European Ombudsman

Proposal of the European Ombudsman for a friendly solution in the inquiry into complaint 1568/2012/(RT)AN against the European Chemicals Agency (ECHA)

Solution - 19/09/2012
Case 1568/2012/AN - **Opened on** 19/09/2012 - **Decision on** 11/12/2014 - **Institution concerned** European Chemicals Agency (Settled by the institution) |

Made in accordance with Article 3(5) of the Statute of the European Ombudsman [1]
The background to the complaint
1. The complainant, PETA Foundation, is an animal protection charity based in the UK. ECHA is the EU specialised agency in charge of the registration, evaluation, authorisation and restriction of chemicals under Regulation 1907/2006 (REACH) [2] , which aims at ensuring " *a high level of protection of human health and the environment as well as the free movement of substances...* [and] *also* [at] *promot* [ing] *the development of alternative methods for the assessment of hazards of substances* " [3] . Moreover, REACH provides for safeguards intended to minimise new animal testing and to enforce the principle that animal testing should not be performed where it can be avoided (the 'last resort principle').

2. In June 2011, ECHA published its first report concerning animal testing (the 'Article 117 Report')., The complainant identified in ECHA's report a series of animal tests which might not comply with the last resort principle, since other methods potentially capable of replacing animal testing existed. These tests involved about 16,000 animals. The complainant also referred to 107 tests, involving an estimate of 57,000 animals, which applicants had conducted directly, although they should have first submitted test proposals to ECHA.

3. The complainant had an extensive exchange of correspondence with ECHA concerning the 107 tests for which testing proposals were not submitted to the latter. It also met with ECHA's representatives. The complainant's position was that ECHA should ensure follow-up of the relevant cases in order to check compliance with REACH.

4. ECHA took the view that the tests in question were not necessarily performed in violation of REACH requirements, as they could have been conducted for reasons other

than REACH compliance. ECHA explained that it was evaluating a number of those cases and, if it concluded that new tests should not have been performed, it would send a request for clarification to the registrants. ECHA had also completed checks in a number of dossiers which showed that 18 of the 107 cases had been submitted under previous chemical legislation, under which testing proposals were not required.

5. In ECHA's view, the best mechanism to follow-up the remaining cases was compliance checking under Article 41 REACH, where the dossier may be systematically examined. However, ECHA noted that *'it is not possible to know how many of the remaining dossiers ... having new tests instead of new testing proposals will be subject to a compliance test'* . This depended mainly on resources and prioritisation of cases.

6. In subsequent contacts the complainant maintained its view that ECHA should make more efforts to verify whether applicants for registration indeed comply with the last resort principle. ECHA reiterated that it was acting within the limits of its competences and available resources.

7. The complainant turned to the European Ombudsman on 23 July 2012.
The inquiry
8. The Ombudsman opened an inquiry into the complaint and identified the following allegations and claims.

Allegations:

(i) When conducting detailed evaluations of selected dossiers, ECHA fails to evaluate properly whether the " *last resort* " principle has been applied.

(ii) ECHA allows and even rewards the use of illegal animal tests, by accepting data resulting from animal tests which are potentially non-compliant with the REACH Regulation.

(iii) ECHA does not apply correctly the provisions of the REACH Regulation (and potentially Directive 2010/63/EU) concerning animal testing requirements and it thereby fails to fulfil some of its specific responsibilities under EU law.

Claims:

(i) The compliance check should include an evaluation of compliance with the requirements of Articles 13 and 25 and Annexes VI and XI to the REACH Regulation.

(ii) ECHA should reject dossiers containing avoidable animal tests on the ground that they infringe EU law. Effective evaluation would require ECHA to develop clear and regularly updated guidance for registrants and its own staff about what would constitute a breach of the requirements of Articles 13 and 25 for any given information requirement. In the event that any non-compliance is identified, competent Member State enforcement authorities

must be informed.

(iii) Wherever IT tools identify evidence of possible breaches of Articles 13 and 25 of the REACH Regulation (for instance, when the test study dates are subsequent to the validation of alternative methods and when testing is conducted without prior testing proposals where these are required), steps should be taken to investigate the reasons for non-compliance. If evidence of non-compliance is found, competent Member State enforcement authorities must be informed.

