FINAL

Comments of the Commission on the European Ombudsman's own-initiative inquiry - Ref. OI/2/2016/RA

I. THE INQUIRY

By letter of 16 February 2016 the European Ombudsman informed of her decision to conduct 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.

The European Ombudsman questioned why the Commission had not yet adopted 216 evaluation decisions pursuant to REACH following the finalisation of the necessary changes to the Test Methods Regulation and Annexes IX and X of the REACH Regulation in February 2015 and asked about measures it had taken to address this issue. She further enquired about the implications for the objectives pursued by the REACH Regulation, such as the protection of human health.

II. COMMENTS TO GENERAL REMARKS OF THE OMBUDSMAN

Between 2011 and 2014 the Commission received, in accordance with Article 51(7) of the REACH Regulation, 216 draft dossier evaluation decisions concerning the reproductive toxicity information requirement, as during this period no unanimous view could be reached within the Member State Committee (MSC) of the European Chemicals Agency (ECHA). The reason for the disagreement lay in the fact that a new test method had been developed (the EOGRTS - Extended One-Generation Reproductive Toxicity Study) to replace the previously existing method (the Two Generation Reproductive Toxicity Study) as the standard information requirement under REACH.

The regulation at the time did not allow the MSC to reject the Two Generation Reproductive Toxicity Study proposed by the registrants, and request instead that the EOGRTS had to be performed. It was therefore necessary to amend some of the annexes of REACH to explicitly include EOGRTS as the new standard information requirement for reproductive toxicity and define the conditions that determine the precise application of this test method under REACH. The amendment, which took place by the adoption of Commission Regulation (EU) 2015/282, ensured legal clarity and unblocked the procedure both in ECHA's MSC for all future cases and in the REACH Committee for the 216 pending cases.

The newly developed EOGRTS is the preferred method when taking into consideration the objectives of REACH: The EOGRTS ensures that less vertebrate animals will be used in testing as required by Articles 13 and 25 of REACH. Moreover, EOGRTS ensures that the most valuable scientific information is generated. This, in turn, will provide the best possible scientific advice to protect human health and environment and help inform adequate risk management measures.

The EOGRTS is, however, more complex to implement as it includes different modules that may or may not be put into operation, depending on the substance-specific circumstances[1]. There was also scientific controversy on the practical application of the new test method, which led to prolonged discussions in the adoption of the amendment of the REACH Annexes.

For both reasons, there was a need to develop clear guidance. The development of this guidance was undertaken by ECHA in collaboration with stakeholders once the REACH Annexes were amended and proved to be difficult as well, for the same reasons as the development of the amendment of the annexes.

For the reasons above the Commission decided to process the decisions only after the adoption of the amendment and the associated guidance (the latter was completed in July 2015)[2].

III. REPLY FROM THE COMMISSION TO THE OMBUDSMAN'S QUESTIONS

1. Given that the necessary changes to the Test Methods Regulation and Annexes IX an X of the REACH Regulation were finalised in February 2015, why has the Commission still not taken decisions in the pending file evaluation decisions?

First, the Commission submits that an adoption of guidance was necessary following the modification of Annexes. In February 2015, following the modification of the REACH Annexes, there were still different views amongst experts on how to most effectively apply the EOGRTS and ensure optimal results.

As explained in the comments to the general remarks above, the careful preparation of the guidance was absolutely imperative given the high level of complexity, and, specifically, the modularity of the EOGRTS. The ECHA Guidance was expected to not just elaborate on the conditions when the individual modules are to be applied, but also to set out what supporting information is to be supplied in the registration dossier that enable the evaluation of the conditions. Given the diverging views among experts, agreement had to be reached in order to prepare the ECHA Guidance on how to implement the EOGRTS for REACH purposes. The guidance was adopted on 22 July 2015. Following the amendment of the REACH Annexes, the Commission prepared an approach to address the 216 cases. The general approach, agreed also with the Member States and ECHA in 2015, was to request registrants to update their registration dossiers in accordance with the new test method. An assessment of each individual case was therefore required. Furthermore, during the 5-year period since the

[1] TG 443 p.1: "Decisions on whether to assess the second generation and to omit the developmental neurotoxicity cohort and/or developmental immunotoxicity cohort should reflect existing knowledge for the chemical being evaluated, as well as the needs of various regulatory authorities."

