



Council of the
European Union

Brussels, 17 March 2023
(OR. en)

7533/23

AGRILEG 49
PESTICIDE 13

COVER NOTE

From:	European Commission
date of receipt:	16 March 2023
To:	General Secretariat of the Council
No. Cion doc.:	D087765/03
Subject:	COMMISSION REGULATION (EU) .../... of XXX amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fish oil, pendimethalin, sheep fat and spirotetramat in or on certain products

Delegations will find attached document D087765/03.

Encl.: D087765/03



EUROPEAN
COMMISSION

Brussels, **XXX**
PLAN/2023/196
(POOL/E4/2023/196/196-EN.docx)
D087765/03
[...](2023) **XXX** draft

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fish oil, pendimethalin, sheep fat and spirotetramat in or on certain products

(Text with EEA relevance)

COMMISSION REGULATION (EU) .../...

of **XXX**

amending Annexes II and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for fish oil, pendimethalin, sheep fat and spirotetramat 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/EEC¹, and in particular Article 5(1) and Article 14(1), point (a), thereof,

Whereas:

- (1) For pendimethalin and spirotetramat, maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. Fish oil and sheep fat are included in Annex IV to that Regulation.
- (2) As regards the active substance pendimethalin, an application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing MRLs was submitted for peas (with pods), beans (with pods) and leeks. As regards the active substance spirotetramat, such an application was submitted for herbs and edible flowers.
- (3) In accordance with Article 8 of Regulation (EC) No 396/2005, those applications were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.
- (4) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the proposed MRLs². It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (5) As regards spirotetramat, in herbs and edible flowers, others, the Authority did not recommend a specific MRL value. Nevertheless, the Authority noted that risk managers may consider to implement the MRL of 10 mg/kg to the whole group of herbs and edible flowers, and that this would be safe for consumers. Therefore, it is appropriate to propose setting the MRL for spirotetramat in herbs and edible flowers,

¹ OJ L 70, 16.3.2005, p. 1.

² Reasoned Opinion on the modification of the existing maximum residue levels for pendimethalin in peas (with pods), beans (with pods) and leeks. EFSA Journal 2023; xx (x):xxxx.
Reasoned Opinion on the modification of the existing maximum residue levels for spirotetramat in herbs and edible flowers. EFSA Journal 2022;20(12):7668.

others, at 10 mg/kg in accordance with the relevant Commission Technical Guidelines³.

- (6) For pendimethalin and spirotetramat, the Authority concluded that all requirements with respect to completeness of data submission were met and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. In so concluding, the Authority took into account the most recent data on the toxicological properties of the substances. Neither the long-term exposure to these substances via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant products showed a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (7) Based on the reasoned opinions of the Authority and taking into account the relevant factors listed in Article 14(2) of Regulation (EC) No 396/2005, it is appropriate to conclude that the proposed modifications to the MRLs fulfil the requirements of that article.
- (8) Fish oil and sheep fat were temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of their evaluation either under Council Directive 91/414/EEC⁴ or under Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁵, and pending the review of MRLs on those active substances in accordance with Article 12 of Regulation (EU) No 396/2005. In the context of applications for renewal of the approval of those active substances under Regulation (EC) No 1107/2009, the Authority issued conclusions on the peer review of the pesticide risk assessment of fish oil and sheep fat⁶. Based on those conclusions, no MRLs are required for fish oil and sheep fat. Therefore, it is appropriate for those substances to remain in Annex IV to Regulation (EC) No 396/2005.
- (9) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (10) 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 IV to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

³ Commission Technical Guidelines on data requirements for setting MRLs, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (SANTE/2019/12752)

⁴ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁵ 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).

⁶ Conclusion on the peer review of the pesticide risk assessment of the active substance fish oil. EFSA Journal 2022;20(1):7079.

Conclusion on the peer review of the pesticide risk assessment of the active substance sheep fat. EFSA Journal 2022;20(1):7073.

Article 2

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

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