

APPROVED: 20 August 2015

PUBLISHED: 8 September 2015

doi:10.2903/j.efsa.2015.4220

Review of the existing maximum residue levels for fuberidazole according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA)

Abstract

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance fuberidazole. In order to assess the occurrence of fuberidazole residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. No information required by the regulatory framework was found to be missing and no risk to consumers was identified.

© European Food Safety Authority, 2015

Keywords: fuberidazole, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, benzimidazole, fungicide

Requestor: European Commission

Question number: EFSA-Q-2009-00118

Correspondence: pesticides.mrl@efsa.europa.eu

Acknowledgement: EFSA wishes to thank the rapporteur Member State the United Kingdom for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), 2015. Reasoned opinion on the review of the existing maximum residue levels for fuberidazole according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(9):4220, 25 pp. doi:10.2903/j.efsa.2015.4220

ISSN: 1831-4732

© European Food Safety Authority, 2015

Reproduction is authorised provided the source is acknowledged.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



Summary

Fuberidazole was included in Annex I to Directive 91/414/EEC on 1 March 2009 by Commission Directive 2008/108/EC, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011. As the active substance was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, EFSA is required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(1) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked RMS, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The PROFile and evaluation report provided by the RMS were made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 21 January 2015 and finalised on 17 March 2015. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 17 April 2015.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS and Member States, EFSA prepared in May 2015 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 22 June 2015 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of fuberidazole was investigated for seed treatment on winter wheat. It was concluded that the residue definition for monitoring and risk assessment should be established as parent compound, by default. The proposed residue definition is limited to cereals only. A validated analytical method is available for monitoring fuberidazole in cereal grain and straw with an LOQ of 0.05 mg/kg. Storage stability studies evaluated during the peer review showed that residues are stable for 24 months in dry commodities stored at -18°C.

Regarding the magnitude of the residues in primary crops, the number of supervised residues trials is sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

A confined metabolism study in rotational crops of Swiss chard, turnips and wheat is available to address the potential for residues to occur in rotational crops. It was concluded that significant residues in rotational crops are not expected, provided that fuberidazole is applied according to the GAPs supported in the framework of this review.

As quantifiable residues of fuberidazole are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Based on the uses reported by the RMS, significant exposures to fuberidazole are not expected for any group of livestock. Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin, is not necessary.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 7 % of the ADI (Danish child) and the highest acute exposure amounted to 0.9 % of the ARfD (wheat).

Table of contents

Abstract.....	1
Summary.....	3
Background.....	5
Terms of reference.....	6
The active substance and its use pattern	6
Assessment.....	7
1. Residues in plants.....	7
1.1. Nature of residues and methods of analysis in plants	7
1.1.1. Nature of residues in primary crops.....	7
1.1.2. Nature of residues in rotational crops	7
1.1.3. Nature of residues in processed commodities.....	7
1.1.4. Methods of analysis in plants	7
1.1.5. Stability of residues in plants	8
1.1.6. Proposed residue definitions	8
1.2. Magnitude of residues in plants.....	8
1.2.1. Magnitude of residues in primary crops	8
1.2.2. Magnitude of residues in rotational crops.....	8
1.2.3. Magnitude of residues in processed commodities	8
1.2.4. Proposed MRLs	8
2. Residues in livestock	9
3. Consumer risk assessment.....	9
Conclusions.....	9
Recommendations.....	9
References.....	11
Abbreviations	13
Appendix A – Summary of authorised uses considered for the review of MRLs.....	15
Appendix B – List of end points.....	16
Appendix C – Input values for the exposure calculations	22
Appendix D – Decision tree for deriving MRL recommendations	23
Appendix E – Used compound code(s)	25

Background

Regulation (EC) No 396/2005¹ establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that regulation stipulates that 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 MRLs for that active substance. As fuberidazole was included in Annex I to Council Directive 91/414/EEC on 1 March 2009 by means of Commission Directive 2008/108/EC,³ and has been deemed to be approved under Regulation (EC) No 1107/2009,⁴ in accordance with Commission Implementing Regulation (EU) No 540/2011,⁵ as amended by Commission Implementing Regulation (EU) No 541/2011,⁶ EFSA initiated the review of all existing MRLs for that active substance.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated, while MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

