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## Review of the existing maximum residue levels for tralkoxydim 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 tralkoxydim. In order to assess the occurrence of tralkoxydim 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. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and all MRL proposals derived by EFSA still require further consideration by risk managers.

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**Keywords:** tralkoxydim, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, cyclohexene oxime, herbicide

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## Summary

Tralkoxydim was included in Annex I to Directive 91/414/EEC on 1 May 2009 by Commission Directive 2008/107/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 the United Kingdom, 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 3 February 2015 and finalised on 1 April 2015. After having considered all the information provided, EFSA prepared a completeness check report which was made available to Member States on 7 May 2015.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by United Kingdom and Member States, EFSA prepared in July 2015 a draft reasoned opinion, which was circulated to Member States for consultation via a written procedure. Comments received by 7 August 2015 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

Primary crop metabolism of tralkoxydim was investigated for foliar treatment in cereals, while rotational crop metabolism was investigated for a bare soil treatment in leafy, root, pulses/oilseed and cereal crops. Metabolic patterns observed in primary and rotational crops were similar. As quantifiable residues of tralkoxydim are not expected in the treated crops, there was no need to investigate the effect of industrial and/or household processing on the nature of residues. Based on the fact that no residues of the parent compound or its structurally related metabolites are expected at measurable level in cereal grains and that uptake from soil in rotational crops was also found to be very limited, the residue definition for monitoring and risk assessment purposes is defined as the sum of the constituent isomers of tralkoxydim. An analytical method for enforcement of the proposed residue definition is available, although further validation of this method is still required. Furthermore, considering that primary crop metabolism was only investigated in cereals, this residue definition is limited to cereals and a general residue definition for plant commodities cannot be derived.

Regarding the magnitude of residues in plants, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for the primary crops under evaluation and, provided that the active substance is applied in compliance with the reported GAPs, measurable levels of relevant residues are not expected to occur in rotational crops. Since tralkoxydim is applied early in the growing season and quantifiable residues are not expected in cereal grains, concentration of residues in processed commodities is also not expected. However, considering that further validation of the analytical method for enforcement purposes is still required, the proposed MRLs are tentative.

Tralkoxydim is authorised for use on wheat and barley, which might be fed to livestock, but the livestock dietary burden calculated for all types of livestock remained below the trigger value of 0.1 mg/kg DM. Also supported by the available metabolism studies in hens and goats, it was concluded that MRLs in commodities of animal origin are 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 1.8% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 1.4 % of the ARfD (wheat).

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## Background

Regulation (EC) No 396/2005<sup>1</sup> 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/EEC<sup>2</sup> a reasoned opinion on the review of the existing MRLs for that active substance. As tralkoxydim was included in Annex I to Council Directive 91/414/EEC on 1 May 2009 by means of Commission Directive 2008/107/EC,<sup>3</sup> and has been deemed to be approved under Regulation (EC) No 1107/2009,<sup>4</sup> in accordance with Commission Implementing Regulation (EU) No 540/2011,<sup>5</sup> as amended by Commission Implementing Regulation (EU) No 541/2011,<sup>6</sup> 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 tralkoxydim and to prepare a supporting evaluation report (United Kingdom, 2010). The PROFile and the supporting evaluation report were submitted to EFSA on 13 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 3 February 2015 and finalised on 1 April 2015. After having considered all the information provided by the United Kingdom and Member States, EFSA prepared a completeness check report which was made available to all Member States on 7 May 2015. Further clarifications were sought from Member States via a written procedure in May 2015.

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 July 2015 a draft reasoned opinion, which was submitted to Member States for commenting via a written procedure. All

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances. OJ L 316, 26.11.2008, p. 4–11.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> 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 7 August 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

Tralkoxydim is the ISO common name for (*RS*)-2-[(*EZ*)-1-(ethoxyimino)propyl]-3-hydroxy-5-mesitylcyclohex-2-en-1-one (IUPAC).

