Active substances, including flumioxazine

European Parliament resolution of 10 June 2021 on Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (2021/2706(RSP))

The European Parliament,

– having regard to Commission Implementing Regulation (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, beflubutamid, benthiavalicarb, bifenazate, boscalid, calcium carbonate, captan, carbon dioxide, cymoxanil, dimethomorph, ethephon, extract from tea tree, famoxadone, fat distillation residues, fatty acids C7 to C20, flumioxazine, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, heptamaloxyloglucan, hydrolysed proteins, iron sulphate, metazachlor, metribuzin, milbemectin, Paecilomyces lilacinus strain 251, phenmedipham, phosmet, pirimiphos-methyl, plant oils/rape seed oil, potassium hydrogen carbonate, propamocarb, prothioconazole, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, tebuconazole and urea¹,


¹ OJ L 160, 7.5.2021, p. 89.
– having regard to the opinion delivered on 30 March 2021 by the Standing Committee on Plants, Animals, Food and Feed,


– having regard to its resolution of 13 September 2018 on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009³,

– 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,


¹ OJ L 67, 12.3.2015, p. 18.
B. whereas a procedure to renew the approval of flumioxazine under Commission Implementing Regulation (EU) No 844/2012\(^1\) has been ongoing since 2010\(^2\) and the respective application has been submitted in accordance with Article 4 of Commission Regulation (EU) No 1141/2010\(^3\) 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\(^4\) and subsequently by one year every year since 2015 by Commission Implementing Regulations (EU) 2015/1885\(^5\),

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(EU) 2016/549\(^1\), (EU) 2017/841\(^2\), (EU) 2018/917\(^3\), (EU) 2019/707\(^4\) and (EU) 2020/869\(^5\), and now again by one year by Implementing Regulation (EU) 2021/745 which extends the approval period until 30 June 2022;

D. whereas the Commission has failed in Implementing Regulation (EU) 2021/745 to explain the reasons for the extension, other than by stating: ‘Due to the fact that the assessment of those active 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 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;

G. whereas Regulation (EC) No 1107/2009 provides 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 the case of flumioxazine, it is clear that no such proportionality exists;

H. whereas in the 18 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 in accordance with the precautionary principle, when the risk 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 properties

K. whereas, according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council, 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;

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M. whereas in 2015 flumioxazine was placed on the list of ‘candidates for substitution’ 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 approved 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 case 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 Regulation (EC) No 1272/2008 but this has not happened yet; 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, an active substance cannot be approved when it is considered to have endocrine-disrupting properties that may cause adverse effects in humans, unless the exposure of humans to that active substance 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 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 Council1;

Q. whereas flumioxazine has been suspected of having endocrine-disrupting properties since 20142; whereas criteria to determine whether a substance is an endocrine disrupter in the context of Regulation (EC) No 1107/2009, as set out in Commission Regulation (EU) 2018/6053, have been applicable since 20 October 20184; whereas the corresponding guidance was adopted on 5 June 20185; whereas, however, the Commission mandated

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5 European Chemicals Agency (ECHA) and European Food Safety Authority (EFSA) with support from the Joint Research Centre (JRC), ‘Guidance for the identification of
EFSA only on 4 December 2019 to assess the endocrine-disrupting potential of
flumioxazine according to the new criteria;

R. whereas EFSA published in September 2020 its updated peer review of the pesticide risk
assessment of the active substance flumioxazine\(^1\), in which it was not able to rule out
endocrine-disrupting properties as several data gaps were identified, also on other safety
aspects, leading to critical areas of concern;

S. whereas more specifically EFSA identified in the area of mammalian toxicology several
data gaps, issues that could not be finalised and critical area of concerns; whereas EFSA
also identified data gaps in the area of residues and consumer safety, EFSA was not able
to finalise the ground water exposure assessment due to data gaps, and the assessment of
the endocrine-disrupting properties of flumioxazine for humans and non-target organisms
could not be finalised due to the incomplete data sets, which meant that EFSA was not
able to reach a conclusion on whether the criteria for endocrine disruption for both
humans and non-target organisms through EATS-modalities as set in point 3.6.5 and point
2018/605, are met;

T. 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;

U. 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 cannot be ruled out to meet the cut-off criteria due to its endocrine-disrupting
properties, which are established to protect human health and the environment, continues
to be allowed for use in the Union, putting human health and the environmental at risk;

V. 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 by asking for more derogations and special
conditions, which leads to unacceptable risks for human health and the environment since,
during this time, exposure to the hazardous substance continues;

W. 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;

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\(^1\) EFSA conclusion on pesticide peer review, ‘Updated peer review of the pesticide risk
assessment of the active substance flumioxazin’, EFSA Journal 2020;18(9):6246,
X. 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’;

Y. whereas Parliament has already objected to two previous extensions of the approval period of flumioxazine in its resolutions of 10 October 2019\(^1\) and of 10 July 2020\(^2\), and the Commission has failed to give a convincing response to those resolutions and has also failed to properly demonstrate that another extension would not exceed its implementing powers;

Z. whereas following the previous extension in 2020 of the approval periods of 26 active substances, including flumioxazine, under Implementing Regulation (EU) 2020/869, the approvals of only four of the 26 substances covered by that Implementing Regulation have been either renewed or non-renewed, while under Implementing Regulation (EU) 2021/745, the approval periods of 44 active substances have been extended, many of them for a third or fourth time;


2. Considers that Implementing Regulation (EU) 2021/745 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

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neither on evidence that that substance can be used safely, nor on a proven urgent need for that substance in food production in the Union;

5. Calls on the Commission to repeal Implementing Regulation (EU) 2021/745 and to submit a new draft to the committee, which takes into account the scientific evidence on the harmful properties of all the substances concerned, especially those of flumioxazine;

6. Calls on the Commission to present a proposal for non-renewal of the approval of flumioxazine in the next meeting of the Standing Committee on Plants, Animals, Food and Feed;

7. Calls on the Commission to communicate to Parliament the specific reasons why the assessment of the substances has been delayed for reasons beyond the control of the applicants, which specific endpoints are still under assessment, and why that assessment requires so much time to be conducted;

8. Reiterates its call on the Commission to present draft implementing regulations to extend the approval periods only 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;

9. Reiterates its call 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;

10. Reiterates its call 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;

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