The United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for fuberidazole and to prepare a supporting evaluation report (United Kingdom, 2010). The PROFile and the supporting evaluation report were submitted to EFSA on 22 October 2010 and made available to the Member States. A request for additional information was addressed to the Member States in the framework of a completeness check period which was initiated by EFSA on 21 January 2015 and finalised on 17 March 2015. After having considered all the information provided by RMS and Member States, EFSA prepared a completeness check report which was made available to all Member States on 17 April 2015. No further clarifications were sought from Member States.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, and the additional information provided by the Member States, EFSA prepared in May 2015 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All

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

³ Commission Directive 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazainam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–13.

⁴ 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. 1–50.

⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.

⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.

comments received by 22 June 2015 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (United Kingdom, 2010) is considered as supporting document to this reasoned opinion and, thus, is made publicly available.

In addition, key supporting documents to this reasoned opinion are the completeness check report (EFSA, 2015a) and the Member States consultation report (EFSA, 2015b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Also the chronic and acute exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMO) are key supporting documents and made publicly available.

Considering the importance of the completeness check and consultation report, all documents are considered as background documents to this reasoned opinion and, thus, are made publicly available.

Terms of reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Fuberidazole is the ISO common name for 2-(2'-furyl)benzimidazole (IUPAC).

Fuberidazole belongs to the group of benzimidazole compounds which are used as fungicides. It acts as a contact and acropetal systemic fungicide, inhibiting mitosis in fungi by interfering with the β -tubulin assembly. After seed treatment, fuberidazole penetrates into cereal grains and is translocated to the leaf tip. Fuberidazole is used as seed treatment application to control *Fusarium* spp., bunt and smut in cereal crops.

The chemical structure of the active substance is reported in Appendix E.

Fuberidazole was evaluated in the framework of Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). The representative uses supported for the peer review process include seed treatment to winter-sown varieties of wheat, barley, oats, rye and triticale. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2008/108/EC, which entered into force on 1 March 2009. According to Regulation (EU) No 540/2011, fuberidazole is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as fungicide only.

The EU MRLs for fuberidazole are established in Annexes IIIA of Regulation (EC) No 396/2005 and CXLs for this active substance are not available.

For the purpose of this MRL review, the critical uses of fuberidazole currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The details of the authorised GAPs for fuberidazole are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the PROfile submitted by the RMS, the evaluation report accompanying the PROfile (United Kingdom, 2010), the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (United Kingdom, 2007), the Review Report on fuberidazole (European Commission, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance fuberidazole (EFSA, 2007b). The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011⁷ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011 and OECD, 2011).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of fuberidazole was investigated in winter wheat after seed treatment with phenyl-labelled fuberidazole at 1N and 5N (EFSA, 2007b). After treatment at 1N, total radioactive residues in grain and straw were very low (0.002 and 0.02 mg eq/kg, respectively). In grain no further characterization of the residue was possible. In straw, apart from parent which amounted to 4 % of the TRR, two other metabolites were identified (accounting for 8 and 13 % of the TRR, respectively) but, due to the low TRR, their levels were not considered relevant.

1.1.2. Nature of residues in rotational crops

A confined rotational crop study has been evaluated during the peer review (United Kingdom, 2007; EFSA, 2007b). In this study Swiss chard, turnips and wheat were sown 30 days after the application of fuberidazole on bare soil at 1N. Residues in rotational crops were always below the LOQ of < 0.001 mg/kg in chard and turnips leaves and tops and were found at 0.004 mg/kg and 0.002 mg/kg in straw and in grain, respectively. Due to the low residue levels, no further characterization of the residue was possible. Therefore it was concluded that metabolic patterns in primary and rotational crops are similar and that residues are not expected in crops grown in rotation with treated cereals.

1.1.3. Nature of residues in processed commodities

As quantifiable residues of fuberidazole are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI (see also section 3), there is no need to investigate the effect of industrial and/or household processing.

1.1.4. Methods of analysis in plants

An analytical method using GC/MS was validated for the monitoring of fuberidazole in cereal (grain and straw) with an LOQ of 0.05 mg/kg. This method is supported by an ILV and, as it was deemed sufficiently specific, does not require a confirmatory method (EFSA, 2007b).