9. In the course of the inquiry, the Ombudsman received the opinion of ECHA on the complaint and, subsequently, the complainant's observations in response to the opinion. The Ombudsman's friendly solution proposal takes into account the opinions and arguments put forward by the parties.

Admissibility of the complaint

10. Prior to entering into the assessment of the substantive arguments of the parties, the Ombudsman notes that, in its opinion, ECHA challenged the admissibility of the complaint because, in its view, the complainant's allegations do not refer to instances of maladministration but concern " *abstract legal questions* ". According to ECHA, " *the scope of the European Ombudsman's review appears to be limited to failures in the administrative process or violations of general principles of law.*. ." Therefore, " *only complaints concerning concrete instances of maladministration are admissible to the Ombudsman* ", who investigates " *in retrospect how the EU administration has acted and, where appropriate, expresses recommendations or critical remarks on concrete administrative practices* ." Hence, " *where a complaint does not refer to an instance of maladministration, but to an abstract legal question, such complaint to the European Ombudsman lacks locus standi.* "

11. Based on the definition approved by the European Parliament, maladministration occurs when a public body fails to act in accordance with a rule or principle binding upon it. The present case mainly refers to ECHA's interpretation of its own competences under the REACH Regulation, which is a concrete rule binding upon the Agency. This clearly falls within the concept of maladministration. Moreover, as regards ECHA's argument that the Ombudsman's inquiries need to be retrospective, it should be noted that the events alleged to constitute maladministration have occurred, to the extent that ECHA's interpretation of its mandate and powers under REACH is already influencing the extent of the checks it performs in relation to registration dossiers. In any event, the Ombudsman notes that a basic tenet of good administration requires any institution, including the Ombudsman, to act proactively and to prevent maladministration from occurring in the first place. Thus, ECHA's objections to the complaint's admissibility cannot be upheld **[4]** .

Applicable legal framework

Article 1 *Aim and scope*

" *1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances...* "

Article 5 *No data, no market*

" *substances ... shall not be manufactured in the* [EU] *or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required* ."

Article 6 *General obligation to register substances...*

" *1. Save where this Regulation provides otherwise, any manufacturer or importer of a substance ... in quantities of one tonne or more per year shall submit a registration to the* [ECHA]".

Article 10 *Information to be submitted for general registration purposes*

" *A registration ... shall include all the following information:*

(a) a technical dossier including: (i) the identity of the manufacturer(s) or importer(s) ...; (ii) the identity of the substance ...; (iii) information on the manufacture and use(s) of the substance ...; (iv) the classification and labelling of the substance ... (v) guidance on safe use of the substance ...; (vi) study summaries ...; (vii) robust study summaries ...; (viii) ... (ix) proposals for testing where listed in Annexes IX and X; (x) ... (xi) ...;

(b) a chemical safety report ...".

Article 12 *Information to be submitted depending on tonnage*

" *The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant..* ."

Article 13 *General requirements for generation of information on intrinsic properties of substances*

" *1. Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods...* "

Article 20 *Duties of the Agency*

" *2. The Agency shall undertake a completeness check of each registration in order to ascertain*

that all the elements required under Articles 10 and 12 or under Articles 17 or 18... have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

The Agency shall undertake the completeness check within three weeks of the submission date... If a registration is incomplete, the Agency shall inform the registrant, before expiry of the [above deadline] as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to the Agency within the deadline set... The Agency shall perform a further completeness check, considering the further information submitted.

The Agency shall reject the registration if the registrant fails to complete his registration within the deadline set..."

Article 22 *Further duties of registrants*

"2 . *A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41...*

3. The Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration. "

Article 25 *Objectives and general rules*

" *1. In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort ...*"

Article 41 *Compliance check of registrations*

" *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;...*

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...

4. The registrant shall submit the information required to the Agency by the deadline set.

5. To ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking... "

12. Moreover, the Annexes to which the first claim refers contain detailed rules concerning

the information requirements contained in Articles 10 (Annex VI), standard information requirements for substances depending on the quantities in which they are marketed (Annexes VII to X) and explain on which grounds a registrant may waive the need for a test under Annexes VII to X (Annex XI).

