

REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for rimsulfuron according to Article 12 of Regulation (EC) No 396/2005¹

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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 rimsulfuron. In order to assess the occurrence of rimsulfuron 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 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.

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KEY WORDS

Rimsulfuron, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, pyrimidinylsulfonyleurea, herbicide.

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SUMMARY

Rimsulfuron was included in Annex I to Directive 91/414/EEC on 01 February 2007, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Germany, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 09 December 2008 and, after having considered several comments made by EFSA, the RMS provided on 27 October 2009 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 17 April 2012 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 22 June 2012 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of rimsulfuron was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.1 mg/kg bw per d. An ARfD was not deemed necessary.

Primary crops metabolism of rimsulfuron was investigated following early foliar application in tomatoes, potatoes and maize, hereby covering three different crop groups. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities can be defined as rimsulfuron. A validated analytical method for enforcement of the residue definition is available with an LOQ of 0.01 mg/kg in dry commodities and in high water content commodities.

Regarding the magnitude of residues, a sufficient number of supervised residue trials is available for all the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs and risk assessment values.

As residues of rimsulfuron are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

Occurrence of rimsulfuron residues in rotational crops was already investigated during the peer review of rimsulfuron. It was concluded that metabolic patterns in primary and succeeding crops are similar and that significant residues in rotational crops are not expected. These conclusions also apply to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, no significant intakes were calculated for the different type of livestock. Consequently, it is concluded by EFSA that no residue definition and no MRL for products of animal origin are needed.

Chronic 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 was calculated for WHO cluster diet B, representing 0.1 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. 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 in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

Minor deficiencies were identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- residue trials carried out with analytical methods achieving an LOQ of 0.01 mg/kg.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: rimsulfuron				
211000	Potatoes	0.05*	0.01*	Recommended ^(a)
231010	Tomatoes	0.05*	0.01*	Recommended ^(a)
234000	Sweet corn	0.05*	0.01*	Recommended ^(a)
500030	Maize grain	0.05*	0.01*	Recommended ^(a)
900030	Chicory roots	0.05*	0.01*	Recommended ^(a)
-	Other products of plant and animal origin	See App. C	-	Further consideration needed ^(b)

(*): Indicates that the MRL is set at the limit of analytical quantification.

(a): 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)

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

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BACKGROUND

Regulation (EC) No 396/2005⁴ establishes the rules governing the setting as well as the review of pesticide MRLs at European level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC⁵ before 02 September 2008. As rimsulfuron was included in Annex I to the above mentioned directive on 01 February 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-625 was included in the EFSA Register of Questions.

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 for all uses authorised within the EU as well as uses authorised in third countries having 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 have 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 electronic inventory of all pesticide residues data relevant to the risk assessment as well as the 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.

Germany, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for rimsulfuron. The requested information was submitted to EFSA on 09 December 2008 and subsequently checked for completeness. On 27 October 2009, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 17 April 2012 and submitted to Member States (MS) for commenting. All MS comments received by 22 June 2012 were considered by EFSA in the finalisation of the reasoned opinion.

⁴ Commission Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.

⁵ Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

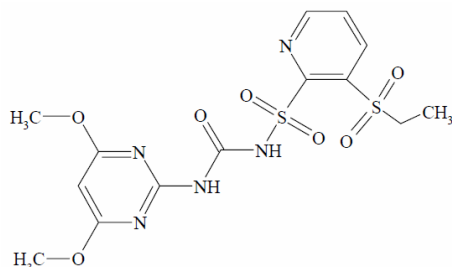
TERMS OF REFERENCE

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

Rimsulfuron is the ISO common name for 1-(4,6-dimethoxypyrimidin-2-yl)-3-(3-ethylsulfonyl-2-pyridylsulfonyl)urea (IUPAC).



Rimsulfuron belongs to the group of pyrimidinylsulfonylurea herbicides. It is a selective systemic herbicide taken up by leaves and roots and acts as an effective inhibitor of plant root and shoot growth by blocking the enzyme acetolalate synthase (ALS). Rimsulfuron is used in pre- and post-emergence for the control of broad leaved and grass weeds.

