FINAL

Comments of the Commission on a further request for information from the European Ombudsman
- Own initiative inquiry, ref. OI/2/2016/RA

I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY

In February 2016, the European Ombudsman opened an own initiative inquiry concerning the delay in the Commission's handling of a number of compliance checks and testing proposals in the framework of the REACH Regulation[1]. The Commission replied to a number of questions from the European Ombudsman in June 2016. This reply allowed the Commission to explain the circumstances of the case and the actions taken in this process.

A meeting between the services of the European Ombudsman and the Commission took place in September 2016 in order to clarify a number of issues. This meeting was very useful also to explain both the procedural and technical constraints which the Commission faces and was welcomed by the European Ombudsman's services who thanked the Commission for its excellent co-operation. That meeting was not only an opportunity to clarify a number of issues orally, it equally gave the Commission the opportunity to provide written answer to some further questions from the European Ombudsman.

II. THE INQUIRY

By letter of 21 December 2016, the European Ombudsman communicated to the Commission that she is likely to take a positive view on the progress now being made by the Commission in dealing with the backlog of cases under REACH. However, she also indicated that she is considering a finding of maladministration on the grounds that the Commission should arguably have contacted all registrants whose cases were pending before it to request them to check and, if necessary, update their registration dossiers. However, before reaching a final conclusion, she invited the Commission to respond.

As this particular issue had not been raised by the European Ombudsman before, the Commission services requested another meeting with the European Ombudsman in order to clarify this issue, in a spirit of loyal cooperation. Further meetings took place on 18 January and 8 February 2017.

III. THE COMMISSION'S RESPONSE TO THE EUROPEAN OMBUDSMAN'S ARGUMENTS

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.

The Commission welcomes the interest shown by the European Ombudsman in this case.

It has carefully considered the arguments made by the European Ombudsman in her letter of 21 December 2016, which focuses on four issues: 1) general communication about the legislative change; 2) communication with individual registrants; 3) the differences in approach taken by the European Chemicals Agency (ECHA) and the Commission in processing the draft decisions; 4) the timeline of the decision-making process.

In response to each of these arguments, the Commission would like to provide the following clarifications:

1) With regard to the ***general communication on the legislative change****:*

The Commission recalls that as with any other EU law, the principle *nemo censetur ignorare legem* applies also in this case. The legislative change to the information requirements in Annex VIII, IX and X of REACH has been first and foremost communicated through the Official Journal of the European Union[2].

Whereas there is no legal obligation for the Commission to communicate beyond the publication in the Official Journal, the legislative change was nevertheless widely communicated or disseminated through various different channels, both by the Commission and by ECHA.

Very soon after its adoption, both the Commission and ECHA announced the legislative change on their respective websites, where all relevant developments about REACH are made known to the public. The announcement on the Commission website[3] also provided links to ECHA website.

As the European Ombudsman mentions in her letter of 21 December 2016, the legislative change and its potential impact on registrants was also made public via ECHA's newsletter, which has over 14,000 subscribers. The Commission also communicated the legislative change publicly via its Expert Group meetings involving the Member States' Competent Authorities for REACH and CLP[4] ('CARACAL meetings'). Other stakeholders, including the chemical industry, NGOs and trade partners also participate in these meetings and are regularly informed orally and in writing about upcoming and adopted legislative changes. The legislative change was reported to the members of CARACAL at the first occasion after it was adopted, i.e. in March 2015[5].

From the above it is clear that the legislative change was duly published in the Official

2 Commission Regulation (EU) 2015/282 of 20 February 2015 amending Annexes VIII, IX and X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards the Extended One-Generation Reproductive Toxicity Study, OJ L 50, 21.2.2015, p. 1.

3 See link: http://ec.europa.eu/environment/chemicals/reach/implementation_en.htm

4 CLP stands for 'Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006'.

5 See Annex 1

Journal and widely disseminated by the Commission.

2) With regard to the ***individual communication to registrants:***

The European Ombudsman states in her letter that, in the manner done by ECHA for cases under examination at ECHA's level, the Commission should have contacted all registrants whose cases were pending before it to request them to check, and if necessary, update their registration dossier.