Arguments presented to the Ombudsman

13. The complainant claimed that ECHA failed to investigate all of the 107 tests which had been conducted without test proposals. As a result, ECHA is unable to identify breaches of the REACH Regulation and Directive 2010/63 and cannot inform national competent authorities of breaches. Moreover, during compliance checks, ECHA evaluates only whether measures taken to avoid animal testing are appropriate. However, it does not evaluate whether animal testing is compliant with the requirements of Article 13 of the REACH Regulation, which provides that alternative test methods to animal testing should be used whenever possible.

14. ECHA's compliance check of the registration dossiers under Article 41(1)(a) REACH involves examining registrations and establishing whether the information provided by the registrants is compliant with REACH. ECHA needs to assess compliance of at least 5% of the dossiers received. The content of the registration dossier is defined by Article 10 of the REACH Regulation. Moreover, Annex VI of REACH provides guidance as regards the steps that need to be followed by registrants in order to avoid unnecessary testing before submitting their registrations to ECHA, namely: a) gather all existing information on the substance, b) consider information needs, c) identify information gaps and d) generate new data to fill those gaps. As regards step d), registrants should undertake animal testing as a last resort (Article 25(1) REACH).

15. However, Article 10 of REACH does not require registrants to include justifications in the registration dossier as to why the animal testing already performed was considered necessary. Therefore, a registrant does not have to demonstrate in the registration dossier that where a vertebrate animal test was conducted, it was performed as a last resort, and thus complied with REACH.

16. As regards the **first allegation and claim** , ECHA stated that a compliance check of the dossier under Article 41(1)(a) is limited to the review of the information that is required to be provided in the registration dossier. This limits ECHA's competence in assessing compliance of registrations with Article 13, which requires the information to be generated " *whenever possible by means other than vertebrate animal tests* ". ECHA does not hold the information it would need in order to assess compliance with this provision, since registrants are not obliged to submit such information.

17. Therefore, when carrying out compliance checks under Article 41(1)(a), ECHA cannot assess compliance with the obligation set out in Article 13(1). Neither does the compliance check procedure serve this purpose. Besides, compliance checks cannot serve as a legal

basis for requesting information to clarify compliance with other provisions of REACH such as Article 13(1) or Article 25(1) because the scope of this procedure is limited. If the information generated by a test fulfils the standard information requirement under REACH, ECHA will not have a legal basis for requesting further information. This does not imply, however, that the way in which the information was generated was compliant with other provisions of the REACH Regulation.

18. With reference to the complainant's claim that effective evaluation would require ECHA to develop clear and regularly updated guidance for registrants and its own staff concerning compliance with Articles 13 and 25, ECHA noted that its guidance is addressed to registrants who bear the responsibility of complying with the above obligations. However, ECHA has not developed Guidance material for its own staff to assess non-compliance with Articles 25(1) and 13(1), as it does not have the competence to evaluate such cases of noncompliance.

19. As regards the **second allegation and claim** , ECHA reiterated that the enforcement of Articles 13 and 25 REACH is a competence of the Member States. There is no legal provision on the basis of which ECHA could reject the use of the data resulting from "potentially illegal" tests or sanction non-compliant registrants. Furthermore, if ECHA did not accept data resulting from "potentially illegal" animal tests, this might lead to duplication of animal testing, since if the data is unusable the registrant needs to perform further testing to demonstrate its safety if it wants the substance to be registered.

20. In its observations, the complainant and provided further exchanges of correspondence between itself and ECHA, in which the latter confirmed the views it had already expressed.

21. As regards the **third allegation and claim** , REACH Regulation requires registrants to comply with the last resort principle of Article 25(1) and the related provision of Article 13 (1). The Member States hold the competence for reviewing compliance with these provisions and sanctioning registrants for non-compliance. Member States can require ECHA's cooperation [5] in their investigations on potential cases of non-compliance. In addition, ECHA informs Member States of cases where non-compliance has occurred. ECHA plays only a supporting role in avoiding unnecessary animal testing [6] .

