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To:	General Secretariat of the Council
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Subject:	COMMISSION REGULATION (EU) .../... of XXX 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 diazinon in or on certain products

Delegations will find attached document D113129/04.

Encl.: D113129/04

EUROPEAN
COMMISSION

Brussels, XXX
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COMMISSION REGULATION (EU) …/…

of XXX

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 diazinon in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

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 diazinon in or on certain products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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), Article 18(1), point (b), and Article 49(2) thereof,

Whereas:

(1) For the active substance diazinon, maximum residue levels ('MRLs') were set in Annex II and Part B of Annex III to Regulation (EC) No 396/2005.

(2) Since the approval of diazinon was withdrawn before 2008, it did not fall within the scope of the systematic review of all existing MRLs under Article 12 of Regulation (EC) No 396/2005. The Commission requested the European Food Safety Authority ('the Authority'), under Article 43 of Regulation (EC) No 396/2005, to review the existing MRLs for diazinon and to examine the available information to screen the quality of the toxicological reference values ('TRVs').

(3) The Authority published its reasoned opinion in 2023. Following that publication the Authority carried out a stakeholder consultation.[2] In 2024, the Authority published an amended reasoned opinion[3] to reflect the outcome of this consultation[4].

(4) For the following plant commodities: almonds, cranberries, pineapples, radishes, onions, sweet pepper/bell peppers, sweet corn, Chinese cabbage/pe-tsai, kohlrabies, hops, seed spices, root and rhizomes spices (liquorice, turmeric/curcuma, others) and sugar beet roots, the Authority concluded that the risk assessment could not be finalised due to the lack of robust TRVs and that the existing MRLs are not supported by sufficient data. Therefore, the existing MRLs for the above listed commodities shall be lowered to the limit of quantification ('LOQ').

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1 OJ L 70, 16.3.2005, p. 1, ELI: http://data.europa.eu/eli/reg/2005/396/oj.

2 Available online: https://www.efsa.europa.eu/en/call/call-expressions-interest-submit-data-10-non-approved-active-substances-review-mrls.

3 EFSA, Targeted review of maximum residue levels (MRLs) for diazinon. EFSA Journal 21(11), e8426. https://www.efsa.europa.eu/en/efsajournal/pub/8426.

4 EFSA, Outcome of the stakeholder consultation on the reasoned opinions for azocyclotin, bifenthrin, chlorfenapyr, cyhexatin, diazinon, dicofol, endosulfan, fenarimol, fenpropathrin and profenofos. EFSA supporting publication 2024:EN-9002. Available online : https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2024.EN-9002.

(5) The Authority concluded that the existing MRLs for liver and kidney of swine, bovine, sheep and goats, as well as those for swine fat, milk from cattle, horse and others, poultry muscle and poultry edible offals, are not sufficiently supported by the available data. The Authority indicated that, for liver and kidney of swine, bovine, sheep and goats, lowering the existing MRLs to the veterinary maximum residue levels established in Commission Regulation (EU) No 37/2010[5] might be considered. It is therefore appropriate to lower the MRLs for swine fat, milk from cattle, horse and others, poultry muscle and poultry edible offals to the LOQ, while lowering the MRLs for liver and kidney of swine, bovine, sheep and goats from 0,03 mg/kg to 0,02 mg/kg.

(6) It is therefore appropriate to delete the MRLs set out for diazinon in Part B of Annex III to Regulation (EC) No 396/2005 and to set all these MRLs in Annex II to Regulation (EC) No 396/2005.

(7) The Commission consulted the European Union reference laboratories for residues of pesticides as regards the need to adapt certain LOQs. Those laboratories proposed product specific LOQs that are analytically achievable.

(8) Through the World Trade Organisation, the trading partners of the Union were consulted on the new MRLs and their comments have been taken into account.

(9) Regulation (EC) No 396/2005 should therefore be amended accordingly.

(10) To allow for the normal marketing, processing and consumption of products, this Regulation should not apply to products which have been produced in the Union or imported into the Union before the new MRLs become applicable and for which a high level of consumer protection is maintained.

(11) A reasonable period should be allowed to elapse before the new MRLs become applicable in order to permit Member States, third countries and food business operators to adapt themselves to the requirements which result from the modification of the MRLs.

(12) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II and III to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Article 2

Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were placed on the market in the Union before [*Office of publications: please insert date = 6 months after the date of entry into force of this Regulation*].

[5] Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1, ELI: http://data.europa.eu/eli/reg/2010/37(1)/oj).

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*Office of publications: please insert date = 6 months after the date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN