



Decision of the European Ombudsman closing the inquiry into complaint 2469/2011/VL against the European Chemicals Agency

Decision

Case 2469/2011/VL - **Opened on** 16/01/2012 - **Decision on** 12/03/2014 - **Institution concerned** European Chemicals Agency (No maladministration found) |

The background to the complaint

General background

1. The complainant is a company operating in the chemicals industry. Its activities fall under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the '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 submit a registration dossier) with the European Chemicals Agency (ECHA). The present complaint arose from a disagreement between ECHA and the complainant as to which information needs to be publicly disseminated in terms of the REACH Regulation.

Legal background

The relevant provisions of the REACH Regulation

2. Article 10 stipulates as follows:

" A registration ... shall include ... (a) a technical dossier including: (i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;

[...]

(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) 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. Article 119 provides as follows:

" *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):*

[...]

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:

[...]

(b) the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered ;

[...].

(d) information, other than that listed in paragraph 1, contained in the safety data sheet;

[...]"

5. Annex II to the REACH Regulation is entitled Requirements for the compilation of safety data sheets. Point 1.3 of Annex II is worded as follows:

"1.3. Details of the supplier of the safety data sheet

The supplier, whether it is the manufacturer, importer, only representative, downstream user or distributor, shall be identified. The full address and telephone number of the supplier shall be given as well as an e-mail address for a competent person responsible for the safety data sheet.

In addition, if the supplier is not located in the Member State where the substance or mixture is placed on the market and he has nominated a responsible person for that Member State, a full address and telephone number for that responsible person shall be given.



For registrants, the information shall be consistent with the information on the identity of the manufacturer or importer provided in the registration.

Where an only representative has been appointed, details of the non-Community manufacturer or formulator may also be provided. "

Factual background

6. On 11 May 2011, ECHA published a press release concerning the interpretation of the scope of application of Article 119(2) of the REACH Regulation. The press release aimed at informing the public that ECHA intended to publish the names of its registrants on the Internet, on the basis of the said provision. ECHA based its interpretation on an opinion of the Commission's Legal Service and a decision of its Management Board.

7. In a letter of 26 September 2011, the complainant expressed its disagreement with ECHA's interpretation of Article 119(2) of the REACH Regulation. In its view, Article 119(2) does not allow the publication of registrants' names. The complainant argued that (i) Article 119(2) concerns only information related to substances; (ii) the name of the supplier indicated in the safety data sheet may be different from the name of the registrant; (iii) disclosure of the name of the registrant would render Article 4 of the REACH Regulation, which provides for the possibility of a third party representative arrangement, meaningless [2]. It thus asked ECHA to re-evaluate its position.

8. On 20 October 2011, ECHA informed the complainant that, following a careful examination, its Management Board and the Commission's Legal Service came to the conclusion that the names of registrants have to be published pursuant to Article 119(2)(d) of the REACH Regulation because they are normally contained in the safety data sheet. Moreover, ECHA pointed out that Article 119(2) is not limited to the intrinsic characteristics of substances. This is demonstrated by point (b) of that provision relating to the total tonnage bands. ECHA also informed the complainant that registrants may make a request for their name not be disclosed. It added that this could be particularly relevant in cases where a third party representative is appointed pursuant to Article 4 of the REACH Regulation.

9. On 2 December 2011, the complainant turned to the European Ombudsman. The subject matter of the inquiry

10. The Ombudsman opened an inquiry into the following allegation and claim:

Allegation:

ECHA had no competence or legal basis to decide to disclose registrants' names.

Claim:



ECHA should not disclose on its website the complainant's name as being one of the registrants.

The inquiry

11. On 16 January 2012, the Ombudsman asked ECHA to submit an opinion on the complaint. On 2 May 2012, ECHA sent its opinion, which was forwarded to the complainant with an invitation to make observations. On 11 July 2012, the complainant submitted its observations.

12. On 5 August 2013, the complainant sent a new complaint concerning essentially the same issue, namely, the publication of the registrants' names.

13. On 9 October 2013, the Ombudsman informed the complainant that it would examine the submissions made in its letter of 5 August 2013 in the framework of the present inquiry. The Ombudsman's analysis and conclusions

Preliminary remarks

14. In its opinion, ECHA questioned the admissibility of the present complaint. It argued that (i) the complainant requested a legal opinion on an abstract question of law and did not allege a concrete case of maladministration, (ii) the complaint related to a hypothetical future administrative practice that was not sufficiently concrete to be investigated, and (iii) ECHA should be allowed to put in place an administrative procedure before the Ombudsman investigates it. In its observations, the complainant disagreed with ECHA's submissions on the inadmissibility of the complaint.

