European Ombudsman

Decision of the European Ombudsman closing the inquiry into complaint 1826/2010/VL against the European Chemicals Agency

Decision
Case 1826/2010/VL - **Opened on** 28/09/2010 - **Decision on** 18/12/2013 - **Institution concerned** European Chemicals Agency (No maladministration found) |

The background to the complaint

In short

1. The complainant is a company that acts in the interests of its subsidiaries, which are active in the chemical industry. The activities of these subsidiaries fall under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH Regulation) [1] , which imposes an obligation on all manufacturers and importers of chemical substances in quantities of more than one tonne per year to register these substances (that is to say, to deposit a registration dossier) with the European Chemicals Agency (ECHA). The present complaint arose from a disagreement between ECHA and the complainant as to what information needs to be publicly disseminated on the basis of the REACH Regulation.

Legal background

The relevant provisions of the REACH Regulation, as applicable at the time, are set out below.

2. Article 10(a)(xi) stipulates: " *A registration ... shall include ... a technical dossier including:* [...] (xi) *a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.* "

3. Article 77(2)(e) provides as follows: " *The Secretariat shall undertake the following tasks:* [...]

(e) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list established in accordance with Regulation (EC) No 1272/2008. It shall make the information identified in Article 119(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 118 ".

4. Paragraphs 1 and 2 of Article 119 provide:

" *1. The following information held by the Agency on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):*

[...]

(e) the result of each toxicological and ecotoxicological study;

[...]

2. The following information on substances whether on their own, in mixtures or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

[...]

(c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e) ...".

5. Paragraphs 28 and 29 of Article 3 provide the following definitions for "robust study summary" and "study summary":

" *28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;*

29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study ".

Regulation (EC) No 45/2001 on the protection of individuals with regard to the processing of personal data

[2]
6. Article 8 of Regulation of 45/2001 provides: " *Without prejudice to Articles 4, 5, 6 and 10, personal data shall only be transferred to recipients subject to the national law adopted for the implementation of Directive 95/46/EC,*

(a) if the recipient establishes that the data are necessary for the performance of a task carried out in the public interest or subject to the exercise of public authority, or

(b) if the recipient establishes the necessity of having the data transferred and if there is no reason to assume that the data subject's legitimate interests might be prejudiced. "

ECHA's Decision on the implementation of Regulation 1049/2001

[3]
7. Article 5(5) is worded as follows: " *The third-party author consulted shall have a deadline for reply which shall be no shorter than five working days but must allow the Agency to abide by its own deadlines for reply. In the absence of an answer within the prescribed period, or if the third party is untraceable or not identifiable, the Agency shall decide in accordance with the rules on exceptions in Article 4 of Regulation (EC) No 1049/2001, taking into account the legitimate interests of the third party on the basis of the information at its disposal.* "

8. Article 5(6) provides: " *If the Agency intends to give access to a document against the explicit opinion of the author, it shall inform the author of its intention to disclose the document after a ten-working day period and shall draw his attention to the remedies available to him to oppose disclosure.* "

9. Article 8(2)(b) provides: " *At least the following documents shall be made directly accessible by electronic means:* [...] *(b) other information to be made publicly available under Regulation (EC) No 1907/2006* ".

Factual background

10. On 18 January 2010, in accordance with the REACH Regulation, the complainant submitted a registration dossier and received a corresponding registration number.

11. On 11 May 2010, ECHA invited the complainant to preview, that is to say, to review, its registration dossier and to express any reservations it might have regarding the information which would be made public on the Internet by 4 June 2010.

12. On 31 May 2010, ECHA informed the complainant that, on 12 May 2010, it had received a request for access to documents, which was made under Regulation 1049/2001 [4] and concerned documents submitted by the complainant on a specific substance. The request for access was submitted in the framework of a public consultation calling for information to avoid

unnecessary animal testing in relation to the substance concerned.

ECHA pointed that it was not clear whether the exception under Article 4(2) of Regulation 1049/2001 relating to the protection of commercial interests, including intellectual property, applied to the requested document. In ECHA's understanding, the document which ECHA had sent the complainant for previewing before its publication on the Internet corresponded to the public information requested in the application for access to documents, as the filtered registration dossier contained only the information that would be published on the Internet under the REACH Regulation.

In order to decide on the request for access to documents within 15 working days, as set out in Regulation 1049/2001, ECHA asked the complainant to reply by 4 June 2010, at the latest. In ECHA's view, the time limit was reasonable in view of the agency's earlier request that the complainant check that document and the information to be disseminated online.