22. As regards the 107 cases of potential non-compliance with the last resort principle identified in ECHA's Article 117 report, ECHA did analyse the matter in more detail, although it was not required to. No actual case of non-compliance has been identified, which led ECHA to consider that there was no need for it to grant further priority to this issue. ECHA rejected the complainant's statement that ECHA should examine all 107 cases. ECHA outlined that it has many regulatory obligations and has to use its resources according to its work programme which is adopted by its Management Board.

23. ECHA also rejected the claim that it should inform Member States of possible violations of the REACH Regulation, and took the view that it should do so when it becomes

aware of facts that demonstrate non-compliance. However, in the present case ECHA did make information stemming from the Article 117 report available to the Member States who are competent to act.

The Ombudsman's preliminary assessment leading to the friendly solution proposal

24. The complainant's allegations and claims concern ECHA's interpretation of the scope of its powers and duties under REACH. In substance, the complainant's first allegation touches upon the scope of ECHA's compliance check under Article 41 REACH, and particularly whether such checks cover the last resort principle. Its second allegation raises the issue of the consequences of a finding of non-compliance with the last resort principle. The third allegation refers to the need for ECHA to investigate all possible violations of REACH that it might come across.

First allegation and claim: Scope of compliance checks

25. Article 41 REACH mandates ECHA to perform compliance checks of registrations. Given the high number of registration requests ECHA receives and the inherent limitation of the resources at ECHA's disposal, the legislator had to strike a balance between, on the one hand, the need to ensure that all registration dossiers are fully compliant with REACH and, on the other hand, the need to avoid paralysing ECHA's activity. The legislator thus explicitly exempted ECHA from reviewing all the registration dossiers received, and set the compliance check minimum at 5% of the dossiers received per each tonnage band.

26. However, this **quantitative limitation** of the number of dossiers was not coupled with a **qualitative limitation** of the scope of the compliance check ECHA is bound to perform. Article 41 REACH clearly states, in paragraph 1, that through compliance checks ECHA should verify that dossiers comply with three specific Articles, namely, 10, 12 and 13. And Article 13 requires in imperative terms that " *for human toxicity, information* shall *be generated whenever possible* by means other than vertebrate animal tests, through the use of alternative methods ." (emphasis added) This is a clear application of the last resort principle otherwise enshrined, in general terms, in Article 25 REACH.

27. Moreover, paragraph 5 of Article 41 adds that compliance checks are meant to ensure that registration dossiers comply " *with* this Regulation " (emphasis added), that is, with all the requirements contained in REACH. For the purposes of the present complaint, the Ombudsman does not consider it necessary to take a stance on whether the above wording necessarily means that ECHA should check compliance with Article 25 REACH. Indeed, the inclusion of Article 13 in the parameters for compliance checks under Article 41(1)(a) shows that **such compliance checks are meant to verify whether the information submitted by registrants was generated in full compliance with the last**

resort principle, as laid down in Article 13 REACH .

28. ECHA's statement that compliance checks do not serve this purpose is thus entirely unwarranted. Accepting this statement would, in fact, amount to suppressing the reference to Article 13 that the legislator consciously chose to include in Article 41. In other words, it would amount to informally amending a piece of EU legislation without any involvement whatsoever of the legislator.

29. The verification mentioned in paragraph 27 above involves a two-step assessment.

30. First, ECHA needs to establish whether the information provided was obtained through animal tests. This is a relatively easy task, inasmuch as Article 10 requires registrants to include in their dossiers study summaries or robust study summaries, that is, more or less detailed summaries of the objectives, methods, results and conclusions of the activity performed to generate the information [7] .

31. Second, ECHA needs to ascertain whether there was another means of obtaining the information generated through animal tests. The Ombudsman agrees with ECHA's position that " *registrations are not required to contain data on the basis of which ECHA could conclude whether the information could have been generated by means other than vertebrate animal tests* ". She also acknowledges ECHA's statement that it does not hold the necessary information to assess such compliance. However, for the following reasons, the Ombudsman does not share ECHA's conclusion that it cannot verify whether the data results from "potentially illegal" tests.