15. The Ombudsman considers it useful to point out that, based on the definition of 'maladministration' 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 concerns ECHA's interpretation of Article 119(2)(d) of the REACH Regulation, that is, of a concrete rule binding upon the agency. More importantly, it is a basic tenet of good administration 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.

A. Alleged lack of competence or legal basis to disclose registrants' names

Arguments presented to the Ombudsman

16. The **complainant** argued that Article 119(2) of the REACH Regulation only refers to information on substances. Thus, the reference to the safety data sheet needs to be understood as relating to information on substances only. An interpretation based only on certain words contained in Article 119(2)(d) taken on their own ignores the wording of the entire provision, in particular, the context and purpose of the provision and of the REACH Regulation.



17. The safety data sheet provides that only the supplier should be mentioned. However, the supplier and the registrant might not be the same entities. According to the complainant, it is thus clear that the dissemination of a registrant's name on the basis of what is stated in Article 119(2)(d) of the REACH Regulation was not envisaged. Moreover, recital 117 of the REACH Regulation [3] provides that EU citizens should have access to information about chemical substances; the identity of the manufacturer does not constitute such information.

18. Furthermore, the third party representative arrangement envisaged in Article 4 of the REACH Regulation would be rendered meaningless if the name of the registrant were to be made public.

19. The registrant's name is a commercial secret because, if it were to be disclosed, the registrant's address, production site and the estimable quantities could then be identified.

20. A request for confidentiality pursuant to Article 10(a)(xi) of the REACH Regulation would not be an adequate alternative solution because (i) it could simply be rejected by ECHA, and (ii) the confidentiality request fee is, in any event, disproportionate to the work to be carried out by ECHA in this respect.

21. In its opinion, **ECHA** explained that the REACH Regulation obliges all manufacturers and importers of chemical substances in quantities of one tonne or more per year to register these substances with ECHA. They have to submit to ECHA a registration dossier containing certain data on the properties of the substance, as well as an assessment and recommendations on how to control the risks relating to the substance. Once a registration dossier is submitted, ECHA includes the information in its database. According to Article 77(2)(e) of the REACH Regulation, ECHA needs to make the information listed in Article 119(1) and (2) publicly available, except where a confidentiality request pursuant to Article 10(a)(xi) is considered justified.

22. Article 119(2)(d) of the REACH Regulation obliges ECHA to make information contained in the safety data sheet, which is not already disseminated on the basis of Article 119(1), publicly available. Since ECHA does not itself receive a copy of the safety data sheet [4], the information that is deemed to correspond to "*information contained in the safety data sheet*" needs to be determined on the basis of the type of information held by the Agency that always needs to be included in the safety data sheet. Initially, ECHA considered that only information on uses and uses advised against was of such nature. However, during a review of the scope of application of Article 119(2)(d), the agency identified additional information which would always need to be contained in safety data sheets, such as the identity of the registrant [5].

23. The safety data sheet contains the name of the registrant because the registrant is the first party supplying the substance and, as such, is obliged to draw up a safety data sheet in accordance with Article 31(1) of the REACH Regulation. The safety data sheet records the identity of the supplier, according to Point 1.3 of Annex II to the REACH Regulation.



24. ECHA stated that all registrants are granted the option pursuant to Article 10(a)(xi) to make a request not to disseminate their name on the Internet.

25. ECHA acknowledged that submitting a confidentiality request is particularly important where the registrant appoints a third party representative under Article 4 of the REACH Regulation. It confirmed that information on the supply chain or on the price calculation and other information that is kept confidential in a competitive market would not be disclosed under Article 119(2) of the REACH Regulation. Given that the publication would be potentially harmful for the commercial interests of the registrant, ECHA would in all likelihood accept a well-justified confidentiality request.

26. As regards the complainant's concern that its production tonnage could be deduced from the publication of its name, ECHA pointed out that according to Articles 10(a)(xi) and 119(2) of the REACH Regulation, every registrant may already submit a confidentiality request in respect of the tonnage band indicated in his/her registration dossier.

27. ECHA added that various legal remedies are foreseen if a confidentiality request is rejected, such as a request for review pursuant to Article 118(3) of the REACH Regulation or a subsequent action for annulment before the General Court.

28. In its observations, the **complainant** referred to the arguments it had previously made. It added that a confidentiality request is not an adequate solution because the amount charged for a confidentiality request is disproportionate in relation to the registration fee and does not reflect the work to be carried out by ECHA pursuant to Article 74(3) of the REACH Regulation.