The principles of legality and legal certainty require that any legal obligation on companies or citizens should be embedded in a formal legal act adopted by the competent authority, e.g. by way of a decision. Therefore an official from the Commission cannot bind the Commission, for instance by sending a letter in which a registrant would be explained what he has to do in a particular case. Hence, the content of any letter to a registrant could at most repeat the general communication on the legislative change already made publicly available.

While the Commission understands in principle the value of targeted and individual communication about legislative changes, ensuring this specific coverage would be disproportionate given the broad outreach ensured through existing communication channels. In line with good administrative practice, the Commission does respond to individual queries from companies and individuals. However, the Commission would point out that neither the general principles of law nor REACH impose on the Commission the obligation to proactively inform individually any existing or potential registrants under REACH of any of its legislative changes. Were the Commission to be obliged to revert to such an approach, this would set a precedent with potentially far-reaching implications not only for other procedures within REACH, but also within other pieces of EU legislation which grant the Commission implementing powers.

As the European Ombudsman acknowledges, according to Article 22 of REACH, registrants are required to update their registration with 'relevant new information' and 'without undue delay'. The fact that the general communication by the Commission and ECHA reached the intended recipients can be inferred from the fact that a number of registrants, including those with evaluation cases pending before the Commission[6], subsequently updated the dossiers with due regard to the amended information requirements.

In view of the above, the Commission found appropriate and compliant with the principle of good administration to send to the registrants concerned all draft Commission Decisions which required further action by them. In doing so, the Commission provided these registrants with the opportunity to take note of their obligations in accordance with the amended annexes of REACH and to comment within 30 days of receipt of the draft Commission Decision. As explained in earlier exchanges with the European Ombudsman, REACH does not place any obligation on the Commission (unlike on ECHA) to communicate its draft decisions to the registrants. However, the Commission decided to do this as a 'good administrative practice'. The Commission considered it was appropriate to do so when the proposals had passed the internal inter-service consultation stage. Notwithstanding the fact that no formal

6 Before September 2016, 11 of the registrants with pending testing proposals examination decision and 2 with pending compliance check decision updated their proposal with EOGRTS testing proposal. They are addressed in separate Commission Decisions.

adoption had taken place when the Commission sent its 'draft decisions' to the registrants, it should be noted that this is the stage in the adoption process at which the Commission usually communicates its draft measures externally, for example when submitting its proposals for amendments to REACH to the REACH Committee.

Even if the consultation of the registrants on the draft decisions which the Commission performed, delays the adoption of the decisions by some months, because of the commenting period granted and the time needed by the Commission to take into account the replies, the Commission believes that this was justified in order to ensure the most appropriate decision would be taken in each individual case. As also explained in earlier exchanges with the European Ombudsman, such draft decisions could only be prepared once all the individual cases were analysed, in view of the Commission's generic approach which had received the full support from the Competent Authorities of the Member States and allowed for shortening and simplification of an otherwise complex and cumbersome adoption procedure for the Commission (which would have involved the individual administrative processing of 216 individual measures).

3) With regard to the **differences in approach taken by ECHA and the Commission with regard to the processing of draft decisions**:

The European Ombudsman in its letter notes that ECHA had engaged in individual contacts with 40 registrants whose testing proposals were being examined and considers that this approach should have been followed by the Commission as well.

The Commission would point out that although ECHA and the Commission are under the same legislative framework when processing testing proposals, there is a fundamental difference in approach by both actors due to their different roles in the decision making process. Pursuant to Article 40 of REACH, ECHA performs a technical and scientific analysis of the testing proposals. ECHA takes decisions on testing proposals after consultation with and on the basis of the unanimous agreement of its Member State Committee. If such agreement is not reached, the draft decision (with all its technical and scientific background) is referred to the Commission. While ECHA has universal powers to examine testing proposals, the Commission's powers in examining testing proposals are limited, by virtue of the principle of conferral of powers, to the testing proposal object of ECHA's draft decision that has been transferred to the Commission. It is therefore clear that ECHA would benefit from updates made by registrants to registration dossiers - regarding testing proposals being processed by ECHA when the amendments to the annexes of REACH came into force. Such updates would enable the registrant to ensure that the technical and scientific analysis performed by ECHA is done on the basis of the new extended one-generation reproductive toxicity study (EOGRTS) and not on the basis of the obsolete Two Generation Reproductive Toxicity Study. However, for the Commission an update of the testing proposal to the new EOGRTS would not change its obligation to decide on the draft decision referred to it earlier. The Commission could not take into consideration the new EOGRTS testing proposals as they would not be part of the object of the referral and hence fall outside its powers.

