

## REASONED OPINION

### Reasoned opinion on the review of the existing maximum residue levels (MRLs) for pendimethalin according to Article 12 of Regulation (EC) No 396/2005<sup>1</sup>

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#### SUMMARY

Pendimethalin was included in Annex I to Directive 91/414/EEC on 01 January 2004, 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 afore mentioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Spain, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 15 July 2009 and, after having considered several comments made by EFSA, the RMS provided on 08 September 2010 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC under the supervision of the European Commission and the additional information provided by the RMS, EFSA issued on 04 November 2011 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 13 January 2012 were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of pendimethalin was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.125 mg/kg bw/d. It was also concluded that the setting of an ARfD is not necessary.

Primary crop metabolism of pendimethalin was investigated in three different crop groups following foliar and soil applications. Metabolic patterns in the different studies were shown to be similar and the relevant residue for both enforcement and risk assessment in all plant commodities treated by foliar and soil application could be defined as pendimethalin. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.05 mg/kg in high water content, high oil content, dry and acidic commodities.

Regarding the magnitude of residues in most of crops reported by the RMS, at least one GAP was supported by a sufficient number of supervised residue trials, which allowed EFSA to estimate the

<sup>1</sup> On request from EFSA, Question No EFSA-Q-2008-602, approved on 26 April 2012.

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expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs, except for strawberries, onions, garlic, shallots, tomatoes, aubergines, peppers, cucurbits with edible and inedible peel, leek and globe artichokes, where data were sufficient to derive tentative MRLs only. For horseradish, parsnips, parsley root, salsify, witloof, rape seed, herbal infusions (flowers), spices (seeds, fruits and berries) and alfalfa no residue trials were available. EFSA was therefore not able to derive tentative MRL proposals for these crops and further residue trials are required as well.

As residues of pendimethalin are all below 0.1 mg/kg and contribution of these residues to chronic consumer exposure is generally low, there was no need to investigate the effect of industrial and/or household processing on the nature and magnitude of pendimethalin residues.

The possible occurrence of pendimethalin residues in rotational and/or succeeding crops was also investigated. It was concluded by the peer review that the nature of residues in rotational crops and primary crops is similar and the relevant residue is pendimethalin. The available rotational crop field studies are not considered fully sufficient to demonstrate the absence of residues in rotational crops because the field trials did not cover the plant-back intervals of 30 and 90 days. EFSA recommends that, when granting an authorisation for the use of pendimethalin on primary crops, Member States apply necessary risk mitigation measures to avoid pendimethalin residues in rotational and/or succeeding crops.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in products of animal origin was therefore defined as pendimethalin. Available studies also demonstrated that residues of pendimethalin are not expected in significant amounts and MRLs in ruminants, poultry and pig can be set at the LOQ of 0.01 mg/kg. It is noted however that further validation of the analytical method for enforcement of pendimethalin residues in liver and kidney is required.

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 represented 1.3 % of ADI (German child). 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 (see table below for a summary). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain tentative MRLs and existing EU MRLs still need to be confirmed by the following data:

- 4 additional residue trials supporting the northern GAP and 8 residue trials supporting the southern GAP on strawberries;
- 8 residue trials on carrots supporting the northern GAPs on horseradish, parsnips, parsley root and salsify;
- 4 additional residue trials supporting the northern GAP and 6 additional residue trials supporting the southern GAP on onions, garlic and shallots;
- 2 additional residue trials on tomatoes and 8 residue trials on cucumbers supporting the northern GAP on tomatoes, peppers and cucurbits with edible and inedible peel;

- 4 additional residue trials on tomatoes and 8 residue trials on cucumbers supporting the southern GAP on solanacea and cucurbits with inedible peel;
- 2 residue trials supporting the indoor GAP on melons;
- 4 residue trials supporting the southern GAP on witloof;
- 2 additional residue trials supporting the northern GAP and 4 residue trials supporting the southern GAP on globe artichoke;
- 6 additional residue trials supporting the northern GAP on leek;
- 8 residue trials supporting the northern GAP on rape seed;
- 4 residue trials on representative crops supporting the northern GAP on herbal infusions (flowers), spices (seeds) and spices (fruits and berries);
- an ILV of the analytical method for enforcement of residues in liver and kidneys.

It is highlighted that some of the 'Recommended' MRLs resulted from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the 'Recommended' MRLs but which might have an impact on national authorisations:

- 8 residue trials supporting the northern GAP on carrots;
- 3 additional residue trials on cauliflower and 8 residue trials on head cabbage supporting the southern GAP on flowering and head brassica;
- 4 residue trials supporting the northern GAP on asparagus;
- 4 residue trials supporting the southern GAP on celery;
- 3 additional residue trials supporting the southern GAP on fennel;
- 8 residue trials supporting the northern GAP on sunflower and soybean
- 4 residue trials supporting the northern GAP and 4 residue trials supporting the southern GAP on alfalfa.

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

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

- a detailed evaluation report for the GC-NPD method used for enforcement of pendimethalin residues in plant commodities;
- a detailed evaluation report for the GC-ECD method used for enforcement of pendimethalin residues in livestock commodities.

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
<b>Enforcement residue definition: pendimethalin</b>				
110000	Citrus fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
120000	Tree nuts	0.05*	0.05*	Recommended <sup>(a)</sup>
130000	Pome fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
140010	Stone fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
151000	Table and wine grapes	0.05*	0.05*	Recommended <sup>(a)</sup>
152000	Strawberries	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
153000	Cane fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
154000	Other small fruit & berries	0.05*	0.05*	Recommended <sup>(a)</sup>
211000	Potatoes	0.05*	0.05*	Recommended <sup>(a)</sup>
213020	Carrots	0.2	0.1	Recommended <sup>(a)</sup>
213030	Celeriac	0.1	0.1	Recommended <sup>(a)</sup>
213040	Horseradish	0.2	0.2	Further consideration needed <sup>(c)</sup>
213060	Parsnips	0.2	0.2	Further consideration needed <sup>(c)</sup>
213070	Parsley root	0.2	0.2	Further consideration needed <sup>(c)</sup>
213090	Salsify	0.05*	0.05*	Further consideration needed <sup>(c)</sup>
220010	Garlic	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
220020	Onions	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
220030	Shallots	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
220040	Spring onions	0.05*	0.05*	Recommended <sup>(a)</sup>
231010	Tomatoes	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
231020	Peppers	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
231030	Aubergines (egg plants)	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
232010	Cucurbits with edible peel	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
233000	Cucurbits with inedible peel	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
234000	Sweet corn	0.05*	0.05*	Recommended <sup>(a)</sup>
241000	Flowering brassica	0.05*	0.05*	Recommended <sup>(a)</sup>
242000	Head brassica	0.05*	0.05*	Recommended <sup>(a)</sup>
243000	Leafy brassica	0.5	0.5	Recommended <sup>(a)</sup>
244000	Kohlrabi	0.3	0.3	Recommended <sup>(a)</sup>
251010	Lamb's lettuce	0.05*	0.6	Recommended <sup>(a)</sup>
251020	Lettuce	0.05*	0.05*	Recommended <sup>(a)</sup>
251030	Scarole (broad-leaf endive)	0.05*	0.05*	Recommended <sup>(a)</sup>
251040	Cress	0.05*	0.6	Recommended <sup>(a)</sup>
251060	Rocket, Rucola	0.05*	0.6	Recommended <sup>(a)</sup>

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
251080	Leaves and sprouts of Brassica spp	0.05*	0.6	Recommended <sup>(a)</sup>
255000	Witloof	0.05*	0.05*	Further consideration needed <sup>(c)</sup>
256010	Chervil	0.6	0.6	Recommended <sup>(a)</sup>
256020	Chives	0.6	0.6	Recommended <sup>(a)</sup>
256030	Celery leaves	0.6	0.6	Recommended <sup>(a)</sup>
256040	Parsley	2	2	Recommended <sup>(a)</sup>
256050	Sage	2	2	Recommended <sup>(a)</sup>
256060	Rosemary	0.6	0.6	Recommended <sup>(a)</sup>
256070	Thyme	0.6	0.6	Recommended <sup>(a)</sup>
256080	Basil	0.6	0.6	Recommended <sup>(a)</sup>
256090	Bay leaves (laurel)	0.6	0.6	Recommended <sup>(a)</sup>
256010	Tarragon	0.6	0.6	Recommended <sup>(a)</sup>
260000	Legume vegetables (fresh)	0.2	0.05*	Recommended <sup>(a)</sup>
270010	Asparagus	0.05*	0.05*	Recommended <sup>(a)</sup>
270030	Celery	0.1	0.1	Recommended <sup>(a)</sup>
270040	Fennel	0.05*	0.1	Recommended <sup>(a)</sup>
270050	Globe artichokes	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
270060	Leek	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
270070	Rhubarb	0.05*	0.05*	Recommended <sup>(a)</sup>
300000	Pulses (dry)	0.2	0.15	Recommended <sup>(a)</sup>
401020	Peanuts	0.1*	0.05*	Recommended <sup>(a)</sup>
401050	Sunflower seed	0.1*	0.05*	Recommended <sup>(a)</sup>
401060	Rape seed	0.1*	0.1	Further consideration needed <sup>(c)</sup>
401070	Soya bean	0.1*	0.05*	Recommended <sup>(a)</sup>
401090	Cotton seed	0.1*	0.05*	Recommended <sup>(a)</sup>
500010	Barley grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500030	Maize grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500040	Millet grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500050	Oats grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500060	Rice grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500070	Rye grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500080	Sorghum grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500090	Wheat grain	0.05*	0.05*	Recommended <sup>(a)</sup>
630000	Herbal infusions (dried, flowers)	0.1*	0.1	Further consideration needed <sup>(c)</sup>

