Opinion of the Commission on a Recommendation from the European Ombudsman Own initiative inquiry, ref. OI/2/2023/MIK

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

On 17 October 2024, the European Ombudsman addressed a letter to the President of the European Commission in relation to its own initiative inquiry OI/2/2023/MIK[1]. While the inquiry initially covered both restrictions and authorisations under REACH[2], as well as the related inclusion of substances in Annex XIV, i.e. 'the authorisation list', the recommendation included in that letter focuses only on how the Commission decides on applications for authorisations for uses of substances of very high concern. The recommendation raises concerns about delays in the decision-making process, and a lack of transparency.

Under REACH, companies can apply for authorisation for the use of substances of very high concern listed in the authorisation list within a deadline, i.e. *the latest application date* according to REACH Article 56(1)(d). The European Chemicals Agency's (ECHA's) Risk Assessment Committee ('RAC') and Socio-economic Analysis Committee ('SEAC') have 10 months to assess the application and issue their opinion. During the ten months, ECHA also carries out a third-party consultation on each application. Upon receipt of the opinion, the Commission has three months to prepare an authorisation decision. If an application is submitted before the latest application date, the applicant can continue using the substances in the EU until a decision is taken by the Commission on their application.

The Ombudsman found that, while the statutory deadline set in REACH is three months for preparing authorisation decisions, it took the Commission on average 14.5 months and, in some cases, several years to prepare draft decisions for granting or refusing authorisations.

The Ombudsman has preliminarily found that the following facts constitute **maladministration**:

- The systemic delays and the Commission's consequent failure to respect statutory deadlines in the decision-making process;
- The Commission failure to ensure sufficient transparency of the decision-making process.

The Ombudsman **recommends** that the Commission:

- Reviews its internal procedures to comply with the deadline of three months for preparing authorisation decisions;
- Applies the rule that it is up to applicants to demonstrate that they have satisfied the legal conditions for obtaining the authorisation by providing sufficient information and swiftly refuse authorisations for non-compliant applications;
- Ensures better transparency of the decision-making process, by publishing more substantial summary records of the REACH Committee meetings.

[1] Recommendation on the risk management of dangerous chemical substances by the European Commission, case OI/2/2023/MIK; https://www.ombudsman.europa.eu/en/case/en/63908

[2] Regulation 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 396/1.

II. THE COMMISSION'S OPINION TO THE EUROPEAN OMBUDSMAN'S RECOMMENDATION

General observations

The Commission stresses that REACH is the most advanced and comprehensive chemicals legislation in the world and that it is fully committed to its effective implementation and to the protection of human health, the environment and industrial competitiveness.

Before addressing in detail each individual recommendation, it is appropriate to clarify the Commission's general understanding of the root causes that have led to delays in the decision-making under REACH authorisations, which substantially differs from the Ombudsman's reading of the facts in the recommendation.

In particular, the key element underlined by the Ombudsman on the delays in the overall process is linked to alleged leniency by the Commission towards applicants, so as to avoid refusing authorisations when applications are incomplete, or when the applicant has not discharged its burden of proof. This does not correspond to the practice implemented so far. This claim also assumes that swift refusals of incomplete applications would have alleviated the delay issues, which, in the Commission's view, is not factually correct.

On the contrary, in the Commission's understanding, other elements, which were not given prominence in the recommendation, have played a substantial role in causing delays in the process, and have severely impacted the decision-making process. The Commission explains this further, in the points below.

a) Significant increase in applications for authorisation

The Commission and ECHA have experienced a steady, and then sharp, increase in the workload related to the number of applications for authorisation since the authorisation system was set up. When the authorisation system was rolled out in 2013, on average 10 to 20 decisions were adopted every year. Over the years, that number has increased steadily, and in 2024 the Commission will have prepared over 90 authorisation decisions which will have been then voted in the REACH Committee (compared to 9 in 2016). This huge influx of applications was unexpected and, neither ECHA, nor the Commission, have the capacity to deal with it, which has led to unwanted delays and backlog.

The inclusion in the authorisation list of substances with wide-spread uses covering many industrial sectors, such as chromium (VI) substances and octyl-phenol ethoxylated, has played a role in creating this backlog and has saturated the entire REACH authorisation system. The Commission takes this situation very seriously.

This heavy workload has had a significant impact on the overall time required to decide on the applications. This time is spent not only on the drafting of decisions (in 2024, the Commission has on average drafted one authorisation decision every three working days), but also and above all, on the verification of the robustness and completeness of ECHA opinions on all substantial elements (e.g. the reasoning on suitability of alternatives, review period, risk management measures) and, ultimately, on ensuring that the decisions are consistent for similar applications.

Verification of the robustness and completeness of ECHA opinions, as well as ensuring consistency, are key Commission tasks, as confirmed by the case law (see point b below). Those tasks have often required joint assessment of opinions on similar applications received at different points in time, to ensure that, while respecting a case-by-case assessment, a consistent way forward was implemented. This has been the case for instance of a significant

number of applications for the functional uses of chromium(VI) in various industry sectors or for the use of octyl-phenol ethoxylated as a surfactant in the pharmaceutical sector.

