

Lēmums lietā 1130/2016/JAS par Eiropas Komisijas un Eiropas Ķīmikāliju aģentūras kopīgo paziņojumu par testēšanu ar dzīvniekiem vielām, ko lieto kosmētiskajos līdzekļos

Lēmums

Lietā 1130/2016/JAS - Uzsākta {0} 03/10/2016 - Lēmums par {0} 21/07/2017 - Iesaistītā iestāde Eiropas Komisija (Nav konstatēta kļūda pārvaldībā) |

Lietā attiecās uz Eiropas Komisijas un Eiropas Ķīmikāliju aģentūras (ECHA) kopīgo 2014. gada oktobra paziņojumu, kurā tiek skaidrota viņu izpratne par attiecību starp Kosmētisko līdzekļu regulu, ar kuru aizliegts veikt testus uz dzīvniekiem, un REACH regulu, ar kuru atļauts veikt testus ar dzīvniekiem ķīmiskajām vielām atsevišķos konkrētos gadījumos, lai izvērtētu risku cilvēku veselībai un videi.

Sūdzības iesniedzēja, dzīvnieku tiesību NVO Apvienotajā Karalistē, vēlējās, lai Komisija un ECHA atsauc savu kopīgo paziņojumu. Tā apgalvoja, ka šis kopīgais paziņojums ir pretrunā ar ES tiesību aktiem un it īpaši ar Kosmētisko līdzekļu regulu. Lai atbalstītu savu nostāju, tā atsaucās uz Eiropas Savienības tiesas spriedumu, kas tika pieņemts pēc tam, kad sūdzība tika iesniegta Ombudam, un kurā sniegta interpretācija Kosmētisko līdzekļu regulā minētajam testēšanas aizliegumam ar dzīvniekiem. Sūdzības iesniedzēja apgalvoja, ka Komisija un ECHA nebija pilnvarotas izsniegt kopīgo paziņojumu. Turklāt sūdzības iesniedzēja apgalvoja, ka kopīgā paziņojuma dēļ dažiem kosmētiskajiem līdzekļiem būs kļūdaini pievienots marķējums “netestēts ar dzīvniekiem”. Komisija un ECHA atteicās atsaukt kopīgo paziņojumu un sūdzības iesniedzēja vērsās pie Ombudes.

Ombude veica jautājuma izmeklēšanu. Viņa uzskata, ka viņai nav nepieciešams paust jebkādu viedokli par pareizu Tiesas sprieduma interpretāciju, lai atrisinātu šo lietu. Tas ir tāpēc, ka kopīgais paziņojums attiecas tikai uz to, kā REACH regulu interpretēt un pielieto Kosmētisko līdzekļu regulas kontekstā. Kopīgā paziņojuma mērķis nav saistīts ar Kosmētisko līdzekļu regulas interpretāciju un tās pielietojumu REACH regulas kontekstā. Tādēļ ombude secina, ka kopīgais paziņojums nav pretrunā ar Kosmētisko līdzekļu regulu vai ES tiesību aktiem kopumā.

Attiecībā uz Komisijas un ECHA tiesībām izsniegt kopīgo paziņojumu ombude uzskata, ka šādas tiesības ir gan Komisijai, gan ECHA, jo abām iestādēm ir pienākumi saskaņā ar REACH regulu. Visbeidzot, nekādi skaidrojumi par kopīgo paziņojumu sakarā ar kosmētisko līdzekļu marķēšanu nav vajadzīgi, jo šis jautājums attiecas uz Kosmētisko līdzekļu regulu, nevis REACH regulu.



The background to the complaint

1. The complainant, a UK-based non-governmental organisation active in the area of animal rights, is concerned about a **joint statement and associated guidance** published by the European Commission and the European Chemicals Agency (ECHA) in October 2014. The joint statement is entitled “ *Clarity on interface between REACH and the Cosmetics Regulation* ” [1] .