13. On 4 June 2010, the complainant replied (by separate letters) to ECHA's letters of 11 May 2010 and 31 May 2010. It objected to the disclosure of the document on the grounds that: (i) disclosure of the relevant document would undermine the protection of important commercial interests and intellectual property; (ii) the generation of information for the purpose of registration involved significant efforts on the part of the registrants and deserved special protection; (iii) disclosure would place the complainant's competitors in an advantageous position as it would enable *free riders* to take advantage of the economic asset that the registration dossier itself constituted; (iv) any disclosure before the deadline for registration had expired would penalize the complainant for having handed in its registration dossier earlier and would provide last minute registrants with an unjustified competitive advantage; and (v) disclosure of even the filtered registration dossier went beyond what was necessary for an informed debate on the reduction of tests on vertebrate animals. Furthermore, the complainant asked ECHA to disclose the name of the applicant in order to engage in a direct discussion with the latter.

14. On 21 June 2010, ECHA informed the complainant that, on 8 June 2010, it had decided to grant access to the information contained in the registration dossier to the extent that the information should be publicly available on ECHA's website pursuant to the REACH Regulation. ECHA forwarded to the complainant the disclosed document for its information and explained that it was legally obliged to make publicly available the information listed in Article 119(1), and in Article 119(2) of the REACH Regulation if no claim for confidentiality was made during the registration. During ECHA's consultation with the complainant, the former had claimed that the information listed in Article 119(2) of the REACH Regulation and contained in the registration dossier should be considered to be confidential business information. ECHA had thus decided not to grant access to this data. However, ECHA decided to grant access to the information set out in Article 119(1) of the REACH Regulation, in accordance with the legal obligation contained therein.

15. On 8 July 2010, the complainant wrote to ECHA and expressed its dissatisfaction with the decision to disclose the document concerned. It regretted that ECHA appeared not to have

taken its concerns into account. In the complainant's view, ECHA's actions contradicted Article 5(6) of ECHA's Decision on the implementation of Regulation 1049/2001, according to which ECHA had to inform the author of its intention to disclose the documents after a period of ten working days and draw his or her attention to the remedies available to him or her to oppose disclosure, which ECHA had not done. This infringed the complainant's right to an effective legal protection of its (intellectual) property. Moreover, Article 5(5) of the Decision on the implementation of Regulation 1049/2001 provided for a period of at least five working days to comment on the application. The complainant underlined that it was given less time because 3 June 2010 was a bank holiday in its country. It contended that, even though ECHA received the application on 12 May 2010, it took it nineteen days to contact the complainant and then gave the complainant less than five days to check and comment on it, which was disproportionate.

16. On 10 August 2010, ECHA informed the complainant that since the letter of 8 July 2010 had been sent to a member of ECHA's staff, it was initially considered to be personal mail and was only registered upon that person's return from holidays. ECHA added that a reply would be sent in due time.

17. On 18 August 2010, not having received such a reply, the complainant turned to the Ombudsman.

The subject matter of the inquiry

18. The Ombudsman opened an inquiry into the following allegation:

Allegation:

ECHA failed to (i) deal properly with the complainant's objections to granting access to its registration dossier; (ii) provide the name of the applicant or make use of its offer to contact the applicant directly; (iii) inform the complainant of the applicable means of legal redress and to grant it a period of ten working days before releasing the relevant document; (iv) provide the complainant with a reasonable period for replying to its letter dated 31 May 2010, in particular in view of the length of time ECHA itself had taken to deal with the request; (v) answer the complainant's letter dated 8 July 2010 within a reasonable period of time; and (vi) inform the complainant as to which data had been passed on to the applicant.

The inquiry

19. On 28 September 2010, the Ombudsman asked ECHA for an opinion on the complaint. On 22 December 2010, ECHA sent its opinion, which was forwarded to the complainant with an invitation to make observations. On 28 February 2011, the complainant submitted its observations.

20. On 12 September 2011, the Ombudsman decided to carry out further inquiries and invited

ECHA to provide certain clarifications. On 31 October 2011, ECHA sent its reply, which was forwarded to the complainant with an invitation to make observations. On 30 January 2012, the complainant stated that it did not wish to make any further observations.

The Ombudsman's analysis and conclusions

Preliminary remarks

21. In its reply to the Ombudsman's further inquiries, ECHA pointed out that the complainant had previously not challenged ECHA's rules that distinguish between "study results" and "study summary".

22. The Ombudsman notes that ECHA did not argue that the above issue should be declared inadmissible for lack of prior administrative approaches. In any event, such an approach would have not succeeded in the present case. This is because the above issue is closely linked to the complainant's argument that ECHA had released information that went beyond that provided for in Article 119(1) of the REACH Regulation. For this reason, clarifying the distinction between "study results" and "study summary" is critical in establishing the scope of Article 119(1) of the REACH Regulation.

