

**DECISION OF THE BOARD OF APPEAL  
OF THE EUROPEAN CHEMICALS AGENCY**

**18 August 2020**

*(Compliance check – Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX – Substance used exclusively as an ingredient in cosmetic products – Relationship between the REACH Regulation and the Cosmetics Regulation – Studies on vertebrate animals – Route of administration for an EOGRTS)*

<b>Case number</b>	A-009-2018
<b>Language of the case</b>	English
<b>Appellant</b>	Symrise AG, Germany
<b>Representatives</b>	Ruxandra Cana, Eléonore Mullier and Hannah Widemann Steptoe & Johnson LLP, Belgium
<b>Intervener</b>	PETA International Science Consortium (PISC) Ltd, United Kingdom
<b>Contested Decision</b>	CCH-D-2114386909-26-01/F of 13 March 2018, adopted by the European Chemicals Agency pursuant to Article 41 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; the 'REACH Regulation')

**THE BOARD OF APPEAL**

composed of Antoine Buchet (Chairman), Andrew Fasey (Technically Qualified Member and Rapporteur) and Sakari Vuorensola (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

## Decision

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### Background to the dispute

1. This appeal concerns the compliance check of a registration dossier for the substance homosalate (EC No 204-260-8, CAS No 118-56-9).
2. Homosalate is included in Annex VI to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (OJ L 342, 22.12.2009, p. 59; the 'Cosmetics Regulation') as an ultraviolet radiation filter allowed for use in cosmetic products with a maximum concentration of 10 %.
3. The Appellant is a registrant of homosalate. The Appellant and/or its downstream users use homosalate exclusively as an ingredient in cosmetic products.
4. On 2 November 2016, the Agency initiated a compliance check of the Appellant's registration dossier in accordance with Articles 41 and 50 of the REACH Regulation (all references to Articles or Annexes hereinafter concern the REACH Regulation unless stated otherwise).
5. On 17 November 2016, the Agency notified a draft decision to the Appellant in accordance with Article 50(1).
6. On 9 January 2017, the Appellant submitted comments on the draft decision.
7. On 7 September 2017, the Agency notified a revised draft decision to the competent authorities of the Member States in accordance with Article 50(1). The competent authority of one Member State proposed amendments to the draft decision in accordance with Article 51(2).
8. On 10 November 2017, the Appellant submitted comments on the proposals for amendment in accordance with Article 51(5).
9. On 13 March 2018, following the unanimous agreement of its Member State Committee, the Agency adopted the Contested Decision in accordance with Article 51(6).

### Contested Decision

10. The Appellant did not submit information on a 90-day subchronic toxicity study under Section 8.6.2. of Annex IX, a pre-natal developmental toxicity ('PNDT') study under Column 1 of Section 8.7.2. of Annex IX, or an extended one-generation reproductive toxicity study ('EOGRTS') under Column 1 of Section 8.7.3. of Annex IX.
11. Instead of information on these studies, the Appellant submitted adaptations under Sections 1.5. and 1.2. of Annex XI.
12. In the Contested Decision, the Agency rejected the Appellant's adaptations. The operative part of the Contested Decision states:  
*'Based on Article 41 of [the REACH Regulation], ECHA requests you to submit information on:*
  1. *Sub-chronic toxicity study (90-day), oral route (Annex IX, Section 8.6.2.; test method: EU B.26./OECD TG 408) in rats with the registered substance [the 'first information requirement'];*
  2. *Pre-natal developmental toxicity study (Annex IX, Section 8.7.2.; test method: EU B.31./OECD TG 414) in a first species (rat or rabbit), oral route with the registered substance [the 'second information requirement'];*

3. *Extended one-generation reproductive toxicity study (Annex IX, Section 8.7.3.; test method: EU B.56./OECD TG 443) in rats, oral route with the registered substance [the 'third information requirement'] specified as follows:*

- *Ten weeks pre-mating exposure duration for the parental (P0) generation;*
- *Dose level setting shall aim to induce some toxicity at the highest dose level;*
- *Cohort 1A (Reproductive toxicity);*
- *Cohort 1B (Reproductive toxicity) without extension to mate the Cohort 1B animals to produce the F2 generation;*
- *Cohorts 2A and 2B (Developmental neurotoxicity); and*
- *Cohort 3 (Developmental immunotoxicity).*

*[...]*

*You may adapt the testing requested above according to the specific rules outlined in Annexes VI to X and/or according to the general rules contained in Annex XI to the REACH Regulation. To ensure compliance with the respective information requirement, any such adaptation will need to have a scientific justification, referring and conforming to the appropriate rules in the respective annex, and adequate and reliable documentation.*

*You are required to submit the requested information in an updated registration dossier by 20 September 2021. You shall also update the chemical safety report, where relevant. The timeline has been set to allow for sequential testing. [...]*

### **Procedure before the Board of Appeal**

13. On 12 June 2018, the Appellant filed this appeal.
14. On 14 August 2018, the Agency submitted its Defence.
15. On 26 November 2018, PETA International Science Consortium Ltd was granted leave to intervene in this case in support of the Appellant.
16. On 30 November 2018, the Appellant submitted observations on the Defence and responded to questions from the Board of Appeal.
17. On 18 February 2019, the Intervener submitted its statement in intervention.
18. On 14 March 2019, the Agency submitted its observations on the Appellant's observations on the Defence and responded to questions from the Board of Appeal.
19. On 8 and 23 April 2019, the Appellant and the Agency submitted their respective observations on the statement in intervention.
20. On 11 December 2019, a hearing was held at the Appellant's request. At the hearing, the Appellant, the Agency and the Intervener made oral submissions and responded to questions from the Board of Appeal.
21. On 15 May 2020, Mr Sakari Vuorensola, alternate member of the Board of Appeal, was designated to replace Ms Sari Haukka in this case, in accordance with the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; the 'Rules of Procedure').

22. On 26 and 27 May 2020 respectively, the Appellant and the Agency agreed, in accordance with the second subparagraph of Article 3(3) of the Rules of Procedure, that the hearing need not be held again. Mr Sakari Vuorensola and the other two members also agreed not to hold the hearing again.

