



Recommendation of the European Ombudsman in case 1336/2017/JAS on the European Commission's refusal to grant access to its catalogue of nanomaterials used in cosmetics, as well as to related notifications from cosmetics manufacturers

Made in accordance with Article 3(6) of the Statute of the European Ombudsman [1]

The case concerned a request for public access to a catalogue of nanomaterials used in cosmetic products and to related notifications made by cosmetics manufacturers. The European Commission, which had not completed the catalogue on time, argued that no such document existed when the complainant, an environmental NGO, made its request. The Commission also argued that it had no existing search tools to extract the requested notifications from its database.

The Ombudsman found that while the final version of the catalogue had not been published when the complainant made its access request, the Commission had failed to consult the complainant as to whether it would want access to any of the existing draft versions. This constituted maladministration.

The Ombudsman also found that some of the notifications could in fact have been extracted from the Commission's database. Concerning the other notifications, the Commission failed to look for a solution in consultation with the complainant. These failures also constituted maladministration.

The Ombudsman therefore recommends that the Commission grant the complainant access to those notifications that can be extracted from its database and that it tries to find a solution regarding the others. As the catalogue of nanomaterials has now been published, the Ombudsman does not consider it necessary to recommend the disclosure of any drafts.

Background to the complaint

1. In December 2016, the complainant, an environmental NGO, asked the European Commission for public access [2] to "the Catalogue foreseen by Article 16(10)(a) [of the Cosmetics Regulation [3]] or, if such catalogue does not yet exist, to the notifications foreseen by Article 13(1)1 for cosmetics including nanomaterials, as well as the information notified under Article 16(3)."

2. The Cosmetics Regulation is the main regulatory framework for cosmetic products. It



establishes rules for cosmetic products to ensure the functioning of the EU market and a high level of protection of human health [4]. Manufacturers must register their cosmetic products on the cosmetic products notification portal [5] (CPNP) [6]. The notification (the “Article 13 notification”) must, among other things, specify whether the product contains **nanomaterials**. The Cosmetics Regulation defines “nanomaterial” as “*an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 [nanometres]*” [7].

3. In addition, cosmetic products containing nanomaterials other than colourants, preservatives and UV-filters, and not otherwise restricted by the Cosmetics Regulation, are subject to an additional procedure. These products require a specific notification (the “Article 16 notification”) on the CPNP six months before placement on the EU market [8].

4. Under the Cosmetics Regulation, the Commission was obliged to make publicly available, by 11 January 2014, a **catalogue of all nanomaterials** used in cosmetic products placed on the market [9]. However, the Commission failed to comply with this deadline.

5. In response to the complainant’s access request, the Commission stated, in December 2016, that the catalogue would be published on its website “*in the next weeks*”. In the meantime, disclosure of the catalogue was prevented by the need to protect the Commission’s decision-making process [10]. Access to the requested notifications was prevented by the need to protect commercial interests [11]. The complainant asked the Commission to review its decision not to disclose the catalogue or the notifications [12].

6. In February 2017, the Commission replied that no document falling within the scope of the complainant’s request for access to the catalogue existed yet. Concerning the “Article 13” and “Article 16” notifications, the Commission argued that it had no routine search tool which would allow extracting the notifications from its database, the CPNP. The Commission claimed to be unable to respond positively to the complainant’s request.

7. In June 2017, the Commission finally published the catalogue of nanomaterials used in cosmetic products placed on the market [13]. The catalogue was based on information notified to the Commission through the CPNP.

8. In July 2017, the complaint turned to the Ombudsman.

The inquiry

9. The Ombudsman opened an inquiry into the complainant’s allegation that the Commission wrongly refused to grant access to the catalogue of nanomaterials and related notifications.

10. The Ombudsman’s inquiry team met with the Commission and inspected the relevant files. The Ombudsman also received the complainant’s comments on the results.



Access to the catalogue of nanomaterials

Arguments presented to the Ombudsman

11. In response to the complainant's review request, the Commission argued that "[a] *though the Commission services are indeed working on preparing a Catalogue of nanomaterials used in cosmetic products placed on the market, no document falling within the scope of your request exists yet*". " *Given that no document has been identified as falling within the scope of your request, the Commission is not in a position to handle the first part of your request*".

