



TEXTS ADOPTED

P8_TA(2019)0195

Objection to an implementing act: Maximum residue levels for several substances including clothianidin

European Parliament resolution of 13 March 2019 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 clothianidin, cycloxydim, epoxiconazole, flonicamid, haloxyfop, mandestrobin, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione in or on certain products (D059754/02 – 2019/2520(RPS))

The European Parliament,

- 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 pesticides¹,
- 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 clothianidin, cycloxydim, epoxiconazole, flonicamid, haloxyfop, mandestrobin, mepiquat, *Metschnikowia fructicola* strain NRRL Y-27328 and prohexadione in or on certain products (D059754/02),
- 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, and in particular Article 5(1) and Article 14(1)(a) thereof²,
- having regard to the reasoned opinion of 25 November 2014 of the European Food Safety Authority (EFSA) on the review of the existing maximum residue levels (MRLs) for clothianidin and thiamethoxam according to Article 12 of Regulation (EC) No 396/2005, published on 4 December 2014³,
- having regard to the EFSA reasoned opinion of 30 August 2018 on modification of the existing maximum residue level for clothianidin in potatoes, published on 20 September

¹ OJ L 309, 24.11.2009, p. 71.

² OJ L 70, 16.3.2005, p. 1.

³ DOI: 10.2903/j.efsa.2014.3918, EFSA Journal 2014;12(12):3918.

2018¹,

- having regard to the opinion delivered on 27 November 2018 by the Standing Committee on Plants, Animals, Food and Feed,
- 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 Commission²,
- having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- having regard to Rule 106(2) and (3), and (4)(c) of its Rules of Procedure,
- A. whereas clothianidin is a neonicotinoid insecticide and a major metabolite of another neonicotinoid, thiamethoxam, that targets a range of insects, including pollinators;
- B. whereas on 21 September 2017, EFSA adopted an opinion on the toxicity of neonicotinoids;
- C. whereas on 28 February 2018, EFSA published updated risk assessments for three neonicotinoids – clothianidin, imidacloprid and thiamethoxam – confirming that most uses of neonicotinoid pesticides represent a risk to wild bees and honey bees³;
- D. whereas clothianidin is one of the three neonicotinoids that are banned in the Union;
- E. whereas several studies suggest that clothianidin has an impact on hepatic and renal metabolism, and has immunotoxic effects on mammals⁴;
- F. 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;
- G. 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’;
- H. 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;
- I. whereas the draft Commission regulation, on the basis of applications for import

¹ DOI: 10.2903/j.efsa.2018.5413, EFSA Journal 2018;16(9):5413.

² OJ L 184, 17.7.1999, p. 23.

³ DOI: 10.2903/sp.efsa.2018.EN-1378.

⁴ Bal R. et al., ‘Effects of clothianidin exposure on sperm quality, testicular apoptosis and fatty acid composition in developing male rats’, *Cell Biol Toxicol*, Vol. 28, No 3, 2012, pp. 187-200; Tokumoto J. et al., ‘Effects of exposure to clothianidin on the reproductive system of male quails’, *J. Vet. Med. Sci.*, Vol. 75, No 6, 2013, pp. 755–760; Wang Y. et al., ‘Metabolism distribution and effect of thiamethoxam after oral exposure in Mongolian racerunner (*Eremias argus*)’, *J. Agric. Food Chem.*, Vol. 66, No 28, 2018, pp. 7376–7383; Wang X. et al., ‘Mechanism of neonicotinoid toxicity: Impact on oxidative stress and metabolism’, *Annu. Rev. Pharmacol. Toxicol.*, Vol. 58, No 1, 2018, pp. 471-507.

tolerances submitted for clothianidin used on potatoes in the United States, considers that higher MRLs are necessary to avoid trade barriers to the importation of such crops;

- J. whereas the Commission's proposal to increase the MRLs for clothianidin raised doubts, on the basis of the precautionary principle, given the data gaps and persistent uncertainty as to the effects of clothianidin on public health, young mammals and the environment;
 - K. whereas EFSA states, in relation to the request to raise the MRLs, that Member States have to amend or withdraw existing authorisations for plant protection products containing clothianidin as an active substance under Commission Implementing Regulation (EU) 2018/784¹ by 19 September 2018 at the latest; whereas such restrictions to the clothianidin conditions of approval are not relevant as the MRL application concerns an imported crop;
 - L. whereas in its opinion of 30 August 2018, EFSA notes that: 'In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience AG submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) to set an import tolerance for the active substance clothianidin in potatoes imported from Canada. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 26 April 2018. The EMS proposed to set an import tolerance for potatoes imported from Canada at the level of 0.3 mg/kg';
 - M. whereas the conclusions drawn by EFSA in its opinion of 30 August 2018 justify the clothianidin MRL increase only on the basis of the need to comply with Canadian normative values, and totally omit to analyse the cumulative environmental impact of neonicotinoids and their use;
 - N. whereas EFSA's conclusions were formulated on the basis of theoretical considerations, particularly as regards the estimate of the maximum daily intake in relation to short-term risk; whereas the theoretical nature of some aspects of EFSA's analysis raises doubts as to its ability to rely on empirical facts and, as a consequence, to represent reality in its results;
 - O. whereas EFSA concluded that an increase in the MRLs of clothianidin was 'unlikely' to pose a risk to consumer health; whereas, however, this verdict involves a degree of probability and therefore leaves some doubt as to the effective safety of the new MRL values;
1. Opposes adoption of the draft Commission regulation;
 2. Considers that the draft Commission regulation exceeds the implementing powers provided for in Regulation (EC) No 396/2005;
 3. Considers that the draft Commission regulation is not compatible with the aim and content of Regulation (EC) No 396/2005;

¹ Commission Implementing Regulation (EU) 2018/784 of 29 May 2018 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance clothianidin (OJ L 132, 30.5.2018, p. 35).

4. Notes that under the draft regulation, the existing MRL of clothianidin would increase from 0,03 to 0,3 mg/kg;
5. Suggests that the MRL of clothianidin should remain at 0,03 mg/kg;
6. Considers that the decision to register clothianidin cannot be justified, as there is insufficient evidence to suggest that unacceptable risks to animals, food safety and pollinators will be prevented;
7. Notes that even if the procedure followed the existing Directive 2009/128/EC on pesticides, the fact that the German applicant company chose as an evaluating Member State the German competent national authority echoes concerns about the pesticide evaluation process raised by several stakeholders, as mentioned in recitals AJ and AK of Parliament's resolution of 16 January 2019 on the Union's authorisation procedure for pesticides¹;
8. Recalls that the use of clothianidin as a pesticide affects pollinators on a global scale²;
9. Considers that EFSA's opinion did not take into account the cumulative risk to human health and bees; believes that effects on pollinators and the environment should be taken into account when evaluating MRLs; calls on the Member States and on EFSA to exercise greater vigilance towards the health of the public and pollinators when evaluating applications for MRLs;
10. Calls on the Commission to withdraw the draft Commission regulation;
11. Calls on the Commission to submit a new act, on the basis of the TFEU, that respects the precautionary principle;
12. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

¹ Texts adopted, P8_TA(2019)0023

² El Hassani, A. K., Dacher, M., Gary, V., Lambin, M., Gauthier, M. and Armengaud, C., 'Effets sublétaux de l'Acétamipride et du Thiamethoxam sur le comportement de l'abeille (*Apis mellifera*)', 23 May 2014, https://www.researchgate.net/publication/255636607_Effets_sublétaux_de_l%27Acetamipride_et_du_Thiamethoxam_sur_le_comportement_de_l%27abeille_Apis_mellifera