Rimsulfuron was evaluated in the framework of Directive 91/414/EEC with Germany being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were outdoor (NEU and/or SEU) post-emergence foliar treatments on maize, potatoes and tomatoes with an application rate up to 20 g a.s./ha in maize and potatoes and up to 27.5 g a.s./ha in tomatoes. 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 2006/39/EC⁶, which entered into force on 01 February 2007. According to Regulation (EU) No 540/2011⁷, rimsulfuron is deemed to have been approved under Regulation (EC) No 1107/2009⁸. This approval is restricted to uses as herbicide only.

The EU MRLs for rimsulfuron are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for rimsulfuron only, are summarised in Appendix C to this document. CXLs for rimsulfuron are not available.

For the purpose of this MRL review, the critical uses of rimsulfuron currently authorised within the EU have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). They include outdoor foliar treatments on potatoes, maize grain and forage, sweet corn, tomatoes and chicory roots.

⁶ Commission Directive 2006/39/EC of 12 April 2006, OJ L 104, 13.4.2006, p. 30-35.

⁷ Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.

⁸ Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p. 1-50.

The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Germany, 2003, 2005), the conclusion on the peer review of the pesticide risk assessment of the active substance rimsulfuron (EFSA, 2005) as well as the evaluation reports submitted during the consultation of Member States (France, 2012; The Netherlands, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁹ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS was submitted and validated with an LOQ of 0.01 mg/kg in dry (maize grain) and high water content (potato, tomato) commodities and 0.05 mg/kg for maize forage and stover (Germany, 2003). This method was taken into account by the RMS, but an ILV fully validated with an LOQ of 0.01 mg/kg is missing.

In addition, after Annex I inclusion, France evaluated an LC-MS/MS method and its ILV which were validated for the determination of rimsulfuron with an LOQ of 0.01 mg/kg in high water content (apple, cherry and plum), acidic (grape, lemon and lime) and dry (corn grain) commodities (France, 2012). The HPLC-MS/MS method from the DAR reported above can be used as confirmatory method for dry and high water content commodities.

Hence, it is concluded that parent rimsulfuron can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in dry and high water content commodities.

1.2. Methods for enforcement of residues in food of animal origin

No analytical method is available for food of animal origin. As there is no significant intake of residues by livestock, no residue definition and no MRL were proposed for commodities of animal origin (see also section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary.

2. Mammalian toxicology

The toxicological assessment of rimsulfuron was peer reviewed under Directive 91/414/EEC and an ADI value was established by EFSA (2005). The toxicological reference values are summarised in Table 2-1.

⁹ Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Rimsulfuron					
ADI	EFSA	2005	0.1 mg/kg bw per d	Rat, 2-year oral study	100
ARfD	EFSA	2005	Not necessary		

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of rimsulfuron was investigated for early foliar application (post-emergence) on fruits and fruiting vegetables (tomatoes), root and tuber vegetables (potatoes) and cereals (maize) both using ¹⁴C-pyridine and ¹⁴C-pyrimidine labelled rimsulfuron (EFSA, 2005). The characteristics of these studies are summarised in Table 3-1.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details			
			Method, F or G ^(a)	Rate (g a.s./ha)	No	Sampling (DAT)
Fruits and fruiting vegetables	Tomatoes	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	Foliar, F	72	1	0, 7, 30, 46, 53, 60
			Foliar, G	178.5, 357.5 or 715	1	Foliage: 0, 7 Fruits: 74
Root and tuber vegetables	Potatoes	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	Foliar, G	70	1	0, 8, 14, 30, 82
					2	0, 7, 14, 14, 28, 68
Cereals	Maize	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine-	Foliar, G	52	1	Silage: 0, 8, 15, 30, 50, 80 Mature crop: 105

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Although plants were treated at 2.6N (tomatoes, maize) and 3.1N (potatoes) the maximum total annual use rate, total radioactive residues in edible plant parts (maize grains, potato tubers and tomatoes) as well as in fractions intended for animal consumption (potato tubers, maize silage and fodder) were always below 0.02 mg eq/kg. The metabolic pathway was therefore established by

characterization of residues in immature foliage. Two primary degradation pathways were identified. A first mechanism is contraction of the sulfonylurea bridge to form IN-70941¹⁰, leading further to IN-70942¹¹ from loss of CONH₂. The second pathway is cleavage of the sulfonylurea bridge to produce IN-E9260¹² and IN-J290¹³. These first degradation products were further metabolised to a number of minor, polar compounds. None of the metabolites formed is found to be of particular concern (EFSA, 2005).