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
810000	Spices (seeds)	0.1*	0.1	Further consideration needed <sup>(c)</sup>
820000	Spices (fruits and berries)	0.1*	0.1	Further consideration needed <sup>(c)</sup>
900020	Sugar cane	0.05*	0.05*	Recommended <sup>(a)</sup>
1011010	Swine meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1011020	Swine fat (free of lean meat)	0.05*	0.01*	Recommended <sup>(a)</sup>
1011030	Swine liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1011040	Swine kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1012010	Bovine meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1012020	Bovine fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1012030	Bovine liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1012040	Bovine kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1013010	Sheep meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1013020	Sheep fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1013030	Sheep liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1013040	Sheep kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1014010	Goat meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1014020	Goat fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1014030	Goat liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1014040	Goat kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1016010	Poultry meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1016020	Poultry fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1016030	Poultry liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1020010	Milk	0.05*	0.01*	Recommended <sup>(a)</sup>
1030000	Birds' eggs	0.05*	0.01*	Recommended <sup>(a)</sup>
-	Other products of plant and animal origin	see App C	-	Further consideration needed <sup>(d)</sup>

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(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): 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 could be identified; no CXL is available (combination E-I in Appendix D).

(c): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).

(d): 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).

## KEY WORDS

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

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## BACKGROUND

Regulation (EC) No 396/2005<sup>4</sup> 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/EEC<sup>5</sup> before 02 September 2008. As pendimethalin was included in Annex I to the above mentioned directive on 01 January 2004, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-602 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 on the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residue 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.

Spain, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for pendimethalin. The requested information was submitted to EFSA on 15 July 2009 and subsequently checked for completeness. On 08 September 2010, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 04 November 2011 and submitted to Member States (MS) for commenting. All MS comments received by 13 January 2012 were considered by EFSA for finalization of the reasoned opinion.

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

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



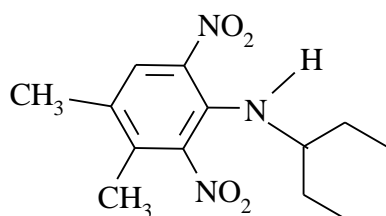
## TERMS OF REFERENCE

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

Pendimethalin is the ISO common name for N-(1-ethylpropyl)-2,6-dinitro-3,4-xylidene (IUPAC).



Pendimethalin belongs to the group of dinitroaniline compounds which are used as herbicide. Pendimethalin is a selective pre- and post-emergence herbicide for the control of a wide range of broad-leaved weeds. It interferes with the microtubule system and thereby inhibits cell division, cell elongation and finally plant growth. Pendimethalin is absorbed by leaves and roots but is not systemic within plants.

Pendimethalin was evaluated in the framework of Directive 91/414/EEC with Spain being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the outdoor treatment of several crops with application rates up to 2 kg a.s./ha in northern and southern Europe. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/31/EC<sup>6</sup>, entering into force on 01 January 2004. According to Regulation (EU) No 540/2011<sup>7</sup>, pendimethalin is deemed to have been approved under Regulation (EC) No 1107/2009<sup>8</sup>. This approval is restricted to uses as herbicide only. As EFSA was not yet involved in the peer review of pendimethalin, a conclusion of EFSA on this active substance is not available.

The EU MRLs for pendimethalin are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for leafy brassica, kohlrabi and herbs (EFSA, 2011) which was already approved by the meeting of the Standing Committee on the Food Chain and Animal Health but which is not yet legally implemented. All existing EU MRLs, which are established for the parent compound only, are summarized in Appendix C to this document. CXLs for pendimethalin are not available.

<sup>6</sup> Commission Directive 2003/31/EC of 11 April 2003, OJ L 101, 23.4.2003, p. 3-9.

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

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

For the purpose of this MRL review, the critical uses of pendimethalin currently authorized within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the Member State's consultation were also considered (see Appendix A). They include a single foliar application in several crops with an application rate ranging from 0.23 to 2 kg a.s./ha in both northern and southern Europe. 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 addenda prepared under Council Directive 91/414/EEC (Spain, 1998a, 1998b, 2000), the Review Report on pendimethalin (EC, 2003) as well as the previous reasoned opinion on pendimethalin (EFSA, 2011) and the Evaluation Reports submitted during the Member States consultation (Belgium, 2012; France, 2012; Italy, 2012; Germany, 2012; Spain, 2012a, 2012b; United Kingdom, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>9</sup> 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, analytical method using GC-ECD was evaluated and validated for the determination of parent pendimethalin in plant matrices with an LOQ of 0.05 mg/kg in high water content (celery, leeks, fresh bean seeds, apples) commodities. Neither an ILV, nor a confirmatory method is available for this method (Spain, 1998a).

In addition, an analytical method using GC-NPD and its ILV were evaluated and validated for the determination of parent pendimethalin in plant matrices with an LOQ of 0.05 mg/kg in high water content (cereals forage), dry (cereals grain,) and acidic (grapes) commodities as well as cereals straw. Furthermore, an analytical method using GC-NPD was evaluated and validated for the determination of parent pendimethalin in plant matrices with an LOQ of 0.05 mg/kg in high oil (sunflower, peanuts soya beans) commodities. However, a detailed evaluation report is not available for the latter method and is therefore still desirable.

During the Member State's consultation, Spain also mentioned that an analytical method using LC-MS/MS was evaluated and validated for the determination of parent pendimethalin in plant matrices with an LOQ of 0.01 mg/kg in high water content (potato, lettuce, onion and pea), high fat content (soybean), acidic (orange) and dry (wheat grain) commodities. Spain also indicated that an ILV of this method was currently on-going. The detailed evaluation report was however not provided; consequently this method and its ILV are not to be considered.

The multi-residue QuEChERS method in combination with HPLC-MS/MS or GC-MS described in European Standard EN 15662:2008 is also available to dose parent pendimethalin with an LOQ of 0.005 mg/kg for acidic and high water content commodities and 0.01 mg/kg for dry commodities (CEN, 2008).

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

**Table 1-1:** Recovery data for the analysis of pendimethalin in different crop groups using the QuEChERS method in combination with HPLC-MS/MS and GC-MS (EURL, 2011)

Commodity group	Chromatography	Spiking levels (mg/kg)		Recoveries			No of labs
		Min.	Max.	Mean (%)	RSD (%)	n	
Acidic	GC	0.005	0.2	106	13	223	7
Watery	GC	0.005	1	103	13	331	11
Dry (cereals, pulses)	GC	0.01	0.2	106	11	217	9
Acidic	LC	0.01	0.1	94	17	54	2
Watery	LC	0.01	0.1	93	20	101	2
Dry (cereals, pulses)	LC	0.02	0.2	89	11	17	2

Hence it is concluded that parent pendimethalin can be enforced in food of plant origin with an LOQ of 0.005 mg/kg in high water and acidic commodities, 0.01 mg/kg in dry commodities, and 0.05 mg/kg in high oil content commodities. An overall LOQ of 0.05 mg/kg is therefore considered suitable for all plant commodities.

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

During the peer review under Directive 91/414/EEC, no analytical method was submitted for food of animal origin.

A DFG S 19 multi-residue method using GC-ECD was evaluated by RMS after the Annex I inclusion for the determination of parent pendimethalin in food of animal origin and validated with an LOQ of 0.01 mg/kg in milk, meat, fat and eggs. However, a detailed evaluation report summarizing the validation data of this method is not available to EFSA and would therefore be desirable.

As the above method was not validated in liver and kidney, Spain provided during the Member States' consultation an analytical method using GC-MS/MS for the determination of pendimethalin. This method was evaluated and validated in food of animal origin with an LOQ of 0.01 mg/kg in kidney and liver (Spain, 2012b). Moreover, this method is confirmed by the validation of two different mass transitions. Spain mentioned that an ILV of this method was on going.

