Evaluation of confirmatory data following the Article 12 MRL review for kresoxim-methyl

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Abstract

The applicant BASF SE submitted a request to the competent national authority in Belgium to evaluate the confirmatory data that were identified for kresoxim-methyl in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the confirmatory data requirement, a new study on the storage stability of kresoxim-methyl residues in animal matrices was submitted. The data gap was considered satisfactorily addressed. The new information provided did not require a revision of the existing MRLs and of the risk assessment performed for kresoxim-methyl.

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Keywords: kresoxim-methyl, confirmatory data, pesticide, MRL review, consumer risk assessment

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Summary

In 2014, when the European Food Safety Authority (EFSA) reviewed the existing maximum residue levels (MRLs) for kresoxim-methyl 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. The following data gaps were noted:

1) further information on the occurrence of metabolites BF 490-2 and BF 490-9 in oranges, grapefruit and pome fruits resulting from the CXLs in these commodities;
2) four residue trials on apricots and four residue trials on peaches supporting the southern outdoor uses on apricots and peaches;
3) four residue trials supporting the northern outdoor use on beet leaves (chard);
4) a study investigating the storage stability of the relevant residue for risk assessment (sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent) in milk, muscle, fat, liver and kidney, covering the storage conditions of the ruminants feeding study.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/1200, including a footnote related to data gap number 4 indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 23 July 2017. Data gaps number 2 and 3 were not implemented in the MRL Regulation since risk managers decided to lower the MRLs in stone fruits and chards/beet leaves (data gaps 2 and 3) to the limit of quantification (LOQ) considering that the use of kresoxim-methyl in those crops is not supported by any data. Also, data gap number 1 was not taken over in the MRL legislation; the CXLs for oranges, grapefruit and pome fruit were established as definitive MRLs without requesting confirmatory data.

To address the data gap number 4, the applicant provided a new storage stability study for commodities of animal origin covering a storage period of 15 months, to demonstrate validity of the feeding study in ruminants.

The summary table below provides an overview of the assessment of confirmatory data and the recommended modifications in the Regulation (EU) No 396/2005:

| Code(a) | Commodity      | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                 |
|---------|----------------|-----------------|--------------|------------------------------------------------------------------------------------------|
|         | Enforcement residue definition for animal products (milk): Metabolite BF 490-9 (2-[2-(4-hydroxy-2-methylphenoxymethyl)phenyl]-2-methoxy-iminoacetic acid) expressed as kresoxim-methyl |               |              |                                                                                           |
| 1011010 | Swine Muscle   | 0.05* (ft)      | 0.05*        | The submitted study is sufficiently addressing the data gap identified in the MRL review. Thus, the footnote in the MRL Regulation can be removed. The previously derived MRLs are still valid. The new information does not require a revision of the previously performed risk assessment for kresoxim-methyl |
| 1011020 | Swine Fat      | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1011030 | Swine Liver    | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1011040 | Swine Kidney   | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1012010 | Bovine Muscle  | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1012020 | Bovine Fat     | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1012030 | Bovine Liver   | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1012040 | Bovine Kidney  | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1013010 | Sheep Muscle   | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1013020 | Sheep Fat      | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1013030 | Sheep Liver    | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1013040 | Sheep Kidney   | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1014010 | Goat Muscle    | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1014020 | Goat Fat       | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1014030 | Goat Liver     | 0.05* (ft)      | 0.05*        |                                                                                           |
| 1014040 | Goat Kidney    | 0.05* (ft)      | 0.05*        |                                                                                           |
| Code<sup>(a)</sup> | Commodity      | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation |
|-----------------|----------------|---------------------------|--------------|---------------------------|
| 1020010         | Milk Cattle    | 0.01*<sup>(ft)</sup>     | 0.01*        |                           |
| 1020020         | Milk Sheep     | 0.01*<sup>(ft)</sup>     | 0.01*        |                           |
| 1020030         | Milk Goat      | 0.01*<sup>(ft)</sup>     | 0.01*        |                           |

MRL: maximum residue level.
*: MRL set at the limit of quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): The residue definition in the Commission database does not correspond to the residue definitions specify for kresoxim-methyl in Commission Regulation (EU) 2016/486.
(ft): The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 23 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 4).
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Assessment