Consequently, due to the rapid and extensive metabolism of rimsulfuron in the tested crops, the residue for enforcement and risk assessment in all plant commodities is defined as rimsulfuron. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1).

3.1.1.2. Magnitude of residues

According to the RMS, the active substance rimsulfuron is authorised for early foliar outdoor treatments in potatoes, sweet corn, tomatoes and maize (see appendix A). To assess magnitude of rimsulfuron residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile by the RMS (Germany, 2009), including residue trials evaluated in the framework of the peer review (EFSA, 2005) and additional data submitted during the consultation of Member States (France, 2012; The Netherlands, 2012). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residue trials and extrapolations were evaluated in view of European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP were reported by the RMS for all crops under assessment, except for tomatoes and potatoes where the number of trials reported is not compliant with the data requirements. However, the reduced number was considered sufficient by EFSA because all available trial results were below the LOQ, indicating that it concerns a no residue situation. Further residue trials are therefore not required.

The potential degradation of residues during storage of the residue trials samples was also assessed in the framework of the peer review; storage stability of rimsulfuron was demonstrated for a period of 24 months at -20°C in commodities with high water content (potatoes and maize forage) and in dry commodities (maize grain). According to the RMS, all residue trials samples reported in the PROFile were stored in compliance with the above reported storage conditions. Degradation of residues during storage of the trial samples is therefore not expected.

Consequently, the available residues data are considered acceptable to derive MRL proposals as well as risk assessment values for all commodities under evaluation. All residue trials were performed with an LOQ of 0.05 mg/kg (except for chicory roots). Nevertheless, as residue levels were all below this LOQ, and according to the metabolism studies that showed a no residue situation at exaggerated rates, it can be concluded that residue levels will be below the enforcement LOQ of 0.01 mg/kg. The elaboration of residue trials with an LOQ of 0.01 mg/kg is therefore still desirable.

¹⁰ N-(4,6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsulfonyl)-2-pyridinyl]urea. See appendix E.

¹¹ N-[3-(ethylsulfonyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimidinamine. See appendix E.

¹² 3-(ethylsulfonyl)-2-pyridinesulfonamide. See appendix E.

¹³ 4,6-dimethoxy-2-pyrimidinamine. See appendix E.

Table 3-2: Overview of the available residues trials data

Commodity	Residue region ^(a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) ^(b)	Highest residue (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement (rimsulfuron)	Risk assessment (rimsulfuron)					
Enforcement residue definition: rimsulfuron									
Potatoes	NEU	Outdoor	9x <0.05	9x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	Residue trials complying with the GAPs but with an LOQ of 0.05 mg/kg. Considering the metabolism studies, it is concluded however that residues will be below the enforcement LOQ of 0.01 mg/kg.
	SEU	Outdoor	7x <0.05	7x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	
Tomatoes	SEU	Outdoor	6x <0.05	6x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	
Sweet corn	NEU	Outdoor	16x <0.05	16x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	
Maize grain	NEU	Outdoor	18x <0.05	18x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	
	SEU	Outdoor	9x <0.05	9x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	
Chicory roots	NEU	Outdoor	4x <0.01	4x <0.01	0.01	0.01	0.01*	1.00	Trials complying with GAP (The Netherlands, 2012).
Maize forage	NEU	Outdoor	6x <0.05	6x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	Residue trials complying with the GAPs but with an LOQ of 0.05 mg/kg. Considering the metabolism studies, it is concluded however that residues will be below the enforcement LOQ of 0.01 mg/kg (France, 2012).
	SEU	Outdoor	10x <0.05	10x <0.05	0.01 ^(e)	0.01 ^(e)	0.01*	1.00	