A. Alleged failure to deal properly with the complainant's objections on granting access to its registration dossier

Arguments presented to the Ombudsman

23. The **complainant** essentially argued that: (i) the disclosure of the relevant document undermined the protection of important commercial interests and intellectual property; (ii) the generation of information for the registration involved significant efforts on the part of registrants and deserved special protection; (iii) disclosure would place the complainant's competitors in an advantageous position as it would enable *free riders* to take advantage of the economic asset that the registration dossier itself constituted; (iv) any disclosure before the expiry of the registration deadline would penalize the complainant for having handed in its registration dossier earlier and would provide last minute registrants with an unjustified competitive advantage; and (v) disclosure of even a filtered dossier would go beyond what was necessary for an informed debate on the reduction of tests on vertebrate animals.

24. In its opinion, **ECHA** argued that the way in which it had dealt with the request for access to documents on the complainant's registration dossier was in no way detrimental to the complainant's rights and procedural guarantees. It had limited the disclosure of the information to that set out in Article 119(1) of the REACH Regulation, which is in any event considered to be in the public domain. It thus had no margin of discretion to refuse access to such information.

25. ECHA pointed out that the REACH Regulation imposes an obligation on all manufacturers and importers of chemical substances in quantities of more than one tonne per year to register them with ECHA. They need to submit to ECHA a "registration dossier" containing certain data on the properties of the substance, including an assessment and recommendations on how to control the risk relating to the substance. These dossiers are submitted in a specific format. The deadlines for submission may vary, depending on the properties of the substance and/or the manufacturing or importation volume.

26. However, all companies that manufacture or import the same substance in the EEA are required to compile and submit a large part of the information required for their registrations jointly. To this end, companies have to form Substance Information Exchange forums (SIEFs) and are obliged to share the costs for generating the information in a fair, transparent and non-discriminatory manner. This obligation to share information and costs applies to all registrants for a given substance, regardless of the fact that some of them may submit their registrations to ECHA earlier and others later.

27. ECHA underlined that from the outset it had limited the potential scope of the access to be granted to the information referred to in Article 119(1), and to that referred to in Article 119(2) for which no request for non-publication on ECHA's website had been included in the registration dossier. The relevant registration dossier of the complainant should have been publicly available on ECHA's website since 18 January 2010, but the publication was delayed for technical reasons.

28. ECHA explained that, in order to make registrants aware of the publication of parts of the registration dossier, it contacted them individually and allowed them to preview the public version of the dossier before publishing it. The complainant had received a request to preview the "public part" of its registration dossier on 11 May 2010 and was invited to express any substantial concerns by 4 June 2010. On 12 May 2010, ECHA received the request for access to the document that forms the subject matter of this inquiry. On 4 June 2010, the complainant replied separately to both (i) ECHA's letter allowing for review of the dossier in view of its publication and (ii) ECHA's request to comment on the request for access to documents in question.

29. In its reply to ECHA's letter of 11 May 2010 concerning the publication of the registration dossier on ECHA's website, the complainant asked ECHA to delay the publication of the dossier until 30 November 2010, and only raised objections in relation to the publication of certain information referred to in Article 119(2) of the REACH Regulation; this concerned trade names (Article 119(2)(e)), information on uses (information in the safety data sheet under Article 119(2)(d)) and study summaries or robust study summaries (Article 119(2)(c)).

30. Given the complainant's above-mentioned objections, ECHA decided to grant access only to information listed in Article 119(1) of the REACH Regulation. It stressed that this information was considered non-confidential and was to be made publicly available without exception as of 1 June 2008. Therefore, ECHA had no grounds for refusing disclosure once this information

became available in its databases, that is to say, once a registration dossier was submitted. The REACH Regulation did not provide any possibility for a registrant to oppose publication of information listed in Article 119(1). This information also fell into the category of " *documents directly accessible to the public* " under Article 8(2)(b) of ECHA's Decision on the implementation of Regulation 1049/2001. Therefore, ECHA concluded that the exceptions in Article 4 of Regulation 1049/2001 were no longer applicable.

31. ECHA further emphasised that: (i) it had no margin of appreciation to refuse access to information referred to in Article 119(1) of the REACH Regulation; (ii) the information listed in that provision only related to basic substance properties and, as such, was not sufficient for any third party to compile a proper registration dossier; and (iii) competitors could not just simply "copy and paste" the information contained in a registration dossier, as Article 10 of the REACH Regulation provided that a registrant, when using publicly available information, needed to be in possession of, or have permission to refer to, the full study report. Registrants were asked to confirm this when submitting their registration dossier to ECHA.