2. The **Cosmetics Regulation** [2] requires cosmetics makers and importers to ensure that cosmetics made available on the EU market are safe. However, it prohibits the use of animal testing for the purpose of meeting the Cosmetics Regulation’s safety requirements (there is a “testing ban”). If animal testing—either on the final product, or on its ingredients—has been used to prove the safety of a cosmetic, the cosmetic cannot be placed on the EU market (there is a “marketing ban”).

3. The **REACH Regulation** (“Registration, Evaluation, Authorisation and Restriction of Chemicals”) [3] deals with risks posed by chemicals to human health and the environment. The REACH Regulation can, under certain conditions (typically as a last resort), require animal testing to provide information on such risks. As the REACH Regulation does not exempt chemicals used in cosmetics from its safety requirements, both the Cosmetics Regulation and the REACH regulation can be simultaneously applicable to certain cosmetic ingredients. To address this, the Commission and ECHA considered that they needed to clarify the relationship between the two Regulations. They did so by publishing the joint statement complained about.

4. The most relevant parts of the joint statement read:

- *“Registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints, with the exception of tests that are done to assess the risks to workers exposed to the substance. Workers in this context, refers to those involved in the production or handling of chemicals on an industrial site, not professional users using cosmetic products as part of their business (e.g. hairdressers).*
- *Registrants of substances that are used for a number of purposes, and not solely in cosmetics, are permitted to perform animal testing, as a last resort, for all human health endpoints.*
- *Registrants are permitted to perform animal testing, as a last resort, for all environmental endpoints.”*

5. In April 2015, the complainant wrote to the Commission and ECHA, asking them to withdraw the joint statement. Not satisfied with the Commission’s and ECHA’s response to this letter, and another one sent by the complainant in May 2016, the complainant turned to the Ombudsman in July 2016.

The inquiry



6. The Ombudsman opened an inquiry into the complaint and identified the following concerns:

- 1) The Commission and ECHA issued a joint statement that contains guidance which is contrary to the Cosmetics Regulation and to EU law;
- 2) The Commission and ECHA did not have the legal power to issue the joint statement;
- 3) The joint statement will result in certain cosmetics being wrongly labelled as free from animal testing, thereby confusing and misleading consumers.

7. In the course of the inquiry, the Ombudsman received a joint reply from the Commission and ECHA on the complaint and, subsequently, the comments of the complainant in response to that reply. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.

The joint statement allegedly contains guidance contrary to EU law

Arguments presented to the Ombudsman

8. The **complainant** argued that the joint statement contains an erroneous interpretation of the Cosmetics Regulation's provisions on animal testing.

9. In making its complaint, the complainant said that the substantive issues it was raising were not at all affected by the judgment of the European Court of Justice then pending in case **C-592/14 European Federation for Cosmetic Ingredients**. Nevertheless, the complainant referred to an **Opinion** in that case submitted to the Court by **Advocate General Bobek**. That case concerned the interpretation of the Cosmetics Regulation's bans related to animal testing. In his Opinion, the Advocate General concluded that the "*marketing ban must be understood as preventing reliance on the results of animal testing for the purpose of meeting the requirements of the Cosmetics Regulation*" [4]. According to the complainant, the joint statement went against that Opinion.

10. The complainant also argued that the three cases mentioned in the joint statement should not be considered to fall outside the Cosmetics Regulation's bans. In particular, the complainant was of the opinion that the exposure of workers during the production of a cosmetic was inextricably linked to the final cosmetic product. Thus, it argued, animal testing used to evaluate the effects of such exposure should be covered by the Cosmetics Regulation's animal testing ban.

11. In their joint reply to the complaint, the **Commission and ECHA** set out their understanding of the Court's judgment in case **C-592/14** [5] (by the time the Ombudsman asked the



Commission and ECHA for their reply, the Court had given its judgment on the case).