Hence it is concluded that the parent pendimethalin can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs. However, an ILV is still required for the determination of residues in liver and kidney.

## 2. Mammalian toxicology

The toxicological assessment of pendimethalin was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2003). These toxicological reference values are summarized in Table 2-1.

**Table 2-1:** Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
<b>Pendimethalin</b>					
ADI	EC	2003	0.125 mg/kg bw/d	2-year dog study	100
ARfD	EC	2003	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 pendimethalin was investigated for foliar or soil application on root and tuber vegetables (potatoes and onions), on pulses and oilseed (soybeans) and on cereals (sweet corn and wheat), using <sup>14</sup>C-labelled pendimethalin (Spain, 1998a). The details 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 <sup>(a)</sup>	Rate (kg a.s./ha)	No	Sampling
Cereals	Sweet corn	<sup>14</sup> C-ethylpropyl and 4- <sup>14</sup> C-methyl pendimethalin	Soil treatment, G	1.60	1	30, 60, 80 DAT
		3,4- <sup>14</sup> C-dimethyl pendimethalin	Foliar treatment, G	1.65	1	2, 6, 12 weeks after treatment
		U- <sup>14</sup> C-phenyl pendimethalin	Foliar treatment, F	2.24	1	14, 30, 60, 81 DAT
	Soil treatment, F		30, 60, 91 DAT			
Wheat	<sup>14</sup> C-ethylpropyl and 4- <sup>14</sup> C-methyl pendimethalin	Soil treatment, F	1.54-1.65	1	30, 60, 120 days after breaking winter dormancy	
Pulses and oilseeds	Soybean	position unknown	Soil treatment	1.68	1	4, 8, 14 weeks after treatment
		3,4- <sup>14</sup> C-dimethyl pendimethalin	Soil treatment	1.65	1	1, 2, 4 months after treatment

Group	Crop	Label position	Application and sampling details			
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	No	Sampling
Root and tuber vegetables	Potatoes	4- <sup>14</sup> C-methyl pendimethalin	Soil treatment	2.20	1	120 DAT
			Soil treatment, G and F	1.10	1	93, 106 DAT
		U- <sup>14</sup> C-phenyl pendimethalin	Foliar treatment	1.68	1	0, 109 DAT
	Onions	U- <sup>14</sup> C-phenyl pendimethalin	Foliar treatment	3.00	2	77 DAT

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

The early studies used <sup>14</sup>C-pendimethalin radiolabeled in one of the three following positions: the 4-methyl group, the 3,4-dimethyl groups or the ethylpropyl group. The more recent studies were conducted with <sup>14</sup>C-pendimethalin that was uniformly ring-labeled.

The studies on the metabolism of pendimethalin in plants demonstrated that after application to plants, pendimethalin was not translocated within the plant. Pendimethalin is extensively metabolized to a variety of natural, water soluble-components as well as other macromolecular plant constituents. Only the following metabolites were identified in addition to the parent compound; the 4-hydroxymethyl metabolite<sup>10</sup> and the 4-carboxylic acid metabolite<sup>11</sup>, none of which exceeded 10 % of the total radioactive residue. All the metabolites were also identified in rats. At harvest, amounts of pendimethalin and its metabolites were not detectable in the mature crop commodities. Metabolic pathways in all studies were found to be similar in all investigated crops. At early sampling intervals (forage stage) which are comparable with the GAPs on short-cycle leafy crops, parent pendimethalin is a valid marker residue in treated crops (EFSA, 2011).

Based on the available studies, the residue for both enforcement and risk assessment in all plant commodities is defined as pendimethalin. 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 pendimethalin is authorised for foliar treatment and soil application on several crops in northern and southern Europe (see Appendix A). To assess the magnitude of pendimethalin residues resulting from these GAPs, EFSA considered all residues trials reported in the PROFile, including residues trials evaluated in the framework of the peer review (Spain, 1998a) and in the framework of a previous MRL application (EFSA, 2011) as well as the additional GAPs reported during the Member State's consultation (Belgium, 2012; France, 2012; Italy, 2012; Germany, 2012; United Kingdom, 2012). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

The number of residues trials and extrapolations were evaluated in view of the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for some crops under assessment but not in the following cases:

<sup>10</sup> 4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol. See Appendix E.

<sup>11</sup> 2-methyl-3,5-dinitro-4-(pentan-3-ylamino)benzoic acid. See Appendix E.

- Orchard trees, wine and table grapes, potatoes, sweet corn, fresh legume vegetables, dry pulses, sugar cane, small grain cereals, rice and maize forage: the number of available residue trials supporting the southern outdoor use is not compliant with the data requirements for these crops but the reduced number was considered sufficient by EFSA because application is made before emergence or during dormancy and a no residue situation is expected. Further residues trials are therefore not required (see also section 3.1.1.1).
- Strawberries: the number of residue trials supporting the northern and southern outdoor GAPs is not compliant with the data requirements for this crop. All available trial results were below the LOQ but a residue situation cannot be excluded (based on the findings in other crops such as celery). Although tentative MRL and risk assessment values can be derived, 4 additional trials complying with the northern GAP are still required. Concerning the southern outdoor GAP, as pendimethalin is not systemic and applied very early (BBCH 00), a no residue situation is expected. Therefore, only 2 trials complying with the southern GAP are required to confirm a no residue situation.
- Carrots: no residue trials complying with the northern outdoor GAP are available. Although appropriate MRL and risk assessment values can be derived from the southern outdoor data, 8 trials complying with the northern outdoor GAP are still required.
- Horseradish, parsnips, parsley root and salsify: no residue trials complying with the northern outdoor GAPs are available. During the Member State's consultation, the United Kingdom made reference to the trials reported in the DAR to support these uses (United Kingdom, 2012). Nevertheless, taking into account the duration of the crop cycle and the application of the product in pre-emergence, these trials are not sufficient to support these uses as in one third of the trials, residue levels exceeded the LOQ (0.05 mg/kg). Consequently, 8 residue trials on carrots complying with the GAPs on horseradish, parsnips, parsley root and salsify are required. Neither MRLs nor risk assessment values can be derived.
- Onions, garlic and shallots: the number of trials supporting the northern and southern uses is not compliant with the data requirements for these crops. Although all available trial results were below the LOQ, a residue situation cannot be excluded (based on the findings in other crops such as celeriac). Although tentative MRL and risk assessment values can be derived, 4 and 6 additional trials complying with the northern and southern GAPs, respectively, are still required.
- Spring onions: the four residue trials submitted during the Member State's consultation by Germany are underdosed and support an application rate of 1.6 kg a.s./ha instead of 2 kg a.s./ha (Germany, 2012). Considering they are within the 25 % deviation, no further trials are required.
- Tomatoes, aubergines, peppers and cucurbits with edible and inedible peel (outdoor uses): the number of residue trials supporting the northern and southern outdoor GAPs is not compliant with the data requirements for these crops (trials on tomatoes and cucumber missing). Although tentative MRL and risk assessment values can be derived from the northern data, 2 additional trials on tomatoes and 8 trials on cucumbers complying with the northern GAP, and 4 additional trials on tomatoes and 8 trials on cucumbers complying with the southern GAP are still required to support the extrapolation to the whole fruiting vegetables group.
- Melons (indoor use): France and Germany are of the opinion that residue trials are not necessary considering the non systemic properties of pendimethalin, considering that the application is performed before the formation of the consumable parts and considering that the residue trials on melon conducted in southern Europe showed a no residue situation



(France, 2012; Germany, 2012). This approach is not supported by EFSA because uptake of residues may depend on the climatic conditions; at least 2 trials complying with the indoor GAP confirming a no residue situation are still required. Meanwhile, tentative MRLs and risk assessment values can be derived based on the outdoor uses (see above).

