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P9_TA(2020)0197

Active substances, including flumioxazine

European Parliament resolution of 10 July 2020 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 beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor (D067115/02 — 2020/2671(RSP))

(2021/C 371/07)

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 beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, cyazofamid, dimethomorph, ethephon, etoxazole, famoxadone, fenamiphos, flumioxazine, fluoxastrobin, folpet, formetanate, metribuzin, milbemectin, *Paecilomyces lilacinus* strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole and S-metolachlor (D067115/02,

— 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 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 ([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 flumioxazine was included in Annex I to Council Directive 91/414/EEC ([5]) on 1 January 2003 by Commission Directive 2002/81/EC ([6]) and has been deemed to be approved under Regulation (EC) No 1107/2009;

([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]) OJ C 433, 23.12.2019, p. 183.
([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 2002/81/EC of 10 October 2002 amending Council Directive 91/414/EEC to include flumioxazine as active substance (OJ L 276, 12.10.2002, p. 28).

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B. whereas a procedure to renew the approval of flumioxazine under Commission Implementing Regulation (EU) No 844/2012 ([7]) has been ongoing since 2010 ([8]) and the respective application has been submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010 ([9]) on 29 February 2012;

C. whereas the approval period for the active substance flumioxazine has already been extended by five years by Commission Directive 2010/77/EU ([10]) and subsequently by one year every year since 2015 by Commission Implementing Regulations (EU) 2015/1885 ([11]), (EU) 2016/549 ([12]), (EU) 2017/841 ([13]), (EU) 2018/917 ([14]), (EU) 2019/707 ([15]) and now again by one year with this draft Commission implementing regulation which would extend the approval period until 30 June 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 all 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;

([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]) OJ L 293, 11.11.2010, p. 48.

([9]) 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 Annex I to Council Directive 91/414/EEC and establishing the list of those substances (OJ L 322, 8.12.2010, p. 10).

([10]) Commission Directive 2010/77/EU of 10 November 2010 amending Council Directive 91/414/EEC as regards the expiry dates for inclusion in Annex I of certain active substances (OJ L 293, 11.11.2010, p. 48).

([11]) Commission Implementing Regulation (EU) 2015/1885 of 20 October 2015 amending 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, pymetrozine, pyraflufen-ethyl, thiabendazole, thifensulfuron-methyl and triasulfuron (OJ L 276, 21.10.2015, p. 48).

([12]) Commission Implementing Regulation (EU) 2016/549 of 8 April 2016 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances bentazone, cyhalofop butyl, diquat, famoxadone, flumioxazine, DPX KE 459 (flupyrsulfuron-methyl), metalaxyl-M, picolinafen, prosulfuron, pymetrozine, thiabendazole and thifensulfuron-methyl (OJ L 95, 9.4.2016, p. 4).

([13]) Commission Implementing Regulation (EU) 2017/841 of 17 May 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, Ampelomyces quisqualis strain: aq 10, benalaxyl, bentazone, bifenazate, bromoxynil, carfentrazone ethyl, chlorpropham, cyazofamid, desmedipham, diquat, DPX KE 459 (flupyrsulfuron-methyl), etoxazole, famoxadone, fenamidone, flumioxazine, foramsulfuron, Gliocladium catenulatum strain: j1446, imazamox, imazosulfuron, isoxaflutole, laminarin, metalaxyl-m, methoxyfenozide, milbemectin, oxasulfuron, pendimethalin, phenmedipham, pymetrozine, s-metolachlor, and trifloxystrobin (OJ L 125, 18.5.2017, p. 12).

([14]) Commission Implementing Regulation (EU) 2018/917 of 27 June 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances alpha-cypermethrin, beflubutamid, benalaxyl, benthiavalicarb, bifenazate, boscalid, bromoxynil, captan, carvone, chlorpropham, cyazofamid, desmedipham, dimethoate, dimethomorph, diquat, ethephon, ethoprophos, etoxazole, famoxadone, fenamidone, fenamiphos, flumioxazine, fluoxastrobin, folpet, foramsulfuron, formetanate, Gliocladium catenulatum strain: J1446, isoxaflutole, metalaxyl-m, methiocarb, methoxyfenozide, metribuzin, milbemectin, oxasulfuron, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, propamocarb, prothioconazole, pymetrozine and s-metolachlor (OJ L 163, 28.6.2018, p. 13).