The review of existing maximum residue levels (MRLs) for the active substance kresoxim-methyl according to Article 12 of Regulation (EC) No 396/2005\(^1\) (MRL review) has been performed in 2014 (EFSA, 2014). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) further information on the occurrence of metabolites BF 490-2 and BF 490-9 in oranges, grapefruit and pome fruits resulting from the CXLs in these commodities;

2) four residue trials on apricots and four residue trials on peaches supporting the southern outdoor uses on apricots and peaches;

3) four residue trials supporting the northern outdoor use on beet leaves (chard);

4) a study investigating the storage stability of the relevant residue for risk assessment (sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent) in milk, muscle, fat, liver and kidney, covering the storage conditions of the ruminants feeding study.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 1127/2014\(^2\), including footnotes for tentative MRLs that specified the type of information that was identified as missing. It is noted that data gaps number 2 and 3 have not been implemented in the MRL legislation, since the uses have not been supported by any residue trial matching the Good Agricultural Practice (GAP) and therefore risk managers decided to lower the MRL to the limit of quantification (LOQ). Also, data gap number 1 was not taken over in the MRL legislation; the CXLs for oranges, grapefruit and pome fruit were established as definitive MRLs without requesting confirmatory data.

Any party having an interest in maintaining the proposed tentative MRL were requested to address the confirmatory data requirement by 23 July 2017.

In accordance with the specific provisions set out in the working document of the European Commission (2016), the applicant, BASF SE, submitted an application to the competent national authority in Belgium (designated rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review and for assessing the uses in peaches, apricots and chards that were lowered to the LOQ following the MRL review.

To address the data gap number (4) identified by EFSA, the applicant provided a new storage stability study in commodities of animal origin covering a storage period of 15 months to demonstrate the validity of the feeding study in ruminants that was used to derive the MRL proposals for commodities of animal origin.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 8 March 2018 (Belgium, 2018). EFSA assessed the application as requested by the European Commission in accordance with Article 9 of Regulation (EC) No 396/2005. It is noted that the original application received covered not only the confirmatory data, but also contained a request to modify the existing MRLs for apricots, peaches and beet leaves (EFSA-Q-2018-00233). Since for this MRL application, EFSA identified points which needed further clarifications, a separate reasoned opinion will be issued by EFSA, once the requested information is provided.

EFSA based its assessment on the evaluation report submitted by the RMS (Belgium, 2018\(^3\)), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 and an additional assessment of kresoxim-methyl performed after the MRL review (EFSA, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^4\) and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 2015/1200 are applicable. The assessment is performed in accordance with the

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\(^1\) Regulation (EC) No 396/2005 of the 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 1127/2014 of 20 October 2014 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 amitrole, dinocap, fipronil, flufenacet, pendimethalin, propyzamide and pyridate in or on certain products. OJ L 305, 24.10.2014, p. 47–99.

\(^3\) It is noted that the evaluation report submitted in support of the application covered not only the confirmatory data, but also contained the assessment of data submitted in support of a request of the setting of MRLs for kresoxim-methyl in stone fruits, apricot, peach and beet leaves (EFSA-Q-2018-00233); this MRL application will be assessed in a separate reasoned opinion.

\(^4\) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

An updated list of endpoints, including the endpoints of relevant in the framework of this confirmatory data, is presented in Appendix B.

The evaluation report submitted by the RMS (Belgium, 2018) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document.

1. **Residues in plants**

   Not relevant for the current assessment.

   The confirmatory data requirement for kresoxim-methyl identified in Commission Regulation (EU) No 2015/1200 does not relate to residues in commodities of plant origin.

2. **Residues in livestock**

   The MRLs derived during the MRL review for food of animal origin were proposed on tentative basis considering that the maximum storage time period for samples of milk, muscle, fat, liver and kidney of the ruminant feeding study were not covered by storage stability data for the metabolites BF 490-1, BF 490-2 and BF 490-9. These metabolites are part of the proposed residue definition for risk assessment of animal origin commodities (EFSA, 2014).

   EFSA asked to demonstrate the stability of BF 490-1, BF 490-2 and BF 490-9 in animal tissues stored under freezer conditions for up to 175 days, in order to confirm the validity of the feeding study (EFSA, 2014). A footnote requesting the missing data related to this data gap was implemented by Commission Regulation (EU) No 2015/1200. This footnote applies to the MRLs for muscle, fat, kidney and liver of ruminants and swine and to the MRLs of ruminants’ milk.