- Flowering and head brassica: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for these crops (trials on cauliflower and head cabbage missing). Although appropriate MRL and risk assessment values can be derived from the northern outdoor data, 3 trials on cauliflower and 8 trials on head cabbage complying with the southern outdoor GAP are still required.
- Lamb's lettuce, cress, rocket rucola, leaves and sprouts of brassica: United Kingdom proposed to use residue trials on lettuce to support the northern outdoor GAPs (United Kingdom, 2012). No information on the open-leaf varieties is provided but as pendimethalin is applied very early this information is not considered very relevant in this case. In fact, the length of the crops cycle is expected to have a more significant impact in this case. While residue levels in lettuce are subject to a significant dilution, the dilution of residue levels seems much lower in lamb's lettuce, cress, rocket rucola and leaves and sprouts of brassica as they have a shorter growth cycle than lettuces. This is confirmed by trials on parsley where residue levels are higher (EFSA, 2011). Consequently, although extrapolation from parsley is not an agreed extrapolation, EFSA is of the opinion that in this case, residue trials on parsley are more appropriate.
- Witloof: no residue trials are available to support the southern use. Considering that it is a minor crop in southern Europe, 4 residue trials complying with the GAP are required. Consequently, neither MRLs nor risk assessment values can be derived.
- Asparagus: no residue trials are available to support the northern outdoor GAP for this crop. Although appropriate MRL and risk assessment values can be derived from the southern data, 4 trials complying with the northern GAP are still required.
- Celery: no residue trials are available to support the southern outdoor GAP for this crop. Although appropriate MRL and risk assessment values can be derived from the northern data, 4 trials complying with the southern GAP are still required.
- Fennel: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. Although appropriate MRL and risk assessment values can be derived from the northern outdoor data, 3 trials complying with the southern outdoor GAP are still required.
- Globe artichoke: the number of residue trials supporting the northern and southern outdoor GAPs is not compliant with the data requirements for this crop. All available northern trial results were below the LOQ but a residue situation cannot be excluded (based on the findings in other crops such as celery). Although tentative MRL and risk assessment values can be derived from the northern data, 2 and 4 trials complying with the northern and southern GAPs, respectively, are still required.
- Leek: the number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. All available trial results were below the LOQ but a residue situation cannot be excluded (based on the findings in other crops such as celery). Although tentative MRL and risk assessment values can be derived from the northern data, 6 additional trials complying with the northern GAP are still required.



- Sunflower seed and soya bean: no residue trials are available to support the northern uses. Although appropriate MRL and risk assessment values can be derived from the southern outdoor data, 8 residue trials on sunflower or soya bean complying with the northern GAP are required.
- Rape seed: no residue trials are available to support the northern outdoor GAP for this crop. The residue trials submitted by Germany during the Member State's consultation were not taken into account as they were performed too early (at BBCH 00 instead of BBCH 16) (Germany, 2012). 8 trials complying with the northern GAP are still required. Consequently, neither MRL nor risk assessment values can be derived.
- Herbal infusions, spices (seeds, fruits and berries): no residue trials are available to support the northern uses. Belgium proposed to extrapolate residue data on parsley and chives (Belgium, 2012) but this approach is not supported by EFSA. Considering that they are minor crops in northern Europe, 4 residue trials on representative crops complying with the northern outdoor GAPs are required. Consequently, neither MRLs nor risk assessment values can be derived.
- Alfalfa: no residue trials are available to support the northern and southern uses. Consequently, 4 residue trials complying with the northern and southern outdoor GAPs are required and neither MRLs nor risk assessment values can be derived.

The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of pendimethalin was demonstrated for a period of 24 months at -20 °C in commodities with high water (onions and potatoes), high acid (grapes), high oil (soyabean, almond) content as well as dry commodities (almond hulls) and wheat straw (Spain, 1998a). According to the RMS, all residues trial samples reported were stored in compliance with the above reported storage conditions. However, no data are available for spices (seeds, fruits and berries) and herbal infusions and might be required if residues trials on these crops are provided in the future.

The available residues data are considered sufficient to derive adequate MRL proposals as well as risk assessment values for most of the commodities under evaluation, except for strawberries, onions, garlic, shallots, tomatoes, aubergines, peppers, cucurbits with edible and inedible peel, leek and globe artichokes where tentative MRLs are derived, and for horseradish, parsnips, parsley root, salsify, witloof, rape seed, herbal infusions (flowers), spices (seeds, fruits and berries) and alfalfa where the available data were insufficient to derive tentative MRLs (see also Table 3-2). In case where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in the table. Tentative MRLs were also derived for cereal straw, in view of the future need to set MRLs in feed items.

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

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Citrus fruit Tree nuts Pome fruit Stone fruit	NEU	Outdoor	16x<0.05	16x<0.05	0.05	0.05	0.05*	1.00	Trials on apples (12) and pears (4) are overdosed (3.2 to 6.4 kg a.s./ha) but considered sufficient for GAPs on tree nuts, pome fruit and stone fruit as residue levels were below the LOQ. Use on citrus fruit not authorized in NEU.
	SEU	Outdoor	Apples: 2x<0.01; <0.05 Pears: <0.05 Peaches: 2x<0.01; <0.05	Apples: 2x<0.01; <0.05 Pears: <0.05 Peaches: 2x<0.01; <0.05	0.01	0.05	0.05*	1.00	Trials on apples (3), pears (1) and peaches (3) (1.1 to 1.8 kg a.s./ha) compliant with the GAP on citrus fruit, pome fruit and stone fruit. Trials with LOQ of 0.01 mg/kg were submitted during the Member States' consultation (Italy, 2012).
Table and wine grapes	NEU	Outdoor	18x<0.05	18x<0.05	0.05	0.05	0.05*	1.00	Trials on grapes compliant with the GAP. No NEU use on table grapes.
	SEU	Outdoor	2x<0.05	2x<0.05	0.05	0.05	0.05*	1.00	Trials on grapes compliant with the GAP.
Strawberries	NEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on strawberries compliant with the GAP.
	SEU	Outdoor	-	-	-	-	-	-	No residue trials available.

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Cane fruit Other small fruit and berries	NEU	Outdoor	22x<0.05	22x<0.05	0.05	0.05	0.05*	1.00	Residue trials on grapes (18) and strawberries (4) compliant with the GAP on other berry shrubs. Trials on strawberries are more critical but are acceptable as all residue levels are <LOQ.
Potatoes	NEU	Outdoor	16x<0.05	16x<0.05	0.05	0.05	0.05*	1.00	Trials on potatoes compliant with the GAP.
	SEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials on potatoes compliant with the GAP.
Carrots	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.
	SEU	Outdoor	7 x <0.05; 0.08	7 x <0.05; 0.08	0.05	0.08	0.1	1.00	Trials on carrots compliant with the GAP (France, 2012).
Celeriac	NEU	Outdoor	3x<0.05; 0.06	3x<0.05; 0.06	0.05	0.06	0.1	1.00	Trials on celeriac compliant with the GAP. Rber = 0.08 Rmax = 0.12
Horseradish Parsnip Parsley root Salsify	NEU	Outdoor	-	-	-	-	-	-	No residue trials are available; see also body text.
Onions Garlic Shallots	NEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on onions compliant with the GAPs.
	SEU	Outdoor	2x<0.05	2x<0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on onions compliant with the GAPs.

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Spring onions	NEU	Outdoor	3x<0.02; 0.027	3x<0.02; 0.027	0.02	0.03	0.05*	1.00	Trials on spring onions are underdosed (1.6 instead of 2 kg a.s./ha) but still within the limit of the 25 % deviation (Germany, 2012).
Tomatoes Aubergines Peppers Cucurbits with edible peel Cucurbits with inedible peel	NEU/ SEU	Indoor	-	-	-	-	-	1.00	Indoor use only authorised for melons but representative trials are anyhow not available.
	NEU	Outdoor	6x<0.05	6x<0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on tomatoes compliant with the GAP for all solanacea and cucurbits. These include 3 overdosed trials on tomatoes as residues are below the LOQ. No authorized use on aubergine in NEU.
	SEU	Outdoor	Tomatoes: 4x<0.05 Melons: 4x<0.01	Tomatoes: 4x<0.05 Melons: 4x<0.01	0.05	0.05	0.05* (tentative)	1.00	Trials on tomatoes (1; 1 x 1.6 kg a.s./ha) and on melons (4; 1 x 1.3 kg a.s./ha) compliant with the GAP for all solanacea and cucurbits with inedible peel. 3 overdosed trials on tomatoes were also considered as residues are below the LOQ. No authorized use on cucurbits with edible peel in SEU.
Sweet corn	NEU	Outdoor	3x<0.05	3x<0.05	0.05	0.05	0.05*	1.00	Trials on sweet corn compliant with the GAP (United Kingdom, 2012).

