European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

B9-0000/2022

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3), and (4)(c) of the Rules of Procedure

on the draft Commission regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for flutianil in or on certain products (D076996/03 – 2022/2524(RPS))

Committee on the Environment, Public Health and Food Safety

Members responsible: Jutta Paulus, Maria Arena, Sirpa Pietikäinen and Mick Wallace

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European Parliament resolution on the draft Commission regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for flutianil in or on certain products (D076996/03–2022/2524(RPS))

The European Parliament,

– having regard to the draft Commission regulation amending Annex II to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for flutianil in or on certain products (D076996/03),

– having regard to 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[1], and in particular Article 14(1), point (a), thereof,

– having regard to the opinion delivered on 30 November 2021 by the Standing Committee on Plants, Animals, Food and Feed,

– 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[2], and in particular Article 1(4), Article 4 and Article 21 thereof,

– having regard to Commission Implementing Regulation (EU) 2019/481 of 22 March 2019 approving the active substance flutianil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011[3],

– having regard to the conclusion adopted by the European Food Safety Authority (EFSA) on 28 July 2014, and published on 6 August 2014[4]

– having regard to the reasoned opinion adopted by EFSA on 7 September 2021, and published on 24 September 2021[5],

– having regard to Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties[6],

– having regard to the ‘Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009’ adopted by the European Chemicals Agency (ECHA) and EFSA with support from the Joint Research Centre (JRC)

[1] OJ L 70, 16.3.2005, p. 1.
[2] OJ L 309, 24.11.2013, p.1.
[3] OJ L 82, 25.3.2019, p. 19.
[4] EFSA conclusion on the peer review of the pesticide risk assessment of the active substance flutianil, EFSA Journal 2014;12(8):3805, https://www.efsa.europa.eu/en/efsajournal/pub/3805
[5] EFSA reasoned opinion on setting of import tolerances for flutianil in various crops, EFSA Journal 2021; 19(9): 6840, https://www.efsa.europa.eu/en/efsajournal/pub/6840
[6] OJ L 101, 20.4.2018, p 33.

on 5 June 2018, and published on 7 June 2018[1],

- having regard to the opinion delivered on 22-23 March 2018 by the Standing Committee on Plants, Animals, Food and Feed,

– having regard to its resolution of 18 April 2019 on a comprehensive European Union framework on endocrine disruptors[2],

– having regard to its resolution of 10 July 2020 on the Chemicals Strategy for Sustainability[3],

– having regard to its resolution of 28 April 2021 on soil protection[4],

– having regard to its resolution of 9 June 2021 on EU Biodiversity Strategy for 2030: Bringing nature back into our lives[5],

– having regard to its resolution of 20 October 2021 on a farm to fork strategy for a fair, healthy and environmentally friendly food system[6],

– having regard to the Summary Report of the Joint Meeting of the Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) on Pesticide Residues (JMPR) published in October 2021[7],

– having regard to the Report 2021 of the JMPR on pesticide residues in food[8],

– having regard to Article 5a(3), point (b), and Article 5a(5) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[9],–having regard to Rule 112(2) and (3), and (4)(c) of its Rules of Procedure,

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

General

A. whereas flutianil is a cyano-methylene thiazolidine fungicide with preventative, residual, eradicative, and antisporulant properties for control of powdery mildew, and inhibits fungal disease and infections in host plants;

B. whereas flutianil is classified by the Fungicide Resistance Action Committee (FRAC) as having an ‘unknown’ (U13) mode of action (MOA)[10]; whereas data collected from greenhouses demonstrated that a high frequency of fungicide resistance is associated