Tralkoxydim belongs to the group of cyclohexene oxime compounds which are used as herbicides. It acts by inhibition of the Acetyl CoA Carboxylase (ACCase) enzyme system, resulting in the inhibition of cell division in target weeds. Tralkoxydim is used for the control of grass weeds in wheat and barley.

The chemical structure of the active substance and its main metabolites are reported in Appendix E.

Tralkoxydim 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 consisted of foliar post-emergence applications in cereal crops, including wheat and barley up to crop growth stage BBCH 32, at a single application rate of 450 g active substance (a.s.)/ha. 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 2008/107/EC, which entered into force on 1 May 2009. According to Regulation (EU) No 540/2011, tralkoxydim is deemed to have been approved under Regulation (EC) No 1107/2009. This approval is restricted to uses as herbicide only.

The EU MRLs for tralkoxydim are established in Annex 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 tralkoxydim currently authorised within the EU have been collected by the RMS and reported in the PROFile. However, only the uses confirmed by the concerned Member States during the completeness check were considered by EFSA. The details of the authorised good agricultural practices (GAPs) for tralkoxydim 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, 2005, 2008), and the conclusion on the peer review of the pesticide risk assessment of the active substance tralkoxydim (EFSA, 2008). 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 546/2011<sup>7</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 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**

In the framework of Directive 91/414/EEC, primary crop metabolism of tralkoxydim was investigated in wheat in conditions of application representative of the authorised GAPs (United Kingdom, 2005). A complex metabolic pattern was observed in forage and straw, consisting of more than 10 individual compounds. The parent compound was not found. The major metabolites identified were R400307, R237434 and R209490 (see appendix E for chemical structures), all present at 10 to 15 % of the Total Radioactive Residues (TRR, 1-2 mg eq/kg). The metabolic pathway proceeds through oxidation of the terminal methyl group of the phenyl ring, oxidative cleavage of the cyclohexyl ring and transformation of the ethoxyiminopropyl function. In grains, the TRR were low (0.01 - 0.02 mg/kg) and essentially non extractable (EFSA, 2008).

Although the E/Z isomer ratio of the active substance may vary depending on the environmental conditions, this is not expected to impact the risk assessment since residue levels are very low, in grain in particular.

#### **1.1.2. Nature of residues in rotational crops**

In the framework of Directive 91/414/EEC, nature of residues following a bare soil treatment with tralkoxydim has been studied in leafy, root, pulses/oilseed and cereal crops (United Kingdom, 2005). TRR were very low for all pre-planting intervals (30, 105 and 300 days) and in most cases below 0.05 mg/kg. The metabolic pattern was similar to that observed in primary crops, consisting of a complex mixture of highly polar metabolites individually present at low level. The identified metabolites were the same as in primary crops. The parent compound was not present. This is consistent with the rapid and extensive degradation of tralkoxydim observed in soil (EFSA, 2008).

#### **1.1.3. Nature of residues in processed commodities**

As quantifiable residues of tralkoxydim are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing on the nature of residues.

#### **1.1.4. Methods of analysis in plants**

An analytical method using LC-MS/MS was validated for the monitoring of tralkoxydim with a limit of quantification (LOQ) of 0.01 mg/kg in dry, acidic, high water content and high oil content commodities, and cereal straw (United Kingdom, 2005). This method is supported by an independent laboratory validation (ILV) and validated for one mass transition. Although this method was previously considered as completely validated by EFSA (2008), it is noted that according to the latest guidance documents on this matter (European Commission, 2010b) validation of second mass transition is now required. Further information regarding the extraction efficiency is in this case not required because residues are expected to be <0.01 mg/kg (see also section 1.2).

<sup>7</sup> 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.

EURLs reported a possible change of isomer ratios during analysis, but this not expected to impact on the validity of the above method because the method investigates the sum of isomers.

#### **1.1.5. Stability of residues in plants**

Stability of tralkoxydim residues was investigated in the framework of Directive 91/414/EEC (United Kingdom, 2005). This study demonstrated stability of tralkoxydim at -18°C for a period of 18 months in dry commodities (wheat grain) and for a period of 9 months in wheat straw. An additional study demonstrated stability of tralkoxydim at -15°C for a period 21 months in high water content commodities (wheat forage).

