Reply by the Commission to the European Ombudsman's Own initiative inquiry - Ref. OI/2/2023/MIK

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY OF THE INQUIRY

The Ombudsman's own initiative inquiry concerns the risk management of hazardous chemicals by the European Commission. In particular, it refers to the time taken for the Commission to adopt measures under the REACH Regulation[1], based on recommendations and opinions of the European Chemicals Agency ('ECHA'), as well as the transparency of the 'comitology procedures'. The Ombudsman highlights that it is of utmost importance for public health and the environment that the Commission fulfils its role as risk manager as swiftly and transparently as possible, recalling the recent REACH evaluation and the ambitions of the 'Chemicals Strategy for Sustainability: Towards a Toxic-Free Environment', where the Commission emphasised the need to respond rapidly to scientific findings regarding dangerous chemical substances.

In a recently conducted public consultation, the Ombudsman received concerns by civil society on the time taken by the Commission to regulate hazardous substances under REACH. Preliminary investigations by the Ombudsman's team confirmed the concerns raised as regards the time taken for inclusion of substances in Annex XIV ("the authorisation list") and adoption of restrictions.

In addition to the concerns regarding the time taken by the Commission to adopt the above types of measures under REACH, the Ombudsman highlights concerns about the lack of transparency of the 'comitology procedures', which the Commission has to follow in the adoption of implementing regulations and decisions under REACH. The concerns put forward are that these procedures provide for limited information being made publicly available, which makes it difficult for the public to hold the Commission and the Member States to account for their actions.

Following the Ombudsman's original inquiry of 8 June 2023, the Commission provided its reply on 29 August 2023. During a meeting with the Ombudsman's inquiry team on 19 September 2023, Commission staff provided answers to a number of additional questions from the Ombudsman's inquiry team, as reflected in the report of the meeting.

The Ombudsman asks the Commission to provide a written reply to 5 questions, which aim at clarifying a number of issues included in the Commission's written reply and discussed during the meeting with the Ombudsman's inquiry team.

[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 L 396, 30.12.2006, p. 1).

II. THE COMMISSION'S COMMENTS TO THE INQUIRY

Question 1

What was the average time taken by the Commission to present a draft measure to the REACH Committee, counting from the receipt of the opinions from the ECHA, in the procedure for inclusion of substances in Annex XIV to the REACH Regulation, for introducing restrictions, and for granting individual authorisations? Please provide the average time separately for each procedure. For each procedure, please provide the average value for five cases in which the time taken by the Commission was the shortest and for five cases in which the time taken by the Commission was the longest.

- Include substances on the authorisation list[2]:
  - average time **14,9 months**
  - average value for five cases with the shortest time taken **10 months**
  - average value for five cases with the longest time taken **21 months**

- Grant/refuse authorisations[3]:
  - average time **14,5 months**
  - average value for five cases with the shortest time taken **2,9 months**[4]
  - average value for five cases with the longest time taken **34,7 months**[5]

- Introduce restrictions[6]:
  - average time **9,9 months**
  - average value for five cases with the shortest time taken **3 months**
  - average value for five cases with the longest time taken **24,9 months**

Question 2

What was the average time given to the members of the REACH Committee to assess the draft before the relevant meeting (discussion)? Please provide the average value separately for each procedure.

- Include substances on the authorisation list: average time given **4,7 weeks**
- Grant/refuse authorisations: average time given **2,8 weeks**[7]

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[2] Data on eight regulations (ten ECHA recommendations), published in the Official Journal until 30 November 2023.

[3] Data on 210 applications for authorisations, with summaries of decisions granting or refusing authorisation published in the Official Journal since the entry into force of REACH until 30 November 2023, as well as 18 applications under discussion in the REACH Committee as of 30 November 2023.

[4] Covering DT_Yara, SD_Gruppo Colle, SD_Bussi 2020, CT_Rimex and Diglyme_Acton2.

[5] Covering CT_HAPOC2, Diglyme_Acton1, CT_REACHlaw,CT_Cromomed and CT_Dornbracht.

