European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2019/2925(RSP)

25.11.2019

DRAFT MOTION FOR A RESOLUTION

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

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 benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (D064213/02 – 2019/2925(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Anja Hazekamp, Tilly Metz, Eleonora Evi

B9-0000/2019

European Parliament 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 benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (D064213/02 – 2019/2925(RSP))

The European Parliament,

– having regard to the draft Commission implementing regulation amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances benfluralin, dimoxystrobin, fluazinam, flutolanil, mancozeb, mecoprop-P, mepiquat, metiram, oxamyl and pyraclostrobin (D064213/02),

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

– 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[3],

– having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009[4],

– 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 dimoxystrobin was included in Annex I to Council Directive 91/414/EEC[5] on 1 October 2006 by Commission Directive 2006/75/EC[6] and has been deemed to be approved under Regulation (EC) No 1107/2009;

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1 OJ L 309, 24.11.2009, p.1.
2 OJ L 67, 12.3.2015, p.18.
3 OJ L 55, 28.2.2011, p. 13.
4 Texts adopted, P8_TA(2018)0356.
5 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).
6 Commission Directive 2006/75/EC of 11 September 2006 amending Council Directive 91/414/EEC to include dimoxystrobin as active substance (OJ L 248, 12.9.2006, p. 3).

B. whereas a procedure to renew the approval of dimoxystrobin under Commission Implementing Regulation (EU) No 844/2012[7] has been ongoing since 2013;

C. whereas the approval period of the active substance dimoxystrobin, which was originally due to have ended on 30 September 2016, has already been extended by 16 months by Commission Implementing Regulation (EU) No 1136/2013[8], followed by a one-year extension by Commission Implementing Regulation (EU) 2018/84[9], then another one-year extension by Commission Implementing Regulation (EU) 2018/1796[10], and is now again to be extended by one year by means of this draft Commission implementing regulation, which would extend the approval period to 31 January 2021;

D. whereas mancozeb was included in Annex I to Directive 91/414/EEC on 1 July 2006 by Commission Directive 2005/72/EC[11] and has been deemed to be approved under Regulation (EC) No 1107/2009;

E. whereas a procedure to renew the approval of mancozeb under Implementing Regulation (EU) No 844/2012 has been ongoing since 2013;

F. whereas the approval period of the active substance mancozeb, which was originally due to have ended on 30 June 2016, has already been extended by 19 months by Commission Implementing Regulation (EU) No 762/2013[12], followed by a one-year extension by Implementing Regulation (EU) 2018/84, then another one-year extension by Implementing Regulation (EU) 2018/1796, and is now again to be extended by one year by means of this draft Commission implementing regulation, which would extend the approval period to 31 January 2021;

G. whereas the Commission fails to explain the reasons for the extensions other than by stating: ‘Due to the fact that the assessment of those substances has been delayed for

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7 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).

8 Commission Implementing Regulation (EU) No 1136/2013 of 12 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances clothianidin, dimoxystrobin, oxamyl and pethoxamid (OJ L 302, 13.11.2013, p. 34).

9 Commission Implementing Regulation (EU) 2018/84 of 19 January 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, clothianidin, copper compounds, dimoxystrobin, mancozeb, mecoprop-p, metiram, oxamyl, pethoxamid, propiconazole, propineb, propyzamide, pyraclostrobin and zoxamide (OJ L 16, 20.1.2018, p. 8).

10 Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron (OJ L 294, 21.11.2018, p. 15).

11 Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ L 279, 22.10.2005, p. 63).