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

(e): According to the metabolism studies a non residue situation is expected, the RMS proposed that all values were set at the LOQ of 0.01mg/kg

(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

As quantifiable residues of rimsulfuron are not expected in edible part of crops and the chronic exposure does not exceed 10 % of the ADI (see also section 4), there is no need to investigate the effect of industrial and/or household processing.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT₉₀ value of rimsulfuron was expected to be lower than 100 days but relevant soil metabolites (IN-70941, IN-70942, IN-E9260) were shown to be more persistent (EFSA, 2005). According to the European guidelines on rotational crops (EC, 1997c), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature and magnitude of residues

The metabolism of rimsulfuron in rotational crops – lettuce, sugar beet, soya bean, sunflower, sorghum, wheat – has been evaluated (Germany, 2003). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of these studies are summarised in Table 3-4.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G ^(a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Lettuce	2- ¹⁴ C-pyridine and 2- ¹⁴ C-pyrimidine	Soil, G	0.052	30	106	-
					120	184	
Root and tuber vegetables	Sugar beet				30	88, 226	-
					120	150, 267	
Pulses and oilseeds	Soya bean				30	60, 121	-
					120	150, 226	
					±300	330, 389	
	Sunflower				120	150, 226	
Cereals	Sorghum				±300	328, 428	-
	Wheat				30	60, 121	
		120	150, 226				
		±300	328, 389				

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Total radioactive residues in consumable parts of all crops planted at each plant-back intervals were below the LOQ of 0.05 mg eq/kg. In wheat straw, TRR reached 0.38-0.46 mg eq/kg when the crop was sown after 30 days ageing. Metabolite IN-70941 was the main identified compound (0.07 mg/kg).

Considering the overdosing factor of the above study and the fact that rimsulfuron was applied to a bare soil (interception of rimsulfuron by the plants might be expected in practice), it can be concluded that a specific residue definition for rotational crops is not deemed necessary and that rimsulfuron residue levels in rotational commodities are not expected to exceed 0.01 mg/kg, provided that rimsulfuron is applied in compliance with the GAPs reported in Appendix A.

3.2. Nature and magnitude of residues in livestock

Rimsulfuron is authorised for use on several crops that might be fed to livestock. The median and maximum 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 Table 3-4.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: rimsulfuron				
Maize grain	0.01	Median residue	0.01	Median residue
Maize silage	0.01	Median residue	0.01	Median residue
Potatoes	0.01	Median residue	0.01	Highest residue

The results of the calculations are reported in Table 3-5. Since the calculated dietary burdens for all types 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.

Table 3-5: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw per d)	Median dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: rimsulfuron					
Dairy ruminants	0.002	0.002	Maize silage	0.06	N
Meat ruminants	0.003	0.003	Potatoes	0.06	N
Poultry	0.001	0.001	Potatoes	0.02	N
Pigs	0.002	0.002	Potatoes	0.05	N

4. Consumer risk assessment

Chronic 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 intake calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Table 4-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: rimsulfuron		
Potatoes	0.01*	Median residue ^(a)
Tomatoes	0.01*	Median residue ^(a)
Sweet corn	0.01*	Median residue ^(a)
Maize grain	0.01*	Median residue ^(a)
Chicory roots	0.01*	Median residue ^(a)

(*): Indicates that the input value is proposed at the limit of analytical quantification.

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

The calculated exposures were compared with the toxicological reference value derived for rimsulfuron (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for WHO cluster diet B, representing 0.1 % of the ADI.

Based on the above calculations, EFSA concludes that the use of rimsulfuron on all crops is fully supported by data and is acceptable with regard to consumer exposure.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of rimsulfuron was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.1 mg/kg bw per d. An ARfD was not deemed necessary.

