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## Objection to an implementing act: Maximum residue levels for cyproconazole

**European Parliament resolution of 18 September 2024 on the draft Commission regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyproconazole and spirodiclofen in or on certain products (D091952/05 – 2024/2759(RPS))**

(C/2024/7210)

*The European Parliament,*

- having regard to the draft Commission regulation amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for cyproconazole and spirodiclofen in or on certain products (D091952/05),
- 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 14(1), point (a), and Article 49(2) thereof,
- 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<sup>(2)</sup>, and in particular Article 4(1) and Article 4(2), first subparagraph, point (a), and point 3.6.4 of Annex II,
- having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety<sup>(3)</sup>, and in particular Article 5(1) thereof,
- having regard to Articles 11, 13, 168 and 191 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to the reasoned opinion adopted by the European Food Safety Authority (EFSA) on 19 February 2021, and published on 22 March 2021<sup>(4)</sup>,
- having regard to the conclusion on pesticide peer review adopted by EFSA on 8 November 2010, and published on 25 November 2010<sup>(5)</sup>,
- having regard to the opinion adopted by the Committee for Risk Assessment (RAC) of the European Chemical Agency on 11 September 2015<sup>(6)</sup>,
- 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<sup>(7)</sup>,
- having regard to Rule 115(2) and (3), and (4)(c) of its Rules of Procedure,

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

<sup>(2)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(3)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(4)</sup> EFSA reasoned opinion on the review of the existing maximum residue levels for cyproconazole according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2021;19(3):e06483, <https://doi.org/10.2903/j.efsa.2021.6483>.

<sup>(5)</sup> EFSA conclusion on the peer review of the pesticide risk assessment of the active substance cyproconazole, EFSA Journal 2010;8(11):1897, <https://doi.org/10.2903/j.efsa.2010.1897>.

<sup>(6)</sup> RAC opinion proposing harmonised classification and labelling at EU level of Cyproconazole (ISO): (2RS,3RS;2RS,3SR)-2-(4-chlorophenyl)-3-cyclopropyl-1-(1H-1,2,4-triazol-1-yl)butan-2-ol, <https://echa.europa.eu/documents/10162/6d98baeb-24aa-a683-28ec-d8adabee5461>.

<sup>(7)</sup> OJ L 184, 17.7.1999, p. 23.

- having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
- A. whereas the farmers' protests that took place in the first half of 2024 had as one of their core demands a fair and equal treatment for products imported from third countries, which should follow the same standards as products produced in the Union;
- B. whereas the adoption of the draft Commission regulation would allow for the continuation of imports into the Union which do not comply with the standards by which Union farmers abide;
- C. whereas such a situation would place Union farmers at a competitive disadvantage;
- D. whereas cyproconazole is a fungicide of the class of azoles, mainly used on cereal crops, coffee, sugar beet, apples and grapes, and peanuts;
- E. whereas the approval of the active substance cyproconazole expired on 31 May 2021; whereas an application for renewal was submitted in September 2018 but was withdrawn in December 2018; whereas all authorisations for plant protection products containing cyproconazole have been revoked;
- F. whereas cyproconazole is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council<sup>(8)</sup> as toxic for reproduction category 1B, toxic if swallowed (acute tox. 3), toxic to the liver (STOT RE 2) as well as very toxic for aquatic life (aquatic acute 1) and very toxic for aquatic life with long-lasting effects (aquatic chronic 1)<sup>(9)</sup>;
- G. whereas cyproconazole belongs to the triazole group of ergosterol-biosynthesis inhibitors, and thus might cause endocrine-disrupting effects<sup>(10)</sup>; whereas its endocrine-disrupting potential has not been assessed by EFSA according to the scientific criteria for the determination of endocrine disrupting properties set out in Commission Regulation (EU) 2018/605<sup>(11)</sup> which has applied since 10 November 2018; whereas endocrine-related effects frequently occur at low-dose levels and endocrine disruptor substances often do not have a safe threshold<sup>(12)</sup>;
- H. whereas a growing number of publications highlight that azole fungicides constitute a significant source of the increasing incidence of environmental resistance to *Aspergillus* spp<sup>(13)</sup>; whereas EFSA has been requested by the Commission to assess the impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* spp; whereas the scientific report requested is not yet published and is only expected to be finalised in December 2024<sup>(14)</sup>;
- I. whereas it is therefore appropriate to delete the existing maximum residue levels (MRLs) set for cyproconazole in Annex II to Regulation (EC) No 396/2005 in accordance with Article 17 of that Regulation according to which the Commission is to delete MRLs that are set out in Annexes II and III to that Regulation to the default value of 0,01 mg/kg or the relevant limit of determination without seeking the opinion of EFSA for an active substance if its authorisation has been revoked;
- J. whereas, in the draft Commission regulation, the Commission is, however, proposing to maintain the MRLs of a large quantity of products (cereals, seeds, meat, liver and kidney) above the relevant limit of determination or the default MRL value of 0,01 mg/kg based on MRLs established by the Codex Alimentarius Commission (CXLs);