12. According to the reply of the Commission and ECHA, the Court ruled that the Cosmetics Regulation prohibits the placing on the EU market of cosmetic products containing an ingredient that has been tested on animals if the resulting data are used, for the purposes of the Cosmetics Regulation, to prove the safety of those products for the purposes of marketing them in the EU. However, the Commission and ECHA stated that the case before the Court concerned animal testing carried out **outside the EU** to comply with **third country regulations**. They argued that the Court had not examined the relationship between the Cosmetics Regulation's animal testing ban and the REACH Regulation. **It was thus not possible to tell whether the Court would come to a similar conclusion if called upon to interpret the relationship between the Cosmetics Regulation's animal testing ban and the REACH Regulation.**

13. 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). In particular, the Commission and ECHA referred to a March 2013 Communication of the Commission [6], in which it stated: *"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."*

14. The Commission and ECHA explained that while the REACH Regulation does not prohibit animal testing, it requires companies to ensure that animal testing is performed as a last resort only. They stated that ECHA has published extensive guidance to help registrants avoid or reduce animal testing.

15. Furthermore, they stated that, following the Ombudsman's decision in case 1606/2013/AN [7], ECHA is systematically requiring companies proposing animal testing to provide evidence that they have considered alternative methods. This evidence is published, together with information on the testing proposal, on ECHA's website. Failure to include such evidence will result in the rejection of the registration application.

16. Concerning the health and safety of **workers involved in the production of cosmetic products**, the Commission and ECHA stated that this issue is not covered by the Cosmetics Regulation. The REACH Regulation requires registrants to demonstrate adequate protection of the health of workers during the manufacturing of cosmetic products. Animal testing may be required to enable an assessment of the risks presented to workers by exposure to the substance.

17. Concerning **substances that can also be used for purposes other than as an ingredient**



in cosmetics , the Commission and ECHA stated that testing on animals may still be carried out under the REACH Regulation, as a last resort, to assess risks to human health.

18. Furthermore, the scope of the Cosmetics Regulation is limited to rules ensuring a high level of protection of human health. Testing done on animals to assess **environmental risks** is thus outside the scope of the Cosmetics Regulation.

19. The Commission and ECHA thus concluded that the existing text of the joint statement is correct.

20. The **complainant** responded by arguing that, according to the Court, a manufacturer or importer triggers the marketing ban once it *relies on the results of animal tests in the safety assessment of a cosmetic product* . The *location* of those tests, and the original *purpose* of those tests, are irrelevant regarding the triggering of the marketing ban. The joint statement was thus not consistent with the Court's reasoning.

21. The complainant considered that although the Court ruled specifically on the question of animal tests carried out outside the EU, rather than inside the EU, the reasoning of the Court in case C-592/14 provided sufficient clarity to conclude that the joint statement is contrary to EU law and should be withdrawn.

The Ombudsman's assessment

Introduction

22. Animal welfare is a value upheld by the European Union [8] . The Treaty on the Functioning of the European Union explicitly provides that both the EU and its Member States shall “ *pay full regard to the welfare requirements of animals* ” when formulating policies [9] . Concerns for animal welfare have led to limits being imposed on animal testing and efforts are made to identify other methods to replace animal tests [10] . In general, EU rules provide that animal testing should be replaced, reduced or refined [11] . However, the current position of the EU legislature is that “ *the use of live animals continues to be necessary to protect human and animal health and the environment* ” [12] in certain areas, for example for the development of new medicines.

23. Another area in which animal testing is still considered necessary is the risk assessment of chemical substances, governed by the REACH Regulation. If information on the safety of a chemical cannot be provided through the sharing of existing data [13] , or the use of methods and approaches other than animal testing [14] , animal testing may be allowed as a last resort, subject to ECHA's approval [15] .

24. In the area of cosmetics, however, the legislature has taken the position that it “ *will gradually become possible to ensure the safety of ingredients used in cosmetic products by using* ”



non-animal alternative methods” [16] . After a gradual tightening of the animal testing rules over the last two decades, the full testing and marketing bans for cosmetics entered into force in March 2013 [17] .

25. Given that the REACH Regulation (with its broad definition of “substances” [18]) and the Cosmetics Regulation may both apply to certain cosmetic ingredients, there is an understandable need to clarify the relationship between a possible requirement under the REACH Regulation to resort to animal testing in certain limited circumstances, and the animal testing bans in the Cosmetics Regulation. However, such clarifications must of course be in line with the law and the Court’s jurisprudence.