2.1. **Nature of residues in livestock**

   An animal metabolism study in lactating goat was evaluated under the framework of the MRL review (EFSA, 2014) and during the peer-review (EFSA, 2010). See Appendix B for further information on the metabolism studies in livestock. The residue definition for risk assessment (ruminants/swine tissues and ruminants milk) was defined as: sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent (EFSA, 2014).

   EFSA derived the following residue definition for monitoring for food commodities of animal origin (ruminants/swine tissues and ruminants milk (EFSA, 2014): Metabolite BF 490-1, expressed as kresoxim-methyl.

   When implementing the MRL proposals derived in the MRL review, risk managers decided to set the following residue definition (Commission Regulation (EU) No 1127/2014): BF 490-9, expressed as kresoxim-methyl.

   Later, the residue definition for monitoring of food commodities of animal origin was revised (Regulation (EC) No 2016/486) as follows:

   - Metabolite BF 490-1 for muscle, fat, liver and kidney expressed as kresoxim-methyl.
   - Metabolite BF 490-9 for milk expressed as kresoxim-methyl.

2.2. **Magnitude of residues in livestock**

   Since the data submitted under the current application confirmed the validity of the feeding study (see Section 2.3), the MRLs and the risk assessment values for animal products (i.e. muscle, fat, liver and kidney of ruminants and swine for milk of ruminants milk) are confirmed.

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5 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

6 Commission Regulation (EU) 2016/486 of 29 March 2016 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 cyazofamid, cycloxydim, difluoroacetic acid, fenoxycarb, flumetralin, fluopicolide, fluopyradifurone, fluxapyroxad, kresoxim-methyl, mandestrobin, mepanipyrim, metalaxyl-M, pendimethalin and tefluthrin in or on certain products. OJ L 90, 6.4.2016, p. 1–66.
2.3. Storage stability data on animal origin commodities

A study investigating the storage stability of the metabolites of kresoxim-methyl (BF 490-1, BF 490-2 and BF 490-9) has been submitted in order to fulfil the identified confirmatory data requirement for kresoxim-methyl and was assessed by the RMS (Belgium, 2018).

The storage stability study was in compliance with the current OECD guideline 506 (OECD, 2007). In the study, residues were analysed in the different animal matrices (milk, fat, muscle, kidney and liver) which have been spiked with the metabolites at the level of 0.1 mg/kg after storage at −20°C for 0, 6, 12 and 15 months. The recoveries in the different tissues ranged from 84% to 108% compared to the fortification level.

According to the RMS, the data provided by the applicant are not complete, since the storage stability was not tested for all matrix/metabolite combinations: no data were provided for storage stability of BF 490-9 in muscle, BF 490-2 in liver and BF 490-1 in milk. However, considering that according to the metabolism study assessed in the MRL review (see Table 1) residues in the matrix/metabolite combinations mentioned are not expected, EFSA is of the opinion that the submitted storage stability study is sufficient to address the data gap. It concluded that the metabolites BF 490-1, BF 490-2 and BF 490-9 are stable for 15 months under frozen conditions in commodities of animal origin. Therefore, the feeding study used to derive the MRL proposals and the risk assessment values are valid.

Table 1: Summary of the expected metabolites in the different animal tissues and the availability of storage stability data to confirm the suitability of the livestock feeding study for MRL setting in products of animal origin

| Animal tissue | Occurrence of major metabolites in animal matrices from the metabolism study in lactating goat (EFSA, 2014) expressed as %TRR | Time intervals for which storage stability was demonstrated | Recovery ranges in the storage stability study expressed in terms of % recovery of the nominal spiking level of 0.1 mg/kg (Belgium, 2018) |
|---------------|---------------------------------------------------------------|----------------------------------------------------------|------------------------------------------------------------------------------------------------------------|
|               | BF 490-1 BF 490-2 BF 490-9 | T (months) | BF 490-1 BF 490-2 BF 490-9 |
| Muscle        | 24 14 – | 0 6 12 15 | 100 98 101 87 | Not analysed |
| Fat           | 23 24 – | 0 6 12 15 | 100 102 102 107 |
| Kidney        | 22 34 30 | 0 6 12 15 | 100 102 107 101 |
| Liver         | 13 – 29 | 0 6 12 15 | Not analysed | 100 105 103 99 |
| Milk          | – – 63 | 0 6 12 15 | Not analysed | 100 86 84 97 |

TRR: total radioactive residue.
3. **Consumer risk assessment**

There is no need to change the MRLs of animal origin commodities; the consumer risk assessment performed in the framework of the MRL review (EFSA, 2014) does not have to be revised.