[2] In accordance with Article 51(7) of REACH, the Commission is not bound by any legal deadline to adopt its decisions.

referral of the first decisions to the Commission, the situation in a number of cases had changed. The changed circumstances included the fact that some registrants had ceased manufacture or changed the registered tonnage, that there has been a replacement of lead registrant in a joint submission addressed by ECHA's original draft etc. The scientific-technical content of 187 out of 216 evaluated dossiers had also been updated by the respective registrants and only an assessment of all the individual dossiers could reveal whether the information related to the reproductive toxicity had also been modified. For example, in a number of cases, the original testing proposal had since been updated with an adaptation (i.e. using *in vitro* tests or existing scientific information instead of animal testing) or had been replaced with a proposal to use the new EOGRTS test method.

As noted in the Ombudsman's inquiry, the Commission indicated in March 2015 that the individual draft decisions would be presented to the REACH Committee from September 2015 onwards (with an attempt to process all 216 cases within approximately 7 consecutive REACH Committee meetings).

The Commission services, however, in view of the additional delays caused by the need of the Guidance and the need to carry out new individual assessments as explained above, eventually developed an approach to group cases that could each be addressed by a single Commission decision. This grouping aims at an optimal use of the Commission's resources, and hence administrative economy, whereby the overall process is simplified. As a consequence, the final drafting (and the adoption procedure via the REACH Committee) had to await conclusion of the full assessment of all cases by the Commission services in order to enable the attribution of individual cases to the different groups, but also that eventually all 216 cases will be discussed and voted on at the same time in the REACH Committee. This approach was coordinated closely with ECHA, which indicated the clear preference, for planning purposes, to receive all updated testing proposals from the registrants at the same time.

2. What measures does the Commission intend to take to ensure that the decisions are now taken with the utmost urgency?

The approach chosen by the Commission is to group most of the draft decisions into generic decisions, while a few are still being addressed in individual decisions because of their specificity. The Commission is currently preparing all draft decisions with a view to submitting them to the REACH Committee for discussion and vote in Summer 2016. This would allow final adoption of all decisions related to the 216 cases at the beginning of 2017.

3. Other than reducing animal testing, what implications has the backlog had for objectives pursued by the Regulation such as the protection of human health?

The delay in the adoption of the Commission decisions does not affect the placing on the market of the substances by the companies concerned. The REACH legislation foresees that pending the outcome of the evaluation, registrants can continue with their operations.

The delay is expected to have limited impact on human health. The obligation to register substances placed on the market above 100 tonnes per year is set to ensure that adequate information on reproductive toxicity of the substance is either compiled from existing sources or generated by testing. Any potential regulatory risk management measure motivated by concerns related to reproductive toxicity can only be adopted once the information is available. The situation when risk requires to be managed while data is still being generated is however anticipated in REACH as in the meantime, companies are required to take precautionary measures as explained in the reply to question 4.

4. Did the Commission adopt any mitigating measures, while the file evaluation procedure was suspended?

As the registrants can continue with their operations pending the outcome of the evaluation, no specific mitigation measure by the Commission was necessary to avoid adverse economic impacts.

Moreover, the REACH Regulation also requires registrants to specify interim measures in the chemical safety report that must be put in place by companies manufacturing and using the chemicals subject to testing proposal decisions (in accordance with REACH Annex I point 0.5.). Such interim measures are expected to underpin the registrant's obligation "to ensure they manufacture, place on the market or use such substance that do not adversely affect human health or the environment." (in accordance with REACH Article 1 paragraph 3). Assessment of compliance with the provision on interim measures is subject to prioritisation under ECHA's compliance check strategy. The adequacy of the - interim and final - risk management measures taken by the economic operators is subject to enforcement by the Member States Enforcement Authorities.

The principal role of the Commission during the suspension of decisions in the 5-year period was to steer the very complex stakeholder process on the application of EOGRTS under REACH. Only through protracted discussions in the dedicated Commission EOGRTS expert group, CARACAL and the REACH Committee was the Commission eventually able to successfully develop and propose the modification of the regulatory system that unblocked the decision making and enabled use of the modern test method that provides the most adequate information and reduces the number of animals used.

IV. CONCLUSION

As explained, the delays were due in the initial 4 years to the persistent disagreement among Member States experts and in the last 10 months to the time and resources required by the Commission to assess the high number of decisions. The latter assessment shows that the Commission took its full responsibility in trying to avoid as much as possible animal testing, while ensuring a high level of protection of human health and the environment.

The Commission is committed to process the pending decisions swiftly.