During the consultation of Member States, the EURLs commented that a lower LOQ of 0.01 mg/kg could be achieved in dry commodities and that analytical methods were also validated for monitoring in high water, high oil and acidic commodities. However, this information could not be verified by EFSA since the supporting data were not made available by the EURLs.

⁷ 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, 11.06.2011, p. 127–175.

Hence it is concluded that fuberidazole can be monitored with an LOQ of 0.05 mg/kg in cereal grain and straw.

1.1.5. Stability of residues in plants

Storage stability studies evaluated during the peer review showed that residues are stable for 24 months in dry commodities (grain) and straw, when stored at -18°C (EFSA, 2007b).

1.1.6. Proposed residue definitions

Since total residues are insignificant in cereals and not expected in crops grown in rotation, there is no particular relevant marker for enforcement. Therefore, the residue definition for monitoring and risk assessment was proposed as parent compound, by default (EFSA, 2007b). Nevertheless, considering that the primary crop metabolism was only investigated in cereals, the proposed residue definition is limited to cereals only. A validated analytical method for enforcement of the proposed residue definition in cereals (grain and straw) is available.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of fuberidazole residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (United Kingdom, 2010), including residue trials evaluated in the framework of the peer review (EFSA, 2007). All residue trial samples considered in this framework were stored in compliance with the demonstrated storage conditions. Decline of residues during storage of the trial samples is therefore not expected.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2011). For all the crops under assessment, available residue trials are sufficient to derive MRL and risk assessment values.

1.2.2. Magnitude of residues in rotational crops

Based on the confined rotational crop study (see also section 1.1.2.), measurable residues are not expected to occur in rotational crops provided that fuberidazole is applied according to GAP. Rotational crop field trials are therefore not required.

1.2.3. Magnitude of residues in processed commodities

Since fuberidazole is used as a seed treatment and quantifiable residues are not expected in cereal grains, concentration of residues in processed commodities is not expected. Further investigation of the effect of processing on the magnitude of residues is therefore not required.

1.2.4. Proposed MRLs

Consequently, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

It is highlighted that MRL proposal in cereal grain is based on the validated monitoring LOQ of 0.05 mg/kg; the LOQ of 0.01 mg/kg, proposed by the EURLs, could not be verified by EFSA (see section 1.1.4). Nevertheless, if this LOQ is considered relevant by risk managers, MRL of 0.01* mg/kg would also be appropriate since quantifiable residues are not expected in cereals grain (also based on metabolism studies).

2. Residues in livestock

Fuberidazole is authorised for use on cereals that might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (European Commission, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Appendix B. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

3. Consumer risk assessment

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix D. Hence, for cereal grains, where MRLs could be derived by EFSA in the framework of this review, median and highest residue values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix C.

The exposures calculated were compared with the toxicological reference values for fuberidazole, derived by EFSA (2007b) under Directive 91/414/EEC. The highest chronic exposure was calculated for Danish children, representing 7 % of the ADI, and the highest acute exposure was calculated for wheat, representing 0.9 % of the ARfD. Therefore, this exposure calculation did not indicate a risk to consumers.

Conclusions

The metabolism of fuberidazole was investigated for seed treatment on winter wheat. It was concluded that the residue definition for monitoring and risk assessment should be established as parent compound, by default. The proposed residue definition is limited to cereals only. A validated analytical method is available for monitoring fuberidazole in cereal grain and straw with an LOQ of 0.05 mg/kg. Storage stability studies evaluated during the peer review showed that residues are stable for 24 months in dry commodities stored at -18°C.

Regarding the magnitude of the residues in primary crops, the number of supervised residues trials is sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

A confined metabolism study in rotational crops of Swiss chard, turnips and wheat is available to address the potential for residues to occur in rotational crops. It was concluded that significant residues in rotational crops are not expected, provided that fuberidazole is applied according to the GAPs supported in the framework of this review.

