

Resolution on the draft Commission regulation amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties

2017/2801(RPS) - 04/10/2017 - Text adopted by Parliament, single reading

The European Parliament adopted by 456 votes to 115 with 60 abstentions a resolution objecting to the draft Commission regulation amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties.

Parliament observed that according to point 3.8.2. of Annex II to [Regulation \(EC\) No 1107/2009](#), an active substance is **only to be approved if it is not considered to have endocrine disrupting properties** that may cause adverse effects on non-target organisms, unless the exposure of non-target organisms to that active substance under realistic proposed conditions of use is negligible (cut-off criterion for the environment). However, the draft regulation presented on 4 July 2017 **excludes a substance with an intended endocrine mode of action from being identified as an endocrine disrupter for non-target organisms**. Parliament stated that this was contrary to the ruling of the General Court in Case T-521/14.

Since, under these circumstances, the draft regulation could not be considered to be based on objective scientific data related to the endocrine system, Parliament stated that it **opposed the adoption of the draft Commission regulation**.

It made the following observations:

- the draft regulation stipulates that if the active substance being assessed, consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as having endocrine disrupting properties with respect to non-target organisms’;
- this stipulation **effectively creates a derogation from the cut-off criterion** laid down in point 3.8.2. of Annex II to Regulation (EC) No 1107/2009; however, the cut-off criterion in Regulation (EC) No 1107/2009 **constitutes an essential element of the regulation**.

Accordingly, Parliament concluded that the draft Commission regulation **exceeds the implementing powers** provided for in Regulation (EC) No 1107/2009, by modifying an essential regulatory element of Regulation (EC) No 1107/2009, contrary to the recognition of its limits of power in the Court hearing in case T-521/14, and contrary to the fundamental Union principle of the rule of law. In this regard, it stated that even if the developments in scientific and technical knowledge were to provide valid grounds for introducing a derogation as regards the approval conditions of substances with an intended endocrine mode of action, **such a derogation could only be introduced through an ordinary legislative procedure** to amend Regulation (EC) No 1107/2009.

Parliament called on the Commission to **withdraw the draft regulation** and submit a new one by deleting the stipulation described above.