### **Form of order sought**

23. The Appellant, supported by the Intervener, requests the Board of Appeal to:
- annul the Contested Decision as regards the first, second and third information requirements,
  - annul the Contested Decision insofar as it requires compliance by a deadline of 42 months,
  - order the refund of the appeal fee, and
  - take such other or further measures as justice may require.
24. The Agency requests the Board of Appeal to dismiss the appeal.

### **Reasons**

#### **1. Relevant provisions**

##### **1.1. The REACH Regulation**

25. Recital 13 provides:
- 'This Regulation should apply without prejudice to the prohibitions and restrictions laid down in [Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.9.1976, p. 169); the 'Cosmetics Directive'] [...] 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 [the Cosmetics Directive] should take place with regard to the uses of those substances in cosmetics.'*
26. Article 2(4)(b) ('Application') provides that the REACH Regulation *'shall apply without prejudice to: [...] [the Cosmetics Directive] as regards testing involving vertebrate animals within the scope of that Directive'*.
27. Article 3(1) ('Definitions') provides:
- '[S]ubstance: 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'.*
28. Article 6(1) ('General obligation to register substances on their own or in mixtures') provides that, *'[s]ave where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year shall submit a registration to the Agency'*.
29. Article 7 ('Registration and notification of substances in articles') provides that producers or importers of articles must, under certain conditions, register the substances contained in those articles with the Agency, and/or notify those substances to the Agency.

30. Article 10 (*'Information to be submitted for general registration purposes'*) provides:  
*'A registration [...] shall include all the following information:*
- (a) a technical dossier including:*
    - [...]*
    - (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;*
      - [...]*
  - (b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.'*
31. Article 11(1) (*'Joint submission of data by multiple registrants'*) provides:  
*'When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.*
- Subject to paragraph 3, the information specified in [amongst others, Article 10(a)(vi) and (vii)] shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) [...].*
- Each registrant shall subsequently submit separately the information specified in [amongst others, Article 10(a)(iii)].*
- [...].'*
32. Article 14 (*'Chemical safety report and duty to apply and recommend risk reduction measures'*) provides:
- 1. Without prejudice to Article 4 of [Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p. 11)], 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.*
- The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a mixture or in an article or a group of substances.*
- [...]*

3. *A chemical safety assessment of a substance shall include the following steps:*
    - (a) human health hazard assessment;*
    - (b) physicochemical hazard assessment;*
    - (c) environmental hazard assessment;*
    - (d) persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.*
  4. *If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to [Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1)]:*

*[...]*

*or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:*

    - (a) exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;*
    - (b) risk characterisation.*

*The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.*
  5. *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].*

*[...]*
33. Article 41 ('Compliance check of registrations') provides:
1. *The Agency may examine any registration in order to verify any of the following:*
    - (a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;*
    - (b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;*
    - (c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;*

*[...]*

3. *On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.*
4. *The registrant shall submit the information required to the Agency by the deadline set.*  
*[...]*
34. Column 1 of Section 8.6.2. of Annex IX ('Standard information required') provides:  
*'Sub-chronic toxicity study (90-day), one species, rodent, male and female, most appropriate route of administration, having regard to the likely route of human exposure.'*
35. Column 1 of Section 8.7.2. of Annex IX ('Standard information required') provides:  
*'Pre-natal developmental toxicity study, one species, most appropriate route of administration, having regard to the likely route of human exposure (B.31 of [Commission Regulation (EC) No 440/2008 laying down test methods pursuant to the REACH Regulation (OJ L 142, 31.5.2008, p. 1); the 'Test Methods Regulation'] or OECD 414).'*
36. Column 1 of Section 8.7.3. of Annex IX ('Standard information required') provides:  
*'Extended One-Generation Reproductive Toxicity Study (B.56 of the Commission Regulation on test methods as specified in Article 13(3) or OECD 443), basic test design (cohorts 1A and 1B without extension to include a F2 generation), one species, most appropriate route of administration, having regard to the likely route of human exposure, if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity.'*
37. Section 3 of Annex XI ('Substance-tailored exposure-driven testing') provides:
  - 3.1. *Testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.*
  - 3.2. *In all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I and shall meet any one of the following criteria:*
    - (a) *the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:*
      - (i) *the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;*

- (ii) a DNEL [Derived No-Effect Level] or a PNEC [Predicted No-Effect Concentration] can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes [...];
- (iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC;

[...].'

## 1.2. The Cosmetics Regulation

38. Article 1 of the Cosmetics Regulation ('Scope and objective') provides:

*'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.'*

39. Article 2(1) of the Cosmetics Regulation ('Definitions') provides:

*'(a) "cosmetic product" means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours;*

*(b) "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;*

[...]

*(f) "end user" means either a consumer or professional using the cosmetic product;*

[...].'

40. Article 3 of the Cosmetics Regulation ('Safety') provides that *'[a] cosmetic product made available on the market shall be safe for human health when used under normal or reasonably foreseeable conditions of use [...]'.*

41. Article 10(1) of the Cosmetics Regulation ('Safety assessment') provides:

*'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.*

*[...]*

42. Article 11 of the Cosmetics Regulation (*'Product information file'*) provides:

*'1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.*

*2. The product information file shall contain the following information and data which shall be updated as necessary:*

*(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;*

*(b) the cosmetic product safety report referred to in Article 10(1);*

*(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;*

*(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;*

*(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.*

*[...]*

43. Article 18(1) of the Cosmetics Regulation (*'Animal testing'*) provides:

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

*[...]*

*(b) the placing on the market of cosmetic products containing ingredients or combinations of ingredients which, in order to meet the requirements of this Regulation, have been the subject of animal testing using a method other than an alternative method after such alternative method has been validated and adopted at Community level with due regard to the development of validation within the OECD;*

*[...]*

*(d) the performance within the Community of animal testing of ingredients or combinations of ingredients in order to meet the requirements of this Regulation, after the date on which such tests are required to be replaced by one or more validated alternative methods listed in [the Test Methods Regulation] or in Annex VIII to this Regulation.*