Primary crops metabolism of rimsulfuron was investigated following early foliar application in tomatoes, potatoes and maize, hereby covering three different crop groups. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities can be defined as rimsulfuron. A validated analytical method for enforcement of the residue definition is available with an LOQ of 0.01 mg/kg in dry commodities and in high water content commodities.

Regarding the magnitude of residues, a sufficient number of supervised residue trials is available for all the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs and risk assessment values.

As residues of rimsulfuron are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

Occurrence of rimsulfuron residues in rotational crops was already investigated during the peer review of rimsulfuron. It was concluded that metabolic patterns in primary and succeeding crops are similar and that significant residues in rotational crops are not expected. These conclusions also apply to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, no significant intakes were calculated for the different type of livestock. Consequently, it is concluded by EFSA that no residue definition and no MRL for products of animal origin are needed.

Chronic 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 was calculated for WHO cluster diet B, representing 0.1 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. 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 in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

Minor deficiencies were identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- residue trials carried out with analytical methods achieving an LOQ of 0.01 mg/kg.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: rimsulfuron				
211000	Potatoes	0.05*	0.01*	Recommended ^(a)
231010	Tomatoes	0.05*	0.01*	Recommended ^(a)
234000	Sweet corn	0.05*	0.01*	Recommended ^(a)
500030	Maize grain	0.05*	0.01*	Recommended ^(a)
900030	Chicory roots	0.05*	0.01*	Recommended ^(a)
-	Other products of plant and animal origin	See App. C	-	Further consideration needed ^(b)

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

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on rimsulfuron prepared by the rapporteur Member State Germany in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 09 December 2008. Last updated on 27 October 2009.

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- EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.
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- The Netherlands, 2012. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for rimsulfuron, June 2012.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Interval (days)		Min. rate			Max. rate	Rate Unit
							Conc.	Unit						Min.	Max.					
Potatoes	<i>Tuber form Solanum Spp</i>	NEU	Outdoor	DE	Cocksbur grass, Bottlegrass, Annual bluegrass, Dicotyledonous grain weeds	WG	250.0	g/kg	Foliar treatment - spraying	11	39	1	2	8	10	20.00	g a.i./ha	n.a.	either 1 x 20 g ai/ha or splitted appl. of 10 g ai/ha	
Sweet corn	<i>Zea mays var. sacharata</i>	NEU	Outdoor	DE	Quackgrass, Slender foxtail, Spring oat, Annual bluegrass, Panicum-like plants, Dicotyledonous grain weeds	WG	250.0	g/kg	Foliar treatment - spraying	10	16	1	2	8	10	13.00	g a.i./ha	n.a.	either 1 x 12.5 g ai/ha or splitted appl. of 7.5 g ai/ha + 5 g ai/ha	
Maize	<i>Zea mays</i>	NEU	Outdoor	DE	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying	10	16	1	2	8	14	20.00	g a.i./ha	n.a.	either 1 x 20 g ai/ha or splitted appl. of 10 g ai/ha. Also used in pre-emergence, 1-2 applications (splitted), total 15 g a.i./ha (FR)	
Chicory roots	<i>Cichorium intybus</i>	NEU	Outdoor	NL	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying		32	1	4	7	2.50	10.00	g a.i./ha	60	Post-emergence application at a maximum rate of 17,5 g ai/ha per season	
Maize (for forage)	<i>Zea mays</i>	NEU	Outdoor	FR	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying	0	18	1	2	7	15.00	g a.i./ha	n.a.	1-2 applications (splitted), total 15 g a.i./ha		