#### **1.1.6. Proposed residue definitions in plants**

Based on the fact that no residues of the parent compound or its structurally related metabolites are expected at measurable level in cereal grains and that uptake from soil in rotational crops was also found to be very limited, the residue definition for monitoring and risk assessment purposes is defined as the sum of the constituent isomers of tralkoxydim (EFSA, 2008). An analytical method for enforcement of the proposed residue definition is available, although further validation of this method is still required. Furthermore, considering that primary crop metabolism was only investigated in cereals, this residue definition is limited to cereals and a general residue definition for plant commodities cannot be derived.

### **1.2. Magnitude of residues in plants**

#### **1.2.1. Magnitude of residues in primary crops**

To assess the magnitude of tralkoxydim 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 (United Kingdom, 2005; EFSA, 2008). 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), and available residue trials are sufficient to derive MRL and risk assessment values in wheat and barley.

#### **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 tralkoxydim is applied according to GAP. Rotational crop field trials are therefore not required.

#### **1.2.3. Magnitude of residues in processed commodities**

Since tralkoxydim is applied early in the growing season 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 in plants**

Hence the available data are considered sufficient to derive MRL proposals as well as risk assessment values for the primary crops under evaluation. However, considering that further validation of the analytical method for enforcement purposes is still required (see section 1.1.4.), the proposed MRLs are tentative. Tentative MRLs were also derived for cereal straw in view of the future need to set MRLs in feed items.

## **2. Residues in livestock**

Tralkoxydim is authorised for use on wheat and barley which might be fed to livestock. Livestock dietary burdens were therefore calculated for different groups of livestock using the agreed European

methodology (EC, 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 dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

This conclusion is also confirmed by one metabolism study in laying hens and two metabolism studies in lactating goats (one with tralkoxydim and the other with one of its major plant metabolites R237434) which were reported in the framework of Directive 91/414/EEC (United Kingdom, 2005). These studies demonstrated that tralkoxydim is absorbed and degraded to a very limited extent. It is present as clearly dominant compound in all edible tissues and clear lipophilic behaviour was observed although not expected from the physico-chemical properties of the active substance. The transfer of metabolite R237434 is very limited and results in TRR below 0.05 mg/kg in all edible tissues. It is expected that the other metabolites observed in forage and straw present a similar behaviour due to their polarity (EFSA, 2008).

### 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 wheat and barley grain, where a tentative MRL 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 tralkoxydim, derived by EFSA (2008) under Directive 91/414/EEC. The highest chronic exposure was calculated for World Health Organization (WHO) Cluster diet B, representing 1.8 % of the acceptable daily intake (ADI), and the highest acute exposure was calculated for wheat, representing 1.4 % of the acute reference dose (ARfD). Although some uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumers.

### Conclusions

Primary crop metabolism of tralkoxydim was investigated for foliar treatment in cereals, while rotational crop metabolism was investigated for a bare soil treatment in leafy, root, pulses/oilseed and cereal crops. Metabolic patterns observed in primary and rotational crops were similar. As quantifiable residues of tralkoxydim are not expected in the treated crops, there was no need to investigate the effect of industrial and/or household processing on the nature of residues. Based on the fact that no residues of the parent compound or its structurally related metabolites are expected at measurable level in cereal grains and that uptake from soil in rotational crops was also found to be very limited, the residue definition for monitoring and risk assessment purposes is defined as the sum of the constituent isomers of tralkoxydim. An analytical method for enforcement of the proposed residue definition is available, although further validation of this method is still required. Furthermore, considering that primary crop metabolism was only investigated in cereals, this residue definition is limited to cereals and a general residue definition for plant commodities cannot be derived.

