## **European Parliament**

2019-2024



Committee on the Environment, Public Health and Food Safety

2019/2826(RSP)

18.9.2019

# 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 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 (D062951/02 – 2019/2826(RSP))

Committee on the Environment, Public Health and Food Safety

Member responsible: Anja Hazekamp

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#### 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 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

(D062951/02 - 2019/2826(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 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 (D062951/02),
- 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<sup>1</sup>, 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<sup>2</sup>,
- 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<sup>3</sup>,
- having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))<sup>4</sup>,
- 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,

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<sup>&</sup>lt;sup>1</sup> OJ L 309, 24.11.2009, p. 1.

<sup>&</sup>lt;sup>2</sup> OJ L 67, 12.3.2015, p. 18.

<sup>&</sup>lt;sup>3</sup> OJ L 55, 28.2.2011, p.13.

<sup>&</sup>lt;sup>4</sup> P8 TA(2018)0356.

Public Health and Food Safety,

- A. whereas chlorotoluron was included in Annex I to Council Directive 91/414/EEC<sup>5</sup> on 1 March 2006 by Commission Directive 2005/53/EC<sup>6</sup> 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<sup>7</sup> has been ongoing since 2013;
- C. whereas the approval period of the active substance chlorotoluron has already been extended by one year by Commission Implementing Regulation (EU) No 533/2013<sup>8</sup>, subsequently by one year by Commission Implementing Regulation (EU) 2017/1511<sup>9</sup>, again by one year in Commission Implementing Regulation (EU) 2018/1262<sup>10</sup>, and now again by one year with this draft Commission implementing regulation which would extend the approval period until 31 October 2020;
- D. whereas the Commission fails to explain the reasons for the extension other than by stating: '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 has been 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

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<sup>&</sup>lt;sup>5</sup> 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).

<sup>&</sup>lt;sup>6</sup> 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).

<sup>&</sup>lt;sup>7</sup> 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).

<sup>&</sup>lt;sup>8</sup> OJ L 159, 11.6.2013, p.9).

<sup>&</sup>lt;sup>9</sup> OJ L 224, 31.8.2017, p.115).

<sup>&</sup>lt;sup>10</sup> 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).

- period should be proportionate to the possible risks inherent in the use of such substances, but such proportionality is obviously lacking;
- H. whereas in the 13 years since its approval as an active substance, chlorotoluron has been identified as a probable endocrine disruptor, and that during this time the (conditions for) its approval have not been revised;
- 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 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 ensures 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 this review may lead to the withdrawal or amendment of the approval of the substance;

#### Endocrine disrupting

- K. whereas, according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>11</sup>, chlorotoluron has a harmonised classification as being 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 in 2015 chlorotoluron was placed on the Candidates for Substitution list by Commission Implementing Regulation (EU) 2015/408 because it is to be considered as having endocrine disrupting properties that may cause adverse effects in humans and because it meets the criteria for it to be considered as a persistent and toxic substance;
- M. whereas, according to point 3.6.5, of Annex II of 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 the exposure of humans 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<sup>12</sup>;
- N. whereas it is unacceptable that a substance which is known to meet the cut-off criteria for active substances that are mutagenic, carcinogenic and/or toxic for reproduction, or

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<sup>&</sup>lt;sup>11</sup> 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)

<sup>&</sup>lt;sup>12</sup> 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).

that have endocrine-disrupting properties, which are set to protect human and environmental health, continues to be allowed for use in the Union, putting public and environmental health at risk;

- O. whereas applicants can take advantage of the automatism build in to the working methods of the Commission to immediately extend the approval periods of active substances when the risk reassessment has not been finalised, by prolonging the reassessment process on purpose by providing incomplete data and by 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;
- Ρ. whereas in September 2018 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";
- Q. whereas the Dutch parliament has expressed its concern with these extensions and demands an end to extensions of substances known to pose a significant threat to biodiversity (in particular bees and bumblebees) or that are carcinogenic, mutagenic, endocrine disrupting and/or toxic for reproduction<sup>13</sup>;
- 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;
- Considers that the decision to extend the application period of chlorotoluron is not in 3. line with the safety criteria laid down in Regulation (EC) No 1107/2009, is not based on evidence that this substance can safely be used nor on a proven urgent need for the active substance chlorotoluron for food production in the Union;
- Calls on the Commission to withdraw its draft implementing regulation and to submit a 4. new draft to the committee that takes into account the scientific evidence on the harmful properties of all the substances concerned, especially those on chlorotoluron;
- 5. Calls on the Commission to in the future only present drafts of implementing regulations to extend the approval periods of substances of which the current state of science is not expected to lead to a Commission proposal for non-renewal of the authorisation of the concerned active substance:
- 6. Calls on the Commission to withdraw the applications of substances for which proof or reasonable doubts exists that they will not meet the safety criteria laid down in

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<sup>&</sup>lt;sup>13</sup> TK 21501-32 nr. 1176

Regulation (EC) No 1107/2009;

- 7. Calls on the Member States to ensure the proper and timely reassessment of the authorisations of the active substances for which they are the Reporting Member States and to ensure that the current delays are effectively solved 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.