32. In its observations, **the complainant** disputed ECHA's view that all of the information that ECHA had released fell under Article 119(1) of the REACH Regulation. In particular, it argued that the information that had been disclosed contained 'study summaries' that fell under Article 119(2)(c) of the REACH Regulation. According to the complainant, these study summaries were entitled " *end-point study report* " and, except for the missing identity of the material, had the character of a "qualified study summary". Moreover, the complainant stated that the disclosed information made it possible to draw conclusions about its production site(s) and thus about the complainant itself. The complainant stressed that it wanted to prevent free-riding on its study summaries by other companies, which would have to submit their registration dossiers at a later stage.

33. In further inquiries, the **Ombudsman** pointed out to ECHA that the complainant argued that not all of the information that the ECHA released fell under Article 119(1) of the REACH Regulation. In particular, the Ombudsman asked ECHA for further comments as regards the complainant's argument that the information that had been disclosed contained 'study summaries' which fell under Article 119(2)(c) of the REACH Regulation.

34. In its reply to the Ombudsman's request for clarifications, **ECHA** reiterated that a registrant submits its dossier in a standardised format based on templates prepared by the Organisation for Economic Co-operation and Development (OECD) containing fields to be filled in by the registrants. ECHA had to determine which information fell within the scope of Article 119(1) and which fell within the scope of Article 119(2) of the REACH Regulation.

35. To this end, ECHA worked in close cooperation with its stakeholders in defining the rules to qualify the information submitted by registrants and regularly consulted with interested parties. In particular, on 6 July 2009, it held a stakeholder round table meeting with industry participants (including the association, in which the complainant is a member), NGOs, trade unions, the OECD, the European Commission and the European Parliament. ECHA carefully analysed the comments received following the round table. This involved a delicate balancing exercise

between the need to protect confidential business information and the obligation to guarantee the usefulness of the information to be published on the Internet. The final outcome of this dialogue was implemented through an IT tool for automated extraction of this information from registration dossiers and supplemented by manuals and an IT tool enabling registrants to simulate the extraction before the submission of their dossiers.

36. ECHA pointed that the REACH Regulation distinguished between "study summaries" and "study results". Whilst "study results" were to be made publicly available without exception, "study summaries" and "robust study summaries" were only to be published on the Internet if no request for confidential treatment was made in the registration dossier. The REACH Regulation provided for a definition of "study summary" and "robust study summary", but did not specify what should be considered a "result" of a study. ECHA submitted that it could be inferred from the definitions of "study summary" and "robust study summary" in Article 3(28) and (29) of the REACH Regulation (see point 5 above) that the scope of the "result of a study" was narrower than the study summary and excluded details on the objectives, methods and conclusions.

37. Based on this approach, ECHA had to determine for each field in the registration dossier where the full study report was mentioned, whether it should qualify as "results", "study summary", "robust study summary", or whether it fell outside the scope of Article 119 of the REACH Regulation altogether. The main criteria for doing so were: (i) the definitions in Article 3(28) and (29) of the REACH Regulation; (ii) the objective qualification of the reported information as a "result" or "study summary" (for example, numerical values vis-à-vis detailed descriptions about methodology and conclusions); (iii) the predictability for the registrants (for instance, if the box had the word "result" in the title); and (iv) the need of the public to receive sufficient information to understand numerical values. Information in the full study reports (that is to say, results and study summaries) was reported in ECHA's submission system under the headings entitled 'end-point study report'; more than 6 200 fields were reported under such a heading. After a careful analysis, ECHA concluded that 2 502 fields corresponded to information qualifying as study results and 1 738 would qualify as information forming part of a study summary or robust study summary, whereas 1 966 fields contained information falling outside the scope of Article 119 of the REACH Regulation. ECHA emphasised that the points set out above were determined in close cooperation with its stakeholders and taking into account the concerns of the industry as well as those of the NGOs.

38. The specific end-point study report highlighted by the complainant corresponded to a particular section of the registration dossier. ECHA submitted an overview of fields' titles for the section of the registration dossier, which were considered to be part of the "result" (and thus have to be disclosed in accordance with Article 119(1)), or to be part of the "study summary". It also submitted that the information disclosed in the context of the request for access to documents was clearly less than what would be considered to be part of the "study summary". Therefore, ECHA had not derogated from its standard rules. It explained that these rules had also been transparently available to registrants since the end of April 2010 in dedicated manuals explaining the applicable rules field by field.

39. Moreover, ECHA added that the complainant had been invited by letter of 2 December

2010 to review its registration dossier in view of publication of the information on ECHA's website, and, if necessary, update the information. Following this request, the complainant updated its dossier on 1 April 2011, and the non-confidential data from the registration dossier was published on ECHA's dissemination portal on 9 June 2011. In ECHA's view, it was remarkable that, when the complainant updated the registration on 1 April 2011, it decided not to make a request for confidential treatment of information reported under the end-point study report, which it referred to in its observations. Thus, it did not use its right to object to the publication under Article 119(2) of the REACH Regulation of the information contained in fields which ECHA would consider to correspond to the "study summary". The information that was publicly available on ECHA's dissemination portal was thus even more detailed than the information that had been disclosed to the person who had made the access request in 2010.

