P9_TA(2019)0026

Active substances, including flumioxazine


The European Parliament,

– having regard to Commission Implementing Regulation (EU) 2019/707 of 7 May 2019 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiazvalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, desmedipham, dimethoate, dimethomorph, diuron, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, metalaxyl-m, methiocarb, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, s-metolachlor and tebuconazole,


1 OJ L 120, 8.5.2019, p. 16.
3 OJ L 67, 12.3.2015, p. 18.
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 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 of the Committee on the Environment,
Public Health and Food Safety,

A. whereas flumioxazine was included in Annex I to Council Directive 91/414/EEC³ on 1
January 2003 by Commission Directive 2002/81/EC⁴ and has been deemed to be
approved under Regulation (EC) No 1107/2009;

B. whereas a procedure to renew the approval of flumioxazine under Commission
Implementing Regulation (EU) No 844/2012⁵ has been ongoing since 2010⁶ and the
respective application has been submitted in accordance with Article 4 of Commission
Regulation (EU) No 1141/2010⁷;

C. whereas the approval period for the active substance flumioxazine has already been
extended by five years by Commission Directive 2010/77/EU⁸ and subsequently by one
year every year since 2015 by Commission Implementing Regulations (EU)

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5 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
7 Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the
procedure for the renewal of the inclusion of a second group of active substances in
91/414/EEC as regards the expiry dates for inclusion in Annex I of certain active
Implementing Regulation (EU) No 540/2011 as regards the extension of the approval
periods of the active substances 2,4-D, acibenzolar-s-methyl, amitrole, bentazone,
cyhalofop butyl, diquat, esfenvalerate, famoxadone, flumioxazine, DPX KE 459
(flupyrsulfuron-methyl), glyphosate, iprovalicarb, isoproturon, lambda-cyhalothrin,
metalaxyl-M, metsulfuron methyl, picolinafen, prosulfuron, pyrimethanil, pyraflufen-
extended again by Commission Implementing Regulation (EU) 2019/707, which extends the approval period until 30 June 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 interests of safety, the approval period for active substances should be limited in time; whereas the approval

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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 16 years since its approval as an active substance, flumioxazine has been identified and classified as toxic for reproduction category 1B and 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 has 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;

**Toxic for reproduction category 1B and endocrine disrupting**

K. whereas, according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council\(^1\), flumioxazine has a harmonised classification of toxic for reproduction category 1B, very toxic to aquatic life and very toxic to aquatic life with long-lasting effects;

L. whereas the European Food Safety Authority concluded already in 2014, and subsequently in 2017 and 2018, that there were critical areas of concern as flumioxazine is classified under reproductive toxicity category 1B and also that the potential endocrine disruption of flumioxazine was an issue that could not be finalised and a critical area of concern;

M. whereas in 2015 flumioxazine was placed on the ‘candidates for substitution’ list by Commission Implementing Regulation (EU) 2015/408 because it is or is to be classified, in accordance with Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B;

N. whereas, according to point 3.6.4 of Annex II to Regulation (EC) No 1107/2009, active substances cannot be authorised when they fall into 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 must be taken to ensure that exposure of humans and the environment to the substance is minimised;

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O. 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 Article 18(1)(b) of Regulation (EC) No 396/2005 of the European Parliament and of the Council;  

P. whereas flumioxazine has a high risk of bioconcentration, is highly toxic to algae and aquatic plants, and is moderately toxic to earthworms, honeybees, fish and aquatic invertebrates;  

Q. 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 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;  

R. whereas applicants can take advantage of the automatism built into the working methods of the Commission to secure an immediate extension of the approval periods of active substances when the risk reassessment has not been finalised, by deliberately prolonging the reassessment process 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;  

S. whereas in its resolution of 13 September 2018 on the implementation of the Plant Protection 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’;  

T. whereas the Dutch Parliament has expressed concern about these extensions and demands an end to extensions of the approval 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;  


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2 TK 21501-32 nr. 1176.
2. Considers that Commission Implementing Regulation (EU) 2019/707 does not respect the precautionary principle;

3. Considers that the decision to extend the approval period for flumioxazine 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 flumioxazine for food production in the Union;

4. Calls on the Commission to repeal Commission Implementing Regulation (EU) 2019/707 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 flumioxazine;

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 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;

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