European Parliament
2019-2024

TEXTS ADOPTED

P9_TA(2021)0133

Objection to an implementing act: Maximum residue levels for certain substances, including flonicamid

European Parliament resolution of 27 April 2021 on the draft Commission regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, acibenzolar-S-methyl, *Bacillus subtilis* strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin in or on certain products (D063854/04 – 2021/2608(RPS))

The European Parliament,

– having regard to the draft Commission regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, acibenzolar-S-methyl, *Bacillus subtilis* strain IAB/BS03, emamectin, flonicamid, flutolanil, fosetyl, imazamox and oxathiapiprolin in or on certain products (D063854/04),

– 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 5(1) and Article 14(1)(a) thereof,

– having regard to the opinion delivered on 18 February 2020 by the Standing Committee on Plants, Animals, Food and Feed,

– having regard to Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides[2],

– having regard to the reasoned opinion adopted by the European Food Safety Authority (EFSA) on 27 May 2019, and published on 2 August 2019[3],

– having regard to the reasoned opinion adopted by EFSA on 17 August 2018, and

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1 OJ L 70, 16.3.2005, p. 1.
2 OJ L 309, 24.11.2009, p. 71.
3 EFSA reasoned opinion on modification of the existing maximum residue levels for flonicamid in strawberries and other berries, EFSA Journal 2019;17(7):5745, https://www.efsa.europa.eu/en/efsajournal/pub/5745

published on 25 September 2018[1],

– having regard to the reasoned opinion adopted by EFSA on 29 August 2018, and published on 18 September 2018[2],

– having regard to the conclusion adopted by EFSA on 18 December 2009, and published on 7 May 2010[3],

– having regard to the opinion of 5 June 2013[4] of the Committee for Risk Assessment of the European Chemicals Agency,

– having regard to Article 5a(3)(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[5],

– 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,

A. whereas the communication of the Commission of 20 May 2020 entitled 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system'[6] promotes a 'global transition to sustainable agri-food systems, in line with the objectives of this strategy and the SDGs';

B. whereas flonicamid is a selective, systemic insecticide that acts by disrupting insect feeding, movement, and other behaviours, resulting in starvation and dehydration followed by death[7];

C. whereas the approval period of flonicamid as an active substance has been extended by Commission Implementing Regulation (EU) 2017/2069[8];

D. whereas the Committee for Risk Assessment of the European Chemicals Agency, in its

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1 EFSA reasoned opinion on modification of the existing maximum residue level for flonicamid in various crops, EFSA Journal 2018;16(9):5410, https://www.efsa.europa.eu/en/efsajournal/pub/5410

2 EFSA reasoned opinion on modification of the existing maximum residue levels for flonicamid in various root crops, EFSA Journal 2018;16(9):5414, https://www.efsa.europa.eu/en/efsajournal/pub/5414

3 EFSA conclusion on the peer review of the pesticide risk assessment of the active substance flonicamid, EFSA Journal 2010; 8(5):1445, https://www.efsa.europa.eu/en/efsajournal/pub/1445

4 Opinion of 5 June 2013 of the Committee for Risk Assessment proposing harmonised classification and labelling at EU level of flonicamid, https://echa.europa.eu/documents/10162/0916c5b3-fa52-9cdf-4603-2cc40356ed95

5 OJ L 184, 17.7.1999, p. 23.

6 COM(2020)0381.

7 https://www.regulations.gov/document/EPA-HQ-OPP-2014-0777-0041

8 Commission Implementing Regulation (EU) 2017/2069 of 13 November 2017 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances flonicamid (IKI-220), metalaxyl, penoxsulam and proquinazid (OJ L 295, 14.11.2017, p. 51).

opinion of 5 June 2013[1], reports about results of rat experiments leading to increased placental weight, delayed vaginal opening, reduced uterus and ovary weights, decreased estradiol and increased LH levels, but finds them to be not related or not relevant; whereas the Danish Member State Competent Authority observes 'clear effects on visceral malformations occurring at non-maternally toxic levels in the rabbit'[2] ;