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Min.	Max.	Interval (days)		Min. rate			Max. rate	Rate Unit
							Conc.	Unit						Min.	Max.					
Potatoes	<i>Tuber form Solanum Spp</i>	SEU	Outdoor	IT	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying	1	30	1	2	4	5	22.50	g a.i./ha	n.a.	12.5 - 20 g ai/ha (total 22.5 g ai/ha), 1-2 application (splitted)	
Tomatoes	<i>Lycopersicum esculentum</i>	SEU	Outdoor	IT	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying	1	18	1	2	7		27.50	g a.i./ha	n.a.	12.5 - 20 g ai/ha (total 27.5 g ai/ha), 1-2 application (splitted). The FR GAP: 1 x 15 g ai/ha, up to BBCH 51 is considered similar (see DAR, 2003).	
Maize	<i>Zea mays</i>	SEU	Outdoor	IT	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying	1	18	1	2	7		20.00	g a.i./ha	n.a.	12.5 - 20 g ai/ha (total 20 g ai/ha), 1-2 application (splitted). Also used in pre-emergence, 1-2 applications (splitted), total 15 g a.i./ha (FR)	
Maize (for forage)	<i>Zea mays</i>	SEU	Outdoor	FR	Broad-leaved weeds, grasses	WG	250.0	g/kg	Foliar treatment - spraying	0	18	1	2	7	15.00	g a.i./ha	n.a.	1-2 applications (splitted), total 15 g a.i./ha		

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Rimsulfuron			
Status of the active substance:	Included	Code no.:	
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.1	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2005	Year of evaluation:	2005

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		No of diets exceeding ADI: ---						
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
0.1	WHO Cluster diet B	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.1
0.1	PT General population	0.1	Potatoes	0.0	Potatoes	0.0	Maize	0.1
0.1	NL child	0.1	Potatoes	0.0	Potatoes	0.0	Maize	0.1
0.1	FR toddler	0.1	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.1
0.1	WHO cluster diet D	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.1
0.1	WHO regional European diet	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.1
0.1	IE adult	0.0	Maize	0.0	Potatoes	0.0	Potatoes	0.1
0.1	WHO cluster diet E	0.0	Potatoes	0.0	Maize	0.0	Potatoes	0.1
0.1	SE general population 90th percentile	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.1
0.0	UK infant	0.0	Potatoes	0.0	Maize	0.0	Potatoes	0.0
0.0	WHO Cluster diet F	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	PL general population	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	FR infant	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.0
0.0	UK Toddler	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.0
0.0	LT adult	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	DE child	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	NL general	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	ES child	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	DK child	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.0
0.0	IT kids/toddler	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	UK vegetarian	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.0
0.0	DK adult	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.0
0.0	UK Adult	0.0	Potatoes	0.0	Potatoes	0.0	Sweet corn	0.0
0.0	ES adult	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	IT adult	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	FI adult	0.0	Potatoes	0.0	Potatoes	0.0	Maize	0.0
0.0	FR all population	0.0	Potatoes	0.0	Potatoes	0.0	FRUIT (FRESH OR FROZEN)	0.0

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Rimsulfuron is unlikely to present a public health concern.

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 30/03/2011 17:31))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweetsies, tangelo, ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,05*
110990	Others	0,05*
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediterranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	0,05*
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes,)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet com	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian comsalad)	0,05*
251020	Lettuce (Head lettuce, lolo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tamagon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
	field beans, cowpeas)	
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine,	