As quantifiable residues of fuberidazole are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

Based on the uses reported by the RMS, significant exposures to fuberidazole are not expected for any group of livestock. Therefore, further investigation of residues as well as the setting of MRLs in commodities of animal origin, is not necessary.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 7 % of the ADI (Danish child) and the highest acute exposure amounted to 0.9 % of the ARfD (wheat).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

It is highlighted that MRL proposal in cereal grain is based on the validated monitoring LOQ of 0.05 mg/kg; the LOQ of 0.01 mg/kg, proposed by the EURLs, could not be verified by EFSA. Nevertheless, if this LOQ is considered relevant by risk managers, MRL of 0.01* mg/kg would also be appropriate since quantifiable residues are not expected in cereals grain (also based on metabolism studies).

Table 1: Summary table

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: fuberidazole				
500010	Barley	0.2	0.05*	Recommended ^(b)
500050	Oats	0.2	0.05*	Recommended ^(b)
500070	Rye	0.2	0.05*	Recommended ^(b)
500090	Wheat	0.2	0.05*	Recommended ^(b)
–	Other products of plant and animal origin	–	–	Further considerations needed ^(c)

* Indicates that the MRL is proposed at the limit of quantification.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

References

- EFSA (European Food Safety Authority), 2007a. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs. EFSA Scientific Report (2007). doi:10.2903/j.efsa.2007.32r
- EFSA (European Food Safety Authority), 2007b. Conclusion on the peer review of the pesticide risk assessment of the active substance fuberidazole. EFSA Scientific Report (2007) 118, 1-65. doi:10.2903/j.efsa.2008.118r
- EFSA (European Food Safety Authority), 2015a. Completeness check report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 17 April 2015. Available online: www.efsa.europa.eu
- EFSA (European Food Safety Authority), 2015b. Member States consultation report on the review of the existing MRLs of active substance prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 20 July 2015. Available online: www.efsa.europa.eu
- European Commission, 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4, 22 July 1996.
- European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.
- European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6, 22 July 1997.
- European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2, 22 July 1997.
- European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5, 22 July 1997.
- European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3, 22 July 1997.
- European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5, 22 July 1997.
- European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
- European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4.
- European Commission, 2008. Review report for the active substance fuberidazole. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 May 2008 in view of the inclusion of fuberidazole in Annex I of Council Directive 91/414/EEC. SANCO/3620/07-rev.1, 20 May 2008.
- European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.
- European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.8.1, 16 November 2010.
- European Commission, 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9, March 2011.
- FAO (Food and Agriculture Organisation of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Ed. FAO Plant Production and Protection Paper 197, 264 pp.

OECD (Organisation for Economic Co-operation and Development), 2008. Guidance document on the magnitude of pesticide residues in processed commodities. In: Series of Testing and Assessment No 96. ENV/JM/MONO(2008)23, 29 July 2008.

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: <http://www.oecd.org>

United Kingdom, 2005. Draft assessment report on the active substance fuberidazole prepared by the rapporteur Member State the United Kingdom in the framework of Council Directive 91/414/EEC, April 2005. Available online: www.efsa.europa.eu

United Kingdom, 2007. Final addendum to the draft assessment report on the active substance fuberidazole, compiled by EFSA, June 2007. Available online: www.efsa.europa.eu

United Kingdom, 2010. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Review of existing MRLs for fuberidazole, October 2010. Available online: www.efsa.europa.eu

Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CS	capsule suspension
CV	coefficient of variation (RSD)
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Commission
EC	emulsifiable concentrate
EDI	estimated daily intake
eq	residue expressed as a.s. equivalent
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
GLP	Good Laboratory Practice
GR	granule
GS	growth stage
HPLC-MS	high performance liquid chromatography with mass spectrometry

HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector
ILV	independent laboratory validation
IPCS	International Programme of Chemical Science
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K _{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PAFF	Standing Committee on Plants, Animals, Food and Feed
PF	processing factor
PHI	pre-harvest interval
ppm	parts per million (10 ⁻⁶)
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R _{ber}	statistical calculation of the MRL by using a non-parametric method
R _{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	southern European Union
tMRL	temporary MRL
WHO	World Health Organization
yr	year