The Ombudsman, in its recommendation, stated on the matter that *"When faced with a significant surge in the number of applications, as happened in the past, the Commission should strictly adhere to the principle that it is up to the applicant to demonstrate that they have fulfilled the conditions for authorisation under the REACH Regulation.*[3]*"* Such statement appears to confirm the Ombudsman's assumption that refusing an authorisation is the solution for reducing the backlog of authorisation applications waiting to be decided upon.

In this regard, it is important to underline that in almost all of these applications processed so far, including the most recent ones, the opinions of RAC and SEAC have been positive, and in principle justifying granting an authorisation by the Commission.[4] A swift refusal in such cases (fulfilling the requirements for an authorisation), would certainly end up in legal challenges. Contrary to the Ombudsman's allegation, the Commission has not hesitated to present to the REACH Committee refusals where it has considered that the burden of proof was not discharged by the applicants (seven decisions[5] in the last two years).

b) Two Court judgments annulling authorisation decisions (2019 and 2023)

The outcome of cases T-837/16 (including the appeal C-389/15 P[6]) and C-144/21[7], annulling two Commission decisions granting authorisations, triggered important changes in the interpretation of REACH requirements for applications for authorisation, compared with the practice followed until then[8]. These changes had a major impact on the duration of the process. The Ombudsman's statement that *"Pending court cases cannot justify the significant and systemic delays encountered by the Commission […]"*[9] does not take into account the complexity of the process triggered by those judgments.

Firstly, given their possible far-reaching impact, the judgments required a thorough analysis, involving the relevant Commission services and ECHA, as well as discussion with the Member States in the REACH Committee. Changes in the ECHA Guidance were also required. During this time, and until the conclusion on the interpretation was finalised, no decisions could be discussed and voted.

Secondly, once this work was finalised, the Commission had to carry out an in-depth re-assessment of all pending applications for authorisation (e.g. for case C-144/21, this meant over 120 applications), to ensure that such applications were compliant with the findings of the judgments. For pending applications that were considered non-compliant with the Courts' interpretation of REACH requirements, the Commission had to give applicants the possibility to complement the information accordingly, given that they could not have known this interpretation when they submitted their applications. This caused additional delays of over a

[3] Paragraph 30.
[4] RAC and SEAC flags possible shortcomings, in their opinion, while the Commission is in charge of granting or refusing an authorisation.
[5] SD_Gruppo Colle, SD_Ormezzano, CTPhT_DEZA, CTPhT_Bilbaina, Lead sulfochromate yellow and Lead chromate molybdate sulphate red_DCC. Maastricht B.V., MOCA_REACHLaw. DEHP_Deza (the last two decisions were not adopted since the applicants withdrew the applications).
[6] Case T-837/16, Kingdom of Sweden v European Commission; appeal Case C-389/15 P, European Commission v Kingdom of Sweden.
[7] Case C-144/21, European Commission v European Parliament.
[8] For instance, the Court required the submission of a substitution plans as mandatory element for certain applications for authorisations, contrary to the practice followed before.
[9] Paragraph 39.

year for the impacted files, since the additional information had to be assessed by SEAC, and dedicated addenda were issued.

c) Significant initial divergences in positions among the Member States

While the regulatory deadline of three months is for the Commission to *prepare* a draft decision to be submitted to the REACH Committee, discussions in the REACH Committee have also impacted the timing of the decision-making process. Positioning of Member States and likelihood of support by a qualified majority are key elements taken into account by the Commission in identifying specific measures/provisions in the decisions before presenting new drafts.

For instance, regarding a group of authorisation applications for 'decorative' uses of chromium trioxide, Member States showed significant divergences on key provisions of the decisions. This required an extensive general discussion, e.g., on the length of the review periods or on the conclusion on whether suitable alternatives are available, before the Commission was able to establish a defined way forward in all decisions for that group, and to present new decisions to the Committee. Such divergences lasted several REACH Committee meetings, resulting in a year-long blockage.

Detailed opinion on the individual recommendations

As recognised in the latest REACH review[10], the REACH authorisation system has delivered benefits in terms of shifting the burden of proof to industry and in increasing substitution of substances of very high concern. However, the system has proven very burdensome to implement, as certain assumptions made when REACH was adopted did not materialise during its implementation, in particular the expectation that entire industry sectors would be covered efficiently by a single 'upstream' application for authorisation made by e.g. a supplier on behalf of all its downstream users.

The REACH authorisation system has matured over the last ten years and has constantly been improving since its outset. Most applications for authorisation submitted today are made by downstream users and are more detailed and better substantiated than they used to be. These users have drawn on the lessons learned from the implementation, the refined interpretation of REACH provided by the case law, and the updated Guidance documents by ECHA.