*2. The Commission [...] has established timetables for the implementation of the provisions under points (a), (b) and (d) of paragraph 1, including deadlines for the phasing-out of the various tests. The timetables were made available to the public on 1 October 2004 and sent to the European Parliament and the Council. The period for implementation was limited to 11 March 2009 in relation to points (a), (b) and (d) of paragraph 1.*

*In relation to the tests concerning repeated-dose toxicity, reproductive toxicity and toxicokinetics, for which there are no alternatives yet under consideration, the period for implementation of paragraph 1(a) and (b) shall be limited to 11 March 2013.*

*[...]*

*In exceptional circumstances, where serious concerns arise as regards the safety of an existing cosmetic ingredient, a Member State may request the Commission to grant a derogation from paragraph 1. The request shall contain an evaluation of the situation and indicate the measures necessary. On this basis, the Commission may, after consulting the SCCS [Scientific Committee on Consumer Safety] and by means of a reasoned decision, authorise the derogation. That authorisation shall lay down the conditions associated with this derogation in terms of specific objectives, duration and reporting of the results.*

*A derogation shall be granted only where:*

- (a) the ingredient is in wide use and cannot be replaced by another ingredient capable of performing a similar function;*
- (b) the specific human health problem is substantiated and the need to conduct animal tests is justified and is supported by a detailed research protocol proposed as the basis for the evaluation.*

*[...]*

44. Article 38 of the Cosmetics Regulation ('*Repeal*') provides:

*'[The Cosmetics Directive] is repealed with effect from 11 July 2013, with the exception of Article 4b which is repealed with effect from 1 December 2010.*

*References to the repealed [Cosmetics Directive] shall be understood as references to this Regulation.*

*[...]*

## **2. Assessment of the Appellant's pleas**

45. The Appellant raises seven pleas in support of its appeal. The Appellant alleges that the Agency:

- committed an error of assessment by requiring the Appellant to carry out studies on vertebrate animals when this is prohibited, and would lead to a marketing ban, under the Cosmetics Regulation (first plea, concerning the first, second and third information requirements),
- committed an error of assessment by considering that studies on vertebrate animals are justified due to worker exposure (second plea, concerning the first, second and third information requirements),
- failed to take into account that homosalate has been found to be safe under the Cosmetics Regulation (third plea, concerning the first, second and third information requirements),
- breached the principle of legal certainty by requiring the Appellant to carry out studies on vertebrate animals when it is not clear whether this will lead to a marketing ban and/or sanctions under the Cosmetics Regulation (fourth plea, concerning the first, second and third information requirements),

- committed an error of assessment and breached Article 25 by holding that an EOGRTS is a standard information requirement for the registration of homosalate (fifth plea, concerning the third information requirement),
  - committed an error of assessment and breached Section 8.7.3. of Annex IX by requiring the Appellant to conduct an EOGRTS using the oral route of administration (sixth plea, concerning the third information requirement), and
  - committed an error of assessment by setting too short a deadline in the Contested Decision (seventh plea).
46. The Board of Appeal will address the Appellant's pleas in the order in which they were put forward. The first and second pleas will be addressed together.

### **2.1. First and second pleas: Errors of assessment concerning the relationship between the REACH Regulation and the Cosmetics Regulation**

#### **Arguments of the Parties and the Intervener**

47. The first and second pleas are directed against the first, second and third information requirements (information on a 90-day subchronic toxicity study, a PNDD study and an EOGRTS).
48. By the first plea, the Appellant, supported by the Intervener, argues that the Agency misconstrued the consequences of carrying out a 90-day subchronic toxicity study, a PNDD study and an EOGRTS under the Cosmetics Regulation. As homosalate is used exclusively as an ingredient in cosmetic products, carrying out a 90-day subchronic toxicity study, a PNDD study and an EOGRTS study on homosalate would:
- trigger the marketing ban for cosmetic products containing ingredients tested on vertebrate animals under Article 18(1)(b) and (2) of the Cosmetics Regulation, and
  - disregard the prohibition on testing ingredients of cosmetic products on vertebrates under Article 18(1)(d) and (2) of the Cosmetics Regulation.
49. The Intervener further argues that carrying out studies on vertebrate animals on a substance used exclusively as an ingredient in cosmetic products is not necessary. The results of those studies cannot be used under the Cosmetics Regulation in order to demonstrate the safety of cosmetic products containing a substance. According to the Intervener, if it is necessary to carry out a study on a substance used as an ingredient in cosmetic products, that study should be required by the Commission on the request of a Member State, in accordance with the derogation procedure under Article 18(2) of the Cosmetics Regulation.
50. By the second plea, the Appellant, supported by the Intervener, argues that the Agency committed an error of assessment in stating, in the Contested Decision, that carrying out a 90-day subchronic toxicity study, a PNDD study and an EOGRTS on homosalate is justified by the fact that workers may be exposed to that substance.
51. The Agency disputes the Appellant's and the Intervener's arguments.

### **Findings of the Board of Appeal**

52. The Contested Decision states:

*'In your comments to the proposal for amendment for an extended one-generation reproductive toxicity study and as you further clarified at the member state committee you explained for the first time that the substance is used exclusively in cosmetic products but there is formulation taking place in the EU. The registration dossier indeed indicates formulation, and thus worker exposure, with no indication of strictly controlled conditions. ECHA's factsheet on the interface between REACH and Cosmetics Regulations [ECHA-14-FS-04-EN], which was developed jointly with the European Commission [...] provides that 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 in the absence of strictly controlled conditions.*

*The requested human health tests are therefore justified for the purposes of assessing hazards for workers. Such testing would not trigger the testing and marketing bans under the Cosmetics Regulation as the testing is to be performed for the purposes of meeting the requirements of the REACH Regulation; see Commission Communication of 11 March 2013 on the animal testing and marketing ban and on the state of play in relation to alternative methods in the field of cosmetics [COM(2013)135].'*

53. By the first and second pleas, the Appellant, supported by the Intervener, argues in essence that these findings in the Contested Decision, and the documents to which they refer, are incorrect.
54. The REACH Regulation and the Cosmetics Regulation are both regulations of the Parliament and Council adopted on the basis of Article 95 of the Treaty establishing the European Community (now Article 114 of the Treaty on the Functioning of the European Union).
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).
57. In order to decide on the Appellant's arguments, it is consequently necessary to examine (i) the relevant rules in the REACH Regulation, (ii) the relevant rules in the Cosmetics Regulation, and (iii) the relationship between those two regulations.