Appendix A – Summary of authorised uses considered for the review of MRLs

Critical outdoor GAPS for Northern Europe																			
Crop		Region	Outdoor/ Indoor	Member state or country	Pest controlled	Formulation			Method	Application						PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			Growth stage	Number		Interval (days)		Rate				
							Conc.	Unit			From BBCH	Until BBCH	Min.	Max.	Min.			Max.	Min.
Barley	Hordeum spp.	NEU	Outdoor	UK, AT, CZ, DE	<i>Fusarium</i> spp., Bunt, Smut	FS	9.0	g/L	Seed treatment - dipping		0		1			4.50	g a.i./100 kg	n.a.	8.1 g as/ha at 180 kg seed/ha
Oats	Avena fatua	NEU	Outdoor	UK, AT	<i>Fusarium</i> spp., Bunt, Smut	FS	9.0	g/L	Seed treatment - dipping		0		1			4.50	g a.i./100 kg	n.a.	8.6 g as/ha at 190 kg seed/ha
Rye	Secale cereale	NEU	Outdoor	UK, AT, SE	<i>Fusarium</i> spp., Bunt, Smut	FS	9.0	g/L	Seed treatment - dipping		0		1			4.50	g a.i./100 kg	n.a.	7.7 g as/ha at 170 kg seed/ha
Wheat	Triticum aestivum	NEU	Outdoor	UK, AT, CZ, SE	<i>Fusarium</i> spp., Bunt, Smut	FS	9.0	g/L	Seed treatment - dipping		0		1			4.50	g a.i./100 kg	n.a.	10.35 g as/ha at 230 kg seed/ha

NEU: northern European Union

Appendix B – List of end points

B.1. Residues in plants

B.1.1. Nature of residues and methods of analysis in plants

B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)
	Cereals/grass crops	wheat	Seed, 1 x 4.5 or 1 x 50 g a.s./100 kg seeds	251, 244
Study evaluated in the EFSA conclusion (EFSA, 2007b). Residues were analysed at in grain and straw (251 and 244 DAT in the 1N and in the 5N study, respectively).				
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
	Root/tuber crops	turnips	Bare soil, 10.35 g a.s./ha	30
	Leafy crops	Swiss chard	Bare soil, 10.35 g a.s./ha	30
	Cereal (small grain)	wheat	Bare soil, 10.35 g a.s./ha	30
Study reported in the final addendum to the DAR (United Kingdom, 2007) and evaluated in the EFSA conclusion (EFSA, 2007b).				
Processed commodities (hydrolysis study)	Conditions		Investigated?	
	Pasteurisation (20 min, 90°C, pH 4)		No	
	Baking, brewing and boiling (60 min, 100°C, pH 5)		No	
	Sterilisation (20 min, 120°C, pH 6)		No	
	Not available and not required.			

Can a general residue definition be proposed for primary crops?

no

Rotational crop and primary crop metabolism similar?

yes

Residue pattern in processed commodities similar to residue pattern in raw commodities?

not applicable

Plant residue definition for monitoring (RD-Mo)

fuberidazole

Plant residue definition for risk assessment (RD-RA)

fuberidazole

Conversion factor (monitoring to risk assessment)

1

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

GC-MS; dry commodities (wheat grain) and straw; LOQ: 0.05 mg/kg (EFSA, 2007b).

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (Months/years)
	High water content	Wheat, green	-18	24 months
	Dry / High starch	Wheat, grain and straw	-18	24 months
Storage stability study evaluated in the EFSA conclusion (EFSA, 2007b).				

B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

Crop	Region/ Indoor (a)	Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg)	Recommendations/comments (OECD calculations)	MRL proposals (mg/kg)	HR (mg/kg) (b)	STMR (mg/kg) (c)
Enforcement and risk assessment residue definition: fuberidazole						
Wheat grain Oats grain Barley grain Rye grain	NEU	12 x <0.05	Combined data set on wheat (5), barley (5) and rye (2) compliant with GAP.	0.05*	0.05	0.05
Wheat straw Oats straw Barley straw Rye straw	NEU	12 x <0.05	Combined data set on wheat (5), barley (5) and rye (2) compliant with GAP.	0.05*	0.05	0.05

* Indicates that the MRL is proposed at the limit of quantification.

(a): NEU: outdoor trials conducted in northern Europe.