Regarding the magnitude of residues in plants, the available data are considered sufficient to derive MRL proposals as well as risk assessment values for the primary crops under evaluation and, provided that the active substance is applied in compliance with the reported GAPs, measurable levels of relevant residues are not expected to occur in rotational crops. Since tralkoxydim is applied early in the growing season and quantifiable residues are not expected in cereal grains, concentration of residues in processed commodities is also not expected. However, considering that further validation of the analytical method for enforcement purposes is still required, the proposed MRLs are tentative.

Tralkoxydim is authorised for use on wheat and barley, which might be fed to livestock, but the livestock dietary burden calculated for all types of livestock remained below the trigger value of 0.1 mg/kg DM. Also supported by the available metabolism studies in hens and goats, it was concluded that MRLs in commodities of animal origin are 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 1.8% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 1.4 % 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). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data (see summary table footnotes for details). In particular, all tentative MRLs need to be confirmed by the following data:

- validation of a second mass transition for the analytical method for enforcement of residues in plants.

If the above reported data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

**Table 1:** Summary table

Code number <sup>(a)</sup>	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
<b>Enforcement residue definition (existing):</b> tralkoxydim				
<b>Enforcement residue definition (proposed):</b> sum of the constituent isomers of tralkoxydim				
500010	Barley grain	0.02*	0.01*	Further consideration needed <sup>(1)</sup>
500090	Wheat grain	0.02*	0.01*	Further consideration needed <sup>(1)</sup>
-	Other products of plant and animal origin	See Reg. 839/2008	-	Further consideration needed <sup>(2)</sup>

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

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

(1): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).

(2): 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).

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## Abbreviations

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
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
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
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 <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
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
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
IEDI	international estimated daily intake
IESTI	international estimate of short-term intake
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K <sub>oc</sub>	organic carbon adsorption coefficient
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
NEU	northern European Union
NOAEL	no observed adverse effect level
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 <sup>-6</sup> )
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
R <sub>ber</sub>	statistical calculation of the MRL by using a non-parametric method
R <sub>max</sub>	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
SC	suspension concentrate
SEU	southern European Union
SG	water soluble granule
SL	soluble concentrate
SP	water soluble powder
TAR	total applied radioactivity
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
tMRL	temporary MRL
WG	water dispersible granule
WHO	World Health Organization
wks	weeks
WP	wettable powder
yr	year

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

### Critical outdoor GAPs for Southern 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.	Max.
Barley	Hordeum spp.	SEU	Outdoor	IT	Weeds	SC	400.0	g/L	Foliar treatment - spraying		32	1	1			0.45	0.45	kg a.i./ha	n.a.	Less critical GAPs are authorised in ES and PT.
Wheat	Triticum aestivum	SEU	Outdoor	IT	Weeds	SC	400.0	g/L	Foliar treatment - spraying		32	1	1			0.40	0.40	kg a.i./ha	n.a.	Less critical GAPs are authorised in ES and PT.

BBCH: growth stages of mono- and dicotyledonous plants; ES: Spain; IT: Italy; PT: Portugal; SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials; SC: suspension concentrate

## 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	Wheat	Foliar, 325-345 g a.s./ha	19, 49, 57, 92
Study with tralkoxydim labelled on both the phenyl and cyclohexyl rings. Source: United Kingdom, 2005				
Rotational crops (available studies)	Crop groups	Crop(s)	Application(s)	PBI (DAT)
	Root/tuber crops	Turnip	Bare soil, 370-390 g a.s./ha	30, 105, 300
	Leafy crops	Mustard Spinach	Bare soil, 370-390 g a.s./ha	30, 105, 300
	Pulses/oilseeds	Peas, Soyabean	Bare soil, 370-390 g a.s./ha	30, 105, 300
	Cereals	Millet, Wheat	Bare soil, 370-390 g a.s./ha	30, 105, 300
Studies with tralkoxydim labelled on both the phenyl and cyclohexyl rings. Source: United Kingdom, 2005				
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
Study is not required due to the low residue levels in cereal grain (<0.01 mg/kg).				
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 relevant.
Plant residue definition for monitoring (RD-Mo)				Sum of the constituent isomers of tralkoxydim (applicable to cereals only)
Plant residue definition for risk assessment (RD-RA)				Sum of the constituent isomers of tralkoxydim (applicable to cereals only)
Conversion factor (monitoring to risk assessment)				Not relevant.
Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)				<u>Acidic, dry, high water content, high oil content and straw:</u> <ul style="list-style-type: none"> <li>HPLC-MS/MS, 0.01 mg/kg, method validated, incl. ILV (United Kingdom, 2005)</li> <li>Only one mass transition was validated</li> </ul>

