European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2020/2853(RSP)

09.11.2020

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron
(2020/2853(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Anja Hazekamp, Maria Arena, Tilly Metz, Eleonora Evi

B9-0000/2020

European Parliament resolution on Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron (2020/2853(RSP))

The European Parliament,

– having regard to Commission Implementing Regulation (EU) 2020/1511 of 16 October 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, paraffin oils, picloram, prosulfocarb, sulphur, triflusulfuron and tritosulfuron[1],

– 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[2], and in particular Article 21 and the first paragraph of Article 17 thereof,

– having regard to Commission Implementing Regulation (EU) 2015/408 of 11 March 2015 on implementing Article 80(7) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and establishing a list of candidates for substitution[3],

– having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[4],

– having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009[5],

– having regard to its resolution of 10 October 2019 objecting to the previous extension of

1 OJ L 344, 19.10.2020, p. 18.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 67, 12.3.2015, p. 18.
4 OJ L 55, 28.2.2011, p. 13.
5 Texts adopted, P8_TA(2018)0356.

the approval period of the active substance chlorotoluron[6],

– having regard to Rule 112(2) and (3) of its Rules of Procedure,

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

A. whereas chlorotoluron was included in Annex I to Council Directive 91/414/EEC[7] on 1 March 2006 by Commission Directive 2005/53/EC[8] and has been deemed to be approved under Regulation (EC) No 1107/2009;

B. whereas a procedure to renew the approval of chlorotoluron under Commission Implementing Regulation (EU) No 844/2012[9] has been ongoing since 2013;

C. whereas the approval period for the active substance chlorotoluron has already been extended by one year by Commission Implementing Regulation (EU) No 533/2013[10], and subsequently by one year every year since 2017 by Commission Implementing

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6 European Parliament resolution of 10 October 2019 on the draft Commission implementing regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanatemethyl, triflusulfuron and tritosulfuron (Texts adopted, P9_TA(2019)0027).

7 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

8 Commission Directive 2005/53/EC of 16 September 2005 amending Council Directive 91/414/EEC to include chlorothalonil, chlorotoluron, cypermethrin, daminozide and thiophanate-methyl as active substances (OJ L 241, 17.9.2005, p. 51).

9 Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

10 Commission Implementing Regulation (EU) No 533/2013 of 10 June 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methyl-cyclopropene, chlorothalonil, chlorotoluron, cypermethrin, daminozide, forchlorfenuron, indoxacarb, thiophanate-methyl and tribenuron (OJ L 159, 11.6.2013, p. 9).

Regulations (EU) 2017/1511[11], (EU) 2018/1262[12], (EU) 2019/1589[13] and now again by one year by Implementing Regulation (EU) 2020/1511, which extends the approval period until 31 October 2021;

D. whereas the Commission has failed to explain the reasons for the extension other than saying: 'Due to the fact that the assessment of those substances has been delayed for reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision is taken on their renewal';

E. whereas Regulation (EC) No 1107/2009 aims to ensure a high level of protection of both human and animal health and the environment, and at the same time to safeguard the competitiveness of Union agriculture; whereas particular attention should be paid to the protection of vulnerable groups of the population, including pregnant women, infants and children;

F. whereas the precautionary principle should apply, and whereas Regulation (EC) No 1107/2009 specifies that substances should only be included in plant protection products where it has been demonstrated that they present a clear benefit for plant production and that they are not expected to have any harmful effect on human or animal health or any unacceptable effects on the environment;

G. whereas Regulation (EC) No 1107/2009 indicates that in the interest of safety the approval period for active substances should be limited in time; whereas the approval period should be proportionate to the possible risks inherent in the use of such substances, but in this case it is clear that no such proportionality exists;

H. whereas in the 14 years since its approval as an active substance, chlorotoluron has been identified as a probable endocrine disruptor, and yet during this time its approval has not been reviewed or withdrawn;

I. whereas the Commission and Member States have the possibility and responsibility to act according to the precautionary principle when the possibility of harmful effects on health have been identified but scientific uncertainty persists, by adopting provisional

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[11] Commission Implementing Regulation (EU) 2017/1511 of 30 August 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, cypermethrin, daminozide, deltamethrin, dimethenamid-p, flufenacet, flurtamone, forchlorfenuron, fosthiazate, indoxacarb, iprodione, MCPA, MCPB, silthiofam, thiophanate-methyl and tribenuron (OJ L 224, 31.8.2017, p. 115).

[12] Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron (OJ L 238, 21.9.2018, p. 62).

[13] Commission Implementing Regulation (EU) 2019/1589 of 26 September 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron (OJ L 248, 27.9.2019, p. 24).

risk management measures that are necessary to ensure a high level of protection of human health;

J. whereas, more specifically, Article 21 of Regulation (EC) No 1107/2009 provides that the Commission may review the approval of an active substance at any time, especially where, in the light of new scientific and technical knowledge, it considers that there are indications that the substance no longer satisfies the approval criteria provided for in Article 4 of that Regulation, and whereas this review may lead to the withdrawal or amendment of the approval of the substance;

Endocrine-disrupting properties

K. whereas, according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[14], chlorotoluron has a harmonised classification of very toxic to aquatic life, very toxic to aquatic life with long lasting effects, suspected of causing cancer (Carc. 2), and suspected of damaging the unborn child (Repr. 2);