#### **2.1.1. Relevant rules in the REACH Regulation**

58. The REACH Regulation aims to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for the assessment of the intrinsic properties of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.
59. Articles 6 and 7 provide a general obligation for manufacturers or importers of substances on their own, in mixtures or in articles in quantities above one tonne per year to register their substances with the Agency.

60. To that end, registrants are required to submit to the Agency a registration dossier containing the information referred to in Article 10. Pursuant to Article 10(a), read in conjunction with Annexes VII to X and Annex XI, this includes information on the intrinsic properties of those substances.
61. Registrants may provide this information by submitting summaries of the relevant studies on their substances under Column 1 of Annexes VII to X, specific adaptations under Column 2 of Annexes VII to X, or general adaptations under Annex XI.
62. Some of the studies listed under Column 1 of Annexes VII to X, including the 90-day subchronic toxicity study, the PNDT study and the EOGRTS at issue in this case, are studies on vertebrate animals.
63. The REACH Regulation contains the following provisions relating to substances used as ingredients in cosmetic products.

- *Article 2(4)(b)*

64. Pursuant to Article 2(4)(b), the REACH Regulation applies without prejudice to the Cosmetics Regulation as regards testing involving vertebrate animals within the scope of the latter regulation (see *BASF Personal Care and Nutrition*, cited in paragraph 56 above, paragraph 43).
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.
68. As an exception, there are certain provisions in the REACH Regulation which exclude substances from the scope of application of (parts of) the REACH Regulation, including the information requirements in Annexes VII to X, depending on the uses to which that substance is put. For example, Article 2(5) provides that the registration requirements in the REACH Regulation do not apply to the extent that a substance is used in medicinal products for veterinary use or as food and feed.
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.
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 a substance as an ingredient in cosmetic products does not constitute the entire life-cycle of that substance.
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.
75. 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, not ensure a high level of protection of human health and the environment.
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.

- *Article 2(6)(b)*

77. Article 2(6)(b) exempts cosmetic products intended for the end user from the requirements concerning the communication of information in the supply chain. This provision has no bearing on the requirement to provide information on the intrinsic properties of a substance used as an ingredient in cosmetic products in accordance with Annexes VII to X.

- *Article 14(5)(b)*

78. Article 14(5)(b) provides that '*[t]he chemical safety report [and therefore also the chemical safety assessment which is reflected in that report] need not include consideration of the risks to human health from the following end uses: [...] in cosmetic products within the scope of [the Cosmetics Directive, now the Cosmetics Regulation]*'.
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.
80. Therefore, Article 14(5)(b) does not exempt 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.

- *Articles 56(5)(a) and 67(2)*

81. Articles 56(5)(a) and 67(2) provide for certain exemptions for uses of substances as ingredients in cosmetic products from the authorisation and restriction requirements under the REACH Regulation. These provisions have no bearing on the requirement to provide information on the intrinsic properties of a substance used as an ingredient in cosmetic products in accordance with Annexes VII to X.

- *Section 3 of Annex XI in conjunction with Article 14(5)(b)*

82. Article 10(a), read in conjunction with Column 1 of Annexes VII to X, requires registrants to generate information on the intrinsic properties of their substances by carrying out certain studies, including studies on vertebrate animals.
83. Article 13(1) provides that information on intrinsic properties of substances should whenever possible (for studies on vertebrate animals) or may (for other studies) be generated by means other than tests, provided that the conditions set out in Annex XI are met.
84. Section 3 of Annex XI allows registrants to submit a general adaptation instead of certain studies, including the PNDT study and the EOGRTS required under Column 1 of Sections 8.7.2. and 8.7.3. of Annex IX. This provision states (emphasis added):
- '3.1. Testing in accordance with Sections 8.6 and 8.7 of Annex VIII and in accordance with Annex IX and Annex X may be omitted, based on the exposure scenario(s) developed in the Chemical Safety Report.*
- 3.2. In all cases, adequate justification and documentation shall be provided. The justification shall be based on a thorough and rigorous exposure assessment in accordance with section 5 of Annex I and shall meet any one of the following criteria:*
- (a) the manufacturer or importer demonstrates and documents that all of the following conditions are fulfilled:*
- (i) the results of the exposure assessment covering all relevant exposures throughout the life cycle of the substance demonstrate the absence of or no significant exposure in all scenarios of the manufacture and all identified uses as referred to in Annex VI section 3.5;*
- (ii) a DNEL [Derived No-Effect Level] or a PNEC [Predicted No-Effect Concentration] can be derived from results of available test data for the substance concerned taking full account of the increased uncertainty resulting from the omission of the information requirement, and that DNEL or PNEC is relevant and appropriate both to the information requirement to be omitted and for risk assessment purposes;*
- (iii) the comparison of the derived DNEL or PNEC with the results of the exposure assessment shows that exposures are always well below the derived DNEL or PNEC;*
- [...]'.*
85. In the context of the registration of a substance used in cosmetic products, Section 3 of Annex XI must be read in conjunction with Article 14(5)(b), which sets out a specific rule for the assessment of the risk to human health due to exposure arising from end uses of a substance in cosmetic products.
86. Article 14(5)(b) 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 (see paragraphs 78 and 79 above).

