as 16 September 2020, the Chair of the ASC, Professor David Main wrote to Mr Reynolds, asking whether the *Symrise* decision was compatible with the Policy. He was therefore apparently unaware that the Policy had changed in February 2019. Notably, the reply did not come until 4 December 2020, when a letter to Professor Main dealt with a different matter which he had raised and told him that his question would be dealt with in a separate letter. No such letter was disclosed in these proceedings.

203. Mr Bates submitted, with some justification, that when the matter was raised by the Claimant in November 2020, in the light of the *Symrise* decisions, the ASRU were less than transparent. They delayed their reply for around 9 months and then failed to disclose that the Policy had been changed in February 2019.

204. Although the circular was issued to stakeholders on 22 July 2022, this was 3.5 years after the change of policy. Even then, submitted Mr Bates, the fact that the original Policy was being withdrawn was not made clear. It was only in September 2022 that

there was wider notification of the policy change but it was still the case that no general public announcement had been made and, astonishingly, the Defendant has not published its revised position pursuant to section 21 of the ASPA.

Discussion and conclusion on Ground 3

205. There is a good deal of force in Mr Bates' criticisms of the way in which the ASRU has gone about changing the Policy and it is plausible that the reasons for this approach included the ones which he suggested. However, the prior question is whether there was a public law duty to notify the Claimant and/or the public, of which the Defendant was therefore in breach. I do not consider that there was and, in any event, the Claimant and the public have been informed, albeit belatedly and in the manner which I have described. The true position is that there was no legitimate expectation on the part of the Claimant or the public to be informed but for as long as the Policy was in place there was an obligation to comply with it absent good reason to do otherwise.

206. *Save Britain's Heritage* concerned section 77 of the Town and Country Planning Act 1990, which empowered the Secretary of State to require applications for planning permission to be referred to him instead of being dealt with by local planning authorities. A written ministerial statement in Parliament in 2001, confirmed in 2012, said that reasons would be given for decisions not to exercise that power in individual cases. In 2014, a decision was taken not to give reasons for such decisions in future, but this was not announced to Parliament or otherwise made public. Save Britain's Heritage brought a claim for judicial review in circumstances where reasons for declining to exercise the section 77 power had not been given. It alleged, amongst other things, that as a result of the ministerial statement there was a legitimate expectation that reasons would be given. The claim was upheld on appeal.

207. Coulson LJ gave the leading judgment. His analysis was that legitimate expectations may be founded on promises or practices. This was a straightforward promise case. At [37] he said that the two principal promise cases were *Attorney General of Hong Kong* [1983] 2 AC 629 and *R (Lumba) v Secretary of State for the Home Department* [2012] 1 AC 245, both of which concerned promises to follow a certain procedure in relation to a particular decision. He cited Lord Fraser of Tullybelton:

> *"The justification for it is primarily that, when a public authority has promised to follow a certain procedure, it is in the interest of good administration that it should act fairly and should implement its promise, so long as implementation does not interfere with its statutory duty. The principle is also justified by the further consideration that, when the promise was made, the authority must have considered that it would be assisted in discharging its duty fairly by any representation from interested parties and as a general rule that is correct."*

208. At [38] Coulson LJ said that in *Lumba "the Supreme Court arrived at the same answer, albeit by a different route"*. He cited Lord Dyson JSC's well known statement of principle that *"a decision-maker must follow his published policy….unless there are good reasons for not doing so"* and he cited [35]-[36] of Lord Dyson's judgment which emphasised that:

> *"The individual has a basic public law right to have his or her case considered under whatever policy the executive sees fit to adopt provided that the adopted*

> *policy is a lawful exercise of the discretion conferred by the statute….There is a correlative right to know what that currently existing policy is, so that the individual can make representations in relation to it."*.

209. At [39] Coulson LJ concluded:

> *"Accordingly, there is the highest possible authority for the proposition that, if a public body indicates a clear and unequivocal policy that will be followed and applied in a particular type of case, then an individual is entitled to expect that policy to be operated, unless and until a reasonable decision is taken that the policy be modified or withdrawn…, or implementation interferes with that body's other statutory duties…*."