[6] Data on 28 restrictions adopted in accordance with the Article 68(1) procedure under REACH and published in the Official Journal since the entry into force of REACH until 30 November 2023, as well as one restriction having received a favourable opinion in written procedure by the REACH Committee and one restriction under discussion in the REACH Committee as of 30 November 2023.

[7] To note that in the latest years the practice is to share the drafts with the Members of the REACH Committee not later than 3 weeks in advance of the meeting, otherwise the relevant agenda items is dropped (unless there are exceptional reasons of urgency justifying the discussion of a file uploaded late).

- Introduce restrictions: average time given **3,7 weeks**

Question 3

How many times has the Commission referred a case to the Appeal Committee in each procedure? What is the role of the Appeal Committee in REACH processes in practice?

As a preliminary observation, the Commission recalls that Regulation 182/2011 ('the Comitology Regulation'), which created the Appeal Committee, does not foresee a role for that committee in the regulatory procedure with scrutiny in accordance with Article 5a of Council Decision 1999/468/EC ('the old Comitology Regulation).

Decisions on inclusions of substances on the authorisation list and restrictions are taken following the regulatory procedure with scrutiny, where the Appeal Committee is not called to play a role. On the other hand, decisions granting or refusing authorisations are taken following the examination procedure in accordance with Article 5 of the Comitology Regulation, which does indeed foresee a role of the Appeal Committee in certain circumstances, as provided for in Articles 5(3) and (4) of that Regulation. However, the Commission has not referred any decisions granting or refusing authorisations to the Appeal Committee so far. Accordingly, the Appeal Committee has not played a role in REACH processes in practice so far.

Question 4

In how many cases has the Commission requested the applicant to submit a substitution plan or complete the application file in another way following judgments of the EU Courts, as discussed in the written reply and during the meeting? How much time was given to the applicants in these cases to provide the missing documents? Please provide this information in table format (case reference, the name of the substance, the name of the applicant, the missing document(s), the date of the request for additional document(s), the deadline for submitting the document(s) and information about any extensions, if granted).

The substitution plans were requested by means of letters from the Commission services for the following applications:

Substance	**Applicant**	**Date of request - timeframe**	**Date of submission**
Chromium trioxide	Chemservice (use 3)	24/02/2020 – 6 months	24/09/2020*
Chromium trioxide	ReachLaw (use 3)	10/03/2020 – 6 months	10/09/2020
Chromium trioxide	Hapoc 1	10/03/2020 – 6 months	10/09/2020
Chromium trioxide	Hapoc 2	10/03/2020 – 6 months	08/12/2020*
Sodium dichromate	Ormezzano	10/03/2020 – 6 months	10/11/2020*

Substance	Applicant	Date of request - timeframe	Date of submission
DEHP	Deza	06/05/2020 – 6 months	08/12/2020*
MOCA	ReachLaw	10/03/2020 – 6 months	12/10/2020*

***** Extension granted by the Commission upon the applicant's request, for reasons of *force majeure* (COVID-19 pandemic).

Question 5

In how many cases has the Commission obtained additional information needed for the assessment of applications for authorisation, not contained in the opinions of the ECHA committees? What has been the source of the additional information? In particular, does the Commissions rely on in-house and/or external specialists in chemical safety assessment and related scientific areas? If so, how many and what are their responsibilities?

The Commission relies on the ECHA scientific opinions for its assessment and for drafting its decisions. Those opinions are conceived as to provide the Commission with all necessary technical and scientific support for the decision-making, thus there is usually no need of additional information to be provided, e.g., by applicants or by other stakeholders[8].

Requests as such have been very exceptional and have been submitted to obtain specific information, not required in the application, although necessary to address certain Member States' concerns, clarify aspects of the applications (e.g., whether a specific risk management measure recommended by RAC is already in place), solve specific issues or unlock the decision-making process. However, in no case additional information has been or can be aimed at remedying incomplete applications where the conditions for authorisations are not met.

Beside the minor requests for clarifications submitted as regards individual applications, the Commission has undertaken a systematic/horizontal exercise only in two circumstances, as explained in the following two paragraphs. Such requests were aimed at obtaining figures indicating the commitment of applicants to reduce the quantities of the substance used throughout the coming years, which the Commission intended to include as an obligation in the authorisation decisions. None of those cases required a scientific/technical assessment by ECHA or external consultants, as the information submitted was factual and it was possible to process it without the need of a specific expertise.