12. The complainant disagreed. It referred to a number of meeting minutes where the Commission had referenced different "finalised" versions of the catalogue [14].

13. At the meeting with the Ombudsman's inquiry team, the Commission explained that the drafting of the catalogue had been difficult and complex, faced with a vast amount of data (the Commission's database contains approximately 1.4 million "Article 13 notifications" and more than 900 "Article 16 notifications") of sometimes questionable quality (for example, some substances registered did not fulfil the criteria of nanomaterials). The Commission therefore had to delay publication and repeatedly go back to the Member State authorities and stakeholders to work together on improving the data notified by operators to be able to publish a catalogue of acceptable quality.

14. When dealing with the complainant's access request, the Commission considered that the catalogue did not yet exist because, although the Commission was working towards finalising the existing internal drafts, these had not yet reached the minimum level of consolidation necessary for them to constitute the "catalogue of nanomaterials" requested by the complainant. The complainant had not requested public access to any drafts, but to "*the Catalogue foreseen by Article 16(10)(a) [of the Cosmetics Regulation]*". That document did not exist when the Commission took its decision on the complainant's review request.

15. The complainant argued that its request had been sufficiently precise to allow the Commission to identify the existing draft version of the catalogue as its subject. In any event, if the Commission was uncertain as to whether the complainant wanted access to the draft version, it should have consulted with the complainant to clarify the request [15].

The Ombudsman's assessment

16. Essentially, the Commission argues that because the catalogue had not yet been completed at the time of the complainant's access request, there was not yet a "catalogue", but merely internal draft versions, which did not fall within the scope of the request.

17. The Ombudsman is not convinced by this argument, which is neither citizen friendly, nor in line with the EU public access rules. If the catalogue had been completed and published,



the complainant would obviously not have had to ask for it. The complainant had clear indications that the Commission had “finalised” versions of the catalogue (see paragraph 12 above). Moreover, the Commission department dealing with the complainant’s access request at the initial stage (as well as a different department dealing with a similar request submitted by the complainant in 2014) had no problem identifying a version of the catalogue that was covered by the complainant’s request (even if it was a draft and might have been covered by an exception to access). These circumstances should at least have raised sufficient doubts to alert the Commission to the need to consult the complainant about the documents which it had and which might have been covered by the request [16] .

18. As established by the EU Courts, “ *whenever the institution to which the application is addressed encounters a lack of clarity in an application for access, for whatever reason, it must contact the applicant in order to define the documents sought as well as possible. The provision is thus one which, in the field of public access to documents, formally translates the **principle of sound administration** , which is one of the guarantees afforded by the legal order of the European Union in administrative procedures. The **duty to assist** is therefore fundamental to ensuring the effectiveness of the right of access [...] . It follows from the foregoing considerations that **the [institution]** may not at the outset reject an application for access on the ground that the document to which it refers does not exist . On the contrary, **it must** in such a case ask the applicant to clarify his request [...] and **assist him** to that end, **in particular by indicating to him the documents which it does hold** that are similar to those referred to in the application for access or which are likely to contain some or all of the information which he seeks. It is only when, despite such clarification, the applicant persists in requesting access to a non-existent document that the [institution] is entitled to reject the application for access on the ground that the subject-matter of that application does not exist ” [17] (emphasis added).*

19. No such consultation took place in this case. The Commission simply rejected the request on the grounds that no catalogue existed. This constitutes maladministration.

20. However, considering that the catalogue requested by the complainant was published in the meantime, it is not necessary for the Ombudsman to recommend disclosure of any drafts.

Access to the Article 13 and Article 16 notifications

Arguments presented to the Ombudsman

21. The Commission stated that the Article 13 and 16 notifications are provided to it through the CPNP. It argued, invoking EU case-law [18] , that “ *there is no routine search tool which would allow extracting [...] the notifications provided by Article 13(1) for cosmetics including nanomaterials, or the information notified under Article 16(3) of Regulation 1223/2009 you request. Therefore, the Commission is not in a position to handle the second part of your request ”.*

22. The complainant argued that the Commission had misapplied the reasoning of the Court



regarding routine search tools.

