European Parliament
2014-2019

Committee on the Environment, Public Health and Food Safety

2017/0000(RPS)

21.9.2017

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 106(2), (3) and (4)(c) of the Rules of Procedure

on the draft Commission regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties
(D048947 – 2017/0000(RPS))

Committee on the Environment, Public Health and Food Safety

Members responsible: Jytte Guteland, Bas Eickhout

B8-0000/2017

European Parliament resolution on the draft Commission regulation amending Annex II to Regulation (EC) 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties

(D048947/06 – 2017/0000 (RPS))

The European Parliament,

– having regard to the draft Commission regulation amending Annex II to Regulation (EC) 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], and in particular Article 4(1), Article 78(1)(a), the second paragraph of point 3.6.5. of Annex II and point 3.8.2 of Annex II thereof,

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

– having regard to the European Parliament 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 Communication by the Commission 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 of 15 June 2016[4],

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

– having regard to European Parliament resolution of 14 March 2013 on the protection of public health from endocrine disrupters[5],

– having regard to the Commission roadmap of June 2014 entitled "Defining criteria for identifying Endocrine Disruptors in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation",

---

1 OJ L 309, 24.11.2009, p. 1.
2 Judgment of the Court of Justice of 16 December 2015, T-521/14, *Sweden v. Commission*, ECLI:EU:T:2015:976.
3 P8_TA(2016)0270.
4 COM(2016) 0350.
5 P7_TA(2013)0091.

– having regard to the General Union Environment Action Programme to 2020 'Living well, within the limits of our planet' ("Seventh Environment Action Programme"), and in particular the third subparagraph of point 50 thereof[6],

– having regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006[7],

– having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products[8], and in particular Article 15 thereof,

– having regard to the Guidance by the European Food Safety Authority on the "Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009"[9],

– having regard to President of the European Commission Jean-Claude Juncker's State of the Union Address of 13 September 2017,

– having regard to the second draft Guidance document of 17 July 2012 for the implementation of the hazard-based criteria to identify endocrine disruptors (EDs) in the context of Regulations (EC) No 1107/2009 and (EU) No 528/2012, developed by the European Food Safety Authority, the European Chemicals Agency, and the Joint Research Centre ("draft guidance");

– 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[10],

– 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 of 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 effect in 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 of 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;

---

6 OJ L 354, 28.12.2013, p. 171.
7 OJ L 353, 31.12.2008, p. 1.
8 OJ L 342, 22.12.2009, p. 59.
9 DOI: 10.2903/j.efsa.2011.2092, EFSA Journal 2011;9(2):2092.

C. whereas the Standing Committee 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»[11] (paragraph 71);

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

G. whereas the draft regulation can therefore not be considered to be based on objective science linked to the endocrine system, as required by the Court; whereas the Commission hereby 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 an 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 it is thus clear that the actual intention of this last paragraph is to effectively create a derogation from the cut-off criterion laid down point 3.8.2 of Annex II of Regulation (EC) No 1107/2009;

J. whereas it is apparent from recitals 6 to 10 as well as from Article 1(3) of Regulation (EC) No 1107/2009 that the legislature, when addressing the complex issue of setting the rules on approving active substances, had to strike a delicate balance between the different and potentially conflicting objectives, i.e. 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

[11] Since the court case T-521/14 exists only in French and Swedish, the English version of the text is provided by the translation services of the European Parliament: ‘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’.

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.»[12] (paragraph 72);

L. whereas this was echoed by the European 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 for 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 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 of Regulation (EC) No 1107/2009 constitutes an essential element of the Regulation;

P. whereas according to 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 according to Commission President Juncker in his State of the Union Address 2017, the rule of law is one of three principles that must always anchor our Union; whereas Commission President Juncker furthermore elaborated in this context that "Accepting and respecting a final judgement is what it means to be part of a Union based on the rule of law. Member States gave final jurisdiction to the European Court of Justice. The judgements of the Court have to be respected by all. To undermine them, or to undermine the independence of national courts, is to strip citizens of their fundamental rights. The rule of law is not optional in the European Union. It is a must.";

R. whereas the Commission has thus 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

---

[12] Since the court case T-521/14 exists only in French and Swedish, the English version of the text is provided by the translation services of the European Parliament: 'In this context, it is important to note that, when adopting Regulation 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.'

assertions in the Commission communication of 15 June 2016 and contrary to the fundamental Union principle of the rule of law evoked by Commission President Juncker;