4. **Conclusion and Recommendations**

The data submitted in support of this application was sufficient to confirm the validity of the feeding study in ruminants which was the basis to derive the MRL proposals and risk assessment values for commodities of animal origin derived during the MRL review. The metabolites BF 490-1, BF 490-2 and BF 490-9 were demonstrated to be stable for 15 months in ruminants and swine tissues (muscle, fat, liver, and kidney) and ruminants’ milk.

The footnote in the MRL Regulation (Annex II), which refers to the confirmatory data submitted in the framework of the current assessment, can be removed.

**References**

Belgium, 2018. Evaluation report on confirmatory data and the modification of MRLs for kresoxim-methyl in apricots, peaches and beet leaves. February 2018, 21 pp.

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance kresoxim-methyl. EFSA Journal 2010;8(11):1891, 88 pp. https://doi.org/10.2903/j.efsa.2010.1891

EFSA (European Food Safety Authority), 2014. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for kresoxim-methyl according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3549, 70 pp. https://doi.org/10.2903/j.efsa.2014.3549

EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue level for kresoxim-methyl in leeks. EFSA Journal 2015;13(8):4215, 18 pp. https://doi.org/10.2903/j.efsa.2015.4215

European Commission, 2016. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3pp., Brussels, 17 June 2016.

OECD (Organisation for Economic Co-operation and Development), 2007. Test No 506: Stability of Pesticide Residues in Stored Commodities, OECD Guidelines for the Testing of Chemicals, Section 5, OECD Publishing, Paris. https://doi.org/10.1787/9789264061927-en

**Abbreviations**

bw  body weight  
CXL  Codex maximum residue limit  
GAP  Good Agricultural Practice  
GC-ECD  gas chromatography with electron capture detector  
HPLC-UVD  high performance liquid chromatography with ultraviolet detector  
InChIKey  International Chemical Identifier Key  
ILV  independent laboratory validation  
LOQ  limit of quantification  
MRL  maximum residue level  
OECD  Organisation for Economic Co-operation and Development  
PRImo  (EFSA) Pesticide Residues Intake Model  
RMS  rapporteur Member State  
SMILES  simplified molecular-input line-entry system  
TRR  total radioactive residue
Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

Not relevant for the current assessment.
Appendix B – List of end points

B.1. Residues in plants

Not relevant for the current assessment.