12 Commission Implementing Regulation (EU) No 762/2013 of 7 August 2013 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, MCPA, MCPB and metiram (OJ L 213, 8.8.2013, p. 14).

reasons beyond the control of the applicants, the approvals of those active substances are likely to expire before a decision has been taken on their renewal';

H. 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;

I. whereas the precautionary principle should apply, and Regulation (EC) No 1107/2009 provides 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;

J. 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 these cases it is clear that no such proportionality exists;

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

L. 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, and whereas this review may lead to the withdrawal or amendment of the approval of the substance;

Endocrine-disrupting properties and toxic for reproduction category 1B

M. whereas in 2015 dimoxystrobin was placed on the 'candidates for substitution' list by Implementing Regulation (EU) 2015/408 because the Acute Reference Dose (ARfD) for that active substance is significantly lower than that of the majority of the approved active substances within their groups, and because it is to be considered as having endocrine-disrupting properties that may cause adverse effects in humans;

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 effects 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 that exclude 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[13];

O. whereas the 47th Meeting of the Committee for Risk Assessment (RAC) of 27 February 2019 agreed to classify mancozeb as toxic for reproduction category 1B;

P. whereas, according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009, active substances cannot be authorised when they are toxic for reproduction category 1B, except in cases where, on the basis of documented evidence included in the application, an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, in which cases risk mitigation measures have to be taken to ensure that exposure of humans and the environment to the active substance is minimised;

Q. whereas exposure to mancozeb is linked to an increase in the risk of Parkinson's disease amongst farmers and other people in rural areas in the Netherlands and France[14];

R. whereas mancozeb is a combination of two other dithiocarbamates namely maneb and zineb, which are no longer authorised for use in the Union because of the risks they pose for human and environmental health;

S. whereas mancozeb is very toxic to aquatic life, is suspected of damaging the human foetus and may cause allergic skin reactions;

T. whereas it is unacceptable that substances which are known to meet the cut-off criteria for active substances that are mutagenic, carcinogenic and/or toxic for reproduction, or that have endocrine-disrupting properties, which are established to protect human and environmental health, continue to be allowed for use in the Union, thereby putting public and environmental health at risk;

U. whereas applicants can take advantage of the automatic system built into Commission working methods, which immediately extends the approval periods of active substances if the risk reassessment has not been finalised, by deliberately prolonging the reassessment process by providing incomplete data and asking for more derogations and special conditions, which leads to unacceptable risks for the environment and human health since, during this time, exposure to the hazardous substance continues;

V. whereas in its resolution of 13 September 2018 on the implementation of the Plant Products Regulation (EC) No 1107/2009, 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

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13 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).

14 https://www.bnnvara.nl/zembla/artikelen/risico-op-ziekte-van-parkinson-bij-blootstelling-aan-landbouwgif, https://www.ncbi.nlm.nih.gov/pubmed/23713084, https://academic.oup.com/ije/article/47/1/299/4609336,

characteristics and are damaging to humans or animals, as is currently the case for substances such as flumioxazine, thiacloprid, chlorotoluron and dimoxystrobin';

W. whereas the Dutch Parliament has expressed its concern with the extension of approval periods and has called for an end to extensions for substances known to pose a significant threat to biodiversity, in particular bees and bumblebees, or that are carcinogenic, mutagenic, endocrine-disrupting or toxic for reproduction[15];

X. whereas the European Food Safety Authority's public consultation on mancozeb had a deadline of 28 April 2018; whereas based on the information currently available from the Union risk assessment, the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb) estimates that sufficient data are available to make a rapid decision on whether or not to renew the approval of mancozeb[16];

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

2. Considers that the draft Commission implementing regulation does not respect the precautionary principle;

3. Considers that the decision to extend the approval periods of dimoxystrobin and mancozeb is not in line with the safety criteria laid down in Regulation (EC) No 1107/2009, and is based neither on evidence that those substances can safely be used, nor on a proven urgent need for them in food production in the Union;

4. Calls on the Commission to withdraw its draft implementing regulation 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 those of dimoxystrobin and mancozeb;

5. Calls on the Commission to present proposals for non-renewal of dimoxystrobin and mancozeb in the next meeting of the Standing Committee on Plants, Animals, Food and Feed;

6. Calls on the Commission to present draft implementing regulations to extend the approval periods only of substances in relation to 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;

7. Calls on the Commission to withdraw the approvals relating to substances, if proof or reasonable doubts exist that they will not meet the safety criteria laid down in Regulation (EC) No 1107/2009;

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

9. Instructs its President to forward this resolution to the Council and the Commission,

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15 TK 21501-32 nr. 1176.
16 TK 27858, nr. 485.

and to the governments and parliaments of the Member States.