##### B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability (Months/years)
	High water content	Wheat forage	-15	21 months
	Dry / High starch	Wheat grain	-18	18 months
	Others	Wheat straw	-18	9 months
Source: United Kingdom, 2005				

## 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)
Barley grain Wheat grain	SEU	<0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01	Combined trials on barley (4) and wheat (4) compliant with GAP (United Kingdom, 2005; EFSA, 2008).	0.01 <sup>*(d)</sup> (tentative)	0.01	0.01
Barley straw Wheat straw	SEU	<0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01; <0.01	Combined trials on barley (4) and wheat (4) compliant with GAP (United Kingdom, 2005; EFSA, 2008).	0.01 <sup>*(d)</sup> (tentative)	0.01	0.01

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

(a): SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue.

(c): Supervised trials median residue.

(d): MRL is tentative because further validation of the analytical method for enforcement of residues is still required.

### B.1.2.2. Residues in succeeding crops

Confined rotational crop study  
(quantitative aspect)

Residues in succeeding crops are unlikely provided  
tralkoxydim is applied according to GAP.

Field rotational crop study

Not required.

### B.1.2.3. Processing factors

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

## B.2. Residues in livestock

	Median dietary burden (mg/kg bw per day)	Maximum dietary burden (mg/kg bw per day)	Highest contributing commodity <sup>(a)</sup>	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy ruminants	0.0003	0.0003	Wheat grain	0.007	N
Meat ruminants	0.0005	0.0005	Wheat grain	0.012	N
Poultry	0.0005	0.0005	Wheat grain	0.008	N
Pigs	0.0004	0.0004	Wheat grain	0.009	N

DM : dry matter; Y/N: Yes/No

(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 per day)	Duration (days)	N rate/comment
	Laying hen	Tralkoxydim: 0.75	10	1500 N rate
	Lactating goat	Tralkoxydim: 0.4	7	1330 N rate / dairy 800 N rate / beef
		R237434: 0.4	7	N rate not applicable
<p>The studies were carried out with substances labelled on the cyclohexyl moiety. Dose rates were reported in mg a.s./kg feed as received, and recalculated on the basis of the following values reported in the studies:</p> <ul style="list-style-type: none"> <li>- Laying hens: a body weight of 2 kg and a daily intake of 0.15 kg of feed as received</li> <li>- Lactating goat: a body weight of 70 kg and a daily intake of 2.8 kg of feed as received</li> </ul> <p>Source: United Kingdom, 2005</p>				

Time needed to reach a plateau concentration in milk and eggs (days)	5 days in milk; 8 days in eggs
Metabolism in rat and ruminant similar (Yes/No)	Yes. Discrete differences noted, but none give rise to toxicological concerns.
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)	Not relevant.
Fat soluble residues (Yes/No)	Not relevant.
Methods of analysis for monitoring of residues (analytical technique, crop groups, 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	Commodity	Residues at closest feeding level (mg/kg)		Estimated value at 1N (mg/kg)		MRL (mg/kg)
		Mean	Highest	STMR	HR	
Not available and not required.	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-
	Milk	-	-	-	-	-
Poultry	Commodity	Residues at closest feeding level (mg/kg)		Estimated value at 1N (mg/kg)		MRL (mg/kg)
		Mean	Highest	STMR	HR	
Not available and not required.	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-
	Eggs	-	-	-	-	-
Pig <sup>(e)</sup>	Commodity	Residues at closest feeding level (mg/kg)		Estimated value at 1N (mg/kg)		MRL (mg/kg)
		Mean	Highest	STMR	HR	
Not available and not required.	Muscle	-	-	-	-	-
	Fat	-	-	-	-	-
	Liver	-	-	-	-	-
	Kidney	-	-	-	-	-

