Lack of confirmatory data following Article 12 MRL reviews for 2,4-D, fenhexamid and iprovalicarb

European Food Safety Authority (EFSA)

Abstract

The European Commission mandated EFSA to issue a statement concerning confirmatory data that were not submitted by the set deadline by the applicant following Article 12 reviews under Regulation (EC) No 396/2005 for the following substances/commodity combination: 2,4-D on buckwheat and other pseudo-cereals, fenhexamid on kiwis, iprovalicarb on lettuces, escaroles/broad-leaved endives and roman rocket/rucola. EFSA prepared a statement containing a final conclusion on the completeness of the data necessary to support the existing tentative maximum residue levels (MRLs) and indications to risk managers whether or not the tentative MRLs currently established by Regulation (EC) No 396/2005 could be maintained. The statement was circulated to Member States for consultation via a written procedure before finalisation.

Keywords: Regulation (EC) No 396/2005, MRLs, peer review, confirmatory data, 2,4-D, fenhexamid, iprovalicarb

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Summary

In August 2021, the European Commission mandated the European Food Safety Authority (EFSA) to issue a statement concerning confirmatory data that were not submitted by the set deadline by the applicant following Article 12 MRL reviews under Regulation (EC) No 396/2005 for the following substances/commodity combination: 2,4-D on buckwheat and other pseudo-cereals, fenhexamid on kiwis, iprovalicarb on lettuces, escaroles/broad-leaved endives and roman rocket/rucola.

In September 2021, EFSA prepared a statement containing a final conclusion on the completeness of the data necessary to support the existing maximum residue levels (MRLs) and indications to risk managers whether or not the tentative MRLs currently established by Regulation (EC) No 396/2005 could be maintained.

The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 17 September 2021 were considered during the finalisation of this statement.

Following consultation with MSs, it is concluded that the confirmatory data related to the existing tentative MRLs for 2,4-D on buckwheat and other pseudo-cereals and to the existing tentative MRLs for iprovalicarb on lettuces, escaroles/broad-leaved endives and roman rocket/rucola were not submitted by the applicant by the established legal deadline. Therefore, the tentative MRLs established for these substances/commodity combinations are not fully supported by data and lowering them to the specific limit of quantification (LOQ) could be considered by risk managers.

For what concerns fenhexamid, it is concluded that, considering the additional information shared during the SCoPAFF meetings, no additional data is required to support the authorised use on kiwi. Therefore, the existing tentative MRL for fenhexamid in this commodity is considered fully supported by data.
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1. Introduction

In August 2021, the European Commission mandated the European Food Safety Authority (EFSA) to issue a statement concerning confirmatory data that were not submitted by the set deadline by the applicant following Article 12 MRL review under Regulation (EC) No 396/2005 for the following substances/commodity combination: 2,4-D on buckwheat and other pseudo-cereals, fenhexamid on kiwis, iprovalicarb on lettuces, escaroles/broad-leaved endives and roman rocket/rucola.

In September 2021 EFSA prepared a statement containing a final conclusion on the completeness of the data necessary to support the existing maximum residue levels (MRLs) and indications to risk managers whether or not the tentative MRLs currently established by Regulation (EC) No 396/2005 could be maintained.

The draft statement was circulated to Member States (MSs) for consultation via a written procedure. Comments received by 17 September 2021 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, 2021).

2. Assessment

2.1. 2,4-D

In 2011, when reviewing the existing MRLs for 2,4-D according to Article 12 of Regulation (EC) No 396/2005\(^1\), EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified (EFSA, 2011b). In particular, the following data gaps were noted by EFSA and implemented in the MRL legislation by Commission Regulation (EU) No 1317/2013\(^2\) indicating that confirmatory data should be provided by a party having an interest in maintaining the proposed tentative MRLs by 17 December 2015:

1) An ILV for enforcement of residues in high oil content commodities.
2) Four residues trials complying with the northern GAP on buckwheat.

Requested confirmatory data related to data gap number 1 were addressed in the framework of the renewal process for 2,4-D (EFSA, 2014b).

Regarding data gap number 2, following consultation with MSs through a written procedure, it is confirmed that no confirmatory data have been submitted within the established deadline.

2.2. Fenhexamid

In 2014, when reviewing the existing MRLs for fenhexamid according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified (EFSA, 2014a). The following data gap was noted by EFSA and implemented in the MRL legislation by Commission Regulation (EU) No 1317/2013\(^2\) indicating that confirmatory data should be provided by a party having an interest in maintaining the proposed tentative MRLs by 23 July 2017:

1) Further clarification of the southern outdoor GAP on kiwi as well as four additional residue trials supporting this GAP.

In 2020 and 2021, during the SCoPAFF meetings, it was clarified that the existing southern outdoor GAP on kiwi is limited to post-harvest treatment (European Commission, 2020) and that, considering that the MRL review was performed according to the old data requirements, the number of residue trials available could be considered sufficient for a post-harvest use (European Commission, 2021). Therefore, the data gap identified during the MRL review is considered fulfilled and no additional data is required.

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\(^1\) 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. OJ L 70, 16.3.2005, p. 1–16.

\(^2\) Commission Regulation (EU) No 1317/2013 of 16 December 2013 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 2,4-D, beflubutiamid, cyclanilide, diniconazole, florasulam, metolachlor and S-metolachlor, and milbemectin in or on certain products. OJ L 339, 17.12.2013, p. 1–43.

\(^3\) Commission Regulation (EU) 2015/1200 of 22 July 2015 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 amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products (Text with EEA relevance) OJ L 195, 23.7.2015, p. 1–36.
2.3. Iprovalicarb

In 2011, when reviewing the existing MRLs for iprovalicarb according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified (EFSA, 2011a). The following data gap was noted by EFSA and implemented in the MRL legislation by Commission Regulation (EU) No 777/2013\(^4\) indicating that confirmatory data should be provided by a party having an interest in maintaining the proposed tentative MRLs by 17 August 2015:

1) A representative study investigating primary crop metabolism in leafy crops

In the reasoned opinion on the MRL review, it was flagged that this study was available to the applicant under Directive 91/414/EEC. Nevertheless, following consultation with MSs through a written procedure, it is confirmed that no confirmatory data related to this data gap and relevant for the existing tentative MRLs for iprovalicarb on lettuces, escaroles/broad-leaved endives and roman rocket/rucola have been submitted within the established deadline.

3. Conclusions and recommendations

Following consultation with MSs, it is concluded that the confirmatory data related to the existing tentative MRLs for 2,4-D on buckwheat and other pseudo-cereals and to the existing tentative MRLs for iprovalicarb on lettuces, escaroles/broad-leaved endives and roman rocket/rucola were not submitted by the applicant by the established legal deadline. Therefore, the tentative MRLs established for these substances/commodity combinations are not fully supported by data and lowering them to the specific limit of quantification (LOQ) could be considered by risk managers.

For what concerns fenhexamid, it is concluded that considering the additional information shared during the SCoPAFF meetings, no additional data is required to support the authorised use on kiwi. Therefore, the existing MRL for fenhexamid in this commodity is considered fully supported by data.

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Abbreviations

GAP Good Agricultural Practice
LOQ limit of quantification
MRL maximum residue level
MS Member States
SANCO Directorate-General for Health and Consumers

\(^4\) Commission Regulation (EU) No 777/2013 of 12 August 2013 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 clodinafop, clomazone, diuron, ethalfluralin, ipoxynil, iprovalicarb, maleic hydrazide, mepanipyrim, metconazole, prosulfocarb and tepraloxydim in or on certain products. OJ L 221, 17.8.2013, p. 1–48.