40. ECHA further observed that the information available in ECHA's dissemination portal showed that the complainant had decided not to remove the alleged references to the production sites when updating the dossier in view of publication.

41. The **complainant** did not make any further observations.

The Ombudsman's assessment

42. It appears that both the complainant and ECHA accept that information that falls under the scope of Article 119(1) of the REACH Regulation needs to be published, whereas information that falls under the scope of Article 119(2) may be published, unless a claim for confidentiality made under Article 10(a)(xi) is accepted.

43. ECHA argued that, in its reply to the request for access to documents, it released only information which it was, in any event, legally required to disseminate, that is to say, the information referred to in Article 119(1) of the REACH Regulation. The complainant contests this by pointing out that the information released contained 'study summaries' (entitled " *end-point study report* ") that fell under Article 119(2)(c) of the REACH Regulation. Furthermore, the complainant referred to specific information, which it believed would allow it to be identified.

44. The decisive question is thus whether ECHA has released information that went beyond the information foreseen in Article 119(1) of the REACH Regulation. The Ombudsman notes that the Court of Justice of the EU has not yet had the opportunity to examine the distinction between information falling under Article 119(1) and that falling under Article 119(2) of the REACH Regulation. In the absence of such an interpretation, ECHA was entitled to develop its own rules of interpretation so as to be able to apply the REACH Regulation, and it is for the Ombudsman to examine whether the interpretation was correct and reasonable.

45. ECHA explained that, pursuant to Article 119(1) of the REACH Regulation, it had to publish "study results" on the Internet. However, given that the REACH Regulation contained no definition of that term, ECHA claimed that it had to come up with its own definition. In that regard, the Ombudsman considers that ECHA's point of departure, which was to assume that

the concept of "study results" had to be narrower than "study summaries" [5] , was indeed reasonable.

46. Taking this interpretation further, ECHA developed an approach with a view to enabling it to decide whether a specific field, out of more than 6 200 fields, fell within the scope of Article 119(1) or Article 119(2) of the REACH Regulation, or outside the scope of those provisions altogether. In so doing, it took into account a number of considerations (see point 37 above) and involved in the process a large group of stakeholders, including the industry association representing the complainant. The information presented to the Ombudsman shows that: (i) this process entailed prior consultation with the stakeholders and interested parties with a view to developing rules for submitting registration dossiers; (ii) the criteria used to decide what needs to be published (for example, the difference between "study results" and "study summary") attempted to strike a fair balance between what were at times distinctly competing interests; and (iii) ECHA took a number of measures to prepare and inform the registrants of the impact of these rules before they submitted their registration dossiers and/or before publication on the Internet. In the absence of any further arguments to the contrary by the complainant, the Ombudsman finds ECHA's approach, aimed at helping it distinguish between information that could be published and information that could be claimed to be confidential, to be reasonable and in line with the spirit of the REACH Regulation.

48. As to the specific document referred to by the complainant (the end-point study report), ECHA highlighted the fact that the information contained therein corresponded to the specific categories for publishing information pursuant to Article 119(1), and thus did not contain information from categories falling under study summaries or robust study summaries (see point 38 above). The Ombudsman notes that the complainant did not contest ECHA's detailed submissions on this point. Therefore, the Ombudsman also finds reasonable ECHA's position regarding the end-point study report referred to by the complainant.

49. The complainant appears to have opposed the disclosure of the relevant information in the registration dossier on the grounds that entities that still had to carry out their registration for the same substances could benefit from its efforts at practically no cost ("free-riding"). However, and as ECHA pointed out, such concerns appear to have been addressed by the REACH Regulation through the "Substance Information Exchange forums" (Article 29 of the REACH Regulation) and a cost-sharing mechanism for subsequent users of studies already carried out by other registrants for the same substances (Article 30 of the REACH Regulation).

50. Finally, it is true that the four items of information which the complainant referred to in particular figured in the document which ECHA disclosed in reply to the access request it had received. The Ombudsman is not in a position to decide whether the relevant items of information are sufficient to allow the complainant to be identified. It should be noted, however, that ECHA had asked the complainant to review the public part of its submission on 11 May 2010. Whilst the complainant, by letter of 4 June 2010, objected to the publication of specific categories in its registration dossier, it did not mention the four items of information in question. Thus, even if the said items of information should have been considered confidential for the purposes of Article 119(1) of the REACH Regulation, the Ombudsman considers that the

complainant could not blame ECHA for the disclosure of that information. Nevertheless, in order to limit the possibility of such situations occurring in the future, it might prove useful for ECHA, insofar it has not yet done so, to warn registrants about inserting information considered confidential in fields that will be published pursuant to Article 119(1) of the REACH Regulation. The Ombudsman will thus make a further remark below.