The additional reduction obligation, discussed for the first time in 2022 during the scrutiny of certain applications for authorisation for the substances 4-tert-OPnEO and 4-NPnEO, was

[8] Sometimes applicants and other stakeholders share spontaneously additional information of relevance for specific cases (e.g. highlighting the importance of granting a certain authorisation, or the improvement of certain risk management measures since the time of submission of their application). The Commission services usually take notes of those submissions and share them with the Member States for transparency reasons, although it is rare that those have an impact on the outcome of decisions, nor that an additional scientific assessment by ECHA or other consultant is required.

aimed at replacing very burdensome and disproportionate risk management measures recommended by ECHA. This approach was supported by the REACH Committee and eventually included in the adopted decisions. It concerned the following files, mostly regarding uses for medical or pharma sector:

1. 4-tert-OPnEO_Siemens 2
2. 4-tert-OPnEO_Abbott1
3. 4-tert-OPnEO_Biokit
4. 4-tert-OPnEO_Becton
5. 4-tert-OPnEO/4-NPnEO_Quiagen
6. 4-tert-OPnEO/4-NPnEO_Roche
7. 4-tert-OPnEO/4-NPnEO_Beckman

[redacted]

III. CONCLUSIONS

As already acknowledged in the reply of 29 August 2023, the Commission fully understands that the time it needs to actually process draft restrictions, inclusions in the authorisation list and authorisation decisions from receipt of the file from ECHA may appear slow. However, a close analysis of the procedures which the Commission is bound to comply with, as well as the practical constraints under which these procedures take place, shows that large parts of the timelines are not within the control of the Commission, while other parts are inextricably linked to the Commission's commitment to Better Regulation and to the Commission's

[9] More cases are upcoming as soon as the specific opinions are assessed and it is concluded that the same approach should be applied.

responsibilities in laying down measures, clarified in particular in the restrictions area by the General Court and in the area of authorisation decisions by the Court of Justice, and considered also in the area of inclusions in the authorisation list. The complexity of recent files, especially due to the tendency towards wide-scope restrictions as well as the number of authorisation decisions, is also becoming an increasingly significant factor affecting timelines. In any event, the Commission is willing to examine how standard internal procedures could be applied in a more efficient manner, while still safeguarding the principles of collegiality and shared responsibility for the coherence and quality of the Commission proposals.

Similarly, as regards authorisations, as explained in detail in the Commission's reply of 29 August 2023, experience has showed that the 3-month deadline laid down in 2006 in Article 64(8) REACH for preparation of a draft authorisation decision has proven certainly unrealistic in the light of the Commission's responsibilities under the authorisation title of the REACH Regulation, including the obligation to carry out a thorough assessment of each application for authorisation and relevant ECHA opinion. This takes into account, among others, the minimum time for the Commission's internal procedures, the complexity of the files in terms of legal and technical issues which often require lengthy discussions between the services and within the REACH Committee, and the significant impact of the recent case law[10].

The Commission has been reflecting on how to improve processes. For this purpose, the activities of a working group involving Member State representatives, ECHA and the Commission have resumed on 13 December 2022 to discuss the most important stumbling blocks in terms of opinion- and decision-making process and ensure simplification and streamlining. Depending on the conclusions still to be agreed, it will be decided whether more meetings would be necessary and the nature and extent of the follow-up actions. The setting of that working group has been used in the past years to discuss other authorisation-related matters (the last time it had been scheduled in 2020).

For the Commission
Thierry BRETON
Member of the Commission

[10] As previously mentioned, lengthy process of re-assessment of all pending files had to be carried out as a result of the General Court judgment T-837/16 of 7 March 2019 (Kingdom of Sweden v European Commission) and relevant appeal case C-389/19 P, as well as the more recent judgment of the case C-144/21 (European Parliament v European Commission). The follow-up included the process of adjusting both ECHA's and the Commission's approach to make it compliant with the relevant findings.