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TEXTS ADOPTED

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**P9\_TA(2021)0132**

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

**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 acclonifen, acrinathrin, *Bacillus pumilus* QST 2808, chlorantraniliprole, ethirimol, lufenuron, penthiopyrad, picloram and *Pseudomonas sp.* strain DSMZ 13134 in or on certain products (D070113/03 – 2021/2590(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 acclonifen, acrinathrin, *Bacillus pumilus* QST 2808, chlorantraniliprole, ethirimol, lufenuron, penthiopyrad, picloram and *Pseudomonas sp.* strain DSMZ 13134 in or on certain products (D070113/03),
- 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<sup>1</sup>, and in particular Article 5(1) and Article 14(1)(a) thereof,
- having regard to the opinion delivered on 4 December 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<sup>2</sup>,
- having regard to the reasoned opinion adopted by the European Food Safety Authority (EFSA) on 15 July 2020, and published on 18 August 2020<sup>3</sup>,
- having regard to the reasoned opinion adopted by EFSA on 18 November 2016, and

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<sup>1</sup> OJ L 70, 16.3.2005, p. 1.

<sup>2</sup> OJ L 309, 24.11.2009, p. 71.

<sup>3</sup> EFSA reasoned opinion on the setting of import tolerances for lufenuron in various commodities of plant and animal origin, EFSA Journal 2020;18(8):6228, <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6228>

published on 5 January 2017<sup>1</sup>,

- having regard to the scientific report approved by EFSA on 30 September 2008, and published on 22 June 2009<sup>2</sup>,
  - having regard to Article 5a(3)(b) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>3</sup>,
  - having regard to Rule 112(2) and (3), and (4)(c) of its Rules of Procedure,
  - having regard to the motion for a resolution by the Committee on the Environment, Public Health and Food Safety,
- A. whereas lufenuron is a benzoylurea pesticide that inhibits the production of chitin in insects, and is used as a pesticide and fungicide; whereas the Union approval of lufenuron expired on 31 December 2019 and no application for renewal was submitted in the framework of Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>4</sup>; whereas lufenuron is no longer approved for use in the Union, but is exported as an agri-food pesticide; whereas according to a study of the German Environment Agency<sup>5</sup>, lufenuron meets the criteria for substances that are persistent, bioaccumulative and toxic, which are laid down in Annex XIII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council<sup>6</sup>;
- B. 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;
- C. whereas Article 168(1) TFEU states that ‘[a] high level of human health protection shall

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<sup>1</sup> EFSA reasoned opinion on the review of existing maximum residue levels for lufenuron according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2017;15(1):4652, <https://doi.org/10.2903/j.efsa.2016.4652>

<sup>2</sup> EFSA scientific report on the conclusion regarding the peer review of the pesticide risk assessment of the active substance lufenuron, EFSA Journal 2009;7(6):189, <https://doi.org/10.2903/j.efsa.2009.189r>.

<sup>3</sup> OJ L 184, 17.7.1999, p. 23.

<sup>4</sup> 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 (OJ L 309, 24.11.2009, p. 1).

<sup>5</sup> Altenburger, R., Gündel, U., Rotter, S., Vogs, C., Faust, M., Backhaus, T., ‘Establishment of a concept for comparative risk assessment of plant protection products with special focus on the risks to the environment’, Text 47/2017, Report No. (UBA-FB) 002256/ENG, [https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2017-06-07\\_texte\\_47-2017\\_umweltrisiken-pflanzenschutzmittel.pdf](https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2017-06-07_texte_47-2017_umweltrisiken-pflanzenschutzmittel.pdf)

<sup>6</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

be ensured in the definition and implementation of all Union policies and activities’;