51. In the light of the considerations set out above, the Ombudsman takes the view that no maladministration can be found with regard to ECHA's alleged failure properly to deal with the complainant's objections to granting access to its registration dossier.

B. Alleged failure to provide the name of the applicant or make use of the complainant's offer to contact the applicant directly

Arguments presented to the Ombudsman

52. The **complainant** alleged that ECHA failed to provide it with the name of the applicant who had asked for access to documents and to make use of its offer to contact the applicant directly.

53. In its opinion, **ECHA** took the view that, since it had decided to grant access to information listed in Article 119(1) of the REACH Regulation, there was no need for the alternative way of proceeding proposed by the complainant. This was provided for by neither Regulation 1049/2001 nor ECHA's Decision on the implementation of Regulation 1049/2001. In addition, the applicant's identity was of no relevance since the data disclosed was supposed to become publicly available. Moreover, considering Regulation 45/2001 and in particular its Article 8, ECHA could not transfer the personal data of the person making such a request, as long as the necessity for the transfer was not established and the legitimate interests of the person concerned might have been prejudiced.

54. In its observations, **the complainant** did not make any further comments concerning this allegation.

The Ombudsman's assessment

55. ECHA essentially put forward two arguments as to why it did not provide the complainant with the name of the applicant, namely that (i) ECHA could not transfer the personal data of the applicant, as long as the necessity for the transfer was not established and the legitimate interests of the person concerned might have been prejudiced, and that (ii) the applicant's identity was of no relevance since the data disclosed was supposed to become publicly available pursuant to Article 119(1) of the REACH Regulation.

56. Article 8 of Regulation 45/2001 provides for two situations in which personal data may be

transferred, namely, either (a) to recipients that need the data for " *the performance of a task carried out in the public interest or subject to the exercise of public authority* " or (b) in cases in which the recipient has established the necessity for the transfer and there is no reason to assume that the data subject's legitimate interests would not be prejudiced.

57. It appears useful to note that the complainant did not argue that it needed the name of the applicant for the performance of a task carried out in the public interest or subject to the exercise of public authority; thus the situation set out above under point (a) did not apply. As for the situation set out above under point (b), the Ombudsman considers, as ECHA correctly pointed out, that the complainant did not establish any necessity for the data transfer, in particular since the information required by the applicant was supposed to be, as established under the first allegation, in the public domain pursuant to Article 119(1) of the REACH Regulation.

58. Consequently, the Ombudsman concludes that ECHA's position was reasonable. Therefore, no maladministration can be found with regard to the second allegation.

C. Alleged failure to inform the complainant of applicable means of legal redress and to grant it a period of ten working days before releasing the relevant document

Arguments presented to the Ombudsman

59. The **complainant** alleged that ECHA failed to inform it, in accordance with Article 5(6) of ECHA's Decision on the implementation of Regulation 1049/2001, of the applicable means of legal redress and to grant it a period of ten working days before releasing the relevant document.

60. In its opinion, **ECHA** underlined that, following the objections raised by the complainant in its letter of 4 June 2010, it decided to disclose only the information that had to be published in accordance with Article 77(e) of the REACH Regulation and Article 8(2)(b) of ECHA's Decision on the implementation of Regulation 1049/2001. ECHA argued that to the extent that the non-confidential character of certain information has been determined by the REACH Regulation itself, ECHA's Decision on the implementation of Regulation 1049/2001 provides for no possibility of opposing disclosure because Article 5 of that Decision no longer applies. At the same time, the REACH Regulation does not provide for any possibility of opposing disclosure of information referred to in its Article 119(1). Had ECHA finalised the technical implementation of the process earlier, the information would have been available on its website immediately after the submission of the registration dossier. In that respect, ECHA regretted that its communication with the complainant may have not been clear enough. However, it submitted that the allegation that it failed to inform the complainant of the applicable means of legal redress and to grant it a period of ten working days before releasing the relevant document was unfounded since ECHA's Decision on the implementation of Regulation 1049/2001was not

applicable.

61. In its observations, **the complainant** did not make any further comments concerning this allegation.

The Ombudsman's assessment

62. ECHA wrote to the complainant on 31 May 2010 in order to consult it on the disclosure of its registration dossier. ECHA did so on the basis of Article 5(5) of its Decision on the implementation of Regulation 1049/2001.