The joint statement and associated guidance

26. The joint statement outlines the Commission’s and ECHA’s understanding of the relationship between the REACH Regulation and the Cosmetics Regulation. It states that companies may be required to resort to animal testing in order to provide information on a substance **under the REACH Regulation** in three types of case . These three types of case are: cases of worker exposure, non-cosmetic uses and environmental risks. The joint statement states (emphasis added):

“ The European Commission, in cooperation with ECHA, has now clarified the relationship between the marketing ban and the REACH information requirements as follows:

- Registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints , with the exception of tests that are done to assess the risks to **workers exposed to the substance** . Workers in this context, refers to those involved in the production or handling of chemicals on an industrial site, not professional users using cosmetic products as part of their business (e.g. hairdressers).*
- Registrants of substances that are **used for a number of purposes** , and not solely in cosmetics, are permitted to perform animal testing, as a last resort, for all human health endpoints.*
- Registrants are permitted to perform animal testing, as a last resort, for all **environmental endpoints** .*

*Therefore, the testing and marketing bans in the Cosmetics Regulation do not apply to **testing required** for environmental endpoints, exposure of workers and non-cosmetic uses of substances under REACH .*

*Registrants of **substances registered exclusively for cosmetic use** will still have to provide the **required information under REACH** wherever possible, by using **alternatives to animal testing** (such as computer modelling, read-across, weight of evidence etc.). ”*

27. The joint statement does **not state** that the animal testing data resulting from tests in one of the three cases mentioned above, **carried out under the REACH Regulation** , can



subsequently be used for the cosmetics safety assessment under the Cosmetics Regulation.

28. A careful reading of the joint statement reveals that it concerns only animal testing data used to fulfil information requirements **under the REACH Regulation** (see the underlined text in the excerpt quoted above). It does not concern animal testing data used to fulfil information requirements **under the Cosmetics Regulation** (the joint statement concerns only how **the REACH Regulation** is interpreted and applied **in light of the Cosmetics Regulation** and does not touch on issues regarding the interpretation and application of the Cosmetics Regulation and its animal testing bans).

29. It is important to be clear that different bodies have primary responsibility for overseeing the implementation of the REACH Regulation and the Cosmetics Regulation. While ECHA and the Commission are responsible for applying the REACH Regulation [19] , ECHA has no role in the implementation of the Cosmetics Regulation. Rather, it is the Member States, with the assistance of the Commission, which are responsible for implementing the Cosmetics Regulation (national authorities are in charge of reviewing the safety assessments and checking cosmetic products already on the market) [20] .

30. Taking into account these different responsibilities, it is understandable that the joint statement, in which ECHA expresses its position together with the Commission and which is published on ECHA's website, **focuses only on the application of the REACH Regulation** , for which ECHA is chiefly responsible. It does not concern how the Cosmetics Regulation should be interpreted and applied, since ECHA has no role in that regard.

31. Since the judgment in case C-592/14 concerns the interpretation of the Cosmetics Regulation's bans on animal testing, which apply to testing *"in order to meet the requirements of this [that is, the Cosmetic s] Regulation "* [21] , and does not concern animal testing for the purposes of complying with the REACH Regulation, the joint statement does not in fact contain any language inconsistent with the complainant's understanding of that judgment.

32. Thus, while the complainant may have concerns about the Commission's and ECHA's interpretation of the judgment in case C-592/14, the Ombudsman considers that it is not necessary for her to take a position on that judgment in order to resolve the present case. The judgment does not deal with the requirements of the REACH Regulation whereas the joint statement is concerned solely with the requirements of the REACH Regulation.

Three specific cases of possible animal testing mentioned in the joint statement

33. The joint statement identifies three types of case in which animal testing might be needed, as a last resort, in order **to comply with the requirements of the REACH Regulation** . The joint statement makes it clear that the provisions of the Cosmetics Regulation do not displace or negative the requirements of the REACH Regulation.



34. The first case 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*” [22] . 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** .