87. Pursuant to Article 14(5)(b), human exposure arising from the use, by the end user, of a cosmetic product containing a substance as an ingredient is therefore not within the scope of the REACH Regulation. Indeed, that exposure is assessed and addressed under the Cosmetics Regulation, whilst other types of exposure – such as worker exposure or environmental exposure – are not.
88. As a consequence, exposure arising from the use, by the end user, of a cosmetic product containing a registered substance as an ingredient does not constitute ‘*relevant exposure*’ within the meaning of Section 3.2.(a)(i) of Annex XI.
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 PNDT 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.
90. Registrants cannot, however, benefit from this exemption automatically, only because their substance is used exclusively as an ingredient in cosmetic products.
91. Section 3 of Annex XI sets out the rules for an adaptation. A registrant who submits an adaptation must set out clearly, in the relevant part of its registration dossier, the provision of Annexes VII to XI on which the adaptation is based, the grounds for the adaptation, and the scientific information which substantiates those grounds. It is not incumbent upon the Agency to develop or improve adaptations on a registrant’s behalf (see Case A-011-2018, *Clariant Plastics & Coatings (Deutschland)*, Decision of the Board of Appeal of 4 May 2020, paragraphs 35 and 37, and the decisions cited).
92. Section 3 of Annex XI therefore exempts registrants of a substance used as an ingredient in cosmetic products from carrying out studies on vertebrate animals only if they establish that all the conditions for such an adaptation are met.

- *Interim conclusion on the relevant rules in the REACH Regulation*

93. 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 adaptation under Section 3 of Annex XI in conjunction with Article 14(5)(b) are fulfilled.

### **2.1.2. Relevant rules in the Cosmetics Regulation**

94. The Cosmetics 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.
95. Article 3 of the Cosmetics Regulation provides that a cosmetic product made available on the market must be safe for human health when used under normal or reasonably foreseeable conditions of use.

96. To that end, pursuant to Articles 10 and 11 of the Cosmetics Regulation, the safety of a cosmetic product must be assessed on the basis of the relevant information, and a safety report must be drafted and included in the cosmetic product information file (see judgment of 12 April 2018, *Fédération des entreprises de la beauté*, C-13/17, EU:C:2018:246, paragraph 24).
97. The Cosmetics Regulation contains the following provisions relating to cosmetic products containing ingredients that are registered under the REACH Regulation.

- *Recital 5 of the Cosmetics Regulation*

98. Recital 5 of the Cosmetics Regulation states that the environmental concerns that substances used in cosmetic products may raise are considered through the application of the REACH Regulation, which enables the assessment of environmental safety in a cross-sectoral manner.
99. Recital 5 of the Cosmetics Regulation therefore clarifies that the Cosmetics Regulation does not address risks to the environment arising from the use of cosmetic products. Indeed, in accordance with Article 67(2) of the REACH Regulation, environmental risks may, for example, lead to restrictions being placed on the use of a substance as an ingredient in cosmetic products.
100. Recital 5 of the Cosmetics Regulation does not however address the relationship between the Cosmetics Regulation and the REACH Regulation as regards testing on vertebrate animals.

- *Article 18(1)(d) and (2) of the Cosmetics Regulation*

101. Article 18(1)(d) and (2) of the Cosmetics Regulation provides for a testing ban. According to this provision, the performance of studies on vertebrate animals on the ingredients of cosmetic products is prohibited, after certain dates, if the studies are conducted *'in order to meet the requirements of [the Cosmetics Regulation]'*.
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.

- *Article 18(1)(b) and (2) of the Cosmetics Regulation*

105. Article 18(1)(b) and (2) of the Cosmetics Regulation provides for a marketing ban. According to this provision, cosmetic products may not be placed on the market if they contain ingredients that were tested on vertebrate animals, after certain dates, *'in order to meet the requirements of [the Cosmetics Regulation]'*.

106. The Court of Justice has held that a study on vertebrate animals is carried out '*in order to meet the requirements of [the Cosmetics Regulation]*' only if the results of that study are relied on in the cosmetic product safety report under Article 10 of the Cosmetics Regulation in order to demonstrate the safety for the end user of products containing the tested substance as an ingredient (see judgment of 21 September 2016, *European Federation for Cosmetic Ingredients*, C-592/14, EU:C:2016:703, paragraph 39).
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.
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 cosmetic 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.
112. It is not, therefore, the act of carrying out studies on vertebrate animals required pursuant to the information requirements set out in the REACH Regulation, but rather the (use of) results of those studies which might lead to a marketing ban under Article 18(1)(b) and (2) of the Cosmetics Regulation.

- *Article 18(1)(a) and (c) of the Cosmetics Regulation*

113. Article 18(1)(a) of the Cosmetics Regulation prohibits the placing on the market of cosmetic products where the final formulation, in order to meet the requirements of the Cosmetics Regulation, has been the subject of animal testing using a method other than an alternative method that has been validated and adopted at European Union level.
114. Article 18(1)(c) of the Cosmetics Regulation prohibits the performance within the European Union of animal testing of finished cosmetic products in order to meet the requirements of the Cosmetics Regulation.

115. The information requirements in the REACH Regulation concern individual substances, not final formulations of ingredients or finished cosmetic products. Therefore, neither of the provisions referred to in paragraphs 113 and 114 above is relevant with regard to studies carried out pursuant to the information requirements in the REACH Regulation.

- *Interim conclusion on the relevant rules in the Cosmetics Regulation*

116. 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.

**2.1.3. Conclusion on the first and second pleas**

117. 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 adaptation under Section 3 of Annex XI in conjunction with Article 14(5)(b) are fulfilled (see Section 2.1.1. above). This conclusion is not called into question by the Cosmetics Regulation (see Section 2.1.2. above).

118. In the present case, the Appellant is therefore required to comply, for the purposes of its registration of homosalate, with the information requirements set out in Annexes VII to IX. Pursuant to Column 1 of Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX, these information requirements include a 90-day subchronic toxicity study, a PNDT study and an EOGRTS.

119. Furthermore, the Appellant has not established that the conditions for an adaptation under Section 3 of Annex XI in conjunction with Article 14(5)(b) are fulfilled, for the following reasons.