[1] ECHA and EFSA with support of JRC, ‘Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009*, EFSA Journal 2018;16(6):5311, https://www.efsa.europa.eu/en/efsajournal/pub/5311
[2] OJ C 158, 30.4.2021. p. 18.
[3] OJ C 371, 15.9.2021, p. 75.
[4] OJ C 506, 15.12.2021, p. 38.
[5] OJ C 67, 8.2.2022, p. 25.
[6] Texts adopted, P9_TA(2021)0425.
[7] https://www.fao.org/3/cb7241en/cb7241en.pdf
[8] https://www.fao.org/3/cb8313en/cb8313en.pdf
[9] OJ L 184, 17.7.1999, p. 23.
[10] https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2021--final.pdf?sfvrsn=f7ec499a_2

with the use of flutianil to control powdery mildew[1];

Safety concerns

C. whereas, the International Union of Pure and Applied Chemistry (IUPAC) classifies flutianil as volatile with low solubility in water and as persistent to very persistent insoils; whereas information on the effects of chronic exposure to fluianil on honeybees, bumble bees and other pollinators and beneficial insects is lacking, and there is a risk to fish, through (acute and chronic exposure) and to sediment dwelling organisms;

D. whereas, IUPAC identifies flutianil as an endocrine disruptor and possible liver and kidney toxicant and classifies the threshold of toxicological concern in human health and protection under Cramer Class III (high concern)[2];

E. whereas the JMPR evaluated the flutianil metabolite 2-fluoro-5-(trifluoromethyl)benzenesulfonic acid (OC56635) as 'fat soluble' which suggests that this metabolite may be absorbed into the lymph nodes, and stored in the liver and fatty tissues;

F. whereas, the Report 2021 of the JMPR[3] found that no information is available on the mechanism and type of any antimicrobial action on the microbiome of the human gastrointestinal tract, antimicrobial spectrum of activity or antimicrobial resistance mechanisms and genetics;

G. whereas, although no information was provided concerning the health of workers involved in the manufacture or use of flutianil, the JMPR concluded that there was adequate information to characterise potential hazards of flutianil use for the general population, foetuses, infants and children[4];

H. whereas, the JMPR acknowledged the persistence and potential accumulation of flutianil in soils after multiple use and uptake of residues that may significantly contribute to the concentrations of flutianil and OC 56635 in food and feed commodities;

I. whereas, the JMPR concluded that further information was required on long-term soil accumulation of flutianil and its metabolites, in particular OC 56635, and their uptake by succeeding crops in the field, addressing soil residues taking into account the estimated soil plateau concentrations after application over multiple years, as well as on the metabolism of OC 56635 in livestock;

J. whereas, in its conclusion of 28 July 2014, EFSA identified the main effects observed of flutianil on(mice and dogs) were atrophy of seminiferous tubules, histopathological changes in the testis, such as (softening and atrophy, and oligospermia) and found that long term exposure to flutianil in rats produced increased incidences of histopathological changes in the liver and pancreas, liver cholangioma, pancreas islet adenomas and carcinomas;

K. whereas EFSA concluded that flutianil should be classified as a carcinogen category 2

[1] Miyamoto, T., Hayashi, K., Ogawara, T., 'First report of the occurrence of multiple resistance to Flutianil and Pyriofenone in field isolates of *Podosphaera xanthii*, the causal fungus of cucumber powdery mildew', European Journal of Plant Pathology (2020) 156:953–963, https://link.springer.com/content/pdf/10.1007/s10658-020-01946-6.pdf

[2] http://sitem.herts.ac.uk/aeru/iupac/Reports/2608.htm

[3] https://www.fao.org/3/cb8313en/cb8313en.pdf

[4] Report 2021 of the JMPR, p. 132.

and reproductive toxicant (for the development) category 2 and that flutianil produced adverse effects on endocrine organs across different species and timelines[1]; and therefore EFSA deemed flutianil not to fulfil the approval criteria for active substances referred to in Article 4(1) of Regulation (EC) No 1107/2009;

L. whereas, on 4 December 2014, the rapporteur Member State, the United Kingdom, notified its intention, based on Regulation (EC) No 1272/2008 of the European Parliament and of the Council[2], to launch a request for harmonised classification and labelling (CLH) for flutianil ;