63. By its subsequent letter of 21 June 2010, after the complainant's objections of 4 June 2010, ECHA informed the complainant that it had decided to grant the applicant access only to information falling under Article 119(1) of the REACH Regulation.

64. In view of her findings in relation to the first allegation, the Ombudsman considers that ECHA was entitled to take the view that it could disclose the relevant document by applying Article 8(2)(b) of its Decision on the implementation of Regulation 1049/2001 and that, as a result, the requirements laid down in Article 5(6) of that Decision, that is to say, the obligation to grant the author of the document a period of ten working days to oppose disclosure and the obligation to provide information concerning the applicable means of legal redress, did not apply. Therefore, the Ombudsman concludes that no maladministration can be established as regards the alleged failure to observe the requirements of Article 5(6) of the Decision on the implementation of Regulation 1049/2001.

65. The Ombudsman nevertheless considers it appropriate to point out that ECHA's communication with the complainant in respect of this aspect of the case was not as clear as it could have been and should have been. In fact, in its letter of 31 May 2010, ECHA first invited the complainant to submit its views on the basis of Article 5(5) of its Decision on the implementation of Regulation 1049/2001, whereas, in its letter of 21 June 2010, it informed the complainant of its decision to disclose the information pursuant to Article 119(1) of the REACH Regulation - without explaining why it considered that Article 5 of its Decision on the implementation of Regulation 1049/2001 no longer applied. Thus, it is understandable that the complainant was led to believe that Article 5(6) of that Decision was applicable.

66. It would appear that the problem regarding publication could have been avoided, if, at the relevant time, ECHA had clarified which parts of the registration dossiers would be published on the Internet and informed the registrants accordingly. The Ombudsman understands that ECHA has, in the meantime, clarified the situation and that it is unlikely, or even impossible, for a situation similar to the one giving rise to the present complaint to occur again. It is for this reason that the Ombudsman considers that no further action is needed as regards this aspect of the case.

D. Alleged failure to provide the complainant with a reasonable period for replying to the letter of 31 May 2010

Arguments presented to the Ombudsman

67. The **complainant** argued that Article 5(5) of the Decision on the implementation of Regulation No 1049/2001 provided for a period of at least five working days to comment on the application. ECHA informed the complainant about the request for access by letter dated 31 May 2010, while an answer was expected from the complainant by 4 June 2010. The complainant stressed that 3 June 2010 was a bank holiday in its country. It contended that even though ECHA had received the application on 12 May 2010, it took it 19 days to pass the application on to the complainant, and then gave it less than five days to check and comment on it, which was disproportionate.

68. In its opinion, **ECHA** acknowledged that the complainant was correct in stating that ECHA's Decision on the implementation of Regulation 1049/2001 provided for a minimum of five working days for third-party authors to submit comments on an application for access to a document. ECHA regretted that it was not aware of the national holiday in question. If the complainant had informed it of this, it would have extended the deadline. ECHA added that, in spite of the short deadline, the complainant managed to answer within the set deadline.

69. Moreover, ECHA also pointed out that the complainant had already had the opportunity to review the "public part" of its registration dossier since 11 May 2010. The deadline for this review was also 4 June 2010. ECHA thus had legitimate expectations that the complainant's review would have been completed by then.

70. ECHA reiterated that it had no margin of discretion in deciding on whether or not to make information referred to in Article 119(1) of the REACH Regulation publicly available. Article 5(5) of ECHA's Decision on the implementation of Regulation 1049/2001 did not apply to the part of the document disclosed. Thus, ECHA concluded that the fact that the complainant lost one day in replying to ECHA's request was in no way detrimental to its rights and procedural guarantees.

71. In its observations, **the complainant** reiterated that ECHA gave itself fifteen working days to deal with the access request. It was thus surprised that ECHA referred to the fact that the complainant was able to meet the deadline.

The Ombudsman's assessment

72. ECHA admitted that the complainant was not given the full five working days to reply to ECHA's letter of 31 May 2010, which is the minimum amount of time provided for by its Decision on the implementation of Regulation 1049/2001. It seems undisputed that this period of time is intended to give the third-party author the possibility of considering whether or not to raise objections to the disclosure of a document he or she has submitted to ECHA.

73. The Ombudsman considers that the fact that the complainant nevertheless managed to reply within the deadline does not affect the conclusion that ECHA erred when setting the deadline for the complainant's reply.

74. The Ombudsman notes, however, that the complainant in effect argued that the amount of time it was given to reply was one day less than what it should have been given. In this context, it should be recalled that, on 11 May 2010, ECHA had already invited the complainant to make observations on the information that ECHA intended to make public on the Internet under the relevant obligation arising from the REACH Regulation. The complainant had been asked to submit any such observations by 4 June 2010. However, in its letter of 31 May 2010 concerning the third-party consultation, ECHA made it clear that what it intended to disclose to the applicant who had asked for access was precisely the information that it also envisaged publishing on the Internet and of which the complainant had already been informed nearly three weeks beforehand.