S. whereas the fact that the Commission exceeded its implementing powers is further corroborated by the statement in the summary report of the Standing Committee on Plants, Animals, Food and Feed held in Brussels on 28 February 2017 that the new clause would be added in a new paragraph, separate from "the commandments" and separate from the principles of assessment so that it is no longer part of the criteria;

T. 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 created through a legislative procedure to amend Regulation (EC) No 1107/2009 in accordance with Article 294 TFEU;

U. whereas according to the Seventh Environment Action Programme, "the Union will further develop and implement approaches to address ... safety concerns related to endocrine disruptors in all relevant Union legislation. In particular, the Union will develop harmonised hazard-based criteria for the identification of endocrine disruptors";

V. whereas according to the Commission roadmap, based on calls by the European Parliament

W. and the Council, and reconfirmed by both co-legislators in the Seventh Environment Action Programme, the Commission should establish *horizontal* hazard-based scientific criteria to identify endocrine disrupters so as to enable their application in the wider legislation covering the regulation of endocrine disrupters in different regulatory settings;

X. whereas the criteria in the draft regulation are however not fit for horizontal application in all relevant Union legislation due to at least two failures:

   a. failure to include a category of *suspected* endocrine disrupters,

   b. failure to include read-across in the operative part of the data to be considered[13],

Y. and therefore not compatible with the aim and content of the Seventh Environment Action Programme;

Z. whereas the failure to include a category of suspected endocrine disrupters means that no action can be taken against such substances, unless a complementary proposal is made to lay down criteria for them,

AA. whereas it would have been very relevant to include a category of *suspected* endocrine disrupters so as to be able to achieve adequate protection against such substances in other sectors, e.g. for cosmetics, which include a ban on substances that are *suspected* of being carcinogenic, mutagenic or toxic to reproduction ("CMR substances"), particularly since the Regulation (EC) No 1223/2009 contains an obligation for the Commission to review

[13] Read-across involves the use of relevant information from analogous substance(s) to predict properties for the'target' substance(s) under consideration [see "Read-across assessment Framework", ECHA, 2017, https://echa.europa.eu/documents/10162/13628/raaf_en.pdf]

that Regulation with regard to substances with endocrine-disrupting properties at the latest on 11 January 2015;

BB. whereas the failure to include a category of suspected endocrine disrupters furthermore means that the draft regulation is not consistent with the existing classification system for CMR substances as laid down in Regulation (EC) No 1272/2008, which includes a classification of suspected CMR substances;

CC. whereas the failure to include read-across in the operative part means that in case the criteria of the draft regulation were to be applied in other areas, each substance would need to be tested on its own and no test data from related chemicals could be used, so that in the absence of substance-specific test data on adverse effects, a substance could not be determined to be an endocrine disrupter, which would therefore reward lack of testing with non-action, and would require unnecessary animal testing to be carried out;

DD. whereas the failure to explicitly include read-across as part of the consideration of all available data is not consistent with the existing classification system for CMR substances as laid down in Regulation (EC) No 1272/2008, which explicitly includes read-across;

EE. whereas one key element in the draft regulation in order to determine whether a substance is an endocrine disrupter is the endocrine mode of action (the second “commandment”); whereas the draft regulation equates “endocrine mode of action” with “alters the function (s) of the endocrine system” to align it with the definition by the World Health Organisation referred to in recital 2 of the draft regulation;

FF. whereas the draft guidance gives a different definition for mode of action: “A biologically plausible sequence of key events leading to an observed effect supported by robust experimental observations and mechanistic data. A mode of action describes key cytological and biochemical events – that is, those that are both measurable and necessary to the observed effect – in a logical framework”.

GG. whereas the guidance thus provides a far more demanding definition for the key term “mode of action” compared to that which is set out in the second commandment of the criteria, and so unduly raises the bar for identifying endocrine disrupters;

HH. whereas the reference to existing guidance on literature data to be used in point (1)(1)(b) of the draft regulation establishes a hierarchy, which gives preference to data generated in accordance with internationally agreed study protocols over other scientific data, yet such study protocols are only available for certain endpoints to test endocrine disrupters, so that there is a serious risk that independent data alone are not considered enough for determining a substance as an endocrine disrupter;

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;

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

5. Calls on the Commission to ensure that the guidance for the implementation of the hazard-based criteria to identify endocrine disruptors (EDs) in the context of Regulations (EC) No 1107/2009 and (EU) No 528/2012 is fully in line with the scientific criteria to determine endocrine-disrupting properties, including the weight of evidence approach of Regulation (EC) No 1272/2008;

6. Calls on the Commission to ensure that the same guidance clarifies that there is no hierarchy between scientific data generated in accordance with internationally agreed study protocols and other scientific data;

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