Therefore, the Commission, as agreed also with Member States' Competent Authorities at CARACAL and the REACH Committee, is bound to conclude the 216 decisions referred to it by rejecting the testing proposals or otherwise finding the procedure without object or, in the case of compliance checks, to find that the registration is or is

not compliant. The Commission will not perform the technical and scientific analysis of the testing proposals updated to the new EOGRTS, as they will have to be examined by ECHA given that they trigger a new testing proposals procedure.

Article 22(e) of REACH requires the registrant to update its registration in case it *'identifies the need to perform a test listed in Annex IX of Annex X, in which cases a testing proposal shall be developed'*. As mentioned above, the Commission has sufficiently informed registrants to enable them to identify the need to perform an EOGRTS. However, the obligation to update a registration only exists as of the moment when a registrant has 'identified the need to perform a test'. The way this requirement is formulated is difficult to enforce and in fact does not provide any incentive for registrants to update their dossier before they are aware an authority will take a decision.

In any event, getting such updates sooner rather than later would have not advanced the procedure of assessing the new EOGRTS testing proposals. This is evidenced by the fact that, for the cases pending in the Commission, ECHA has not taken any decision on the already updated testing proposals as the Agency is waiting until the Commission has made its decisions. This is the case in spite of the fact that the Commission decisions have no bearing on the new EOGRTS testing proposal examination procedure as they will close a different administrative procedure.

In summary, the argument made by the European Ombudsman that *"this could have helped avoid further delays in the implementation of REACH in that more registrants could have provided all the necessary updates, with the result that ECHA would be in a position to move forward with the file evaluations more rapidly"* is based on a misunderstanding, as ECHA is currently not processing any of the updated files from the 216 cases pending decisions by the Commission.

As a consequence, the Commission believes the approach taken, with the support of Member States' Competent Authorities and stakeholders, was the one that best ensured the implementation of the general principle of good administration in view of the complexity of the issue, both scientifically and in in terms of the changes in the applicable legislation, the unusually high number of cases the Commission had to handle with the limited resources available and the existing potential risk of sending an unnecessary and misleading communication to registrants. This approach provides the best scientific result in the shortest time and brings clarity and legal certainty to the administered.

It is important for the Commission to stress that at each stage of this administrative procedure[7], the Commission services have carefully analysed the best way to handle these files, taking into account their scientific nature and the many actors that participate in the procedure: the other services of the Commission, Member States representatives, stakeholders and ECHA. The time invested in ensuring that the most appropriate choices were made and in securing the support of these actors for the proposed way forward allowed the Commission to gain time in the final stages of the process.

The Commission notes the European Ombudsman's concern with events related to this file during the period between July 2015 and January 2016. As explained below and documented in Annex I and II to this reply, the Commission services were, at every step

7 See attachment 2

in the administrative proceeding, searching for the most appropriate way to handle the numerous cases swiftly while ensuring that they would be legally and scientifically sound, as well as clear in terms of obligations for the registrants.

The Commission's work in the period July 2015 to January 2016 focused on a number of major tasks. First, it had to decide if grouping the individual ECHA draft decisions in batches of Commission Decisions was legally sound and administratively appropriate. It was concluded that adopting 216 separate Commission Decisions would be impractical and lengthy. Therefore, after consulting the different Commission services concerned, it was decided that, instead of having 216 separate decisions, the number would be reduced to 16, most of them being addressed to multiple registrants. To be able to group them appropriately, ECHA's draft decisions had to be analysed first. Once the grouping was done, the drafting exercise could start. The difficulty at that stage was to find the appropriate balance between sufficiently precise wording so that the registrants would know what their obligations are, and a scope that was broad enough to encompass the differences between cases and extract only the main obligations. Since the Commission Decisions would be similar to each other, it was found most efficient to agree with the services concerned on a template for a decision, which would be adapted to fit the other situations.