- D. 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 by promoting alternative approaches;
  - E. whereas the United Nations Stockholm Convention on Persistent Organic Pollutants and the meeting of the Persistent Organic Pollutants Review Committee 2012<sup>1</sup> identified the high potential of lufenuron to meet all persistent organic pollutants criteria;
  - F. 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’<sup>2</sup> promotes a ‘global transition to sustainable agri-food systems’ not only within the Union’s borders but also outside, and aims to ‘take into account environmental aspects when assessing requests for import tolerances for pesticide substances no longer approved in the EU while respecting WTO standards and obligations’;
  - G. whereas the draft Commission regulation has been proposed following an application submitted for import tolerances for lufenuron used in Brazil on grapefruits and sugar canes, which states that higher maximum residue levels (MRLs) are necessary to avoid non-tariff trade barriers for the importation of those crops;
  - H. whereas the draft Commission regulation gives rise to concerns regarding the safety of lufenuron on the basis of the precautionary principle, given the data gaps related to the effect of lufenuron on public health and the environment;
  - I. whereas, in its opinion of 15 July 2020, EFSA notes: ‘In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Portugal (evaluating Member State, EMS) to set import tolerances for the active substance lufenuron in various crops and products of animal origin on the basis of authorised uses of lufenuron in Brazil, Chile and Morocco. 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 24 May 2019’; whereas the EMS proposed to raise MRLs for lufenuron in grapefruits (x30) and sugar canes (x2) from Brazil, and also to raise MRLs for lufenuron in commodities of animal origin;
  - J. whereas the conclusions drawn by EFSA in its opinion of 15 July 2020 justify the increase of the MRLs for lufenuron only on the basis of the need to comply with normative values in Brazil, and omit any consideration concerning the long term cumulative effect of lufenuron on reproductive toxicity, developmental neurotoxicity and its immunotoxic potential following prolonged ingestion;
- 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. Considers that the draft Commission regulation exceeds the implementing powers

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<sup>1</sup> UNEP/POPS/POPRC.8/INF/29.

<sup>2</sup> COM(2020)0381.

provided for in Regulation (EC) No 396/2005; notes that recital 5 of that Regulation states that MRLs should be set at the lowest achievable level with a view to protecting vulnerable groups such as children and unborn children;

4. Notes that, under the draft Commission regulation, the existing MRLs of lufenuron would increase from 0,01 mg/kg to 0,30 mg/kg for grapefruits and from 0,01 mg/kg to 0,02 mg/kg for sugar canes;
5. Notes that a recent scientific report concluded that lufenuron can induce teratogenic effects and histopathologic changes to the liver and kidney in rats, which suggests that pregnant women and their unborn children could be at risk<sup>1</sup>;
6. Notes that exposure to insecticides induces biochemical alterations, including oxidative stress, and that maternal environmental exposure to chemical pollutants was recently ranked as the second most important cause of infant mortality in developing countries<sup>2</sup>;
7. Reiterates that the trans-generational effects of pesticide exposure are insufficiently studied and that the effects of pesticide exposure in humans in the gestational period are seldom studied; underlines that there is increasing evidence concerning the role of repeated exposures during early life;
8. Suggests that the MRLs for lufenuron should remain at the lowest level of determination;
9. Considers that the decision to increase the MRLs for lufenuron cannot be justified, as there is insufficient evidence to suggest that the risk to pregnant women and their unborn children and to food safety is acceptable;
10. Calls on the Commission to withdraw the draft regulation and submit a new one to the committee, respecting the precautionary principle;
11. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

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<sup>1</sup> Basal, W.T., Rahman T. Ahmed, A., Mahmoud, A.A., Omar, A.R., 'Lufenuron induces reproductive toxicity and genotoxic effects in pregnant albino rats and their fetuses', Scientific reports, 2020: 10:19544,  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7658361/>

<sup>2</sup> Cremonese, C., Freire, C., Machado De Camargo, A., Silva De Lima, J., Koifman, S., Meyer, A., 'Pesticide consumption, central nervous system and cardiovascular congenital malformations in the South and Southeast region of Brazil', International Journal of Occupational Medicine and Environmental Health. 2014; 27(3), p. 474-86,  
<https://pubmed.ncbi.nlm.nih.gov/24847732/>