STATEMENT

Pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA)

Abstract

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. Among the active substances that need to be reviewed under Article 12(1), EFSA identified two active substances for which a review of MRLs is no longer considered necessary. EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete. The relevant question numbers are considered addressed by this statement.

KEYWORDS
etridiazole, MRLs, peer review, Pythium oligandrum strain M1, Regulation (EC) No 396/2005
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SUMMARY

Regulation (EC) No 396/2005 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion on the relevant assessment report prepared under Directive 91/414/EEC or Regulation (EC) No 1107/2009. The reasoned opinion should cover all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance, including analytical methods and limit of determination (LOD) for enforcement of the proposed MRLs. All proposed MRLs should accommodate uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade. Among the active substances that need to be reviewed under Article 12(1), EFSA identified two active substances for which a review of MRLs is no longer considered necessary.

EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete. The corresponding question numbers are considered addressed by this statement. Furthermore, for one additional active substance, the MRL review was addressed in the framework of the renewal (combined assessment) from November 2022 (after the approval of the previous statement) until the approval of this statement. This active substance is listed in an Annex to this statement.

The statement was circulated to Member States for consultation via a written procedure before finalisation.
1 | INTRODUCTION

Regulation (EC) No 396/20051 establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC2 a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance. According to the legal provisions, EFSA shall base its reasoned opinion on the relevant assessment report prepared under Directive 91/414/EEC or Regulation (EC) No 1107/2009.3 The reasoned opinion should cover all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance, including analytical methods and limit of determination (LOD) for enforcement of the proposed MRLs. All proposed MRLs should accommodate uses authorised within the European Union (EU), and uses authorised in third countries that have a significant impact on international trade.

Among the active substances that need to be reviewed under Article 12(1) of Regulation (EC) No 396/2005, EFSA identified two active substances for which a review of MRLs is no longer considered necessary. EFSA prepared a statement explaining the reasons why a review of MRLs for these substances became obsolete.

Furthermore, for one additional active substance, the MRL review was addressed in the framework of the renewal (combined assessment) from November 2022 (after the approval of the previous statement) until the approval of this statement. This active substance is listed in Annex A.

The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 3 November 2023 were considered during the finalisation of this statement. The collation of comments received on the draft statement is considered as a background document to this statement and is made publicly available (EFSA, 2023).

2 | ASSESSMENT

The following substances have been assessed by EFSA in this statement.

The active substance etridiazole was initially not included in Annex I to Council Directive 91/414/EEC by Decision 2008/9344 following the withdrawal of the support for the inclusion by the applicant. After resubmission of an application according to Regulation 33/2008,5 the draft assessment report (DAR) and the additional report to the DAR prepared by the Netherlands were peer reviewed by EFSA (2010). Etridiazole was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/29/EU6 and the use was restricted as fungicide in non-soil bound systems in greenhouse. No Codex maximum residue limits (CXLs) are established by the Codex Alimentarius Commission and no import tolerances are currently in place for etridiazole. The approval of this active substance expired on 31 May 2021, and therefore, etridiazole is currently not any longer approved. The draft Regulation SANTE/2023/946, lowering the MRLs for this active substance to the relevant limits of determination (LODs) according to Art 18(1)(b) of Regulation (EC) No 396/2005, has been favourably voted by the Standing Committee on Plants, Animals, Food and Feed (SCoP AFF) in September 2023. Once the Regulation will be adopted (expected in early 2024), the review of MRLs for this substance will become obsolete.