B.2. Residues in livestock

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | Comment/source |
|-------------------------------|--------|------------------------|----------------|---------------|
| Lactating goat                |        |                        |                |               |
|                               |        | Dosage by intubation (3 animals) |        |               |
|                               |        | Goat A: 0.25 | |               |
|                               |        | Goat B: 25       | Goat C: 25     |               |
|                               |        | Goat A: 5       | Goat B: 8      | Goat C: 8     |               |
|                               |        | Label position: $^{14}$C-phenyl; $^{13}$C-kresoxim-methyl$^\text{(a)}$ | |               |
|                               |        | (a): Different ratios according to the goats: goat A, $^{14}$C/$^{13}$C/unlabelled: 3/0/1; goat B, $^{14}$C/$^{13}$C/unlabelled: 1/4/10; goat C, $^{14}$C/$^{13}$C/unlabelled: 1/0/20 | |               |
|                               |        | Sampling: milk, urine and faeces sampled daily; at sacrifice$^\text{(b)}$: muscle, liver, kidney, fat | |               |
|                               |        | (b): Sacrifice occurred within 24 h of the last administration (23 h for goat A, 4 h for goats B and C) | |               |
| Lactating goat                |        | By oral gavage, once per day: 13.9 mg/kg in the diet | 5 | Label position: $^{14}$C-phenoxy |
|                               |        | Sampling: milk (twice per day), urine and faeces daily and at sacrifice: liver, kidney, bile, rumen, gastrointestinal tract, muscle, fat | |               |
| Laying hen                    |        | Dosage by oral gavage, once per day | 6 | Label position: $^{14}$C-phenyl; $^{13}$C-kresoxim-methyl$^\text{(c)}$ | |
|                               |        | 1 (group 1: 5 hens); 19 (group 2:10 hens) | | (c): Different ratios according to the poultry groups: ratio $^{14}$C/unlabelled: 1/1 (group 1), ratio $^{14}$C/$^{13}$C/unlabelled: 1/4/3 (group 2) | |
|                               |        | Sampling: eggs, excreta daily; At sacrifice: muscle, liver, kidney, fat, skin, gastrointestinal tract | |               |
| Pig                           |        | – | – | – | |
| Fish                          |        | – | – | – | |
| Time needed to reach a plateau concentration in Milk and eggs (days) | Milk: – Not reported |
|---|---|
| Eggs: – Not reported |
| Metabolism in rat and ruminant similar | Yes EFSA (2014) |
| Can a general residue definition be proposed for animals? | Yes | Residue definitions applicable for ruminant matrices including milk and pig matrices were derived. For poultry tissues and eggs, no residue definitions were derived EFSA (2014) |
| Animal residue definition for monitoring (RD-Mo) | Proposal from MRL review (EFSA, 2014): Metabolite BF 490-1, expressed as kresoxim-methyl |
| Two different residue definitions in Regulation (EU) No 2016/486: | |
| – BF 490-9 expressed as kresoxim-methyl (milk) | |
| – BF 490-1 expressed as kresoxim-methyl (for other animal origin products except milk and honey) | |
| Animal residue definition for risk assessment (RD-RA) | Ruminants/swine tissues and ruminants milk: Sum of the metabolites BF 490-1, BF 490-2 and BF 490-9, expressed as parent (EFSA, 2014) |
| Poultry tissues and eggs: none | |
| Fat-soluble residues | No EFSA (2014) |
| Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs) | HPLC-UV + ILV available |
| BF 490-1: meat, fat, liver and kidney LOQ 0.01 mg/kg | |
| BF 490-2: milk LOQ 0.002 mg/kg; fat, kidney LOQ 0.01 mg/kg | |
| BF 490-9: milk LOQ 0.002 mg/kg; fat, kidney, meat and liver LOQ 0.01 mg/kg | |
| GC-ECD (not highly specific) | |
| Kresoxim-methyl (parent): eggs, fat LOQ 0.01 mg/kg | |
| BF 490-3: eggs LOQ 0.01 mg/kg | |
| LC–MS/MS + ILV available | |
| BF 490-1: meat, milk, fat, liver and kidney LOQ 0.01 mg/kg | |
B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|-------------------------------------|--------|-----------|--------|-----------------|-------------------|---------------|
|                                     | Ruminants | Muscle\(^{(a)}\) | –18 | 15 Months | BF 490-1 BF 490-2 | Belgium (2018) |
|                                     | Ruminants | Fat | –18 | 15 Months | BF 490-1 BF 490-9 | Belgium (2018) |
|                                     | Ruminants | Liver\(^{(a)}\) | –18 | 15 Months | BF 490-1 BF 490-9 | Belgium (2018) |
|                                     | Ruminants | Kidney | –18 | 15 Months | BF 490-1 BF 490-9 | Belgium (2018) |
|                                     | Ruminants | Milk\(^{(a)}\) | –18 | 15 Months | BF 490-2 BF 490-9 | Belgium (2018) |
|                                     | Poultry | Eggs | – | – | – | – |

\(^{(a)}\): Storage stability has not been demonstrated for the following metabolite-matrix combinations: BF 490-9 in muscle, BF-490-2 in liver and BF 490-91 in milk; however, it is not required considering that these metabolite-matrix combinations are not expected according to the ruminant metabolism study.

B.2.2. Magnitude of residues in livestock

Not relevant for the current assessment.

B.3. Consumer risk assessment

The consumer risk assessment does not need to be updated, provided that the existing MRLs for products of animal origin remain unchanged.
B.4. **Recommended MRLs**