35. In terms of the application of the Cosmetics Regulation, animal testing in the context of “worker exposure” raises an issue about the eventual labelling of a cosmetic. If a cosmetic contains an ingredient that has been tested on animals **under the REACH Regulation** in order to assess the risk to workers, the final cosmetic product **cannot be labelled as being “free from animal testing”** [23] . It may also be the case that a manufacturer or importer might not, depending on one’s interpretation of Case C-592/14, be allowed to include the results of such testing in a **cosmetics safety assessment submitted to a Member State authority under the Cosmetics Regulation** to prove the safety of the cosmetic. However, **the joint statement makes no reference** to the issue of labelling and makes no reference to the use of testing, carried out **under the REACH Regulation**, being relied upon in a **cosmetics safety assessment**.

36. 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.

37. A labelling issue arises under the Cosmetics Regulation where animal testing has been done in the case of “dual-use” chemicals. If a “dual-use” ingredient has been tested on animals **under the REACH Regulation** , the final cosmetic product **cannot be labelled as being “free from animal testing”** . It may also be the case that a manufacturer or importer might not be allowed to include the results of such testing in a **cosmetics safety assessment submitted to a Member State authority under the Cosmetics Regulation** . However, again, the joint statement makes no reference to the issue of labelling and makes no reference to the use of testing carried out under the REACH Regulation being submitted as part of a **cosmetics safety assessment to a Member State authority under the Cosmetics Regulation**.

38. The third case concerns environmental risks. The Commission and ECHA rightly state that the Cosmetics Regulation deals with risks to human health only and does not cover **environmental risks** . The REACH Regulation might require that certain ingredients used in cosmetics undergo an environmental risk assessment, which may include animal testing as a last resort.



39. Again, if such testing on animals has been carried out **under the REACH Regulation**, the final cosmetic product **cannot be labelled as being “free from animal testing”**. It may also be the case that a manufacturer or importer might not be allowed to include the results of such testing in a **cosmetics safety assessment submitted to a Member State authority under the Cosmetics Regulation**. However, again, the joint statement makes no reference to the issue of labelling and makes no reference to the use of testing carried out under the REACH Regulation being submitted as part of a **cosmetics safety assessment submitted to a Member State authority under the Cosmetics Regulation**.

40. **The joint statement does not, therefore, contain guidance contrary to the Cosmetics Regulation or to EU law. The Ombudsman thus concludes that there was no maladministration concerning this aspect of the complaint.**

41. For the sake of completeness, the Ombudsman notes that in their reply to the Ombudsman (but not in the joint statement at issue in this inquiry), the Commission and ECHA expressed a view which is contrary to the interpretation of case C-592/14 put forward by the complainant. In their reply to the Ombudsman in the course of this inquiry, the Commission and ECHA appear to accept that in certain cases a company *may* rely on the results from animal testing for the purposes of a cosmetic safety assessment. However, the present case concerns solely the allegation that the **joint statement** is incorrect. The Ombudsman notes that the **joint statement** of the Commission and ECHA does not in fact contain any view on whether animal testing can ever be acceptable for the purposes of the Cosmetics Regulation.

Legal power to issue the joint statement

Arguments presented to the Ombudsman

42. The complainant argued that the Commission and ECHA do not have the legal power to issue guidance on the relationship between the Cosmetics Regulation and the REACH Regulation.

The Ombudsman's assessment

43. The Ombudsman agrees that ECHA does not have any role or responsibility regarding the application of the Cosmetics Regulation. Accordingly, ECHA should not purport to give guidance on its application. However, the Ombudsman notes that the joint statement provides non-binding guidance for manufacturers or distributors of chemicals which might fall within the scope both of the REACH Regulation and of the Cosmetics Regulation. The joint statement clarifies, in that context, **how the REACH Regulation will apply to those substances**. The application of the **REACH Regulation** clearly does fall within the responsibility of both the Commission and ECHA. Thus, it is entirely appropriate that both the Commission and ECHA would give their views on the matter.