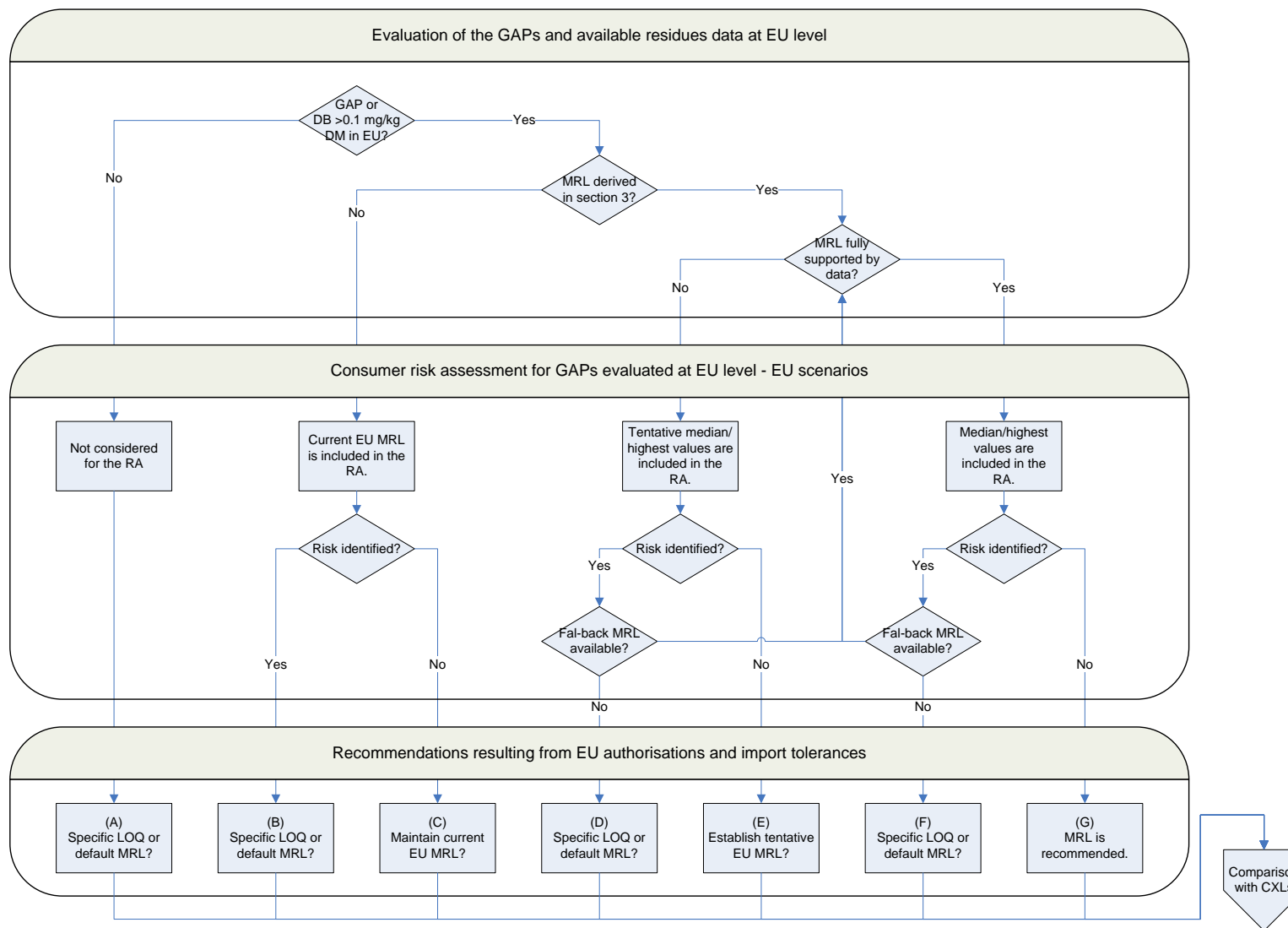
Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
	dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	