<sup>(8)</sup> 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).

<sup>(9)</sup> <https://www.echa.europa.eu/substance-information/-/substanceinfo/100.130.443>.

<sup>(10)</sup> EFSA conclusion on pesticide peer review of 8 November 2010; Draskau, M.K., and Svingen, T., 'Azole Fungicides and Their Endocrine Disrupting Properties: Perspectives on Sex Hormone-Dependent Reproductive Development', *Frontiers in Toxicology* 2022, 4:883254, <https://doi.org/10.3389/ftox.2022.883254>.

<sup>(11)</sup> 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 (OJ L 101, 20.4.2018, p. 33).

<sup>(12)</sup> EFSA scientific report of the Endocrine Active Substances Task Force, EFSA Journal 2010;8(11):1932, <https://doi.org/10.2903/j.efsa.2010.1932>.

<sup>(13)</sup> Zhang, J., Jimenez, L.L., Snelders, E., Debets, A.J.M., Rietveld, A.G., Zwaan, B.J., Verweij, P.E., Schoustra, S.E., 'Dynamics of *Aspergillus fumigatus* in Azole Fungicide-Containing Plant Waste in the Netherlands (2016-2017)', *Applied and Environmental Microbiology* 2021, 87:e02295-20, <https://doi.org/10.1128/AEM.02295-20>; The Danish Environment and Food Committee on azole resistance, <https://www.ft.dk/samling/2018/1/almel/MOF/bilag/407/2016336.pdf>; Snelders, E., Camps, S.M.T., Karawajczyk, A., Schaftenaar, G., Kema, G.H.J., van der Lee, H.A., et al., 'Triazole Fungicides Can Induce Cross-Resistance to Medical Triazoles in *Aspergillus fumigatus*', *PLoS ONE* 2012, 7(3): e31801. <https://doi.org/10.1371/journal.pone.0031801>.

<sup>(14)</sup> <https://open.efsa.europa.eu/question/EFSA-Q-2022-00040>.

K. whereas the Commission is proposing to set the MRLs at their levels of CXLs for peas (without pods), beans, peas, barley, buckwheat and other pseudocereals, maize/corn, common millet/proso millet, oat, rye, wheat, coffee beans and sugar beet roots, muscle and fat of swine, cattle, sheep, goat and horse, and muscle, fat and liver of poultry, milk of cattle, sheep, goat and horse, and birds eggs; whereas it means that MRLs for the liver and kidney of swine, bovine, sheep, goat and horse would be maintained at the existing levels of 0,5 mg/kg, for rapeseeds/canola seeds at 0,4 mg/kg and soybeans at 0,07 mg/kg; whereas for all other products, for which there are no CXLs or import tolerances, the MRLs are lowered to product-specific limits of determination varying between 0,01 and 0,05 mg/kg;

L. whereas, in 2024, the Commission lowered the MRLs for thiacloprid, an active substance classified as toxic to reproduction category 1B, to the relevant limit of determination arguing that '[p]ending the conclusion of this additional risk assessment [on endocrine-related effects] by the Authority, and given the available pertinent information with regard to potentially harmful effects on human health, it is appropriate to provisionally lower the MRLs ... [for those products]'<sup>(15)</sup>;