120. First, the Appellant has not included an adaptation based on Section 3 of Annex XI in conjunction with Article 14(5)(b) in its registration dossier. As a consequence, the Agency was not required to assess whether the conditions for such an adaptation are fulfilled.

121. Second, it is not contested that cosmetic products containing homosalate as an ingredient are formulated in the European Union. Workers – other than professional users as defined in Article 2(1)(f) of the Cosmetics Regulation – may therefore be exposed to homosalate. At least one of the conditions for an adaptation under Section 3 of Annex XI (absence of, or no significant, relevant exposure) is therefore not fulfilled.

122. It follows that, contrary to the Appellant's and the Intervener's arguments, the Agency committed no errors of assessment in requiring the Appellant to bring its dossier into compliance with Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX by submitting information on a 90-day subchronic toxicity study, a PNDT study and an EOGRTS or – alternatively – acceptable adaptations.

123. The first and second pleas must therefore be rejected.

## **2.2. Third plea: Error of assessment concerning the risk posed by homosalate**

### **Arguments of the Parties and the Intervener**

124. The third plea is directed against the first, second and third information requirements (information on a 90-day subchronic toxicity study, a PNDT study and an EOGRTS).
125. By this plea, the Appellant, supported by the Intervener, argues that the Agency failed to take into account the fact that homosalate has been found to be safe for end users under the Cosmetics Regulation. According to the Appellant, workers are likely to be exposed to lower quantities of homosalate than the end users of cosmetic products containing that substance. As a consequence, the safety assessment carried out for end users under the Cosmetics Regulation already ensures that there is no risk to workers from exposure to homosalate.
126. The Agency disputes the Appellant's arguments.

### **Findings of the Board of Appeal**

127. The REACH Regulation requires registrants to submit information on the intrinsic properties of a substance in accordance with Annexes VII to X even if, based on its current uses, the substance can be shown to pose no risk due to limited or absent exposure (see, to this effect, Case A-006-2016, *Climax Molybdenum*, Decision of the Board of Appeal of 11 December 2018, paragraphs 129 to 136).
128. Therefore, even assuming that the Appellant could establish that homosalate does not at present pose a risk to workers, this would not entitle it to forgo providing information on a 90-day subchronic toxicity study, a PNDT study and an EOGRTS. The Appellant can achieve this result only by submitting acceptable adaptations under Annex XI or Column 2 of Annexes VII to X in its registration dossier.
129. Furthermore, pursuant to its Article 3, the Cosmetics Regulation ensures the safe use of cosmetic products by the end users of those products. Article 2(1)(f) of the Cosmetics Regulation defines 'end user' as '*either a consumer or professional using the cosmetic product*'.
130. Therefore, the risks arising from other sources of exposure than the end use of cosmetic products are not assessed and managed under the Cosmetics Regulation. For example, the Cosmetics Regulation does not address the risks that exposure to a substance might pose to workers during the formulation of cosmetic products containing that substance as an ingredient.
131. The third plea must therefore be rejected.

## **2.3. Fourth plea: Breach of the principle of legal certainty concerning the consequences of the Contested Decision under the Cosmetics Regulation**

### **Arguments of the Parties and the Intervener**

132. The fourth plea is directed against the first, second and third information requirements (information on a 90-day subchronic toxicity study, a PNDT study and an EOGRTS).

133. By this plea, the Appellant, supported by the Intervener, argues that the Agency breached the principle of legal certainty by requiring the Appellant to carry out studies on vertebrate animals when it is not clear what consequences this will have under the Cosmetics Regulation. If Member States or the European Commission disagree with the Agency's interpretation of Article 18(1)(b) and (d) of the Cosmetics Regulation, sanctions might be imposed if the Appellant complies with the Contested Decision.
134. The Agency disputes the Appellant's and the Intervener's arguments.

### **Findings of the Board of Appeal**

135. The principle of legal certainty is a general principle of European Union law. It requires that every act of the administration which produces legal effects should be clear and precise so that the person concerned is able to know without ambiguity what his rights and obligations are and to take steps accordingly (see judgment of 1 October 1998, *Langnese-Iglo v Commission*, C-279/95 P, EU:C:1998:447, paragraph 78).
136. As regards the first, second and third information requirements (information on a 90-day subchronic toxicity study, a PNDT study and an EOGRTS), the Contested Decision is expressly based on Article 41 in conjunction with Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX. This allows the Appellant to ascertain unequivocally the scope and consequences of the Contested Decision. The Appellant must bring its dossier into compliance with Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX by submitting information on a 90-day subchronic toxicity study, a PNDT study and an EOGRTS or – alternatively – acceptable adaptations.
137. Furthermore, the Contested Decision is an act of an agency of the European Union. Member States and their organs cannot adopt measures contrary to such acts unless they are annulled or declared invalid by the European Union courts (see, to that effect, judgment of 6 October 2015, *Schrems*, C-362/14, EU:C:2015:650, paragraph 52 and the case-law cited). Consequently, the Appellant cannot be sanctioned for carrying out a 90-day subchronic toxicity study, a PNDT study and an EOGRTS following the Contested Decision.
138. The Contested Decision consequently complies with the principle of legal certainty.
139. The fourth plea must therefore be rejected.

### **2.4. Fifth plea: Information on an EOGRTS is not standard information for the registration of homosalate**

#### **Arguments of the Parties**

140. The fifth plea is directed against the third information requirement (information on an EOGRTS).
141. By this plea, the Appellant argues that the Agency committed an error of assessment and breached Article 25. According to the Appellant, an existing reproduction/developmental toxicity screening study (the 'OECD TG 422 study') shows some adverse effects. However, these effects do not mean that information on an EOGRTS is standard information for the registration of homosalate for the following reasons.