The active substance Pythium oligandrum strain M17 was initially included in Annex I to Council Directive 91/414/EEC by Commission Directive 2008/113/EC.7 Following the EFSA peer review of the pesticide risk assessment (EFS A, 2020), the approval of Pythium oligandrum strain M1 was renewed by Commission Implementing Regulation (EU) 2022/2314.8 In the peer review, EFSA concluded that some information was not available as regards the dietary risk assessment for consumers and that further consideration by risk managers was required. It should be noted that the concerns identified in the EFSA conclusion were discussed by the SCoPAFF in view of the renewal of the approval of Pythium oligandrum strain M1 in accordance with Regulation (EC) No 1107/2009. The Committee concluded that Pythium oligandrum strain M1 is not pathogenic to humans and that the risk to humans through metabolites is negligible (European Commission, 2022). The draft Regulation SANTE/2023/1697, including permanently the active substance Pythium oligandrum strain M1 in Annex IV of Regulation (EC)

1Regulation (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. OJ L 70, 16.3.2005, p. 1–16.

2Council 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. 1–32. Repealed by Regulation (EC) No 1107/2009.

3Regulation (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. 1–50.

4Commission Decision of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p. 11–14.

5Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.1.2008, p. 5–12.

6Commission Directive 2011/29/EU of 7 March 2011 amending Council Directive 91/414/EEC to include etridiazole as active substance and amending Commission Decision 2008/934/EC. OJ L 61, 8.3.2011, p. 9–11.

7Commission Implementing Regulation (EU) 2022/2314 of 25 November 2022 renewing the approval of the active substance Pythium oligandrum strain M1 in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 307, 28.11.2022, p. 47–51.
No 396/2005, has been favourably voted by the SCOPAFF in September 2023. Once the Regulation will be adopted (expected in early 2024), the review of MRLs for this substance will become obsolete.

Based on the above explanation, the following question numbers are considered addressed (Table 1).

### TABLE 1 List of active substances that do not require MRL review.

| No | Question number (MRL review) | Active substance | RMS | Status under Reg (EU) No 1107/2009 | Assessment made by EFSA | MRL Regulation |
|----|-----------------------------|-----------------|-----|-----------------------------------|------------------------|----------------|
| 1. | EFSA-Q-2009-00047           | Etridiazole     | NL  | Not approved                      | EFSA (2010)            | Draft Regulation SANTE/2023/946 |
| 2. | EFSA-Q-2009-00133           | Pythium oligandrum strain M1 | SE  | Approved                           | EFSA (2020)            | Draft Regulation SANTE/2023/1697 |

### 3 CONCLUSIONS

Among the active substances that need to be reviewed under Article 12 of Regulation (EC) No 396/2005, EFSA identified two active substances for which a review of MRLs is not needed. EFSA therefore prepared a statement explaining the reasons why a review of MRLs is no longer necessary for these active substances. The corresponding question numbers are considered addressed by this statement.

### CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

### REQUESTOR

European Commission

### QUESTION NUMBERS

EFSA-Q-2009-00047, EFSA-Q-2009-00133.

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### ABBREVIATIONS

- CXL: codex maximum residue limit
- DAR: draft assessment report
- LOD: limit of determination
- MRL: maximum residue level
- RMS: rapporteur Member State
- SCOPAFF: Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH)

### REFERENCES

EFSA (European Food Safety Authority). (2010). Conclusion on the peer review of the pesticide risk assessment of the active substance etridiazole. EFSA Journal, 8(10), 1823. https://doi.org/10.2903/j.efsa.2010.1823

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EFSA (European Food Safety Authority). (2023). Member States consultation report on the active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005 prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 8 November 2023. www.efsa.europa.eu

European Commission. (2022). Final Review report for Pythium oligandrum strain M1. Finalised by the Standing Committee on Plants, Animals, Food and Feed at its meeting on 14 October 2022 in view of the renewal of the approval of Pythium oligandrum strain M1 in accordance with Regulation (EC) No 1107/2009. SANTE/10332/2021-rev. 3, 14 October 2022.

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ANNEX A

Active substance for which the Article 12 review was addressed in the framework of the peer review for the renewal

| Question number  | Active substance     | RMS | Approval date | Link                                      |
|------------------|----------------------|-----|---------------|-------------------------------------------|
| EFSA-Q-2009-00169 | Hydrolysed proteins  | ES  | 26/05/2023    | https://www.efsa.europa.eu/en/efsajournal/pub/8079 |