210. At [44] he said that it would be

> *"a recipe for administrative chaos if a legitimate expectation can be generated by an unequivocal ministerial promise, only for it then to be lost as a result of an unadvertised change of practice".*

211. And at [48]:

> *"Since a promise had been made to operate a particular procedure then, as a matter of good administration and transparent governance, any change to that policy also had to be announced publicly".*

212. With respect, I do not read *Save Britain's Heritage* as saying anything more than that a policy will remain in effect until it is effectively withdrawn. Having been announced by ministerial statement, the policy in that case had not been effectively withdrawn by an unpublished and unpublicised change of practice, and the Secretary of State was therefore required to apply it at the time of the decision not to exercise his section 77 powers in the particular case under consideration. Save Britain's Heritage did not argue for a separate and free standing duty to notify it or the public of the withdrawal of the policy and no such duty was upheld by the Court of Appeal.

213. Ms Leventhal also referred to the discussion and rejection of a suggested common law duty of transparency in *R (Manchester Airports Holdings Ltd) v Secretary of State for Transport* [2021] EWHC 2031 (Admin), [2021] 1 WLR 6190. At [43] the Divisional Court said this:

> "Neither [paragraph 51] from Law LJ's judgment in *Bhatt Murphy* nor para 68 of his judgment in *Nadarajah* seeks to establish duties of "good administration" or "transparency" as freestanding legal norms. They are concerned with the underlying reasons as to why a public body may be obliged to comply with a clear and unambiguous representation giving rise to a legitimate expectation and the circumstances in which a public authority might resile from such a legitimate expectation."

214. [51] of Laws LJ's judgment in *Bhatt Murphy* had said:

> "I would only draw from *Ex p Nadarajah* the idea that the underlying principle of good administration which requires public bodies to deal straightforwardly and

> consistently with the public, and by that token commends the doctrine of legitimate expectation, should be treated as a legal standard … Any departure from it must therefore be justified by reference among other things to the requirement of proportionality (see *Ex p Nadarajah*, para 68)."

215. Ms Leventhal also pointed out that this is not a case like *Pathan v Secretary of State for the Home Department* [2020] UKSC 41, [2020] 1 WLR 4506 where the duty of fairness required the notification of an individual of the withdrawal of a particular benefit, allowance or licence so as to facilitate an opportunity to mitigate the effects of that withdrawal. When I asked Mr Bates what purpose notification of the Claimant or the public would serve in this case absent a duty to consult, he said that there would have been an opportunity to argue against the decision and to protest. But it seemed to me that this was not analogous and, in any event, that opportunity has been afforded given that the Claimant has been aware of the Government's position on the law since the 2015 judicial review and this was reiterated by DEFRA, for example in November 2020. It has also strongly suspected a change in the ASRU's policy position since then and this was confirmed by the letter of 3 August 2021 which was the subject of these proceedings. The Claimant has therefore been in a position to draw the attention of the public to this matter since then.

216. Obviously, this is not to say that a failure to announce a change in policy is irrelevant as a matter of public law. As I have noted, the public law consequence of this is that the policy remains in effect and decisions have to be taken in accordance with it unless there is good reason to do otherwise. Mr Bates might, therefore, have argued that the Policy had not been effectively withdrawn and sought a declaration to this effect, albeit he would not necessarily have succeeded. One can see, for example, potential issues as to standing given that the Claimant is not a prospective licensee, as to whether the steps taken thus far have been effective and as to relief given that the licensing decisions taken thus far are irreversible and/or the licensees would have an interest in any such argument. What such a claim would have achieved is also unclear.

217. But, in any event, that is not how the case was pleaded. As far as Mr Bates' pleaded case is concerned, he has not established a legitimate expectation that the change of policy would be notified to the Claimant or the public more generally. There is no evidence of a promise to notify the Claimant of any such changes, nor of any practice of doing so. The practice has been for the Claimant to raise questions about law and policy from time to time over the years in the light of developments in the EU and for these questions to be responded to. Indeed, the Claimant's own case is that they have been responded to by the ASRU tardily and in an obfuscatory manner. Nor has Mr Bates established that it was an abuse of power or irrational to fail to notify it earlier, nor that it was a breach of the duty to act fairly to fail to do so.