M. whereas, following the United Kingdom's request, the CLH report for flutianil published in May 2015 assigned the following hazard statements: H361d - Suspected of damaging the unborn child; Aquatic Chronic 1; H410 – Very toxic to aquatic life with long lasting effects and that precautionary statements were not required[3];

N. whereas, in March 2016, the Risk Assessment Committee (RAC) of ECHA proposed that flutianil should not be classified as carcinogenic or toxic to reproduction;

O. whereas following a request of the Commission, EFSA adopted on 5 July 2018 a statement[4] acknowledging that the harmonised classification proposed by RAC was based on 'new information' differing from the classification previously used by EFSA in its conclusion;

P. whereas the 'new information' extrapolated from the CLH report for flutianil did not assess endocrine disruption and is based on an extensive number of unpublished animal studies with heavily redacted references which make it impossible to peer review;

Q. whereas in its statement of 5 July 2018, EFSA identified a number of outstanding issues that could not be finalised due to a lack of information available with regard to residues of the highly persistent soil metabolite OC 56635;

R. whereas, the consumer risk assessment was not finalised with regard to residues of metabolite OC 56635 in situations where groundwater is used as drinking water, and therefore, further assessment of that metabolite for groundwater is relevant for environmental fate and behaviour;

S. whereas, the consumer risk assessment was not finalised with regard to the unknown nature of residues that might be present in drinking water, consequent to water treatment following abstraction of surface and groundwater water that might contain metabolites OC 56635, AP5A and OC 53276 which is relevant for environmental fate and behaviour;

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[1] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2014.3805

[2] 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).

[3] CLH report for flutianil based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2, UK CLP Competent Authority, May 2015, https://echa.europa.eu/documents/10162/cee7e1cb-a737-2d6d-26e6-16afdec1e960, p. 8.

[4] EFSA statement on the impact of the harmonised classification on the conclusion on the peer review of the pesticide risk assessment of the active substance flutianil, EFSA Journal 2018;16(7):5383, https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5383

T. whereas, futianil produced adverse effects on endocrine organs across different species and timelines and an endocrine-mediated mode of action could not be ruled out, but this issue could not be finalised since mechanistic information was not available and such information is relevant for toxicology and ecotoxicology ;

U. whereas on 4 October 2018, the active substance flutianil was included by Commission Regulation (EU) 2018/1480[1] in Part 3 of Annex VI to Regulation (EC) No 1272/2008 with no classification as carcinogenic or toxic to reproduction or endocrine disruption;

V. whereas, in relation to the new criteria to identify endocrine disrupting properties set in Regulation (EU) 2018/605, although adverse effects on the thyroid were observed, and histopathological changes in testicular, prostate and uterine tissues were found, EFSA inferred that it is 'highly unlikely that flutianil is an endocrine disruptor via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities' (EATS)[2];

W. whereas, however, the ECHA and EFSA Guidance of 5 June 2018 states that 'where adverse is based on "EATS-mediated" parameters ..., the underlying knowledge of the likely endocrine nature of the effects may be such that judgement can be reached on the biological plausibility of a link without recourse to a detailed MoA analysis[3];

X. whereas, according to the ECHA and EFSA Guidance of 5 June 2018 'there may be situations where an adverse effect has been identified which, based on current knowledge, is highly likely to be E, A or S but due to the complexity and cross-talk of the endocrine system it is difficult to identify the specific modality. In such cases, this should be considered an ED regardless through which modality the substance causes adversity'[4].

Y. whereas Regulation (EC) No 1107/2009 is underpinned by the precautionary principle in order to ensure that substances do not adversely affect human and animal health or the environment; whereas, therefore, simply inferring that flutianil effects are not endocrine-related without providing robust evidence is contrary to the precautionary principle and should be considered illegal under Union law;

Z. whereas, in Implementing Regulation (EU) 2019/481, the Commission concluded that particular attention is required for the protection of operators and workers, the risk to aquatic organisms, and the risk to groundwater from metabolites, if the substance is applied under vulnerable soil or climatic conditions.

