Active substances, including chlorotoluron

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, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fluioxonil, flufenacet, fosthiazate, indoxacarbaz, 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, clomazone, cypermethrin, daminozide, deltamethrin, dicamba, difenoconazole, diflubenzuron, diflufenican, fenoxaprop-P, fenpropidin, fluioxonil, flufenacet, fosthiazate, indoxacarbaz, lenacil, MCPA, MCPB, nicosulfuron, picloram, prosulfocarb, pyriproxyfen, thiophanate-methyl, triflusulfuron and tritosulfuron (D062951/02),


² OJ L 67, 12.3.2015, p. 18.
exercise of implementing powers¹,

– having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009²,

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

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


B. whereas a procedure to renew the approval of chlorotoluron under Commission Implementing Regulation (EU) No 844/2012⁵ 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 533/2013⁶, subsequently by one year by Commission Implementing Regulation (EU) 2017/1511⁷, again by one year in Commission Implementing Regulation (EU) 2018/1262⁸, and now again by one year by means of this draft Commission implementing regulation, which

would extend the approval period until 31 October 2020;

D. whereas the Commission has failed to explain the reasons for the extension other than saying: ‘Due to the fact that the assessment of the 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 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 13 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 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, 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, 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);

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L. whereas in 2015 chlorotoluron was placed on the ‘list of candidates for substitution’ by Commission 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;

M. 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;

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

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

P. 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 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 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;

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

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3 TK 21501-32 nr. 1176.
2. Considers that the draft Commission implementing regulation 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 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 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.