(b): Highest residue

(c): Supervised trials median residue

B.1.2.2. Residues in succeeding crops

Confined rotational crop study
(quantitative aspect)

No residues above the enforcement LOQ of 0.05 mg/kg are expected in crops grown in rotation.

Field rotational crop study

-

B.1.2.3. Processing factors

Processed commodity	Number of studies ^(a)	Processing Factor (PF)	
		Individual values	Median PF
Not available and not required.	-	-	-

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur)

B.2. Residues in livestock

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity ^(a)	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy ruminants	0.0013	0.0013	Wheat grain	0.035	N
Meat ruminants	0.0025	0.0025	Wheat grain	0.058	N
Poultry	0.0026	0.0026	Wheat grain	0.041	N
Pigs	0.0019	0.0019	Wheat grain	0.047	N

(a): Calculated for the maximum dietary burden

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/d)	Duration (days)	N rate/comment
Not available and not required.				

Time needed to reach a plateau concentration in milk and eggs (days)

-

Metabolism in rat and ruminant similar (Yes/No)

-

Animal residue definition for monitoring (RD-Mo)

Not required.

Animal residue definition for risk assessment (RD-RA)

Not required.

Conversion factor (monitoring to risk assessment)

-

Fat soluble residues (Yes/No)

-

Methods of analysis for monitoring of residues (analytical technique, tissue, LOQs)

Not required.

B.2.1.2 Stability of residues in livestock

Animal products (available studies)	Animal	Commodity	T (°C)	Stability (Months/years)
Not available and not required.				

B.2.2. Magnitude of residues in livestock

B.2.2.1. Summary of the residue data from livestock feeding studies

Ruminants Not available and not required.	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)
		Mean (mg/kg)	Highest (mg/kg)	STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	
	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-
	Milk	-	-	-	-	-
Poultry Not available and not required.	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)
		Mean (mg/kg)	Highest (mg/kg)	STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	
	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-
	Eggs	-	-	-	-	-
Pig Not available and not required.	Commodity	Residues at closest feeding level		Estimated value at 1N		MRL (mg/kg)
		Mean (mg/kg)	Highest (mg/kg)	STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	
	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-

* Indicates that the MRL is proposed at the limit of quantification.

n.a. not applicable

(a): Closest feeding level and N dose rate related to the maximum dietary burden.

(b): Mean residue level recalculated at the 1N rate for the median dietary burden.

(c): Highest residue level for tissues and eggs and mean residue level for milk recalculated at the 1N rate for the maximum dietary burden.

B.3. Consumer risk assessment

ADI	0.0072 mg/kg bw per day (EFSA, 2007)
Highest IEDI, according to EFSA PRIMo	7 % ADI (DK, child)
Assumptions made for the calculations	The calculation is based on the median residue levels in the raw agricultural commodities. The contributions of commodities where no GAP was reported in the framework of this review, were not included in the calculation.
ARfD	0.08 mg/kg bw (EFSA, 2007)
Highest IESTI, according to EFSA PRIMo	0.9 % ARfD (wheat)
Assumptions made for the calculations	The calculation is based on the highest residue levels in the raw agricultural commodities.

B.4. Proposed MRLs

Code number ^(a)	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: fuberidazole				
500010	Barley	0.2	0.05*	Recommended ^(b)
500050	Oats	0.2	0.05*	Recommended ^(b)
500070	Rye	0.2	0.05*	Recommended ^(b)
500090	Wheat	0.2	0.05*	Recommended ^(b)
-	Other products of plant and animal origin	-	-	Further considerations needed ^(c)

* Indicates that the MRL is proposed at the limit of quantification.

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005

(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

Appendix C – Input values for the exposure calculations

C.1. Livestock dietary burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: fuberidazole				
Wheat, barley, rye and oat grain	0.05*	STMR	0.05*	STMR
Wheat, barley, rye and oat straw	0.05*	STMR	0.05*	HR
Wheat and rye bran	0.05	STMR ^(a)	0.05	STMR ^(a)

* Indicates that the input value is proposed at the limit of quantification.

(a): For cereal bran, no default processing factor was applied because fuberidazole is applied early in the growing season and residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.