STMR: supervised trials median residue; HR: highest residue

## B.3. Consumer risk assessment

ADI	0.005 mg/kg bw per day (EFSA, 2008)
Highest IEDI, according to EFSA PRIMo	1.8 % ADI (WHO Cluster diet B)
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	0.01 mg/kg bw (EFSA, 2008)
Highest IESTI, according to EFSA PRIMo	1.4 % 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
<b>Enforcement residue definition (existing):</b> tralkoxydim				
<b>Enforcement residue definition (proposed):</b> sum of the constituent isomers of tralkoxydim				
500010	Barley grain	0.02*	0.01*	Further consideration needed <sup>(1)</sup>
500090	Wheat grain	0.02*	0.01*	Further consideration needed <sup>(1)</sup>
-	Other products of plant and animal origin	See Reg. 839/2008	-	Further consideration needed <sup>(2)</sup>

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

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

(1): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).

(2): 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
Cereal grain and bran	0.01*	STMR <sup>(a)</sup>	0.01*	STMR <sup>(a)</sup>
Cereal straw	0.01*	STMR	0.01*	HR

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

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

STMR: supervised trials median residue; HR: highest residue; PF: processing factor

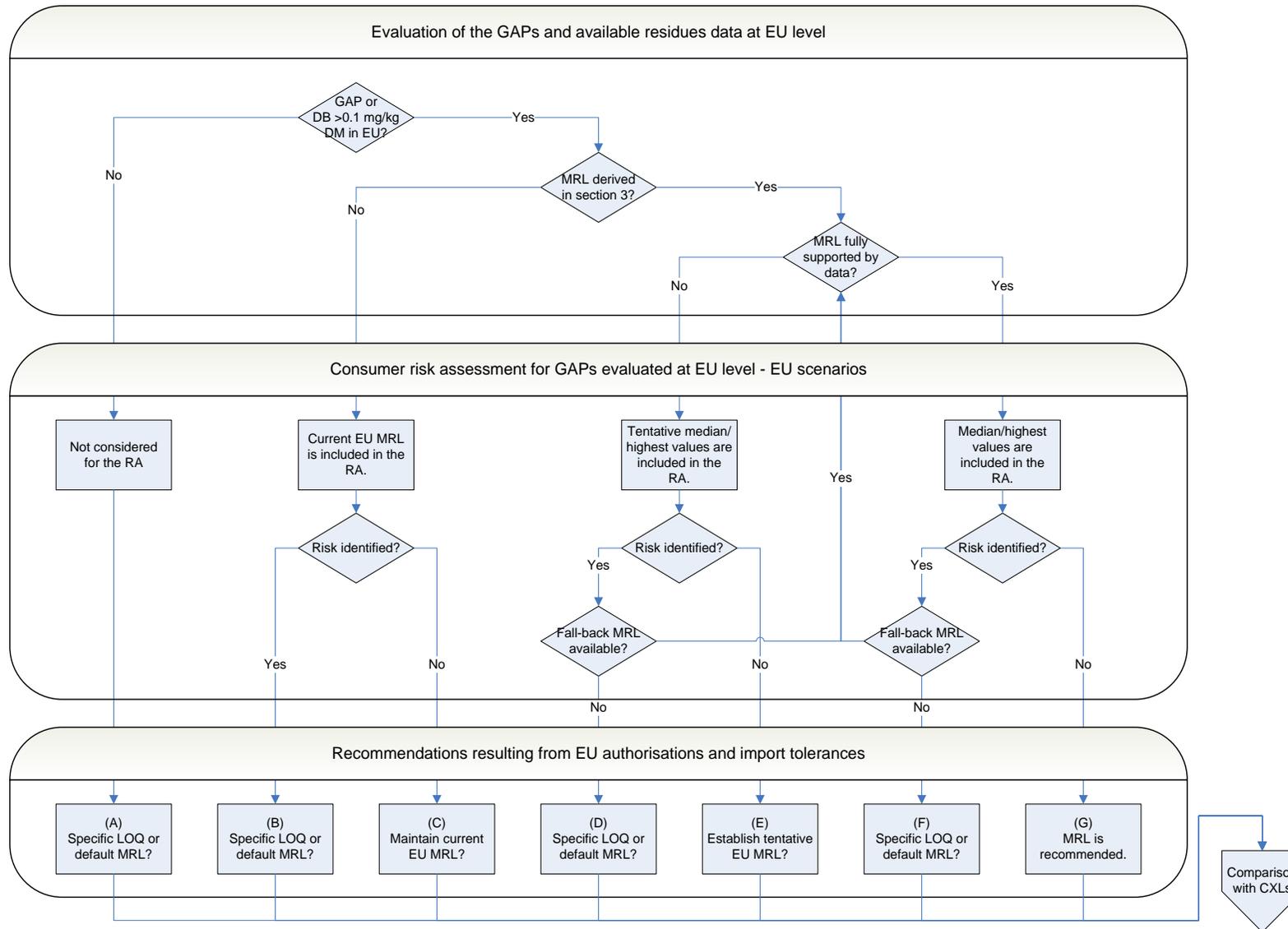
### C.2. Consumer risk assessment

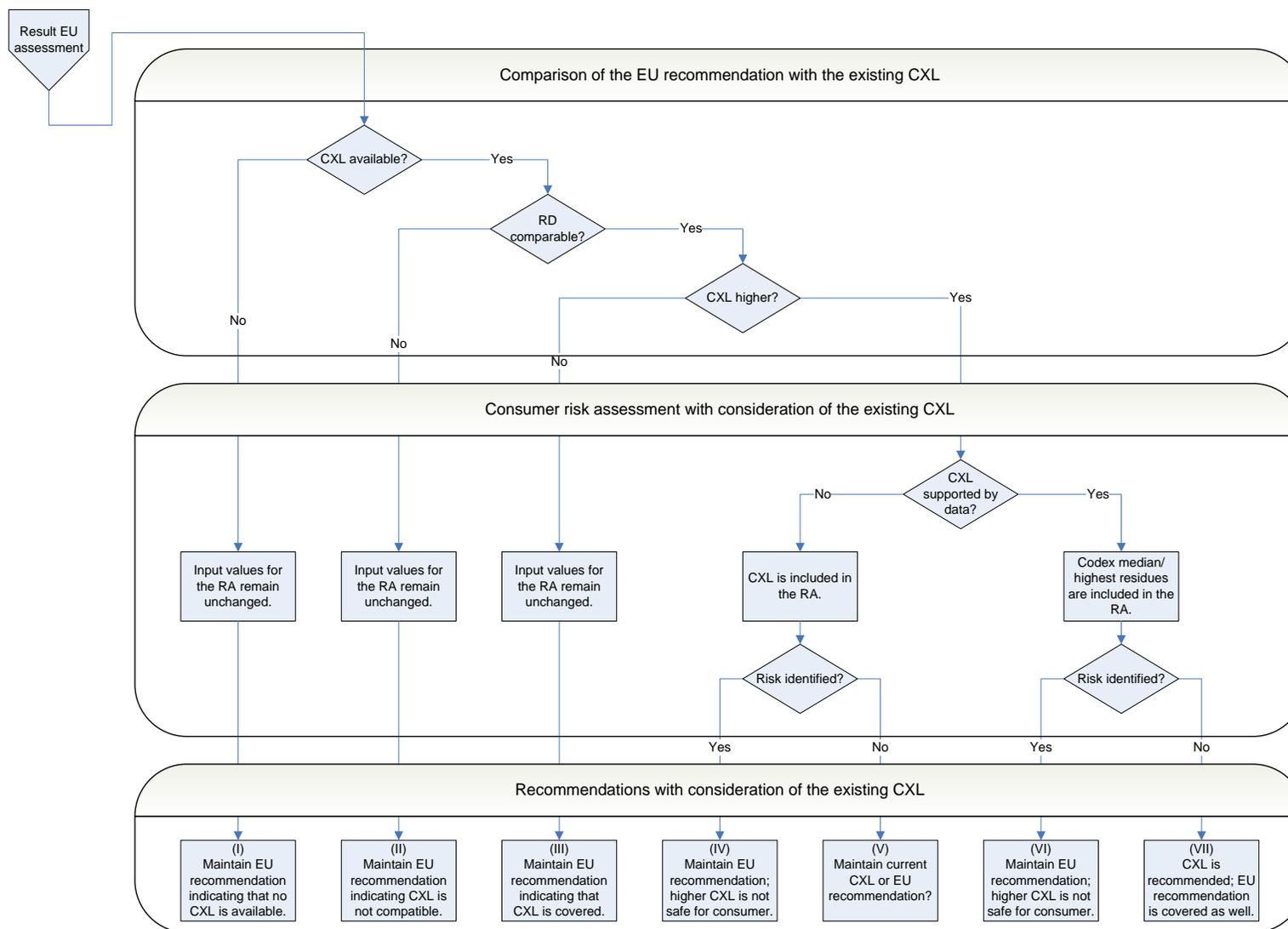
Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Barley grain	0.01*	STMR	0.01*	HR
Wheat grain	0.01*	STMR	0.01*	HR