AA. whereas, in Implementing Regulation (EU) 2019/481, the Commission also concluded that the applicant must submit confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater when

[1] Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).
[2] Commission Implementing Regulation (EU) 2019/481 of 22 March 2019 approving the active substance flutianil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 82, 25.3.2019, p.19).
[3] ECHA and EFSA Guidance of 5 June 2018, p. 39.
[4] ECHA and EFSA Guidance of 5 June 2018, p. 40.

surface water or ground water is abstracted for drinking water, and as regards updated assessment confirming that flutianil is not an endocrine disruptor;

Draft Commission regulation

AB. whereas the draft Commission regulation has been proposed following an application to increase maximum residue levels (MRLs) for import tolerances for flutianil used in the United States on apples, cherries (sweet), strawberries, cucumbers, courgettes and melons;

AC. whereas the applicant claims that the authorised uses of flutianil on crops in the United States lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation into the Union of those crops;

AD. whereas, the draft Commission regulation gives rise to concerns regarding the safety of flutianil on the basis of the precautionary principle, given the data gaps related to endocrine disruption and the cumulative and synergistic effects on public health, soil health and the aquatic environment;

Precautionary principle

AE. whereas, Article 191(2) of the Treaty on the Functioning of the European Union (TFEU) sets out the precautionary principle as one of the fundamental principles of the Union;

AF. whereas, Article 168(1) TFEU states that '[a] high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities';

AG. whereas, when setting MRLs, cumulative and synergistic effects need to be taken into account, and it is of the upmost importance to urgently develop the appropriate methods for this assessment;

1. Opposes adoption of the draft Commission regulation;

2. Considers that the draft Commission regulation is not compatible with the aim and content of Regulation (EC) No 396/2005;

3. Regrets that the assessment of the cumulative risk of the impacts of chemicals on public health, the environment and biodiversity tends to be underestimated in the socio-economic analysis during the authorisation process;

4. Calls on the Commission, in its role as risk manager, to duly apply the precautionary principle when following an assessment of available information, so that the risk of harmful effects, including chronic and long-term effects on human health, the environment, biodiversity and animal welfare is quantified;

5. Acknowledges that EFSA is working on methods to assess cumulative effects of pesticides and residues; therefore requests EFSA and the Commission to address the problem as a matter of urgency;

6. Calls on the Commission and Member States to undertake updated assessments to address the data gaps and confirm that fluitanil is not an endocrine disruptor in accordance with Annex II to Regulation (EC) No 1107/2009 and prioritise further research and analysis and collect and publish all data on the endocrine-disrupting properties of flutianil;

7. Calls on the Commission and Member States to ensure that time-cumulative, up-to-date, peer-reviewed and eco-toxicological tests for non-target species in the soil and aquatic environment are included in the risk assessment, and also, that the risk assessment includes residues in the air, soil and water; including the long-term, cumulative effects, and specifies which independent, peer-reviewed scientific studies and scientific opinions were considered;

8. Calls on the Commission to ensure also that such a risk assessment is transparent and serves to better protect human, health, biodiversity and aquatic ecosystems, insects, earthworms and soil microorganisms; stresses that this information should be publicly accessible;

9. Notes that under the draft Commission regulation, the MRLs for flutianil would increase from 0,01 to 0,15mg/kg for apples, from 0,01 to 0,40mg/kg for sweet cherries, from 0,01 to 0,30 mg/kg for strawberries, from 0,01 to 0,03mg/kg for cucumbers, and from 0,01 to 0,03 mg/kg for courgettes;

10. Considers that free trade rules should never lead to the lowering of the Union's protective standards;

11. Recalls that by raising import tolerance levels of flutianil MRLs for crops that are also grown within the Union would place Union producers at a competitive disadvantage and suggests that the MRLs for flutianil should remain at 0,01 mg/kg;

12. Calls on the Commission and Member States to ensure equal standards and effective checks on agricultural products imported from third countries;

13. Calls on the Commission to withdraw the draft regulation;

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