**P10_TA(2024)0006**

# Objection to an implementing act: Maximum residue levels for carbendazim and thiophanate-methyl

**European Parliament resolution of 18 September 2024 on the draft Commission regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benomyl, carbendazim and thiophanate-methyl in or on certain products (D089819/05 – 2024/2758(RPS))**

(C/2024/7209)

*The European Parliament,*

— having regard to the draft Commission regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benomyl, carbendazim and thiophanate-methyl in or on certain products (D089819/05),

— 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 ([1]), and in particular Article 14(1), point (a), 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 ([2]), and in particular Article 4(1) and Article 4(2), first subparagraph, point (a), and points 3.6.2, 3.6.4 and 3.6.5 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 ([3]), 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,

— having regard to the reasoned opinion adopted by the European Food Safety Authority (EFSA) on 5 July 2021, and published on 23 August 2021 ([4]),

— having regard to the updated reasoned opinion adopted by EFSA on 10 January 2024, and published on 20 February 2024 ([5])

— having regard to the conclusion on pesticides peer review adopted by EFSA on 30 April 2010, and published on 12 May 2010 ([6]),

— having regard to the conclusion on pesticides peer review adopted by EFSA on 8 December 2017, and published on 17 January 2018 ([7]),

([1]) OJ L 70, 16.3.2005, p. 1.
([2]) OJ L 309, 24.11.2009, p. 1.
([3]) OJ L 31, 1.2.2002, p. 1.
([4]) EFSA reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl, EFSA Journal 2021;19(8):e06773, https://doi.org/10.2903/j.efsa.2021.6773.
([5]) EFSA updated reasoned opinion on the toxicological properties and maximum residue levels (MRLs) for the benzimidazole substances carbendazim and thiophanate-methyl, EFSA Journal 2024;22(2):e8569, https://doi.org/10.2903/j.efsa.2024.8569.
([6]) EFSA conclusion on the peer review of the pesticide risk assessment of the active substance carbendazim, EFSA Journal 2010;8(5):1598, https://doi.org/10.2903/j.efsa.2010.1598.
([7]) EFSA conclusion on the peer review of the pesticide risk assessment of the active substance thiophanate-methyl; EFSA Journal 2018;16(1):e05133, https://doi.org/10.2903/j.efsa.2018.5133.

— having regard to the statement adopted by EFSA on 27 March 2024, and published on 13 May 2024 ([8]),

— having regard to the opinion adopted by the Committee for Risk Assessment (RAC) of the European Chemical Agency on 5 December 2019 ([9]),

— 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 ([10]),

— having regard to Rule 115(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 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 the approval of the active substance carbendazim expired on 30 November 2014 and no application for its renewal was submitted;

E. whereas carbendazim meets the criteria for classification as mutagen category 1B and toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([11]) and two of the persistent, bioaccumulative and toxic (PBT) criteria (P and T) in accordance with point 3.7.2 of Annex II to Regulation (EC) No 1107/2009;

F. whereas carbendazim is also classified in accordance with Regulation (EC) No 1272/2008 as very toxic to aquatic life, is very toxic to aquatic life with long-lasting effects and may cause an allergic skin reaction;

G. whereas it is therefore appropriate to delete the existing maximum residue levels (MRLs) set for carbendazim in Annex II to Regulation (EC) No 396/2005 in accordance with Article 14(1), point (a), and Article 17 of that Regulation;

H. whereas, in the draft Commission regulation, the Commission is, however, proposing to maintain the MRLs based on import tolerances for carbendazim above the limit of determination for use in lemons, limes, mandarins, and okra/lady's fingers for import purposes based on EFSA's reasoned opinion of 5 July 2021;

I. whereas, in the draft Commission regulation, the Commission proposes to maintain the MRLs based on import tolerances for lemons, limes and mandarins at the existing levels of 0,7 mg/kg, and to set the MRLs for okra/lady's fingers at a new level established by EFSA of 1,5 mg/kg;