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Flowering brassica Head brassica	NEU	Outdoor	27x<0.05	27x<0.05	0.05	0.05	0.05*	1.00	Trials on head cabbage (10) and on cauliflower (17) compliant with the GAPs; some of them are overdosed (1.98 to 2.64 kg a.s./ha) but acceptable as all residue levels were below the LOQ (France, 2012).
	SEU	Outdoor	5x<0.05	5x<0.05	0.05	0.05	0.05*	1.00	Trials on cauliflower compliant with the GAPs (France, 2012).
Leafy brassica	NEU	Outdoor	3x<0.05; 0.25	3x<0.05; 0.25	0.05	0.25	0.5	1.00	Trials on kale compliant with the GAP on leafy brassica (EFSA, 2011). Rber = 0.4 Rmax = 0.6
Kohlrabi	NEU	Outdoor	2x<0.05; 0.06; 0.13	2x<0.05; 0.06; 0.13	0.06	0.13	0.3	1.00	Trials compliant with the GAP (EFSA, 2011). Rber = 0.23 Rmax = 0.27
Lettuce Scarole (broad-leaf endive)	SEU	Outdoor	12x<0.05	12x<0.05	0.05	0.05	0.05*	1.00	Trials on lettuce compliant with the GAP on lettuce and scarole.
Witloof	SEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Lamb's lettuce Cress Rocket Leaves and sprouts of brassica sp Herbs (except sage and parsley)	NEU	Outdoor	<0.02; 2x0.026; 0.034; <0.05; 0.065; 0.094; 0.1; 0.39	<0.02; 2x0.026; 0.034; <0.05; 0.065; 0.094; 0.1; 0.39	0.05	0.39	0.6	1.00	Trials on parsley compliant with the GAPs on chives and celery leaves (EFSA, 2011), as well as lamb's lettuce, cress, rocket, leaves and sprouts of brassica, chervil, rosemary, thyme, basil, bay leaves and tarragon. Rber = 0.19 Rmax = 0.44
Parsley Sage	NEU	Outdoor	0.064; 0.12; 0.28; 0.76	0.064; 0.12; 0.28; 0.76	0.2	0.76	2	1.00	Trials on parsley compliant with the GAP on chervil, parsley and sage only (EFSA, 2011). Rber = 1.28 Rmax = 1.93
Beans (with and without pods) Peas (with and without pods) Lentils fresh	NEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	Trials on peas (with pods) compliant with the GAP on fresh beans and fresh peas (Germany, 2012); extrapolation to less critical GAP on lentils possible as residue levels were always below the LOQ (France, 2012).
	SEU	Outdoor	4x<0.05	4x <0.05	0.05	0.05	0.05*	1.00	Trials on peas (with pods) compliant with the GAP on fresh beans and fresh peas (France, 2012); extrapolation to less critical GAP on lentils possible as residue levels were always below the LOQ (France, 2012).

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Asparagus	NEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
	SEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	Trials on asparagus compliant with the GAP.
Celery	NEU	Outdoor	3x <0.02; 0.03; 0.045; 2x<0.05; 0.07	3x <0.02; 0.03; 0.045; 2x<0.05; 0.07	0.04	0.07	0.1	1.00	Trials on celery compliant with the GAP. Rber = 0.1 Rmax = 0.1
	SEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
Fennel	NEU	Outdoor	3x <0.02; 0.03; 0.045; 2x<0.05; 0.07	3x <0.02; 0.03; 0.045; 2x<0.05; 0.07	0.04	0.07	0.1	1.00	Direct extrapolation from the northern GAP on celery is possible.
	SEU	Outdoor	<0.01	<0.01	-	-	-	1.00	No sufficient residue trials available. One trial on fennel compliant with the GAP (Italy, 2012).
Globe artichokes	NEU	Outdoor	2x<0.05	2x<0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on artichokes compliant with the GAP.
	SEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
Leek	NEU	Outdoor	2x<0.05	2x<0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on leek compliant with the GAP.
Rhubarb	NEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials on rhubarb compliant with the GAP.



Commodity	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 <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Beans (dry) Peas (dry) Lupins	NEU	Outdoor	Dry beans: 2x<0.05; 2x<0.06; 9x0.06 Dry peas: 4x<0.07; 8x0.07	Dry beans: 2x<0.05; 2x<0.06; 9x0.06 Dry peas: 4x<0.07; 8x0.07	<b>0.06</b>	<b>0.07</b>	<b>0.15</b>	<b>1.00</b>	Trials on dry beans (13) and dry peas (12) compliant with the GAP (Germany, 2012); extrapolation to less critical GAP on lentils possible as residue levels were always below the LOQ. Rber = 0.12 Rmax = 0.07
	SEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials on dry peas compliant with the GAP on dry peas and beans (France, 2012; Spain, 2012a); extrapolation to less critical GAP on lentils possible as residue levels were always below the LOQ.
Peanuts	SEU	Outdoor	8x<0.05	8x<0.05	0.05	0.05	0.05*	1.00	Trials on peanuts compliant with the GAP.
Rape seed	NEU	Outdoor	-	-	-	-	-	1.00	No residue trials available.
Sunflower seed Soya bean Cotton seed	NEU	Outdoor	-	-	-	-	-	1.00	No residue trials available. No authorized use on cotton in NEU.
	SEU	Outdoor	13x<0.05	13x<0.05	0.05	0.05	0.05*	1.00	Trials on sunflower (4), soya bean (7) and cotton (2) compliant with the GAP (Spain, 2012a).
Maize grain	NEU	Outdoor	10x<0.05	10x<0.05	0.05	0.05	0.05*	1.00	Trials on maize compliant with the GAP.
	SEU	Outdoor	10x<0.05	10x<0.05	0.05	0.05	0.05*	1.00	Trials on maize compliant with the GAP.

Commodity	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 <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Millet Sorghum	NEU	Outdoor	14x<0.05	14x<0.05	0.05	0.05	0.05*	1.00	Trials on maize compliant with the GAP on sorghum and millet (France, 2012).
	SEU	Outdoor	6x<0.05	6x<0.05	0.05	0.05	0.05*	1.00	Trials on maize compliant with the GAP on sorghum and millet (France, 2012).
Rice grain	SEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials on rice compliant with the GAP (Spain, 2012a).
Barley grain Oats grain Rye grain Wheat grain	NEU	Outdoor	16x<0.05	16x<0.05	0.05	0.05	0.05*	1.00	Trials on wheat (14) and barley (2) compliant with the GAP for small grain cereals. No authorized use on oats in NEU.
	SEU	Outdoor	2x <0.05	2x <0.05	0.05	0.05	0.05*	1.00	Trials on wheat compliant with the GAP for small grain cereals.
Barley straw Oats straw Rye straw Wheat straw	NEU	Outdoor	13x<0.05; 0.06; 0.12; 0.14	13x<0.05; 0.06; 0.12; 0.14	0.05	<b>0.14</b>	<b>0.4</b>	1.00	Trials on wheat (14) and barley (2) compliant with the GAP for small grain cereals. No authorized use on oats in NEU.
	SEU	Outdoor	0.05; 0.08	0.05; 0.08	<b>0.07</b>	0.08	0.2	1.00	Trials on wheat compliant with the GAP for small grain cereals. Rber = - Rmax = 0.62
Herbal infusions (flowers)	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.
Spices (seeds, fruits and berries)	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.

Commodity	Region <sup>(a)</sup>	Outdoor/Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) <sup>(b)</sup>	Highest residue (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (pendimethalin)	Risk assessment (pendimethalin)					
Sugar cane	Overseas (FR)	Outdoor	3x<0.05	3x<0.05	0.05	0.05	0.05*	1.00	Trials on sugar cane overdosed (2.24 to 3.36 kg a.s./ha) but acceptable as residue levels were below the LOQ (France, 2012).
Alfalfa	NEU	Outdoor	-	-	-	-	-	-	No residue trials available.
	SEU	Outdoor	-	-	-	-	-	-	No residue trials available.
Maize forage	NEU	Outdoor	2x<0.05	2x<0.05	0.05	0.05	0.05*	1.00	Trials on maize forage overdosed (1.98 to 2 kg a.s./ha) but acceptable as residue levels all below the LOQ (France, 2012).
	SEU	Outdoor	4x<0.05	4x<0.05	0.05	0.05	0.05*	1.00	Trials on maize forage overdosed (1.98 to 2 kg a.s./ha) but acceptable as residue levels all below the LOQ (France, 2012).

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(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.

(\*): 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 pendimethalin are not expected in the edible parts of most crops under consideration, and as consumer exposure is far below 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

Some crops evaluated in the framework of this MRL review might be grown in rotation with other crops. During the peer review under Directive 91/414/EEC, it was also demonstrated in several degradation studies that pendimethalin is persistent in soil and that  $DT_{90}$  values exceed the trigger value of 100 days (Spain, 1998a). A detailed assessment of the nature and magnitude of pendimethalin residues is therefore considered relevant.

### 3.1.2.2. Nature of residues

The nature of pendimethalin residues in rotational crops was investigated using  $^{14}\text{C}$ -labelled pendimethalin. Four metabolism studies were submitted on cotton seed, soya bean, red beets, lettuce, winter and spring wheat, snap beans, carrots and radishes. These studies were used also for assessing the magnitude of pendimethalin residues in rotational crops (Spain, 1998b). The characteristics of these studies are summarised in Table 3-3.