The Ombudsman's assessment

29. The present complaint concerns the interpretation of Article 119(2)(d) of the REACH Regulation. The Ombudsman notes that the Court of Justice of the EU has not yet had the opportunity to examine that particular provision. In the absence of an interpretation by the Court of Justice, 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. However, the highest authority that can provide an interpretation of the REACH Regulation, and the only one that can provide a binding one, is the Court of Justice.

30. In its opinion, ECHA explained that Article 119(2)(d) of the REACH Regulation obliges it to make publicly available the information contained in the safety data sheet which is not already disseminated on the basis of Article 119(1). The complainant does not dispute that a registrant's name forms part of that information.

31. The complainant argued, however, that (i) Article 119(1) and (2) only requires the publication of information " *on substances* ", and (ii) ECHA's interpretation is contrary to recital 117. As regards argument (i), the complainant's interpretation is compatible with the



wording of the relevant provision. However, and as ECHA correctly observed, Article 119(2)(b) of the REACH Regulation also obliges ECHA to make publicly available information on the total tonnage band in which the substance was registered. This type of information does not constitute information " *on substances* " in the strict sense advocated by the complainant. Given that Article 119(2)(b) of the REACH Regulation obliges ECHA to publish information contained in the safety data sheet (other than information that already has to be published pursuant to Article 119(1) of the REACH Regulation) and that it is undisputed that a registrant's name forms part of that information, the Ombudsman considers that ECHA's interpretation is plausible. ECHA did not specifically address argument (ii). However, there is nothing in recital 117 that would suggest that ECHA's interpretation was manifestly wrong.

32. The complainant also criticised ECHA's approach by referring to the third party representative arrangements foreseen in Article 4 of the REACH Regulation. It appears that where such an arrangement is used, it is not the registrant's name but that of the third party representative that appears on the safety data sheet. However, ECHA correctly observed that Article 10(a)(xi) of the REACH Regulation offers the possibility to request that certain data not be made publicly available on the Internet. It emerges from ECHA's opinion that it would be favourably disposed towards accepting any such request in relation to names. In fact, it emerged from the correspondence between the complainant and ECHA (see point 12 above) that, in the meantime, the complainant made a number of such requests to ECHA which were all approved. ECHA also advised the complainant to consider doing so with regard to the publication of further registration dossiers. In these circumstances, it appears that the publication of registrants' names is not unavoidable and that ECHA would not proceed to such publication if a justified request for confidentiality to that effect is made.

33. Against this background, the Ombudsman considers that ECHA's interpretation of Article 119(2)(d) of the REACH Regulation is reasonable.

34. Finally, the complainant argued that the amount charged for a confidentiality request is disproportionate in relation to the registration fee and does not reflect the work to be carried out by ECHA pursuant to Article 74(3) of the REACH Regulation. In this context, it is appropriate to note that the fees to be charged by ECHA, including fees for a confidentiality request pursuant to Article 10(a)(xi) of the REACH Regulation, are laid down in Commission Regulation 340/2008 [6] . It follows that, in principle, since it complied with Regulation 340/2008, ECHA could not be found to have committed maladministration. It may also be useful to add that Regulation 340/2008 provides that the structure and amount of the fees should take account of the work required by the REACH Regulation and should be fixed at a level which ensures that the revenue derived therefrom, together with other sources of ECHA's revenue, is sufficient to cover the cost of the services delivered [7] .

35. In light of the foregoing, the Ombudsman closes this case with a finding of no maladministration.

B. Conclusion



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

No maladministration was found in the present case.

The complainant and ECHA will be informed of this decision.

Emily O'Reilly

Done in Strasbourg on 12 March 2014

[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] *" Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users. "*

[3] The relevant parts of recital 117 read as follows: *" EU citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. A transparent means of achieving this is to grant them free and easy access to basic data held in the Agency's database, including brief profiles of hazardous properties, labelling requirements and relevant Community legislation including authorised uses and risk management measures... "*

[4] The obligation to compile a safety data sheet is intended for the benefit of third parties.

[5] The review process was initiated by ECHA's Management Board Advisory Group on Dissemination. The Advisory Group was composed of members of the Management Board from different Member States, and representatives of the Commission, industry, trade unions and NGOs. The industry representative came from the European Chemical Industry Council, of which the complainant was a member.

[6] Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and



Restriction of Chemicals (REACH), OJ 2008 L 107, p. 6.

[7] See recital 2 of Regulation 340/2008.