European Parliament
2014-2019

TEXTS ADOPTED
Provisional edition

P8_TA-PROV(2017)0376

Objection to an implementing act: Scientific criteria for the determination of endocrine disrupting properties

European Parliament resolution of 4 October 2017 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 (D048947/06 – 2017/2801(RPS))

The European Parliament,

– having regard 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 (D048947/06) ('draft regulation'),

– having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[1], in particular Articles 4(1) and 78(1)(a) thereof and the second paragraph of point 3.6.5. and point 3.8.2. of Annex II thereto,

– having regard to the judgment of the General Court of the Court of Justice of the European Union of 16 December 2015[2], and in particular paragraphs 71 and 72 thereof,

– having regard to its resolution of 8 June 2016 on endocrine disruptors: state of play following the judgment of the General Court of the European Union of 16 December 2015[3],

– having regard to the Commission communication of 15 June 2016 on endocrine disruptors and the draft Commission acts setting out scientific criteria for their determination in the context of the EU legislation on plant protection products and biocidal products (COM(2016)0350),

– having regard to the summary report of the Standing Committee on Plants, Animals, Food and Feed held in Brussels on 28 February 2017,

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1 OJ L 309, 24.11.2009, p. 1.
2 Judgment of the Court of Justice of 16 December 2015, *Sweden* v *Commission*, T-521/14, ECLI:EU:T:2015:976.
3 Texts adopted, P8_TA(2016)0270.

– having regard to its resolution of 14 March 2013 on the protection of public health from endocrine disrupters[1],

– having regard to Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[2],

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

– having regard to Rule 106(2), (3) and (4)(c) of its Rules of Procedure,

A. whereas, in accordance with 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);

B. whereas, in accordance with the second paragraph of point 3.6.5. of Annex II to Regulation (EC) No 1107/2009, the Commission is to present to the Standing Committee on the Food Chain and Animal Health a draft of the measures concerning specific scientific criteria for the determination of endocrine disrupting properties by 14 December 2013;

C. whereas the Standing Committee on Plants, Animals, Food and Feed delivered a positive opinion on the draft regulation on 4 July 2017, with three Member States voting against, and four Member States abstaining;

D. whereas the last paragraph of the draft regulation stipulates that ‘if the intended plant protection mode of action of 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’;

E. whereas the General Court in its judgment in case T-521/14 clearly stated that ‘la spécification des critères scientifiques pour la détermination des propriétés perturbant le système endocrinien ne peut se faire que de manière objective, au regard de données scientifiques relatives audit système, indépendamment de toute autre considération, en particulier économique’[3] (paragraph 71);

F. whereas it is not scientific to exclude a substance with an intended endocrine mode of action from being identified as an endocrine disrupter for non-target organisms;

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1 OJ C 36, 29.1.2016, p. 85.

2 OJ L 184, 17.7.1999, p. 23.

3 Given that case T-521/14 was only heard in French and Swedish, the English version of the text has been provided by Parliament’s translation services: ‘the specification of scientific criteria for the determination of endocrine-disrupting properties may only be performed objectively, in the light of scientific data relating to that system, independently of all other considerations, in particular economic ones’.

G. whereas the draft regulation can therefore not be considered to be based on objective scientific data related to the endocrine system, as required by the Court; whereas the Commission thereby exceeds its implementing powers;

H. whereas the actual intention of this last paragraph is clearly spelled out in the summary report of the Standing Committee on Plants, Animals, Food and Feed held in Brussels on 28 February 2017, which states that 'furthermore, the rationale behind the provision on active substances with intended endocrine mode of action (below called growth regulators (GR)) was explained. [...] The provision on GR allows that the cut-off criteria will not be applied to substances with an intended endocrine mode of action [...]';

I. whereas this last paragraph 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;

J. whereas it is apparent from recitals 6 to 10 and Article 1(3) of Regulation (EC) No 1107/2009 that, when addressing the complex issue of setting the rules on approving active substances, the legislature had to strike a delicate balance between the different and potentially conflicting objectives, namely agricultural production and the internal market, on the one hand, and the protection of health and the environment, on the other;

K. whereas the General Court stated the following in the judgment referred to above: 'Dans ce contexte, il importe de relever que, en adoptant le règlement n° 528/2012, le législateur a procédé à une mise en balance de l'objectif d'amélioration du marché intérieur et de celui de la préservation de la santé humaine, de la santé animale et de l'environnement, que la Commission se doit de respecter et ne saurait remettre en cause [...]. Or, dans le cadre de la mise en œuvre des pouvoirs qui lui sont délégués par le législateur, la Commission ne saurait remettre en cause cet équilibre, ce que cette institution a d'ailleurs en substance admis lors de l'audience'[1] (paragraph 72);

L. whereas this was echoed by Parliament in its resolution of 8 June 2016, which stresses that 'the General Court ruled that the specification of scientific criteria can only be carried out in an objective manner on the basis of scientific data related to the endocrine system, independently of any other consideration, in particular economic ones, and that the Commission is not entitled to change the regulatory balance laid down in a basic act via the application of powers delegated to it pursuant to Article 290 [of the Treaty on the Functioning of the European Union (TFEU)]';

M. whereas the same limitations of power apply to the Commission in the context of an implementing act under the regulatory procedure with scrutiny;

N. whereas, according to the Commission communication of 15 June 2016, 'the issue faced by the Commission in this exercise is to establish criteria to determine what is or is not an

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[1] Given that case T-521/14 was only heard in French and Swedish, the English version of the text has been provided by Parliament's translation services: 'In this context, it is important to note that, when adopting Regulation (EU) No 528/2012, the legislature weighed up the objective of improving the internal market and that of protecting human health, animal health and the environment, arriving at conclusions which the Commission must respect and cannot call into question [...]. In the context of the exercise of the powers delegated to it by the legislator, the Commission cannot call that balance into question, a fact which, moreover, that institution has in essence accepted during the hearing'.

endocrine disruptor for the purposes of plant protection products and biocidal products – not to decide how to regulate these substances. The regulatory consequences have already been set by the legislator in the legislation on plant protection products (2009) and biocidal products (2012)';

O. whereas the cut-off criterion laid down in point 3.8.2. of Annex II to Regulation (EC) No 1107/2009 constitutes an essential element of the regulation;

P. whereas, in accordance with long-standing case law, the adoption of regulatory elements that are essential to a given matter is reserved to the EU legislature and may not be delegated to the Commission;

Q. whereas the Commission has exceeded its implementing powers 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, contrary to its assertions in the Commission communication of 15 June 2016 and contrary to the fundamental Union principle of the rule of law;

R. whereas, 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 a legislative procedure to amend Regulation (EC) No 1107/2009 in accordance with Article 294 TFEU;

1. Opposes adoption of the draft Commission regulation;

2. Considers that the draft Commission regulation exceeds the implementing powers provided for in Regulation (EC) No 1107/2009;

3. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee without delay;

4. Calls on the Commission to modify the draft regulation by deleting its last paragraph;

5. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.