32. Ascertaining whether an alternative method to obtain the relevant information existed is indeed a complex task which requires extensive technical, scientific and even market knowledge. Despite its immense expertise in the chemicals industry, ECHA's specific knowledge of a particular substance, and of the tests that could have been performed in order to prove its safety, is necessarily less than that of the registrant, who has been, or has direct access to the entity having been, involved in its development. In any event, due to its limited resources, ECHA cannot be expected to identify all possible means of testing on behalf of the registrant.

33. The Ombudsman thus considers that it is for the registrants to demonstrate to **ECHA, upon request, that** the data obtained though animal testing could not reasonably have been obtained though alternative methods, and thus that they complied with Article 13.

34. In fact, Article 41(3) specifically allows ECHA to request the registrant subject to compliance check to submit " any information *needed to bring the registration(s) into compliance with the* relevant information requirements " (emphasis added). For the Ombudsman, it is clear from the wording of Article 41 and from the titles of Articles 10, 12 and 13 that " *information requirements* " pursuant to REACH include the requirement that data should not be obtained through animal testing if an alternative method was available.

35. It is true that there is no specific REACH provision requiring registrants to provide this sort of information in their registration dossiers. However, it is just as true that nothing in REACH prevents registrants form doing so. Reasonably, a diligent registrant which has fulfilled its obligations under REACH, including the obligation to perform all the necessary tests in order to prove substance safety while duly respecting the last resort principle, will be able to show why it has conducted an animal test and, where applicable, why it believed that no non-animal method was apt to provide the same information.

36. It follows that **REACH also provides for a clear procedure through which ECHA can require registrants to (a) clarify whether the information they submitted complies with all the necessary requirements** and **(b) if necessary, complete their registrations with compliant data** , that is, data obtained through the non-animal method the existence of which makes animal testing unnecessary [8] . Article 41(4) REACH obliges the registrant to do so within the deadline set by ECHA.

37. In light of the above, the Ombudsman makes the preliminary finding that ECHA's restrictive interpretation of the scope of application of compliance checks is not in line with the spirit and the content of REACH.

Second allegation and claim: Consequences of non-compliance with the last resort principle

38. In spite of the above, in light of the framework of existing EU legislation the Ombudsman agrees with ECHA that, even if it were proved that an animal test was performed in violation of REACH, ECHA would have no legal basis to reject a registration due to the inclusion of such a test.

39. Indeed, while Article 20(2), last subparagraph, of REACH allows ECHA to **"** *reject the* [initial] *registration if the registrant fails to complete his registration within the deadline set* ", Article 22(3) has no such provision in the case of a failure to update a registration following a request under Article 41. Therefore, if a registrant refuses to complete its application with compliant information following a request from ECHA, the latter must rely on Member States to investigate and sanction the non-compliance, but it cannot sanction the registrant, since the legislator has not provided for this possibility.

40. The complainant's second allegation and part of its second claim are thus unfounded.

41. This situation, however, in no way impedes ECHA from effectively checking compliance with the last resort principle in the way described in paragraphs 29 to 33 above. On the one hand, it is highly unlikely for a registrant to refuse to provide the data required by ECHA and expose itself not only to investigations by the competent Member State, but also to a potentially stricter attitude of ECHA in the context of future registrations. On the other hand, nothing suggests that Member States might not follow-up on the information

received from ECHA, particularly knowing that the previous exchanges between ECHA and the registrant in this context will provide a solid basis for Member States to start an investigation.

42. The Ombudsman, therefore, considers that **ECHA could systematically inform Member States of any registrant's refusal to supply compliant data following ECHA's finding, in the context of a compliance check, that the last resort principle has been violated.**

Third allegation and claim: Exhaustive investigation of possible breaches of the last resort principle

43. The Ombudsman fully shares the complainant's concern for animal welfare and the avoidance of unnecessary animal tests under REACH. She also takes the view that ECHA's expertise in the chemical substances field uniquely equips it to investigate compliance with the provisions of REACH.

44. However, the Ombudsman notes that REACH has not entrusted ECHA with the general competence to verify compliance with its provisions. This responsibility was explicitly granted to Member States [9] . Moreover, in order to avoid institutional paralysis ECHA needs to make reasonable and balanced use of its limited resources in carrying out its multiple tasks under REACH. **In this context, the Ombudsman agrees with ECHA that it cannot perform systematic and exhaustive investigations of all possible instances of non-compliance with the last resort principle by registrants.** From this perspective, the complainant's allegation and claim are not grounded.

