European Ombudsman

Emily O'Reilly
European Ombudsman

Mr Jean-Claude Juncker
President
European Commission

Strasbourg, 21/12/2016

Own-initiative inquiry OI /2/2016/RH: request for information

Dear Mr President,

In February 2016, I opened an own-initiative inquiry into delays in the Commission's handling, under the REACH Regulation, of compliance check files and proposals aimed at testing the reproductive toxicity effects of over 200 chemicals. The Commission sent its reply at the end of June 2016. A meeting took place between Commission and Ombudsman staff in September to clarify issues falling within the scope of the inquiry in order to help us fully understand the ongoing processes before deciding on the next step in the inquiry.

I am writing now to convey to you that I am considering a finding of maladministration in this case and would like the response of the Commission before I reach any final conclusion. Please allow me to signal that I am also likely to take a positive view of the progress now being made by the Commission in dealing with the backlog of cases under REACH.

As regards the nature of the possible finding of maladministration, it relates to the delay on the part of the Commission in communicating directly with registrants once the necessary guidance was finalised by the European Chemicals Agency (ECHA) in July 2015.

Specifically, I understand that the Commission intended that registrants would be informed of the amended information requirement for reproductive toxicity via ECHA's Newsletter of April 2015. The Newsletter invited registrants to check that the information in their registration dossiers compliedwith the amended information requirement. I find it difficult to understand why the Commission chose to inform registrants of the regulatory update via an article on page 18 of a 20 page ECHA Newsletter. The article includes the following: *'ECHA has contacted over 40 registrants whose testing proposals are being examined by ECHA to explain the changed information requirements and give timelines for the next steps. Those who need to update*

1 avenue du Président Robert Schuman
CS 30403
F - 67001 Strasbourg Cedex

T. + 33 (0)3 88 17 23 13
F. + 33 (0)3 88 17 90 62

www.ombudsman.europa.eu
eo@ ombudsman.europa.eu

their dossiers with revised testing proposals will receive further advice in the next few months. In addition, there are more than 200 draft dossier evaluation decisions with requests for information on reproductive toxicity pending decision by the Commission.'

Given that some files had been pending since 2011, the Commission —as ECHA did in the case of 40 registrants whose testing proposals it was examining — should arguably have contacted all registrants whose cases were pending before it to request them to check and, if necessary, update their registration file.

I am aware that registrants are themselves required to update their registration 'with relevant new information' and 'without undue delay' (Article 22 of REACH) and submit this information to ECHA. However, the fact remains that ECHA informed registrants individually about the regulatory update, while the Commission did not. The fact that general information was available on ECHA's website, about the EOGRTS as the new information requirement for reproductive toxicity, does not alter this assessment.

My understanding is that the earlier the Commission contacted the registrants, and requested a review of the information already provided by the registrants, the sooner the registrants would have been put on notice that they needed to review and update the information already provided. My view is that an early notification from the Commission would have put them on notice of the need to act. 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.

It is important, however, that the Commission is given an opportunity to respond on this matter before I reach any final conclusion on a finding of maladministration.

It would also be helpful if, in your response, you could confirm that the Commission is adhering to the timetable it has set out, namely, final adoption of all decisions related to the 216 cases at the beginning of 2017. If that is not the case, please outline the new timetable in detail in your reply.

I would appreciate a response at your earliest convenience and at the latest by 28 February 2017.

Yours sincerely,

Emily O'Reilly
European Ombudsman