Total radioactive residues found in the harvested commodities of lettuce, carrots and snap beans planted back at 30-DAT were in the range of 0.07 mg eq./kg (snap bean seeds) to 0.52 mg eq./kg (snap bean plants). The 30-DAT radish and spring wheat crops suffered phytotoxic damage and were not analysed. At the 90-DAT plant back interval, TRR levels at harvest were in the range of 0.02 mg eq./kg (snap bean seeds) to 0.16 mg eq./kg (snap bean plants). Radishes at the 90-DAT plant back interval still showed signs of phytotoxic damage. Beet roots planted about six months after pendimethalin treatment of a corn crop contained TRR levels of 0.04 mg eq./kg. At the plant back interval 365-DAT, the TRR levels in the harvested commodities of lettuce, snap bean seeds, carrot roots, and spring wheat were in the range of 0.02 mg eq./kg (wheat grain) to 0.15 mg eq./kg (wheat straw). Winter wheat and spring wheat planted back at 110-DAT and 270-DAT, respectively, contained total residues of 0.03-0.02 mg eq./kg (grain) and 0.19-0.15 mg eq./kg (straw). The spring wheat planted back at 120-DAT showed signs of phytotoxicity; spring wheat at 365-DAT contained residues in the range of 0.02 mg eq./kg (grain) to 0.15 mg eq./kg (straw).

In general, studies show that rotational crops, planted back at various intervals after pendimethalin applications up to 2.2 kg a.s./ha contain low TRR levels in the harvested crop commodities. Most of the residue is attributable to incorporation into naturally occurring structural cell components and/or metabolism to water-soluble degradates. Only small percentages of the total residue were identified as pendimethalin (9 – 51 % TRR) and the 4-hydroxymethyl metabolite (1 – 4 % TRR). Pendimethalin is extensively metabolised to a complex mixture of water-soluble components and other minor components, some of which incorporate into macromolecular plant material such as cellulose and lignin (Spain, 1998b).

In the peer review, it was concluded based on the above studies that the metabolic pathway of pendimethalin in rotational crops is similar to that in primary crops and no formation of new metabolites was observed (Spain, 1998b). Hence the same residue definition of as for primary crops applies to the rotational crops.

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

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G <sup>(a)</sup>	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Lettuce	3,4- <sup>14</sup> C-dimethyl pendimethalin	Soil treatment	2.20	30, 90	90, 120, 150	
					365	Maturity and half maturity	
Root and tuber vegetables	Red beet	4- <sup>14</sup> C-methyl pendimethalin		1.68	180	210, 270, 330	
	Carrot	3,4- <sup>14</sup> C-dimethyl pendimethalin		2.20	30, 120	140	
					365	Half mature size and maturity	
					30, 90	-	Important signs of phytotoxicity observed
Radishes							
Pulses and oilseeds	Cotton	4- <sup>14</sup> C-methyl pendimethalin		1.10	± 120	138, 154, 184, 254	
	soybean						
	Snap bean	3,4- <sup>14</sup> C-dimethyl pendimethalin					
		365	Half maturity and maturity				
Cereals	Wheat	3,4- <sup>14</sup> C-dimethyl pendimethalin	2.20	30,120	-	Important signs of phytotoxicity observed	
				365	Maturity and half maturity		

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

### 3.1.2.3. Magnitude of residues

In addition to the metabolism studies on rotational crop, several rotational crop studies were evaluated in the framework of the peer review (Spain, 1998a). The magnitude of pendimethalin residues was investigated on carrot, fodder beet, onions, broccoli, lettuce, cotton, soybean, wheat, ryegrass, barley, oat and maize as following crops sown within different plant-back intervals (approximately 180 and 365 days depending on the crop) from the application of the active substance on bare soil at 1 x 0.84 to 6.72 kg a.s./ha. At harvest, pendimethalin residues were generally below the LOQ of 0.05 mg/kg in all mature plant parts.

These studies are in principle not considered sufficient to demonstrate the absence of residues in rotational crops because the trials did not cover the plant-back intervals of 30 and 90 days. However, metabolism studies demonstrate phytotoxic effects of pendimethalin in several rotational crops rotated within the shorted plant back intervals of 30 and 90 days.

EFSA recommends that, when granting an authorisation for the use of pendimethalin on primary crops, Member States apply necessary risk mitigation measures to avoid pendimethalin residues in rotational and/or succeeding crops.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden of livestock

Pendimethalin 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 summarized in Table 3-4. EFSA assumes that concentration of residues will not occur in those processed commodities that are used as animal feed because residue levels in the raw agricultural commodities were all below the LOQ. In addition, residue levels in the different fraction of the raw commodities are not expected to be significantly different because pendimethalin is applied at an early stage in the growing season. Default concentration factors were therefore not considered

**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
<b>Risk assessment residue definition: pendimethalin</b>				
Cabbage	0.05	Median residue	0.05	Highest residue
Kale	0.05	Median residue	0.25	Highest residue
Maize silage	0.05	Median residue	0.05	Highest residue
Citrus pomace	0.01	Median residue	0.01	Median residue
Apple pomace	0.05	Median residue	0.05	Median residue
Cereal grain (and bran)	0.05	Median residue	0.05	Median residue
Cereal straw	0.07	Median residue	0.14	Highest residue

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pulses	0.06	Median residue	0.07	Median residue
Potatoes	0.05	Median residue	0.05	Highest residue
Cotton seed (meal)	0.05	Median residue	0.05	Median residue
Sunflower seed (meal)	0.05	Median residue	0.05	Median residue
Soya bean (meal)	0.05	Median residue	0.05	Median residue
Peanuts (meal)	0.05	Median residue	0.05	Median residue

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

**Table 3-5:** Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy ruminants	0.028	0.010	Maize silage	0.78	Yes
Meat ruminants	0.036	0.014	Potatoes	0.83	Yes
Poultry	0.013	0.008	Potatoes	0.20	Yes
Pigs	0.019	0.011	Potatoes	0.49	Yes

### 3.2.2. Nature of residues

The nature of pendimethalin residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Spain, 1998a). Reported metabolism studies include three studies in lactating goats and one study in laying hens, all using U-<sup>14</sup>C-phenyl labelled pendimethalin. The basic characteristics of the metabolism studies are summarized in Table 3-6.

Lactating goats were dosed with 0.5, 1.5, 2.1, 6.3, 6.5, 20 mg/kg DM of <sup>14</sup>C-pendimethalin (Spain, 1998b). A significant proportion of pendimethalin was eliminated via excreta (70-80 % of the AR) and elimination via milk was minor. After sacrifice, the highest TRR levels in goats were encountered in liver (0.17 mg eq/kg). In other tissues, except at the higher dose, TRR levels were always lower than LOQ. Residues in liver mainly consisted of unresolvable mixtures of polar components, none accounting for >7 % (0.005 mg eq/kg) of the TRR.

Laying hens were dosed with 0.5 and 10 mg/kg DM/d (Spain, 1998b). At the low dose, residues were not detectable (< 0.01 mg eq/kg) in tissue and eggs; at the high dosing level, residues were found in liver, skin with adhering fat and muscle (0.205, 0.035 and < 0.01 mg eq/kg respectively). Thus pendimethalin is extensively metabolised in the laying hen to a large number of polar minor components. No major metabolites were observed. As in goat liver, the majority of residue in poultry liver consisted of several component which could not be resolved due to their polar nature.



The metabolic patterns identified for goats and hens were consistent with the rat metabolism and, pendimethalin is by default considered as the only relevant indicator compound in commodities of animal origin. Hence the relevant residue for enforcement and risk assessment in commodities of animal origin is defined as parent pendimethalin.

In the framework of the peer review, pendimethalin was considered to be fat soluble based on the fact that its log  $P_{ow}$  is higher than 3 (Spain, 1998). EFSA therefore concludes that the proposed residue for commodities of animal origin is fat soluble.

**Table 3-6:** Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg DM)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	U- <sup>14</sup> C-phenyl pendimethalin	3	2.1 and 6.3	7	Urine and faeces	Daily
						Tissues	After sacrifice
						Milk	Daily
		position unknown	4	0.5, 1.5 and 20	10	Urines and faeces	Daily
						Tissues	At sacrifice
						Milk	Daily
	4- <sup>14</sup> C-methyl pendimethalin	3	6.5	7	Urine and faeces	Daily	
					Tissues	At sacrifice	
Laying poultry	Hens	U- <sup>14</sup> C-phenyl pendimethalin	3 groups of 5 and 2 groups of 10	0.5 and 10	7	Eggs	Twice daily
						Excreta	Once daily
						Tissues	After sacrifice

### 3.2.3. Magnitude of residues

According to the above mentioned metabolism studies in lactating goats and laying hens, residues of pendimethalin or any metabolites exceeding 0.01 mg/kg are not expected at the calculated dietary burden. It is therefore concluded that significant residues in edible matrices of ruminants, poultry and pigs are not expected and that MRLs for these commodities can be established at the LOQ of 0.01 mg/kg. It is noted however that further validation of the analytical method for enforcement of pendimethalin residues in liver and kidney is required (see also section 1.2). MRL proposals in liver and kidney are therefore considered on a tentative basis only.