L. whereas chlorotoluron has been associated with endocrine-disrupting properties in scientific publications[15];

M. whereas in 2015 chlorotoluron was placed on the 'list of candidates for substitution' by Implementing Regulation (EU) 2015/408 because it is considered to have endocrine-disrupting properties that may cause adverse effects in humans, and because it meets the criteria for it to be considered a persistent and toxic substance;

N. whereas, according to point 3.6.5 of Annex II to Regulation (EC) No 1107/2009, active substances cannot be authorised when they are considered to have endocrine-disrupting properties that may cause adverse effect in humans, unless human exposure to that active substance, safener or synergist in a plant protection product, under realistic proposed conditions of use, is negligible, that is, the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005 of the European Parliament and of the Council[16];

O. whereas it is unacceptable for a substance which is likely to meet the cut-off criteria for active substances that have endocrine-disrupting properties to continue to be allowed for use in the Union, thereby putting public and environmental health at risk;

P. whereas applicants can take advantage of the automatic system built in to Commission working methods which immediately extends the approval periods of active substances if the risk reassessment has not been finalised, by prolonging the reassessment process on purpose by providing incomplete data and asking for more derogations and special

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[14] 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 (OJ L 353, 31.12.2008, p. 1).

[15] See inter alia: Hong, M., Ping, Z., Jian, X., 'Testicular toxicity and mechanisms of chlorotoluron compounds in the mouse', Toxicology Mechanisms and Methods 2007;17(8):483-8.

[16] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

conditions, which leads to unacceptable risks for the environment and human health since during this time exposure to the hazardous substance continues;

Q. whereas in its resolution of 13 September 2018 on the implementation of the Plant Products Regulation (EC) No 1107/2009[17] Parliament called on the Commission and Member States 'to ensure that the procedural extension of the approval period for the duration of the procedure, pursuant to Article 17 of the Regulation, will not be used for active substances that are mutagenic, carcinogenic, toxic for reproduction and therefore in category 1A or 1B, or active substances that have endocrine disrupting characteristics and are damaging to humans or animals, as is currently the case for substances such as flumioxazine, thiacloprid, chlorotoluron and dimoxystrobin';

R. whereas Parliament has already objected to the previous extension of the approval period of chlorotoluron in its resolution of 10 October 2019[18];

S. whereas the Commission in its response[19] to the previous objection to the extension of the approval period of chlorotoluron only refers to the 'study underpinning the impact assessment conducted prior to the adoption of Commission Regulation (EU) 2018/605'[20] in which 'chlorotoluron was not identified as a potential endocrine disruptor', but fails to acknowledge that that study did not lead to the removal of chlorotoluron from the list of candidates for substitution;

T. whereas after the adoption of Commission Delegated Regulation (EU) 2017/2100[21] and Regulation (EU) 2018/605, the Commission tasked the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) with developing harmonised guidance to ensure that the endocrine disruptor criteria adopted by the Union are applied consistently for the assessment of biocides and pesticides in the Union; whereas this guidance which incorporates new OECD tests was published in June 2018[22], but has not been used to assess the endocrine-disrupting properties of chlorotoluron;

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17 Texts adopted, P8_TA(2018)0356.

18 Texts adopted, P9_TA(2019)0027.

19 Commission follow up to the European Parliament non-legislative resolution on the draft Commission implementing regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, beta-cyfluthrin, bifenox, chlorotoluron, clofentezine, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fludioxonil, flufenacet, fosthiazate, indoxacarb, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron, SP(2019)669, https://oeil.secure.europarl.europa.eu/oeil/popups/ficheprocedure.do?reference=2019/2826(RSP)&l=en

20 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101 20.4.2018, p. 33).

21 Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

22 EFSA and ECHA Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009, EFSA Journal 2018, 16(6):5311, http://www.efsa.europa.eu/en/efsajournal/pub/5311.

U. whereas therefore, chlorotoluron has not been properly assessed to allow for it to be no longer considered as an endocrine disrupter;

V. whereas the draft renewal assessment report in relation to chlorotoluron has not yet been assessed by EFSA;

W whereas following the previous extension in 2019 of several active substances, including chlorotoluron, under Implementing Regulation (EU) 2019/1589, only three of the 29 substances have been either renewed or non-renewed, while under Implementing Regulation (EU) 2020/1511, the approval periods of 27 substances have been extended again, many of them for a third or fourth time;

1. Considers that Implementing Regulation (EU) 2020/1511 exceeds the implementing powers provided for in Regulation (EC) No 1107/2009;

2. Considers that Implementing Regulation (EU) 2020/1511 does not respect the precautionary principle;

3. Considers that the decision to extend the approval period for chlorotoluron is not in line with the safety criteria laid down in Regulation (EC) No 1107/2009, and is based neither on evidence that this substance can safely be used, nor on a proven urgent need for the active substance chlorotoluron in food production in the Union;

4. Calls on the Commission to repeal Implementing Regulation (EU) 2020/1511 and to submit a new draft to the committee that takes into account the scientific evidence on the harmful properties of all the substances concerned, especially of chlorotoluron;

5. Calls on the Commission only to present draft implementing regulations to extend the approval periods of substances for which the current state of science is not expected to lead to a Commission proposal for non-renewal of the authorisation of the active substance concerned;

6. Calls on the Commission to withdraw the approvals for substances if proof or reasonable doubt exists that they will not meet the safety criteria laid down in Regulation (EC) No 1107/2009;

7. Calls on the Member States to ensure the proper and timely reassessment of the authorisations for the active substances for which they are the reporting Member States, and to ensure that current delays are solved effectively as soon as possible;

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