Notwithstanding the above, the Commission is still of the view that the authorisation system is too burdensome to efficiently and effectively achieve its intended objectives, in particular for substances with wide-dispersive uses.

In the sections below, the Commission provides its opinion on individual recommendations.

i) Review internal procedures to comply with the legal deadline of three months: Lessons from the specific case of a chromium(VI) restriction

The experience with **chromium(VI)** has demonstrated clearly that the authorisation system under REACH is not equipped to efficiently risk-manage substances with wide-dispersive uses. For such substances, the system leads to an (excessively) high number of applications. The Commission is therefore working together with ECHA to control the risk of those substances with a REACH restriction, and consequently remove them from the authorisation

[10] Commission Staff Working Document accompanying the Commission General Report on the operation of REACH and review of certain elements (SWD(2018)58 final).

list. On 27 September 2023, the Commission sent a mandate[11] to ECHA requesting it to develop a restriction dossier with a view to manage the risk from several chromium(VI) substances. ECHA is expected to finalise this work and send the dossier to RAC and SEAC by April 2025, after which the committees have one year to formulate their opinions before those opinions are sent to the Commission. Once the Commission has presented its proposal for a restriction to the REACH Committee, all substances as covered by the chromium(VI) restriction will be proposed to be *de-listed* from the authorisation list. This would remove the authorisation requirement for those substances for which there are hundreds of applications for authorisation in the system.

In parallel, the Commission is also being more cautious in adding new substances to the authorisation list, excluding those which may cause a very high number of applications (e.g. lead, Azodicarbonamide, borates). In this respect, there is an ongoing exercise to improve the ECHA recommendations to the Commission on the inclusion of substances in the authorisation list, by reviewing the prioritisation criteria for such inclusion.

As regards the overall functioning of the authorisation process, the Commission will take the opportunity of the announced **REACH revision** to simplify and streamline it. The dual system of authorisations and restrictions will be reviewed to substantially reduce the need for individual authorisations. The relevant regulatory deadlines and internal procedures will be adapted to take such an improved regulatory framework into account.

ii) Apply the rule that the burden of proof is on the applicants and promptly dismiss applications that do not contain sufficient information

The Commission has acknowledged the key importance of the burden of proof in applications for authorisations (following cases T-837/16 including the appeal C-389/15 P, see footnote 6 and is already applying the principle in its assessment. In particular, the Commission no longer includes measures intended to remedy key shortcomings of applications for authorisation (i.e. affecting conditions for granting an authorisation) that should have instead led to a refusal of the authorisation. The Commission has tightened its approach accordingly after that case law.

After the judgments, the Commission has also carefully scrutinised all pending cases to verify their compliance with the findings of the Court. As regards new cases, the Commission is no longer introducing such measures, e.g. remedying a flawed risk assessment or analysis of alternatives. Furthermore, where conditions for granting an authorisation were not met, the Commission has proposed refusals, as already mentioned under point a) above.

Another indication demonstrating a tighter approach in this regard, is the issuing of 'partial' refusals (or 'partial' authorisations), used quite frequently by the Commission. In those cases, the authorisations have been granted only for parts of the uses where the information was complete, while at the same time other 'sub-uses/utilisations' covered by the application were refused where information was insufficient.

iii) Publish more substantial summary records of the REACH Committee

The Commission is committed to transparency and will continue to provide to the public each draft authorisation decision that is up for discussion in the REACH Committee via the comitology registry. As regards this specific Ombudsman's recommendation, the Commission

[11] https://echa.europa.eu/documents/10162/17233/restdp_chromium_vi_mandate_redacted_en.pdf

is ready to implement it by providing more substantial summary records[12] of the REACH Committee's proceedings. These records will include detailed references to the actions undertaken and topics discussed per agenda point.

III. CONCLUSION

The Commission takes note of the Ombudsman's analysis and recommendation following the inquiry and reiterates its full commitment in the implementation of REACH. In general, the authorisation system under REACH has allowed to achieve important goals (e.g. substitution) and has matured over the years.

The Commission acknowledges that the implementation of the authorisation system has experienced difficulties, resulting in delays and, as a consequence, the inability to meet statutory deadlines in REACH. Nevertheless, the Commission does not share the Ombudsman's analysis on the root causes of these issues, as this analysis does not take into account important factual elements. Hence, the Commission considers that the Ombudsman's main recommendations would not necessarily best address the existing difficulties, issues and delays. Further, the Ombudsman's main recommendations relate, to a certain extent, to practices/approaches that are already implemented by the Commission. The Commission has already triggered actions to tackle the delays, including the future restriction of chromium (VI) substances and the REACH revision.

The Commission confirms its commitment to transparency and is open to revise its approach as regards the summary records of the REACH Committee, to provide more substantial information to the public.

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

[12] Summary records are kept in the register in accordance with Article 10(1)(c) of Regulation EC No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, OJ L 55, 28.2.2011, p. 13–18.