STMR: supervised trials median residue; HR: highest residue

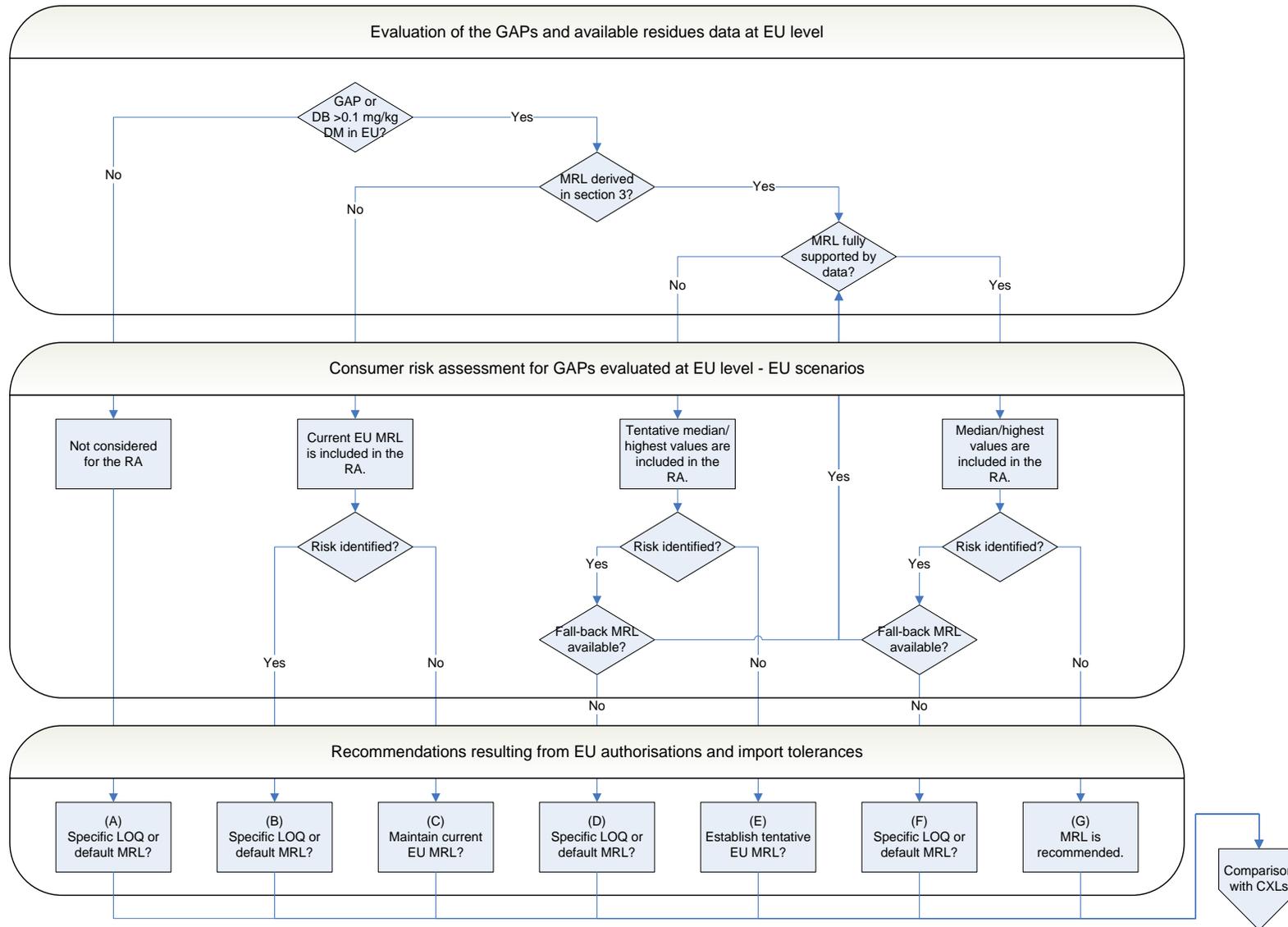
C.2. Consumer risk assessment

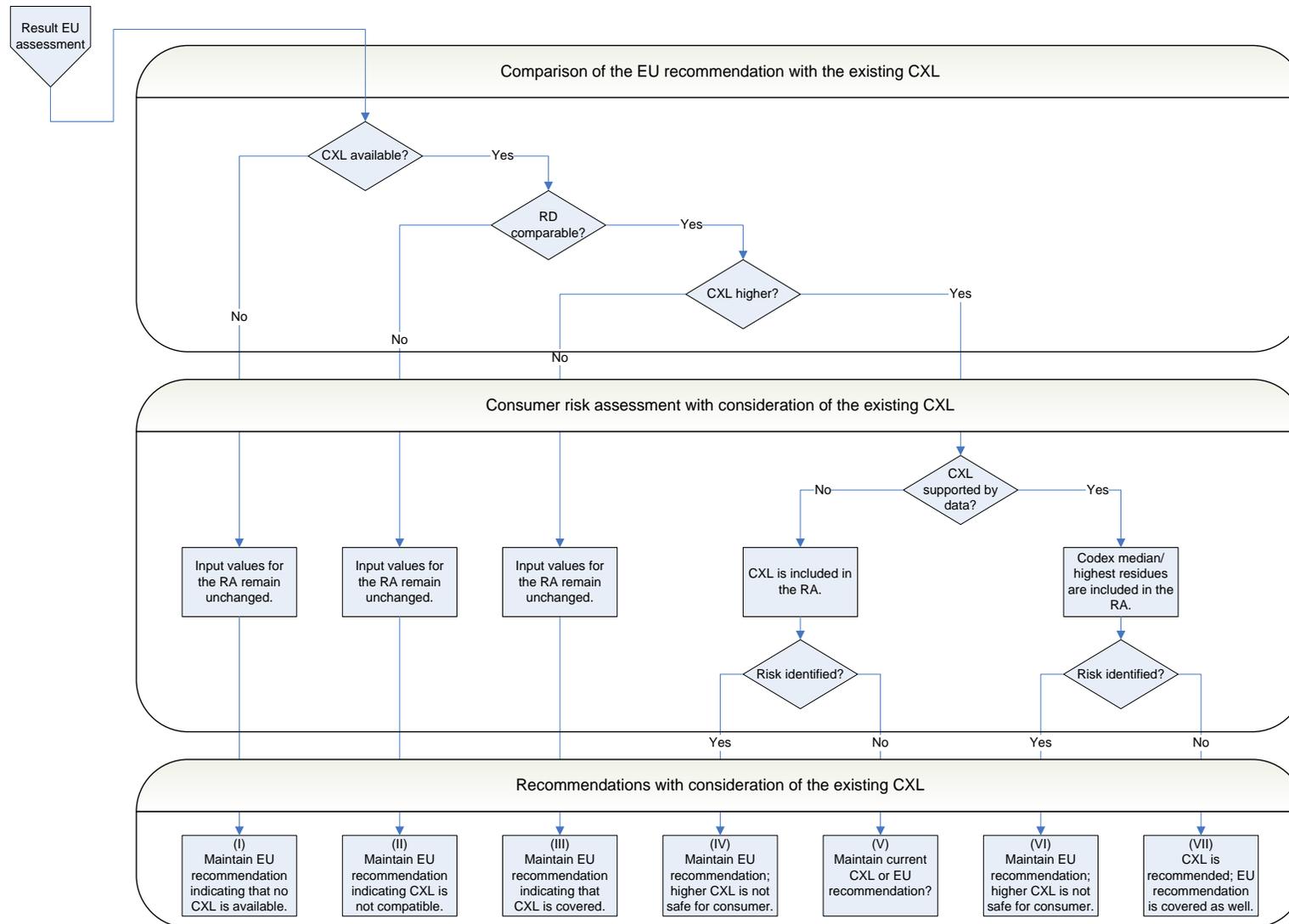
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: fuberidazole				
Wheat, barley, rye and oat grain	0.05*	STMR ^(a)	0.05*	HR ^(a)

* Indicates that the input value is proposed at the limit of quantification.

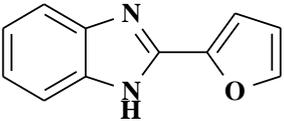
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.

Appendix D – Decision tree for deriving MRL recommendations





Appendix E – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation ^(a)	Structural formula ^(a)
fuberidazole	2-(2'-furyl)benzimidazole	

(a): ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).