European Ombudsman

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European Ombudsman

Mr Jean-Claude Juncker
President
European Commission

Strasbourg, 16/02/2016

Own-initiative inquiry[1] (OI/2/2016/RA): Delay 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

Dear Mr President,

This is to inform you of my decision to conduct an inquiry on my own initiative under the heading set out above. In deciding on this inquiry, I was concerned in particular with the possible negative consequences for human health and the environment as a result of delays in the testing/compliance regime.

The European Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (hereinafter 'REACH') aims to improve the protection of human health and the environment from the risks posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. The Regulation also promotes alternative methods for the hazard assessment of substances in order to reduce animal testing. The Regulation seeks to attain these objectives by requiring companies to generate information on the chemicals they produce or import. It is in the public's interest that the Regulation is applied properly and fully

It has come to my attention that, over the past five years, a backlog of at least 216 pending file evaluation decisions (183 proposals aimed at testing reproductive toxicity[2] effects and 33 compliance checks)[3] has built up. My understanding is that the situation dates back to 2011, when the Member State Committee of the European Chemicals Agency (ECHA), the body responsible for processing file evaluations under REACH, began to forward all decisions on

[1] The Ombudsman shall conduct own-initiative inquiries for which she finds grounds. Such inquiries may help to uncover maladministration or to clarify any suspected maladministration. They are intended to be helpful to the public and to the particular institution by addressing systemic matters and promoting good administrative practice.
[2] Reproductive toxicity entails the potential impairment of male and female sexual function and fertility, harmful effects on the developing organism during pregnancy and post-birth, and effects on or via lactation.
[3] The Commission mentioned these figures in material presented to a meeting of CARACAL (Competent Authorities for REACH and CLP, an expert group on the REACH Regulation) on 26 - 27 March 2015.

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reproductive toxicity to the Commission, owing to the lack of the required unanimity within that Committee. Since then, the decisions have been pending before a comitology committee (the REACH Committee), which operates under the joint responsibility of DG Environment and DG Internal Market, Industry, Entrepreneurship and SMEs.

The Commission decided to suspend all file evaluation decisions on reproductive toxicity until the relevant Test Methods Regulation[4] and REACH information requirements were updated to require registrants to conduct a newly available Extended One-Generation Reproductive Toxicity Study (EOGRTS). This decision seems to have been based primarily on the legal obligation under Article 13(2) REACH to reduce animal testing, as EOGRTS is expected to require up to 50% fewer animals than the corresponding previous standard test method. I appreciate also that the Commission expects EOGRTS to contribute to ensuring a high level of protection of human health by identifying adverse effects on reproduction more accurately.

While it is thus somewhat possible to understand the suspension prior to the aforementioned regulatory update on EOGRTS in February 2015, it is difficult to understand the ongoing delay.

In March 2015, the Commission explained to CARACAL (an expert group on the REACH Regulation) that it planned to reject the pending cases and request registrants to resubmit their files in accordance with the updated test method. The Commission expected to present the first draft decisions in the third quarter of 2015. I have not been able, in the meantime, to find information on the progress of the pending cases. Bearing in mind that some of the files have been pending for up to five years, I would in particular appreciate an account on whatever measures the Commission has taken to ensure that the decisions are now taken with the utmost urgency. While Article 51(7) REACH does not set out a particular timeframe for the Commission to adopt a file evaluation decision, it is bound by Article 41(1) of the Charter of Fundamental Rights and by principles of good administration. Recital 50 REACH furthermore notes that *"[i]t is in the public interest to ensure the quickest possible circulation of test results on human health or environmental hazards of certain substances to those natural or legal persons which use them, in order to limit any risks associated with their use."*

I would therefore appreciate if the Commission could respond to the following questions:

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

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

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

[4] Council Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 142, 31.5.2008, p. 1–739.

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

As this concerns a significant number of chemical substances in use in the EU, I would be grateful for your response as soon as possible and by 31 May 2016 at the latest. Please note that I intend to publish the present letter on my website, as well as the Commission's reply.

Should your staff have any queries concerning this inquiry, they may contact Ms Rosita Agnew (+ 32 2 284 25 42), Head of Strategic Inquiries in the European Ombudsman's Office.

Yours sincerely,

Emily O'Reilly