23. At the inquiry team meeting, the Commission demonstrated the use of the CPNP.

24. The Commission showed that the “Article 13 notifications” requested by the complainant could not be retrieved from the database using its routine search tool because the volume of the data led to a “time-out” (that is, the system aborted the search after a defined period of time before producing any results). The Commission demonstrated that the volume of data was so large that even a search for notifications containing nanomaterials limited to one single Member State was not possible. The Commission explained that the database was not used for such extensive searches, but was mainly used to look up single notifications. Only the Commission’s IT department could have extracted all relevant “Article 13 notifications”, using methods other than “routine search tools”. These other methods were not accessible to Commission staff outside the IT department.

25. The Commission then demonstrated the search for “Article 16 notifications” using the CPNP’s routine search tools. This search was successful and resulted in a list of all such notifications uploaded to the portal. This data could also easily be extracted from the CPNP database. It thus became clear that the Commission’s statements to the complainant on this point had been inaccurate. However, the Commission argued that the list extracted by the CPNP search tool had not been used to create the catalogue, but was used only for facilitating the work of scientific officers. The data used to create the catalogue had been extracted from the database by the IT department using methods other than “routine search tools”. Therefore, the Commission did not consider the CPNP search for “Article 16 notifications” to constitute a “routine” search tool.

26. The complainant argued that, as, in fact, there was a pre-programmed search tool, but given that there was a problem with the volume of data requested, the Commission should at least have contacted it to find “ *a fair solution* ”, in application of the EU public access rules [19] . Since it was possible to search for individual Article 13 notifications, it might have been possible to agree on a sample to be disclosed.

27. Regarding the Article 16 notifications, the complainant argued that the fact that these documents could easily be extracted from the CPNP database means that the Commission’s decision on the complainant’s review request was erroneous. The Commission’s argument that the information used to compile the catalogue was not extracted from the CPNP database by using the standard search but by using the Commission’s IT department is irrelevant to the question whether the Commission was justified to refuse access to the Article 16 notifications based on the statement that “ *there is no routine search tool which would allow extracting [...] the information notified under Article 16(3)* ” of the Cosmetics Regulation.

The Ombudsman’s assessment leading to a recommendation



Article 13 notifications

28. The complainant requested access to all Article 13 notifications that included nanomaterials (not all notified cosmetics do). These notifications are part of the Commission's CPNP database.

29. The case law states: "*The Court has already held that the right of access to documents of the institutions applies only to **existing documents** [...] and that [the EU public access rules] may not be relied upon to oblige an institution to create a document which does not exist. [...] Consequently, so far as electronic databases are concerned, the distinction between an existing document and a new document must be made on the basis of a criterion adapted to the technical specificities of those databases and in line with the objective of [the EU public access rules], whose purpose, [...] is 'to ensure the **widest possible access to documents**'. It is not disputed that the information contained in databases, depending on the structure and the restrictions imposed by the programming of such databases, may be regrouped, linked and presented in different ways using programming languages. However, the programming and IT management of such databases are not included among the operations carried out in the context of **general use by final users**. Those users access information contained in a database by using **pre-programmed search tools**. [...] In those circumstances, **all information which can be extracted from an electronic database by general use through pre-programmed search tools [...] must be regarded as an existing document**. It follows that the institutions [...] may be led to establish a document from information contained in a database by using existing search tools. On the other hand [...] any information whose extraction from a database calls for a **substantial investment** must be regarded as a new document and not as an existing document. Accordingly, any information which would, in order to be obtained, require an **alteration either to the organisation of an electronic database or to the search tools currently available** for the extraction of information must be considered to be a new document*" [20].

30. The demonstration of the CPNP database showed that the Commission does have a pre-programmed search tool to look for Article 13 notifications. The Commission's statement to the contrary was thus incorrect. The issue was not a lack of a pre-programmed search tool but the volume of the information to be extracted, which in document terms would mean a very long document or a very large number of documents.