218. I accept that it is a matter of concern that the Defendant has not amended the Operational Guidance to reflect the ASRU's revised policy position, particularly given the statutory duties under sections 5B(9) and 21 of the ASPA. The effect of this is that the Operational Guidance and other statements of the Defendant, which remain available to the public on the internet, are inaccurate. But the Operational Guidance is principally directed at those who are or may be involved directly or indirectly in animal experimentation, for example establishment licence holders, rather than campaigners or the public more generally: see "Who this Guidance is for" at pages 3 and 4 of the document. The evidence is that interested parties will be well aware of the change of

approach. Moreover, again, although reference was made to section 21 and to the fact that the Operational Guidance had not been revised, it was not a pleaded ground of review that there had been a failure to comply with the duties under this section.

219. As far as the more general complaint that there has been no public announcement of the change of policy is concerned, again, this is regrettable but I am satisfied that all relevant stakeholders were aware of the position as a result of the 22 July and 13 September 2022 communications referred to above. As I have said, the Claimant has also been in a position to raise public awareness for some time and, as Ms Leventhal pointed out, these proceedings have been conducted in public. I would therefore likely have refused relief even if I had concluded that Ground 3 is well founded.

220. Ground 3 is therefore dismissed.

GROUND 1: alleged failure to carry out the harm/benefit balancing exercise and unlawful delegation of ASPA functions to other regulators

221. This Ground ultimately resolved itself into a factual dispute given that there was no difference between the parties as to what the ASPA requires. Mr Bates' case was that the Defendant's approach to applications for a licence to test cosmetics and ingredients for cosmetics on animals was and is to grant such applications automatically where the tests are required by other regulators, such as the HSE for the purposes of UK REACH. Although, in this situation, the requirements of section 5B(2)(a) of the ASPA would be satisfied – the carrying out of the programme of work would be *"required by law"* - the Defendant is still required to assess the other matters specified by the ASPA including by carrying out the harm/benefit assessment under section 5B(2)(d) but this was not being done. In effect, therefore, the Defendant was also wrongly delegating her statutory responsibilities under the ASPA to other regulators such as the HSE.

222. The principal basis for this contention was the following passage from the Defendant's letter of 3 August 2021:

> "Please note that as the regulator for the use of animals in science ASRU does not set the requirements for animal testing by other regulators. If any animal testing is required in law by any United Kingdom (UK) regulator this will be authorised by ASRU in line with the standards and outcomes required by the regulator in question. All UK regulators are legally bound to follow the principles of the 3Rs in setting their requirements for animal testing."

223. Mr Bates also took me to the pro forma used by ASRU to assess applications and to internal ASRU documents evidencing the consideration of licensing applications which, he submitted, showed no sign of the harm/benefit analysis being carried out.

224. However, the Defendant's case is that this Ground is founded on a misunderstanding of the 3 August 2021 letter. Her position in the pre-action correspondence, in her pleaded case and in her evidence is that the passage relied on by the Claimant did not say that the harm/benefit analysis is not carried out. It did not say anything, one way or the other, about this analysis and, in fact, this analysis is carried out in relation to all such applications.

225. Dr Chandler's evidence, at [13]-[17] of her first witness statement, describes the assessments, including the harm/benefit analysis, which she says are carried out in every case. She reiterates this at [7]-[10] of her second witness statement and, again, at [5]-[9] of her third witness statement, responding to Dr Taylor's observations on the internal ASRU documents on which Mr Bates relied. Dr Chandler supports her evidence by referring to Appendix I of the Operational Guidance which explains, in detail, how the harm/benefit analysis is carried out, and she points out that the pro forma to which Dr Taylor refers has a section which specifically directs assessors to conduct a "Harm-benefit analysis".

226. Applying well established principles (e.g. *R (Singh) v Secretary of State for the Home Department* [2018] EWCA Civ 2861 at [16]), there was no basis on which I could or should go behind Dr Chandler's evidence on this issue. Nor do I have reason to doubt it. Moreover, given that the requirements of the ASPA were common ground, there is no relief which I could sensibly grant in relation to Ground 1.

227. Ground 1 is therefore also dismissed.

CONCLUSION

228. For all of these reasons, I dismiss the Claim.