#### 4. Consumer risk assessment

Chronic exposure calculations for all crops supported 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 summarized in Table 4-1. The (tentative) median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities. For those commodities where data were insufficient to derive an MRL in section 3, EFSA considered the existing EU MRL for an indicative calculation. The contributions of other commodities, for which no authorised use 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: pendimethalin		
Citrus fruit	0.01	Median residue (=LOQ) <sup>(a)</sup>
Tree nuts	0.05	Median residue (=LOQ) <sup>(a)</sup>
Pome fruit	0.05	Median residue (=LOQ) <sup>(a)</sup>
Stone fruit	0.05	Median residue (=LOQ) <sup>(a)</sup>
Table and wine grapes	0.05	Median residue (=LOQ) <sup>(a)</sup>
Strawberries	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Cane fruit	0.05	Median residue (=LOQ) <sup>(a)</sup>
Other small fruit and berries	0.05	Median residue (=LOQ) <sup>(a)</sup>
Potatoes	0.05	Median residue (=LOQ) <sup>(a)</sup>
Carrots	0.05	Median residue (=LOQ) <sup>(a)</sup>
Celeriac	0.05	Median residue (=LOQ) <sup>(a)</sup>
Horseradish	0.20	EU MRL <sup>(c)</sup>
Parsnips	0.20	EU MRL <sup>(c)</sup>
Parsley root	0.20	EU MRL <sup>(c)</sup>
Salsify	0.05	EU MRL <sup>(c)</sup>
Garlic	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Onions	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Shallots	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Spring onions	0.02	Median residue (=LOQ) <sup>(a)</sup>
Tomatoes	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Peppers	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Aubergines (egg plants)	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Cucurbits with edible peel	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Cucurbits with inedible peel	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Sweet corn	0.05	Median residue (=LOQ) <sup>(a)</sup>
Flowering brassica	0.05	Median residue (=LOQ) <sup>(a)</sup>
Head brassica	0.05	Median residue (=LOQ) <sup>(a)</sup>
Leafy brassica	0.05	Median residue (=LOQ) <sup>(a)</sup>
Kohlrabi	0.06	Median residue <sup>(a)</sup>
Lamb's lettuce	0.05	Median residue (=LOQ) <sup>(a)</sup>
Lettuce	0.05	Median residue (=LOQ) <sup>(a)</sup>
Scarole (broad-leaf endive)	0.05	Median residue (=LOQ) <sup>(a)</sup>
Cress	0.05	Median residue (=LOQ) <sup>(a)</sup>
Rocket, rucola	0.05	Median residue (=LOQ) <sup>(a)</sup>
Leaves and sprouts of Brassica spp	0.05	Median residue (=LOQ) <sup>(a)</sup>
Witloof	0.05	EU MRL (=LOQ) <sup>(c)</sup>
Chervil	0.05	Median residue (=LOQ) <sup>(a)</sup>
Chives	0.05	Median residue (=LOQ) <sup>(a)</sup>
Celery leaves	0.05	Median residue (=LOQ) <sup>(a)</sup>
Parsley	0.20	Median residue <sup>(a)</sup>
Sage	0.20	Median residue <sup>(a)</sup>
Rosemary	0.05	Median residue (=LOQ) <sup>(a)</sup>
Thyme	0.05	Median residue (=LOQ) <sup>(a)</sup>
Basil	0.05	Median residue (=LOQ) <sup>(a)</sup>
Bay leaves (laurel)	0.05	Median residue (=LOQ) <sup>(a)</sup>
Tarragon	0.05	Median residue (=LOQ) <sup>(a)</sup>
Legume vegetables (fresh)	0.05	Median residue(=LOQ) <sup>(a)</sup>
Asparagus	0.05	Median residue (=LOQ) <sup>(a)</sup>
Celery	0.04	Median residue <sup>(a)</sup>
Fennel	0.04	Median residue <sup>(a)</sup>
Globe artichokes	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Leek	0.05	Median residue (=LOQ) (tentative) <sup>(b)</sup>
Rhubarb	0.05	Median residue (=LOQ) <sup>(a)</sup>
Pulses (dry)	0.06	Median residue <sup>(a)</sup>
Peanuts	0.05	Median residue (=LOQ) <sup>(a)</sup>
Sunflower seed	0.05	Median residue (=LOQ) <sup>(a)</sup>
Rape seed	0.10	EU MRL <sup>(c)</sup>
Soya bean	0.05	Median residue (=LOQ) <sup>(a)</sup>
Cotton seed	0.05	Median residue (=LOQ) <sup>(a)</sup>
Barley grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Maize grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Millet grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Oats grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Rice grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Rye grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Sorghum grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Wheat grain	0.05	Median residue (=LOQ) <sup>(a)</sup>
Herbal infusions (dried, flowers)	0.10	EU MRL <sup>(c)</sup>
Spices (seeds)	0.10	EU MRL <sup>(c)</sup>
Spices (fruits and berries)	0.10	EU MRL <sup>(c)</sup>
Sugar cane	0.05	Median residue (=LOQ) <sup>(a)</sup>
Swine meat	0.01	Median residue (=LOQ) <sup>(d)</sup>
Swine fat (free of lean meat)	0.01	Median residue (=LOQ) <sup>(d)</sup>
Swine liver	0.01	Median residue (=LOQ) (tentative) <sup>(e)</sup>
Swine kidney	0.01	Median residue (=LOQ) (tentative) <sup>(e)</sup>
Ruminant meat	0.01	Median residue (=LOQ) <sup>(d)</sup>
Ruminant fat	0.01	Median residue (=LOQ) <sup>(d)</sup>
Ruminant liver	0.01	Median residue (=LOQ) (tentative) <sup>(e)</sup>
Ruminant kidney	0.01	Median residue (=LOQ) (tentative) <sup>(e)</sup>
Poultry meat	0.01	Median residue (=LOQ) <sup>(d)</sup>
Poultry fat	0.01	Median residue (=LOQ) <sup>(d)</sup>
Poultry liver	0.01	Median residue (=LOQ) (tentative) <sup>(e)</sup>

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Ruminant milk	0.01	Median residue (=LOQ) <sup>(d)</sup>
Birds' eggs	0.01	Median residue (=LOQ) <sup>(d)</sup>

- (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 are used for the exposure calculations.
- (b): Use reported by the RMS is not fully supported by data but the risk assessment value derived in section 3 are used for indicative exposure calculations.
- (c): Use reported by the RMS is not fully supported by data; the existing EU MRL is used for indicative exposure calculations
- (d): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
- (e): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for pendimethalin (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for German children, representing 1.3 % of the ADI.

Based on the above calculations, EFSA concludes that the use of pendimethalin on crops fully supported by data (footnote a in Table 4-1), is acceptable with regard to consumer exposure. For all remaining crops, major uncertainties remain due to the data gaps identified in section 3 but considering a tentative MRL or the existing EU MRL in the exposure calculation did not indicate a risk to consumers.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of pendimethalin was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.125 mg/kg bw/d. It was also concluded that the setting of an ARfD is not necessary.

Primary crop metabolism of pendimethalin was investigated in three different crop groups following foliar and soil applications. Metabolic patterns in the different studies were shown to be similar and the relevant residue for both enforcement and risk assessment in all plant commodities treated by foliar and soil application could be defined as pendimethalin. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.05 mg/kg in high water content, high oil content, dry and acidic commodities.

Regarding the magnitude of residues in most of crops reported by the RMS, at least one GAP was supported by a sufficient number of supervised residue trials, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs, except for strawberries, onions, garlic, shallots, tomatoes, aubergines, peppers, cucurbits with edible and inedible peel, leek and globe artichokes, where data were sufficient to derive tentative MRLs only. For horseradish, parsnips, parsley root, salsify, witloof, rape seed, herbal infusions (flowers), spices (seeds, fruits and berries) and alfalfa no residue trials were available. EFSA was therefore not able to derive tentative MRL proposals for these crops and further residue trials are required as well.

As residues of pendimethalin are all below 0.1 mg/kg and contribution of these residues to chronic consumer exposure is generally low, there was no need to investigate the effect of industrial and/or household processing on the nature and magnitude of pendimethalin residues.

The possible occurrence of pendimethalin residues in rotational and/or succeeding crops was also investigated. It was concluded by the peer review that the nature of residues in rotational crops and primary crops is similar and the relevant residue is pendimethalin. The available rotational crop field studies are not considered fully sufficient to demonstrate the absence of residues in rotational crops because the field trials did not cover the plant-back intervals of 30 and 90 days. EFSA recommends that, when granting an authorisation for the use of pendimethalin on primary crops, Member States apply necessary risk mitigation measures to avoid pendimethalin residues in rotational and/or succeeding crops.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in products of animal origin was therefore defined as pendimethalin. Available studies also demonstrated that residues of pendimethalin are not expected in significant amounts and MRLs in ruminants, poultry and pig can be set at the LOQ of 0.01 mg/kg. It is noted however that further validation of the analytical method for enforcement of pendimethalin residues in liver and kidney is required.