142. First, the Appellant argues that the OECD TG 422 study does not trigger the requirement to provide information on an EOGRTS under Column 1 of Section 8.7.3. of Annex IX because it is technically flawed. During its conduct, the test animals were subject to continuous exposure to light (24 hours/day), instead of a regular light/dark cycle (12 hours/day), which may have caused adverse reproductive effects.
143. Second, the Appellant argues that the adverse effects identified in the OECD TG 422 study do not in any event mean that information on an EOGRTS is standard information for the registration of homosalate. Some of these effects occurred at high dose-levels (750 mg/kg bw/day) which also induced severe systemic toxicity and some lethality. The results also cannot be extrapolated to humans due to the difference in the regulation of the thyroid pathway between rats and humans, namely the '*rat specific mechanism of thyroid hypertrophy*'.
144. The Agency disputes the Appellant's arguments.

### **Findings of the Board of Appeal**

145. Column 1 of Section 8.7.3. of Annex IX requires registrants to submit information on an EOGRTS '*if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, OECD 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity*'.
146. The Agency found, in the Contested Decision, that information on an EOGRTS is a standard information requirement for the registration of homosalate under Column 1 of Section 8.7.3. of Annex IX because the OECD TG 422 study contained in the Appellant's registration dossier showed adverse effects in relation to reproductive toxicity (increase in post-implantation loss at 300 mg/kg bw/day; changes in sperm morphology and sperm motility correlating with reduced weights of prostate and seminal vesicles at 750 mg/kg bw/day; increased incidence and/or severity of diffuse hypertrophy of the follicular epithelium in thyroid glands in females at 300 mg/kg bw/day and in both sexes at 750 mg/kg bw/day). In addition, according to the Contested Decision, an *in vitro* androgen receptor binding assay showed that homosalate inhibited the binding of the test ligand methyltrienolone to the androgen receptor investigated.
147. By the fifth plea, the Appellant argues that those findings are incorrect.
148. By its first argument, the Appellant argues that the OECD TG 422 study does not trigger the requirement to provide information on an EOGRTS under Column 1 of Section 8.7.3. of Annex IX because it is technically flawed.
149. This argument must be rejected for two reasons.
150. First, during the conduct of the OECD TG 422 study the test animals were subject to continuous exposure to light instead of a regular light/dark cycle. However, there is no reason to believe that this shortcoming wholly invalidates the results of the study. The study has been assessed as being reliable with restrictions (Klimisch score 2) due to the exposure of the animals to continuous light. It was otherwise carried out in accordance with OECD test guideline 422 and the principles of good laboratory practice.
151. Second, in the OECD TG 422 study, all groups of test animals – including the control group – were continuously exposed to light. Adverse effects on reproduction which were not observed in the control group were observed in groups of animals treated with the test substance. The results of the OECD TG 422 study therefore show that the adverse effects observed in the treated animals were not, or at least not only, due to the exposure of the animals to continuous light.

152. By its second argument, the Appellant argues that the adverse effects identified in the OECD TG 422 study do not trigger the requirement to submit information on an EOGRTS pursuant to Column 1 of Section 8.7.3. of Annex IX. According to the Appellant, adverse reproductive effects were observed in the OECD TG 422 study at a dose-level of 750 mg/kg bw/day. As considerable systemic toxicity was observed at the same dose-level, the adverse reproductive effects at that dose-level must be considered secondary.
153. This argument must also be rejected for two reasons.
154. First, according to paragraph 29 of OECD test guideline 422, the highest dose level used in such a study should be selected with the aim of inducing toxic effects but not death or obvious suffering. The highest dose-level used in the OECD TG 422 study (750 mg/kg bw/day) was therefore selected appropriately. The effects observed at that dose-level (changes in sperm morphology and sperm motility correlating with reduced weights of prostate and seminal vesicles), which were considered substance-related and adverse in the study, cannot therefore be ignored.
155. Second, the adverse effects observed in the OECD TG 422 study at 750 mg/kg bw/day are not the only reason why the Agency found, in the Contested Decision, that the Appellant is required to provide information on an EOGRTS. The Contested Decision also refers to other relevant effects, such as effects on fertility and gestation, which were observed at lower dose-levels. Even assuming that the effects observed at 750 mg/kg bw/day should be disregarded because they are secondary to systemic toxicity, the remaining adverse effects identified by the Agency would be sufficient in themselves to trigger the requirement for an EOGRTS under Section 8.7.3. of Annex IX.
156. By its third argument, the Appellant argues that adverse effects observed in the OECD TG 422 study cannot be extrapolated to humans because there are differences in the regulation of the thyroid pathway between rats and humans.
157. This argument must also be rejected for two reasons.
158. First, it is common ground between the Parties that there are species-specific differences between humans and rats in thyroid hormone production, metabolism, binding and elimination. However, different substances can exert their effects through different pathways or mechanisms which may or may not be the same in humans and rats. The Appellant's argument that there are differences in the regulation of the thyroid pathway between humans and rats is generic in nature and is not based on any information or justification specifically concerning homosalate. The Appellant, therefore, has not established that the adverse thyroid effects observed in the OECD TG 422 study (increased incidence and/or severity of diffuse hypertrophy of the follicular epithelium in thyroid glands in females at 300 mg/kg bw/day and in both sexes at 750 mg/kg bw/day) cannot be extrapolated to humans.
159. Second, the adverse thyroid effects observed in the OECD TG 422 study (increased incidence and/or severity of diffuse hypertrophy of the follicular epithelium in thyroid glands in females at 300 mg/kg bw/day and in both sexes at 750 mg/kg bw/day) are not the only reason why the Agency found, in the Contested Decision, that the Appellant is required to provide information on an EOGRTS. The Contested Decision also refers to other adverse effects observed in the OECD TG 422 study (such as increase in post-implantation loss at 300 mg/kg bw/day and changes in sperm morphology and sperm motility correlating with reduced weights of prostate and seminal vesicles at 750 mg/kg bw/day), as well as the results of an *in vitro* androgen receptor binding assay. Even assuming that the adverse thyroid effects observed in the OECD TG 422 study were not relevant to humans due to a mechanism of thyroid hypertrophy specific to the rat, the remaining adverse effects identified by the Agency would be sufficient in themselves to trigger the requirement for an EOGRTS under Section 8.7.3. of Annex IX.