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

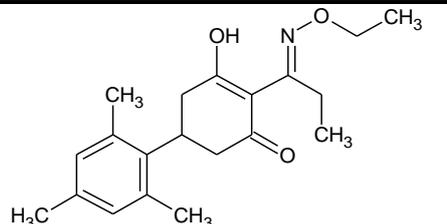
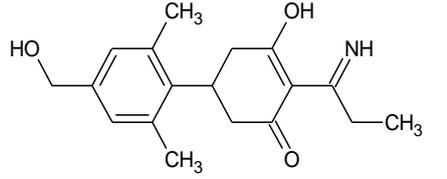
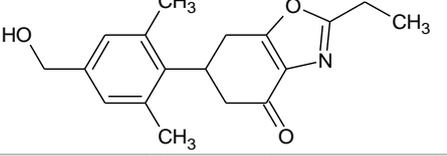
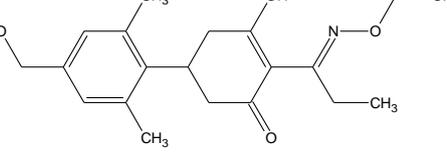
STMR: supervised trials median residue; HR: highest residue

## Appendix D – Decision tree for deriving MRL recommendations





## Appendix E – Used compound code(s)

Code/trivial name	Chemical name/SMILES notation <sup>(a)</sup>	Structural formula <sup>(a)</sup>
Tralkoxydim	2-[1-(ethoxyimino)propyl]-3-hydroxy-5-mesitylcyclohex-2-enone  <chem>CC/C(=N\OCC)C1=C(O)CC(CC1=O)c2c(C)cc(C)cc2C</chem>	
R400307	3-hydroxy-5-[4-(hydroxymethyl)-2,6-dimethylphenyl]-2-propanimidoylcyclohex-2-en-1-one  <chem>CCC(=N)C1=C(O)CC(CC1=O)c2c(C)cc(CO)cc2C</chem>	
R237434	2-ethyl-6-[4-(hydroxymethyl)-2,6-dimethylphenyl]-6,7-dihydro-1,3-benzoxazol-4(5H)-one  <chem>Cc3cc(CO)cc(C)c3C2Cc1oc(nc1C(=O)C2)CC</chem>	
R209490	2-[(1E)-N-ethoxypropanimidoyl]-3-hydroxy-5-[4-(hydroxymethyl)-2,6-dimethylphenyl]cyclohex-2-en-1-one  <chem>CC/C(=N\OCC)C1=C(O)CC(CC1=O)c2c(C)cc(CO)cc2C</chem>	

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