M. whereas recital (5) of Regulation (EC) No 396/2005 provides that residues should not be present at levels presenting an unacceptable risk to humans and, where relevant, to animals;

N. whereas Article 4(2), first subparagraph, point (a), of Regulation (EC) No 1107/2009 provides that residues of plant protection products shall not have any harmful effect on human health, including that of vulnerable groups, or animal health, taking into account known cumulative and synergistic effects; whereas point 3.6.4 of Annex II to that Regulation provides that an active substance classified, in accordance with Regulation (EC) No 1272/2008, as toxic for reproduction category 1A or 1B shall not be approved unless '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'; whereas Article 18(1), point (b), of Regulation (EC) No 396/2005 sets a default value of 0,01 mg/kg;

O. whereas Article 3(2), point (g), of Regulation (EC) No 396/2005 provides that import tolerance is an MRL set for imported products when 'the use of the active substance in a plant protection product on a given product is not authorised in the Community for reasons other than public health reasons for the specific product and specific use'; whereas cyproconazole does not meet those criteria as it has been banned for health reasons since it is classified as toxic to reproduction category 1B;

P. whereas Article 5(1) of Regulation (EC) No 178/2002 provides that food law is to pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking into account, where appropriate, the protection of animal health and welfare, plant health and the environment;

Q. whereas the Commission announced in its communication of 20 May 2020 on 'A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system'<sup>(16)</sup> that '[t]he EU will support the global transition to sustainable agri-food systems, in line with the objectives of this strategy and the SDGs', and that '[t]he EU can play a key role in setting global standards with this strategy'; whereas the Commission explicitly stated in the strategy that '[a] more sustainable EU food system also requires increasingly sustainable practices by our trading partners. In order to promote a gradual move towards the use of safer plant protection products, the EU will consider, in compliance with WTO rules and following a risk assessment, to review import tolerances for substances meeting the "cut-off criteria" and presenting a high level of risk for human health';

R. whereas the practice of setting high MRLs is promoting a double standard between Union farmers and farmers in third countries, as the non-Union farmers may continue producing the foods concerned using cyproconazole and exporting them to the Union, which places Union farmers at a competitive disadvantage; whereas on the other hand, the use of this pesticide is jeopardising the health of agricultural workers, the health of the general population and the environment in the producing countries;

S. whereas Article 191(2) TFEU sets out the precautionary principle as one of the fundamental principles of the Union;

T. whereas the Commission must protect the environment and European citizens on the basis of the available scientific information, using the obligations and legal possibilities that Regulations (EC) No 396/2005 and (EC) No 178/2002 provide for to ensure a high level of protection of human and animal health and the environment;

<sup>(15)</sup> <https://ec.europa.eu/transparency/comitology-register/screen/documents/089880/5/consult?lang=en>.

<sup>(16)</sup> COM(2020)0381.

- U. whereas the proposed MRLs do not protect the health of citizens in Europe, and they are therefore contrary to Regulations (EC) No 396/2005 and (EC) No 178/2002;
- V. whereas MRLs should not be set for active substances that are not approved in the Union due to health concerns; whereas therefore no CXLs exceeding the relevant limit of determination or the default value of 0,01mg/kg should be considered safe for consumers as cyproconazole is classified as toxic for reproduction category 1B;
- W. whereas when setting MRLs, cumulative and synergistic effects need to be taken into account, and it is of the utmost importance to urgently speed up the development of 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 Regulations (EC) No 396/2005 and (EC) No 178/2002, as well as with Regulation (EC) No 1107/2009, including point 3.6.4 of its Annex II;
- 3. Calls on the Commission to apply the precautionary principle and to withdraw the draft regulation and submit a new one to the committee;
- 4. Calls on the Commission to submit a new draft regulation to the committee lowering all MRLs for cyproconazole to the limit of determination or the default value of 0,01 mg/kg for all uses and to refuse any requests for import tolerances;
- 5. 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;
- 6. 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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