160. It follows that the Appellant has not established that the Agency committed an error of assessment or breached Article 25 by finding that information on an EOGRTS is a standard information requirement for the registration of homosalate under Column 1 of Section 8.7.3. of Annex IX.
161. The fifth plea must consequently be rejected.

**2.5. Sixth plea: The oral route is not the most appropriate route of administration for conducting an EOGRTS on homosalate**

**Arguments of the Parties**

162. The sixth plea is directed against the third information requirement (information on an EOGRTS).
163. By this plea, the Appellant argues that the Agency committed an error of assessment and breached Section 8.7.3. of Annex IX by requiring the Appellant to conduct an EOGRTS using the oral route of administration. In view of its use as an ingredient in cosmetic products for dermal application, humans are most likely to be exposed to homosalate via the dermal route. According to the Appellant, the dermal route is therefore the most appropriate route of administration for conducting an EOGRTS.
164. The Agency disputes the Appellant's arguments.

**Findings of the Board of Appeal**

165. The Contested Decision states:
- 'ECHA considers that the oral route is the most appropriate route of administration for substances except gases to focus on the detection of hazardous properties on reproduction as indicated in ECHA Guidance on information requirements and chemical safety assessment (version 6.0, July 2017) R.7a, chapter R.7.6.2.3.2. Since the substance to be tested is a liquid, ECHA concludes that testing should be performed by the oral route.'*
166. By the sixth plea, the Appellant argues that those findings are incorrect.
167. Column 1 of Section 8.7.3. of Annex IX provides that an EOGRTS, if required, must be conducted using the *'most appropriate route of administration, having regard to the likely route of human exposure'*.
168. Column 1 of Section 8.7.3. of Annex IX refers to test method B.56, as set out in the Annex to the Test Methods Regulation.
169. Test method B.56, which corresponds to OECD test guideline 443, sets out the method for conducting an EOGRTS. Point 18 of test method B.56 provides:
- 'Selection of the route should take into consideration the route(s) most relevant for human exposure. Although the protocol is designed for administration of the test chemical through the diet, it can be modified for administration by other routes (drinking water, gavage, inhalation, dermal), depending on the characteristics of the chemical and the information required.'*
170. It is therefore clear from test method B.56 that the likely route of human exposure cannot be the only element to take into account in deciding on the route of administration for the conduct of an EOGRTS. Other elements – such as the study design and the known properties of a substance – must also be taken into account.

171. The Appellant's arguments must therefore be rejected for two reasons.
172. First, based on its current use as an ingredient in cosmetic products for dermal application, humans are likely to be exposed to homosalate via the dermal route. However, exposure to homosalate may also occur in other ways, for example during the course of the formulation of cosmetic products containing homosalate as an ingredient.
173. Second, the conduct of an EOGRTS requires the foetus to be exposed to the test substance. Uptake through dermal exposure is normally low. Indeed, the Agency submits – without being contradicted on this point by the Appellant – that existing information shows that only 2 to 10 % of homosalate administered via the dermal route would be systemically available in the test animals. Administering homosalate in an EOGRTS using the dermal route would therefore be unlikely to lead to sufficient foetal exposure to give meaningful results. Conducting the EOGRTS by the oral route, by contrast, would maximise the likelihood of obtaining useful results from that study.
174. It follows that the Agency did not commit an error of assessment or breach Section 8.7.3. of Annex IX by requiring the Appellant to use the oral route of administration if it carries out an EOGRTS on homosalate.
175. The sixth plea must therefore be rejected.

## **2.6. Seventh plea: Error of assessment concerning the deadline imposed by the Contested Decision**

### **Arguments of the Parties**

176. The Appellant argues that the Agency should have set the deadline in the Contested Decision in such a way as to allow the Appellant to carry out the PNDT study and the EOGRTS in sequence. This would allow the Appellant to submit an improved adaptation instead of carrying out an EOGRTS, depending on the results of the PNDT study.
177. The Appellant further argues that the Agency failed to take into account the fact that, due to the limited capacity of test houses – especially for EOGRT studies – and the impending registration deadline in 2018, it may be difficult to carry out the studies at issue within the deadline set by the Contested Decision.
178. The Agency disputes the Appellant's arguments.

### **Findings of the Board of Appeal**

179. The Contested Decision set a time-limit of three years, six months and seven days for the submission of the information required.
180. First, the Appellant argues that the time-limit set in the Contested Decision is too short to carry out the studies in sequence and to submit an improved adaptation instead of carrying out an EOGRTS, depending on the results of the PNDT study.
181. However, the Agency has no legal obligation, under Article 41, to wait for a registrant to improve the justification for an adaptation (see Case A-005-2016, *Cheminova*, Decision of the Board of Appeal of 30 January 2018, paragraph 49).
182. Moreover, there is no scientific reason why the studies required following the Contested Decision should be carried out one after the completion of the other.
183. The Appellant's first argument must therefore be rejected.

184. Second, the Appellant argues that the test houses did not have the capacity to carry out the studies at issue at the time of the Contested Decision because of the 2018 registration deadline.
185. However, the present appeal had suspensive effect, and the registration deadline has expired.
186. The Appellant's second argument must therefore also be rejected.
187. The seventh plea must consequently be rejected.
188. As all the Appellant's pleas are rejected, the appeal must be dismissed.

### **Refund of the appeal fee**

189. The appeal fee is not refunded in accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6).

### **Effects of the Contested Decision**

190. The Contested Decision required the Appellant to submit the information at issue by 20 September 2021, which is three years, six months and seven days from the date of its notification.
191. Pursuant to Article 91(2), an appeal has suspensive effect.
192. The Appellant must therefore provide the information required by the Contested Decision within three years, six months and seven days from the notification of this decision of the Board of Appeal, which means by 25 February 2024.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Dismisses the appeal.**
- 2. Decides that the information required by the Contested Decision must be provided by 25 February 2024.**
- 3. Decides that the appeal fee is not refunded.**

Antoine BUCHET  
Chairman of the Board of Appeal

Alen MOČILNIKAR  
Registrar of the Board of Appeal