([15]) 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, benthiavalicarb, 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 (OJ L 120, 8.5.2019, p. 16).

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 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 17 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;

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 of that Regulation, 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 ([16]), 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 (EFSA) 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 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;

O. whereas on 1 February 2018, the Rapporteur Member State, in light of new scientific data, submitted to the European Chemicals Agency (ECHA) a proposal for harmonised classification and labelling of flumioxazine under Regulation (EC) No 1272/2008; whereas on 15 March 2019, the Risk Assessment Committee (RAC) of ECHA adopted an opinion modifying the classification of flumioxazine from toxic for reproduction category 1B to toxic for reproduction category 2; whereas this is likely to lead to a reclassification of flumioxazine in Annex IV to the CLP Regulation at the end of 2020 or the beginning of 2021; whereas until then, flumioxazine remains classified as toxic for reproduction category 1B;

P. 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

([16]) 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).

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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 ([17]);

Q. whereas flumioxazine has been suspected of having endocrine disrupting properties since 2014 ([18]); whereas criteria to determine whether a substance is an endocrine disrupter in the context of Regulation (EC) No 1107/2009 have been applicable since 20 October 2018 ([19]); whereas the corresponding guidance was adopted on 5 June 2018 ([20]); whereas, however, the Commission mandated EFSA only on 4 December 2019 to assess the endocrine disrupting potential of flumioxazine according to the new criteria; whereas the timeline of the delivery of this assessment remains unclear;

R. 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;

S. whereas it is unacceptable that a substance which currently meets the cut-off criteria for active substances that are mutagenic, carcinogenic and/or toxic for reproduction, and which is likely to meet the cut-off criteria due to its endocrine disrupting properties, continues to be allowed for use in the Union, putting public and environmental health at risk;

T. 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;

U. whereas following an initial proposal for non-renewal of the approval by the Commission in 2014, based on the fact that flumioxazine met the cut-off criteria of toxic for reproduction category 1B, the applicant requested a derogation from the application of these cut-off criteria; such a derogation, however, required the development of the relevant assessment methodologies which did not yet exist, despite the fact that Regulation (EC) No 1107/2009 had been applying for three years, resulting in the non-renewal process being stalled for several years;

V. 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';

W. whereas Parliament has already objected to the previous extension of the approval period of flumioxazine in its resolution of 10 October 2019 ([21]), and the Commission has failed to give a convincing response to that resolution as well as failing to properly demonstrate that another extension would not exceed its implementing powers;

([17]) 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).

([18]) EFSA Journal, Volume 12, Issue 6, June 2014, 'Conclusion on the peer review of the pesticide risk assessment of the active substance flumioxazin'.

([19]) OJ L 101, 20.4.2018, p. 33.

([20]) EFSA Journal, Volume 16, Issue 6, June 2018, 'Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009'.

([21]) European Parliament resolution of 10 October 2019 on 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 alphacypermethrin, beflubutamid, benalaxyl, benthiavalicarb, 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 (Texts adopted, P9_TA(2019)0026).

X. whereas following the previous extension in 2019 of several active substances, including flumioxazine, under Implementing Regulation (EU) 2019/707, only 8 of the 34 substances have been either renewed or non-renewed, while under this draft Commission implementing regulation, 26 substances will be extended again, many of them for a third or fourth time;

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 is not consistent with Union law in that it does not respect the precautionary principle;

3. Strongly denounces the serious delays in the reauthorisation process and in the identification of endocrine disrupting substances;

4. Considers that the decision to extend the approval period for flumioxazine again 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;

5. 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 flumioxazine;

6. 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 approval of the active substance concerned;

7. 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;

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, and to the governments and parliaments of the Member States.