E. whereas the Interim Registration Review Decision (Case Number 7436) of 14 December 2020 of the United States Environmental Protection Agency (EPA) on flonicamid finds that '[a] more complete assessment of risk to bees cannot be conducted without higher-tiered pollinator data', that '[t]he available Tier I acute oral toxicity study was not adequate for quantitative use, and Tier II and Tier III pollinator studies are not available for flonicamid at this time' and that '[t]he adult acute oral honeybee toxicity test and the Tier II and III honeybee data (i.e., semi-field/field studies) requirements remain unfulfilled'[3] ;

F. whereas the Attorney General of California, Xavier Becerra, criticises, in his comments of 2 November 2020[4] to the proposed Interim Registration Review Decision, that EPA lacks sufficient information to characterise flonicamid's risks to pollinators;

G. whereas the Attorney General further explains, referring to the EPA ecological risk assessment, that a new chronic adult honeybee study included an extended observation period designed to capture flonicamid's delayed toxicity, since effects are often not observed until many days later, after insects have starved; whereas the new study found that flonicamid is extremely toxic to adult bees; whereas, based on these results, EPA determined that the registered uses of flonicamid would expose bees to 17 to 51 times the amount of flonicamid that would cause substantial harm; whereas, during the extended observation period, mortality continued to increase at all test concentrations in a dose dependent manner; whereas mortality did not stabilise by the end of the extended observation period in the flonicamid arms of the study;

H. 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;

I. 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';

J. whereas Directive 2009/128/EC aims to achieve a sustainable use of pesticides in the Union by reducing the risks and impacts of pesticide use on human and animal health and the environment and by promoting the use of integrated pest management and of alternative approaches or techniques, such as non-chemical alternatives to pesticides;

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1 Opinion of 5 June 2013 of the Committee for Risk Assessment proposing harmonised classification and labelling at EU level of flonicamid, https://echa.europa.eu/documents/10162/0916c5b3-fa52-9cdf-4603-2cc40356ed95

2 Annex 2 to opinion of 5 June 2013 of the Committee for Risk Assessment proposing harmonised classification and labelling at EU level of flonicamid, https://echa.europa.eu/documents/10162/1e59e8be-0905-5fc1-8e76-a35628fa5833

3 Docket Number EPA-HQ-OPP-2014-0777, https://www.regulations.gov/document/EPA-HQ-OPP-2014-0777-0041, p. 13 and p. 18.

4 https://oag.ca.gov/sites/default/files/FINAL%20Flonicamid%20PID%20Comment%20Letter.pdf

K. whereas when setting maximum residue levels (MRLs), cumulative and synergistic effects need to be taken into account, and it is of the utmost importance to develop urgently appropriate methods for this assessment;

L. whereas, under the draft Commission regulation, the MRLs for flonicamid would increase from 0,03 mg/kg, which corresponds to the current limit of detection, to 0,7 mg/kg for strawberries, to 1 mg/kg for blackberries and raspberries, to 0,7 mg/kg for rose hips, mulberries, azaroles/Mediterranean medlars, elderberries, and other small fruits and berries, to 0,8 mg/kg for blueberries, cranberries, currants, gooseberries, to 0,3 mg/kg for other root and tuber vegetables generally, but to 0,6 mg/kg for radishes, to 0,07 mg/kg for lettuces and salad plants, and to 0,8 mg/kg for pulses;

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. Acknowledges that EFSA is working on methods to assess cumulative risks, but also notes that the problem of the assessment of cumulative effects of pesticides and residues has been known for decades; therefore requests EFSA and the Commission to address the problem as a matter of absolute urgency;

4. Suggests that the MRLs for flonicamid should remain at 0,03 mg/kg;

5. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee;

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