| Code(a) | Commodity  | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------|----------------|--------------|---------------------------|
| 1011010 | Swine Muscle | 0.05* (ft) | 0.05* | A new storage stability study demonstrates that residues of kresoxim-methyl and its metabolites included in the residue definition for risk assessment (i.e. BF 490-1, BF 490-2 and BF 490-9) are stable in animal origin commodities for 15 months. The submitted study is sufficiently addressing the data gap identified in the MRL review. Thus, the footnote in the MRL Regulation can be removed. The previously derived MRLs are still valid. The new information does not require a revision of the previously performed risk assessment for kresoxim-methyl |
| 1011020 | Swine Fat | 0.05* (ft) | 0.05* |
| 1011030 | Swine Liver | 0.05* (ft) | 0.05* |
| 1011040 | Swine Kidney | 0.05* (ft) | 0.05* |
| 1012010 | Bovine Muscle | 0.05* (ft) | 0.05* |
| 1012020 | Bovine Fat | 0.05* (ft) | 0.05* |
| 1012030 | Bovine Liver | 0.05* (ft) | 0.05* |
| 1012040 | Bovine Kidney | 0.05* (ft) | 0.05* |
| 1013010 | Sheep Muscle | 0.05* (ft) | 0.05* |
| 1013020 | Sheep Fat | 0.05* (ft) | 0.05* |
| 1013030 | Sheep Liver | 0.05* (ft) | 0.05* |
| 1013040 | Sheep Kidney | 0.05* (ft) | 0.05* |
| 1014010 | Goat Muscle | 0.05* (ft) | 0.05* |
| 1014020 | Goat Fat | 0.05* (ft) | 0.05* |
| 1014030 | Goat Liver | 0.05* (ft) | 0.05* |
| 1014040 | Goat Kidney | 0.05* (ft) | 0.05* |
| 1020010 | Milk Cattle | 0.01* (ft) | 0.01* |
| 1020020 | Milk Sheep | 0.01* (ft) | 0.01* |
| 1020030 | Milk Goat | 0.01* (ft) | 0.01* |

MRL: maximum residue level.

*: MRL set at the limit of quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): The residue definition in the Commission database does not correspond to the residue definitions specify for kresoxim-methyl in Commission Regulation (EU) 2016/486.
(ft): The European Food Safety Authority identified some information on storage stability as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 23 July 2017, or, if that information is not submitted by that date, the lack of it. (Footnote related to data gap No 4).
Appendix C – Pesticide Residue Intake Model (PRIMo)

Not relevant for the current assessment.
Appendix D – Input values for the exposure calculations

D.1 Livestock dietary burden calculations
Not relevant for the current assessment.

D.2. Consumer risk assessment
Not relevant for the current assessment.
## Appendix E – Used compound codes

| Code/trivial name<sup>a</sup> | IUPAC name/SMILES notation/InChiKey<sup>b</sup> | Structural formula<sup>c</sup> |
|-------------------------------|-----------------------------------------------|-------------------------------|
| Kresoxim-methyl | methyl (E)-methoxyimino[α-(o-tolyloxy)-o-toly]acetate  
O=C(OC)(=N)C1cccc1C0c1cccc1C | ![Structural formula for methyl (E)-methoxyimino[α-(o-tolyloxy)-o-toly]acetate](image) |
| BF 490-1  
(acid of kresoxim-methyl) | (E)-methoxyamino[α-(o-tolyloxy)-o-toly]acetic acid  
O=C(O)\(\{=-N\}\)C1cccc1C0c1cccc1C | ![Structural formula for (E)-methoxyamino[α-(o-tolyloxy)-o-toly]acetic acid](image) |
| BF 490-2  
(2E)-(2-[2-(hydroxymethyl)phenoxy]methyl]phenyl) (methoxyimino)acetic acid  
O=C(O)\(\{=-N\}\)C1cccc1C0c1cccc1C | ![Structural formula for (2E)-(2-[2-(hydroxymethyl)phenoxy]methyl]phenyl) (methoxyimino)acetic acid](image) |
| BF 490-9  
(2E)-(2-[4-hydroxy-2-methylphenoxy]methyl]phenyl) (methoxyimino)acetic acid  
O=C(O)\(\{=-N\}\)C1cccc1C0c1cccc1C | ![Structural formula for (2E)-(2-[4-hydroxy-2-methylphenoxy]methyl]phenyl) (methoxyimino)acetic acid](image) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup>                                                                 | Structural formula<sup>(c)</sup> |
|---------------------------------|------------------------------------------------------------------------------------------------------------------|---------------------------------|
| BF 490-3                        | methyl (2E)-(hydroxyimino)\{2-[(2-methylphenoxy)methyl]phenyl\}acetate  
O=C(OC)(C=N)=Oc1cccc1COc1cccc1C  
NNHDCYABCHZSQT-FBMGVBCBSA-N | ![Structural formula image]                                                     |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).
(c): ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).