31. The Ombudsman considers that, in line with its duty to assist citizens wishing to obtain documents held by the EU institutions, the Commission should have informed the complainant of this fact and it should have given it the opportunity to find a fair solution, such as by limiting the scope of its access request [21]. The failure to have done so and the incorrect statement that no search tool existed constitutes maladministration.

32. The Ombudsman will therefore recommend that the Commission contact the complainant with a view to establishing whether it would be interested in obtaining a sample of Article 13 notifications and, if it would, to agreeing the possible size and scope of such a sample.



Article 16 notifications

33. The demonstration of the CPNP database showed that a pre-programmed search tool allowing all Article 16 notifications to be extracted does indeed exist (there are a lot fewer Article 16 than Article 13 notifications [22]). This aspect of the request could therefore have been readily fulfilled and the Commission's statement to the contrary was incorrect.

34. The Ombudsman considers it irrelevant whether that search tool was used to create the catalogue or not. The complainant's request for the notifications was not made in those terms. When the Court mentions " *normal and routine search* " [23] , it simply refers to searches carried out using the standard, that is, routine, pre-programmed search tools [24] , regardless of the purpose of that search tool. The CPNP search tool clearly is such a pre-programmed search tool.

35. The Commission's failure to grant the complainant access to the Article 16 notifications constitutes maladministration. The complainant has indicated to the Ombudsman its continued interest in obtaining such access.

36. The Ombudsman will therefore recommend that the Commission provide the complainant with the list of all Article 16 notifications uploaded to the CPNP, redacting only those parts that are covered by an exception to access provided by law [25] .

Recommendation

On the basis of the inquiry into this complaint, the Ombudsman makes the following recommendations to the Commission:

The Commission should ask the complainant if it wants a sample of Article 13 notifications and provide the complainant with the list of all Article 16 notifications uploaded to the CPNP, redacting only those parts that are covered by an exception to access provided by law.

The Commission and the complainant will be informed of this recommendation. In accordance with Article 3(6) of the Statute of the European Ombudsman, the Commission shall send an opinion by **15 June 2018** .

Emily O'Reilly

European Ombudsman

Strasbourg, 14/03/2018



[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] In accordance with 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.

[3] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, OJ 2009 L 342, p. 59, consolidated version available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1516965777619&uri=CELEX:02009R1223-20171225>

[4] Article 1 of the Cosmetics Regulation.

[5] https://ec.europa.eu/growth/sectors/cosmetics/cnpn_en

[6] Article 13(1) of the Cosmetics Regulation.

[7] Article 2(1)(k) of the Cosmetics Regulation.

[8] Article 16(3) of the Cosmetics Regulation.

[9] Article 16(10)(a) of the Cosmetics Regulation.

[10] Article 4(3) of Regulation 1049/2001.

[11] Article 4(2), first indent, of Regulation 1049/2001.

[12] By making a so-called "confirmatory application".

[13] Available at: <http://ec.europa.eu/docsroom/documents/24521>

[14] For example: At its meeting of 21 September 2016, the Commission informed the Working Group on Cosmetic Products that "*the draft catalogue **has been finalized** and that internal approval is being awaited before its publication*" (emphasis added, minutes available at:

<http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=31239&no=2>).

[15] In accordance with Article 6(2) of Regulation 1049/2001.

[16] Article 6(2) of Regulation 1049/2001.

[17] Judgment of the General Court of 26 October 2011, *Dufour v ECB*, T-436/09, ECLI:EU:T:2011:634, paragraphs 30-31.



[18] Judgment of the Court of 11 January 2017, *Typke v Commission* , C-491/15 P, ECLI:EU:C:2017:5.

[19] Article 6(3) of Regulation 1049/2001.

[20] Judgment in *Typke v Commission* , cited above, ECLI:EU:C:2017:5, paragraphs 31-40.

[21] Article 6(3) of Regulation 1049/2001.

[22] See paragraph 13.

[23] Judgment in *Dufour v ECB* , cited above, ECLI:EU:T:2011:634, paragraph 153.

[24] See also Judgment in *Typke v Commission* , cited above, ECLI:EU:C:2017:5, paragraph 47.

[25] Article 4 of Regulation 1049/2001.