75. In view of the above circumstances, the Ombudsman considers that, even though, in its letter of 31 May 2010, ECHA did not grant the complainant the minimum of five working days for replying provided for by Article 5(5) of its Decision on the implementation of Regulation 1049/2001 and thus did not correctly apply that Decision, it would not be appropriate to make a finding of maladministration. However, the Ombudsman will make a further remark in order to remind ECHA of the need to ensure that the relevant deadline actually includes five working days in future cases.

E. Alleged failure to reply to the complainant's letter of 8 July 2010 within a reasonable period of time

Arguments presented to the Ombudsman

76. The **complainant** argued that, when it lodged its complaint with the Ombudsman, it had not received a reply to its letter of 8 July 2010.

77. In its opinion, **ECHA** pointed that, on 10 August 2010, it sent the complainant an acknowledgment of receipt to its letter of 8 July 2010. The delay was due to the complainant's letter being addressed personally to a Head of Unit, who was absent from the office when the letter arrived. The letter was therefore initially considered to be personal mail. The letter was officially registered only upon this person's return to the office. ECHA replied on 26 August 2010, which was within 15 working days from the acknowledgement of receipt, and in line with ECHA's Code of Good Administrative Behaviour. ECHA therefore considered the complainant's allegation to be unfounded. It added that it had taken further steps to ensure that official mail is registered by the Agency also during a staff member's holidays.

78. In its observations, the **complainant** stated that it had not yet received a detailed reply

from ECHA to its letter of 8 July 2010.

The Ombudsman's assessment

79. The Ombudsman notes that in its opinion, ECHA submitted a copy of its reply of 26 August 2010, by which it replied to the complainant's letter of 8 July 2010. A copy of the same letter was attached to the opinion transmitted to the complainant by the Ombudsman.

80. In its observations, the complainant nevertheless put forward that it had not yet received a detailed reply to its letter of 8 July 2010, without explaining why it considered ECHA's reply of 26 August 2010 to be inadequate.

81. The Ombudsman considers that ECHA's reply of 26 August 2010 not only replied to the letter of 8 July 2010, but also did so in a sufficiently precise and adequate manner. Therefore, no maladministration can be found with regard to the fifth allegation.

F. Alleged failure to inform the complainant as to which information had been disclosed to the applicant for access to documents

Arguments presented to the Ombudsman

82. In its complaint, the **complainant** argued that ECHA failed to inform it as to which information had been disclosed to the applicant for access to documents.

83. In its opinion, **ECHA** pointed to its letter of 21 June 2010, in which it explained that only the information referred to in Article 119(1) of the REACH Regulation had been disclosed. The file disclosed to the applicant was forwarded as an attachment to the said letter for complainant's information.

84. In its observations, the **complainant** did not make any further comments concerning this allegation.

The Ombudsman's assessment

85. In its letter of 21 June 2010, ECHA provided the complainant with a copy of the document released to the applicant. A copy of this letter was made available to the Ombudsman in ECHA's reply to further inquiries. The complainant did not contest this in its observations. Therefore, no maladministration has been found with regard to the sixth allegation.

G. Conclusions

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

No maladministration has been established with regard to the present complaint.

The complainant and ECHA will be informed of this decision.

Further remarks

Even though ECHA asked the complainant to review the public part of its submission and released a version of the registration dossier with only the fields containing the information that had to be made publicly available in accordance with Article 119(1) of the REACH Regulation, it might prove useful for ECHA, insofar as it has not yet done so, to warn registrants not to insert information considered confidential in fields that will be published pursuant to Article 119(1) of the REACH Regulation.

When ECHA consults third-party authors of documents in relation to which it has received a request for access to documents, it has to grant these third parties a minimum of five working days to express their views. It would be good administrative practice if ECHA could carefully check in such cases that this minimum is indeed respected.

Emily O'Reilly

Done in Strasbourg on 18 December 2013

[1] 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, OJ 2006 L 396, p. 1, as amended.

[2] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, OJ 2001 L 8, p. 1.

[3] Decision on the implementation of Regulation (EC) No 1049/2001 of the European Parliament and of the Council regarding public access to documents to European Parliament, Council and Commission documents: adopted by ECHA Management Board on 23 April 2008 and amended on 25 March 2009.

[4] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ 2001 L 145, p. 43.

[5] Indeed, the definitions in Article 3(28) and (29) of the REACH Regulation would suggest that "robust study summaries" are more detailed than "study summaries".