45. Where ECHA has the capacity to follow-up possible non-compliant cases identified through IT tools, in the context of the Article 117 reports or otherwise, ECHA should, of course, do so as far as possible. In the present case, ECHA has made reasonable efforts in this regard. It requested clarifications to registrants in a number of registrations identified as potentially non-complaint in its Article 117 report. In a good number of those, the registrations were originally submitted under the previous chemicals legislation where no testing proposals were required. According to ECHA, the testing may have also been carried out in order to fulfil other non-EU regulatory purposes, in which case registrants can lawfully use the information in their REACH registrations.

46. Given that ECHA's verifications have not led to identifying any actual case of non-compliance with the last resort principle, the Ombudsman considers that ECHA is entitled not to assign further resources to the matter. On this aspect also, the complainant's first allegation and claim do not require any further inquiries.

47. However, in the exercise of its mission, ECHA is bound by the principle of sincere cooperation between the Union's institutions and Member States enshrined in Article 4(3)

TEU. Therefore, regardless of the existence of a concrete provision in REACH, compliance with this principle would require ECHA to always inform Member States of possible instances of non-compliance with REACH, not only of proven violations **, in order to facilitate their enforcement tasks** . Moreover, providing this sort of information to the competent Member States' authorities would not be a disproportionate burden for ECHA, but might be of significant assistance for the latter in enforcing REACH at national level. The Ombudsman notes that, in its further exchanges of correspondence with the complainant [10] , ECHA clearly stated that in the present case, all the cases in which " *there was no apparent reason for performing the* [animal] *test were brought to the attention of the* [Member States' competent authorities] *for their eventual follow-up action* ". This constitutes a very positive and constructive attitude of ECHA and is in line with the Ombudsman's findings.

The proposal for a friendly solution
Taking into account the above findings, the Ombudsman proposes to ECHA that it:

(1) acknowledges that, under Article 41 REACH compliance checks are meant to verify whether the information submitted by registrants was generated in compliance with Article 13 REACH, which requires the information to be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods;

(2) acknowledges that, pursuant to Article 41(3) REACH, ECHA can require registrants to (a) clarify whether the information they submitted complies with all the necessary requirements and **(b) if necessary, complete their registrations with compliant data within the deadline set by ECHA;**

(3) considers informing Member States of any registrant's refusal to supply compliant data following ECHA's finding, in the context of a compliance check, that Article 13 REACH has been violated;

(4) pursuant to the principle of sincere cooperation enshrined in Article 4(3) TEU, considers informing Member States not only of proven violations of REACH, but also of possible instances of non-compliance with it, in order to facilitate their enforcement tasks.

Emily O'Reilly

European Ombudsman

Done in Strasbourg on 19 June 2014

[1] Decision of the European Parliament of 9 March 1994 on the regulations and general conditions governing the performance of the Ombudsman's duties (94/262/ECSC, EC, Euratom), OJ 1994 L 113, p. 15.

[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

[3] Article 1(1) REACH.

[4] The Ombudsman has already taken a similar view case 2469/2011/VL concerning ECHA, in which the latter raised identical arguments (see paragraph 15).

[5] For instance, Member States have access to ECHA's registration database.

[6] In this context, ECHA supports registrants by providing them with guidance. ECHA also contributes to the avoidance of unnecessary animal testing by facilitating the data-sharing on substances between registrants.

[7] See the definitions in Article 1 REACH.

[8] This means that, contrary to ECHA's submissions, rejecting non-compliant data would not amount to a duplication of prohibited tests, since the second set of data should necessarily be obtained through a compliant, *i.e.* , non-animal method. If this is not possible, then the only logical conclusion is that the initial data was compliant.

[9] Pursuant to Article 125, Member States shall maintain a system of official controls, and in accordance with Article 126 they shall lay down the provisions on penalties applicable for infringement of the provisions of the REACH Regulation.

[10] ECHA's letter dated 3 July 2013.