44. The joint statement does not constitute a legally binding interpretation of the rights and duties of manufacturers or distributors. Furthermore, the fact that the Commission and ECHA may issue such guidance does not prejudice the issue of whether their guidance is correct [24] . It is for the Court of Justice to provide a definitive interpretation of EU law.

45. There was thus no maladministration concerning this aspect of the complaint.

The joint statement allegedly leading to incorrect labelling as free from animal testing

Arguments presented to the Ombudsman

46. The complainant argued that the joint statement could lead to certain cosmetics, the ingredients of which were subject to animal testing for one of the three types of case mentioned in the joint statement, being wrongly labelled as “free from animal testing”. This could confuse and mislead consumers.

47. In their replies to the issues raised by the complainant in the course of this inquiry, the Commission and ECHA expressed the view that a product “ *must not be labelled as being ‘free from animal testing’ if it contains a substance which was tested on animals for whatever reason , including one of the three cases mentioned in the Joint Statement ”* .

48. The complainant pointed out that this is not expressly made clear in the joint statement.

The Ombudsman’s assessment

49. The Ombudsman appreciates the clarifications provided by the Commission and ECHA on this issue.

50. As to whether these clarifications need to be included in the joint statement, the Ombudsman notes that as the issue of labelling of a cosmetic falls under the Cosmetic Regulation only, it would not be appropriate for ECHA, which has no role in the application of the Cosmetics Regulation, to give its views publicly on the issue of labelling of a cosmetic. Thus, the Ombudsman does not agree that the joint statement needs to be clarified in this respect.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following conclusion :



There was no maladministration by the European Commission and the European Chemicals Agency.

The complainant, the Commission and ECHA will be informed of this decision.

Emily O'Reilly European Ombudsman

Strasbourg, 21/07/2017

[1] Available at:

https://echa.europa.eu/view-article/-/journal_content/title/clarity-on-interface-between-reach-and-the-cosmetics-regulation
[Saite]

[2] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ 2009 L 342, p. 59.

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ 2006 L 396, p. 1.

[4] Opinion of Advocate General Bobek delivered on 17 March 2016, *European Federation for Cosmetic Ingredients*, C-592/14, ECLI:EU:C:2016:179, paragraph 139.

[5] Judgment of the Court of Justice of 21 September 2016, *European Federation for Cosmetic Ingredients*, C-592/14, ECLI:EU:C:2016:703.

[6] Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52013DC0135>
[Saite]

[7] Decision in case 1606/2013/AN on how the European Chemicals Agency applies rules concerning animal testing, available at:
<https://www.ombudsman.europa.eu/en/cases/decision.faces/en/60909/html.bookmark> [Saite]

[8] Recital 2 of Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes, OJ 2010 L 276, p. 33.

[9] Article 13 of the Treaty on the Functioning of the European Union.



[10] See Decision in case 1609/2016/JAS on the European Commission's response and follow-up to the European Citizens' Initiative "Stop Vivisection", paragraphs 16-17, available at: <https://www.ombudsman.europa.eu/en/cases/decision.faces/en/78182/html.bookmark> [Saite]

[11] http://ec.europa.eu/environment/chemicals/lab_animals/3r/alternative_en.htm [Saite]

[12] Recital 10 of Directive 2010/63/EU.

[13] See Title III of the REACH Regulation.

[14] Article 13 of the REACH Regulation.

[15] Article 40 of the REACH Regulation.

[16] Recital 42 of the Cosmetics Regulation.

[17] More information available at:
https://ec.europa.eu/growth/sectors/cosmetics/animal-testing_en [Saite]

[18] Article 3(1) of the REACH Regulation: *"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"*.

[19] Article 75 of the REACH Regulation.

[20] Article 22 of the Cosmetics Regulation.

[21] Article 18 of the Cosmetics Regulation.

[22] Article 3 of the Cosmetics Regulation.

[23] Article 20(3) of the Cosmetics Regulation.

[24] While it would be reasonable to expect that both ECHA and the Commission will themselves act in a manner consistent with the content of the joint statement, ECHA has no role in relation to the Cosmetics Regulation and the Commission plays just a support role to the authorities of the Member States.