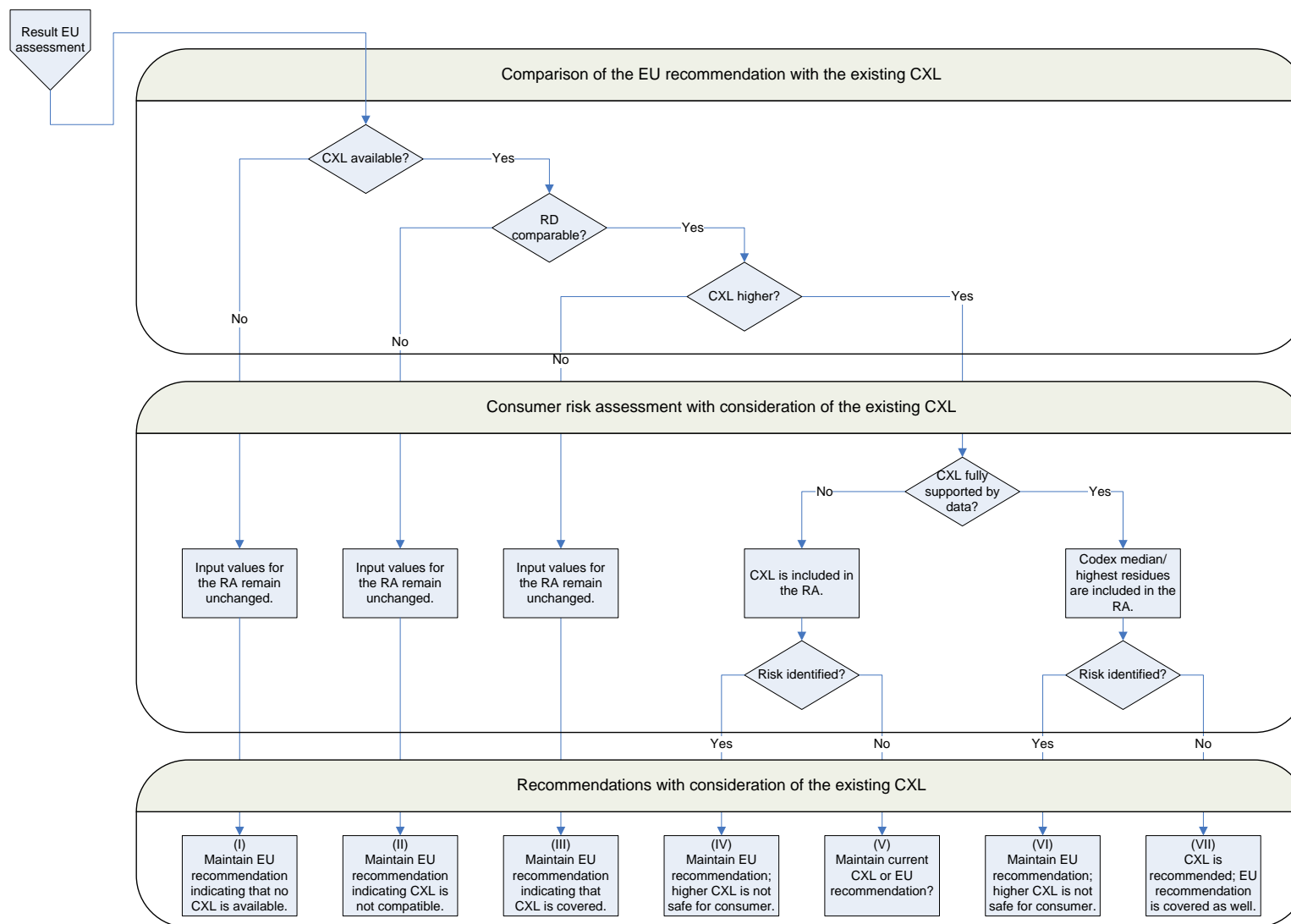
Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Rimsulfuron
	added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

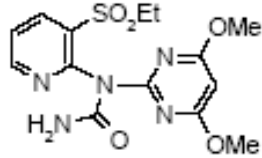
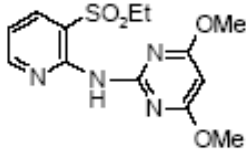
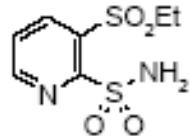
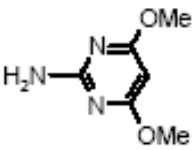
(*) Indicates lower limit of analytical determination

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS





APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
IN-70941	N-(4,6-dimethoxy-2-pyrimidinyl)-N-[3-(ethylsulfonyl)-2-pyridinyl]urea	
IN-70942	N-[3-(ethylsulfonyl)-2-pyridinyl]-4,6-dimethoxy-2-pyrimidinamine	
IN-E9260	3-(ethylsulfonyl)-2-pyridinesulfonamide	
IN-J290	4,6-dimethoxy-2-pyrimidinamine	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ALS	acetholathe synthase
ARfD	acute reference dose
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States

NEU	northern European Union
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
RMS	rapporteur Member State
SEU	southern European Union
TRR	total radioactive residue
WHO	World Health Organisation