J. whereas the approval of the active substance thiophanate-methyl was not renewed on 15 October 2020 after an application for renewal was withdrawn by the applicant;

K. whereas thiophanate-methyl meets the criteria for classification as mutagen category 2 and reproductive toxicant category 2 in accordance with Regulation (EC) No 1272/2008 ([12]);

([8]) EFSA statement on the assessment of quality of data available to EFSA to derive the health-based guidance values for carbendazim, EFSA Journal 2024;22(5):e8756, https://doi.org/10.2903/j.efsa.2024.8756.

([9]) RAC opinion proposing harmonised classification and labelling at EU level of carbendazim (ISO); methyl benzimidazol-2-ylcarbamate; https://www.echa.europa.eu/documents/10162/5eb9760e-6c73-7f2c-1226-98d92ed847d1

([10]) OJ L 184, 17.7.1999, p. 23.

([11]) 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).

([12]) 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).

L. whereas in its updated reasoned opinion of 10 January 2024, EFSA identified thiophanate-methyl as an endocrine disruptor (T modality) of relevance to humans according to the scientific criteria for the determination of endocrine disrupting properties set out in Commission Regulation (EU) 2018/605 ([13]);

M. whereas carbendazim is a major plant metabolite of thiophanate-methyl;

N. whereas the EFSA conclusion on pesticides peer review of 8 December 2017 concluded that, given the clastogenic potential of thiophanate-methyl, toxicological reference values for consumer and operator risk assessment could not be derived;

O. 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]' ([14]);

P. whereas it is therefore appropriate to delete the existing MRLs set for thiophanate-methyl in Annex II to Regulation (EC) No 396/2005 in accordance with Article 14(1), point (a), and Article 17 of that Regulation;

Q. whereas, in the draft Commission regulation, the Commission is, however, proposing to maintain the MRLs based on import tolerances for thiophanate-methyl above the limit of determination for use in limes and okra/lady's fingers for import purposes based on EFSA's reasoned opinion of 5 July 2021; whereas the MRL for thiophanate-metyl on limes is set at 6 mg/kg, 600 times the limit of determination;

R. 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;

S. 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 3.6.2 of Annex II to that Regulation provides that an active substance classified, in accordance with Regulation (EC) No 1272/2008, as mutagen category 1A or 1B shall not be approved; whereas point 3.6.4 of that Annex 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 point 3.6.5 of that Annex provides that an active substance shall not be approved if it has endocrine-disrupting properties 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;

T. 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 carbendazim does not meet those criteria as it can no longer be approved in the Union as a result of its classification as mutagenic category 1B and toxic to reproduction category 1B; whereas thiophanate-methyl also does not meet those criteria since it has been identified as an endocrine disruptor (T modality) of relevance to humans according to the scientific criteria for the determination of endocrine disrupting properties set out in Regulation (EU) 2018/605;

U. 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;

([13]) 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).

([14]) https://ec.europa.eu/transparency/comitology-register/screen/documents/089880/5/consult?lang=en.

V. 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' ([15]) 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';

W. 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;

X. 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;

Y. whereas MRLs should not be set for active substances that are not approved in the Union due to health concerns; whereas therefore no import tolerances should be set for thiophanate-methyl as it is identified as an endocrine disruptor or for carbendazim as it is classified as mutagenic category 1B and toxic for reproduction category 1B;

Z. 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 carbendazim and thiophanate-methyl and exporting them to the Union, which places Union farmers at a competitive disadvantage; whereas on the other hand, the use of those pesticides is jeopardising the health of agricultural workers, the health of the general population and the environment in the producing countries;

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 points 3.6.2, 3.6.4 and 3.6.5 of its Annex II;

3. Calls on the Commission 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 carbendazim and thiophanate-methyl to the relevant limit of determination for all uses and to refuse any requests for import tolerances;

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

([15]) COM(2020)0381.