Once drafted, the decisions would have to be translated. Here also a carefully balanced decision was taken to ensure efficient use of the Commission's resources (only request translation in the languages that were needed) while respecting the principle that every addressee should receive the decision in its own language. There were also a number of ancillary but important issues, for example related to confidentiality, which needed to be solved.

At the same time, the Commission dedicated efforts to general communication on the progress made. For instance, the Commission services prepared papers and presentations for meetings with Member State representatives and stakeholders and drafted minutes of these meetings (see attachments), all of which resulted in unanimous votes via written procedure for the three decisions that have been submitted to the REACH Committee. This avoided the often numerous rounds of discussions at the REACH Committee meetings and thereby gained time.

In addition to the administrative efficiency, the approach chosen by the Commission provides the registrants an additional means of legal redress, since they will be able to apply not only to the Courts (for any Commission Decision) but also to ECHA's Board of Appeal (for any decision of ECHA on the updated EOGRTS proposal).

Finally, the Commission wishes to recall that neither registrants, nor NGOs, nor individual citizens have complained to or requested information from the Commission regarding the treatment of these dossier evaluations.

The elements described above show that the Commission exhausted all possible legal and administrative means to speed up the administrative procedure in handling the 216 cases. They also demonstrate that the Commission communicated as much as it could in light of the various constraints and using all available opportunities.

4) With regard to the **timeline of the decision-making**:

A distinction needs to be made between the three Decisions that have taken less time to handle (amongst other reasons because they did not require registrants to be consulted) and the other thirteen Decisions. As mentioned before, the Members of the REACH Committee voted unanimously on the three first draft Decisions by written procedure that closed on 28 of November 2016. The Commission adopted the first decision in February 2017, the second in March 2017 and the third is expected to be adopted at the latest in May 2017[8]. They are sent to registrants shortly after adoption. Once adopted, the Permanent Representations of the Member States were informed of the adoption.

The other thirteen draft Decisions have been sent to registrants for comments on 17 November 2016. The reason for this change in timing compared to the planning submitted in the initial reply to the European Ombudsman is that the Commission decided to revisit the cases and look at the updates made before September 2016 instead of January 2016. The aim was to avoid imposing unnecessary obligations on registrants who have already updated their dossiers and ensure that the cut-off date is closer to the date of adoption of the decisions. The Commission also had to take into account some suggestions by the Members of the REACH Committee. The registrants were granted a commenting period of 30 days from the receipt of the draft Decision. The Commission processed the comments and took them into account in the drafting of the concerned final Commission Decisions.

The Commission will soon submit the draft Decisions for comments to the Members of the REACH Committee for a two week commenting period. Depending on the number and extent of any potential comments from the Members of the REACH Committee, the Commission will modify the draft Decisions again before submitting them to the REACH Committee for a vote (normally by written procedure).The adoption by the Commission should normally take place around two months after this vote. This is expected to take place in July 2017.

IV. CONCLUSIONS

The Commission invites the European Ombudsman, in her assessment of the handling of this case from the point of view of administrative good practice, to fully consider the clarifications set out above related to the administrative, legal and technical constraints faced by the Commission in communicating developments related to the REACH registration dossiers in question.

The Commission continues to treat these cases with utmost priority and expedite them as quickly and transparently as possible.

For the above reasons, the Commission considers that there has been no maladministration in this case.

List of enclosures

- Attachment 1. CARACAL Document CA/19/2015

8 See attachment 3

- Attachment 2. Documents illustrating the different stages of the Commission's administrative procedure between July 2015 and January 2016.

- Attachment 3. Commission implementing Decision C(2017) 690 final , adopted on 9 February 2017 and Commission implementing Decision C(2017) 1384 final, adopted on 9 March 2017 (confidential).