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 represented 1.3 % of ADI (German child). 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 (see table below for a summary). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain tentative MRLs and existing EU MRLs still need to be confirmed by the following data:

- 4 additional residue trials supporting the northern GAP and 8 residue trials supporting the southern GAP on strawberries;
- 8 residue trials on carrots supporting the northern GAPs on horseradish, parsnips, parsley root and salsify;
- 4 additional residue trials supporting the northern GAP and 6 additional residue trials supporting the southern GAP on onions, garlic and shallots;
- 2 additional residue trials on tomatoes and 8 residue trials on cucumbers supporting the northern GAP on tomatoes, peppers and cucurbits with edible and inedible peel;
- 4 additional residue trials on tomatoes and 8 residue trials on cucumbers supporting the southern GAP on solanacea and cucurbits with inedible peel;

- 2 residue trials supporting the indoor GAP on melons;
- 4 residue trials supporting the southern GAP on witloof;
- 2 additional residue trials supporting the northern GAP and 4 residue trials supporting the southern GAP on globe artichoke;
- 6 additional residue trials supporting the northern GAP on leek;
- 8 residue trials supporting the northern GAP on rape seed;
- 4 residue trials on representative crops supporting the northern GAP on herbal infusions (flowers), spices (seeds) and spices (fruits and berries);
- an ILV of the analytical method for enforcement of residues in liver and kidneys.

It is highlighted that some of the 'Recommended' MRLs resulted from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the 'Recommended' MRLs but which might have an impact on national authorisations:

- 8 residue trials supporting the northern GAP on carrots;
- 3 additional residue trials on cauliflower and 8 residue trials on head cabbage supporting the southern GAP on flowering and head brassica;
- 4 residue trials supporting the northern GAP on asparagus;
- 4 residue trials supporting the southern GAP on celery;
- 3 additional residue trials supporting the southern GAP on fennel;
- 8 residue trials supporting the northern GAP on sunflower and soybean
- 4 residue trials supporting the northern GAP and 4 residue trials supporting the southern GAP on alfalfa.

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

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

- a detailed evaluation report for the GC-NPD method used for enforcement of pendimethalin residues in plant commodities;
- a detailed evaluation report for the GC-ECD method used for enforcement of pendimethalin residues in livestock commodities.

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
<b>Enforcement residue definition: pendimethalin</b>				
110000	Citrus fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
120000	Tree nuts	0.05*	0.05*	Recommended <sup>(a)</sup>
130000	Pome fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
140010	Stone fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
151000	Table and wine grapes	0.05*	0.05*	Recommended <sup>(a)</sup>
152000	Strawberries	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
153000	Cane fruit	0.05*	0.05*	Recommended <sup>(a)</sup>
154000	Other small fruit & berries	0.05*	0.05*	Recommended <sup>(a)</sup>
211000	Potatoes	0.05*	0.05*	Recommended <sup>(a)</sup>
213020	Carrots	0.2	0.1	Recommended <sup>(a)</sup>
213030	Celeriac	0.1	0.1	Recommended <sup>(a)</sup>
213040	Horseradish	0.2	0.2	Further consideration needed <sup>(c)</sup>
213060	Parsnips	0.2	0.2	Further consideration needed <sup>(c)</sup>
213070	Parsley root	0.2	0.2	Further consideration needed <sup>(c)</sup>
213090	Salsify	0.05*	0.05*	Further consideration needed <sup>(c)</sup>
220010	Garlic	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
220020	Onions	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
220030	Shallots	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
220040	Spring onions	0.05*	0.05*	Recommended <sup>(a)</sup>
231010	Tomatoes	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
231020	Peppers	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
231030	Aubergines (egg plants)	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
232010	Cucurbits with edible peel	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
233000	Cucurbits with inedible peel	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
234000	Sweet corn	0.05*	0.05*	Recommended <sup>(a)</sup>
241000	Flowering brassica	0.05*	0.05*	Recommended <sup>(a)</sup>
242000	Head brassica	0.05*	0.05*	Recommended <sup>(a)</sup>
243000	Leafy brassica	0.5	0.5	Recommended <sup>(a)</sup>
244000	Kohlrabi	0.3	0.3	Recommended <sup>(a)</sup>
251010	Lamb's lettuce	0.05*	0.6	Recommended <sup>(a)</sup>
251020	Lettuce	0.05*	0.05*	Recommended <sup>(a)</sup>
251030	Scarole (broad-leaf endive)	0.05*	0.05*	Recommended <sup>(a)</sup>
251040	Cress	0.05*	0.6	Recommended <sup>(a)</sup>
251060	Rocket, Rucola	0.05*	0.6	Recommended <sup>(a)</sup>



Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
251080	Leaves and sprouts of Brassica spp	0.05*	0.6	Recommended <sup>(a)</sup>
255000	Witloof	0.05*	0.05*	Further consideration needed <sup>(c)</sup>
256010	Chervil	0.6	0.6	Recommended <sup>(a)</sup>
256020	Chives	0.6	0.6	Recommended <sup>(a)</sup>
256030	Celery leaves	0.6	0.6	Recommended <sup>(a)</sup>
256040	Parsley	2	2	Recommended <sup>(a)</sup>
256050	Sage	2	2	Recommended <sup>(a)</sup>
256060	Rosemary	0.6	0.6	Recommended <sup>(a)</sup>
256070	Thyme	0.6	0.6	Recommended <sup>(a)</sup>
256080	Basil	0.6	0.6	Recommended <sup>(a)</sup>
256090	Bay leaves (laurel)	0.6	0.6	Recommended <sup>(a)</sup>
256010	Tarragon	0.6	0.6	Recommended <sup>(a)</sup>
260000	Legume vegetables (fresh)	0.2	0.05*	Recommended <sup>(a)</sup>
270010	Asparagus	0.05*	0.05*	Recommended <sup>(a)</sup>
270030	Celery	0.1	0.1	Recommended <sup>(a)</sup>
270040	Fennel	0.05*	0.1	Recommended <sup>(a)</sup>
270050	Globe artichokes	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
270060	Leek	0.05*	0.05*	Further consideration needed <sup>(b)</sup>
270070	Rhubarb	0.05*	0.05*	Recommended <sup>(a)</sup>
300000	Pulses (dry)	0.2	0.15	Recommended <sup>(a)</sup>
401020	Peanuts	0.1*	0.05*	Recommended <sup>(a)</sup>
401050	Sunflower seed	0.1*	0.05*	Recommended <sup>(a)</sup>
401060	Rape seed	0.1*	0.1	Further consideration needed <sup>(c)</sup>
401070	Soya bean	0.1*	0.05*	Recommended <sup>(a)</sup>
401090	Cotton seed	0.1*	0.05*	Recommended <sup>(a)</sup>
500010	Barley grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500030	Maize grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500040	Millet grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500050	Oats grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500060	Rice grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500070	Rye grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500080	Sorghum grain	0.05*	0.05*	Recommended <sup>(a)</sup>
500090	Wheat grain	0.05*	0.05*	Recommended <sup>(a)</sup>
630000	Herbal infusions (dried, flowers)	0.1*	0.1	Further consideration needed <sup>(c)</sup>

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
810000	Spices (seeds)	0.1*	0.1	Further consideration needed <sup>(c)</sup>
820000	Spices (fruits and berries)	0.1*	0.1	Further consideration needed <sup>(c)</sup>
900020	Sugar cane	0.05*	0.05*	Recommended <sup>(a)</sup>
1011010	Swine meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1011020	Swine fat (free of lean meat)	0.05*	0.01*	Recommended <sup>(a)</sup>
1011030	Swine liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1011040	Swine kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1012010	Bovine meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1012020	Bovine fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1012030	Bovine liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1012040	Bovine kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1013010	Sheep meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1013020	Sheep fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1013030	Sheep liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1013040	Sheep kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1014010	Goat meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1014020	Goat fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1014030	Goat liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1014040	Goat kidney	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1016010	Poultry meat	0.05*	0.01* <sup>(F)</sup>	Recommended <sup>(a)</sup>
1016020	Poultry fat	0.05*	0.01*	Recommended <sup>(a)</sup>
1016030	Poultry liver	0.05*	0.01*	Further consideration needed <sup>(b)</sup>
1020010	Milk	0.05*	0.01*	Recommended <sup>(a)</sup>
1030000	Birds' eggs	0.05*	0.01*	Recommended <sup>(a)</sup>
-	Other products of plant and animal origin	see App C	-	Further consideration needed <sup>(d)</sup>

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

(F): MRL is expressed as mg/kg of fat contained in the whole product.

(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): 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 could be identified; no CXL is available (combination E-I in Appendix D).

(c): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).

(d): 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 pendimethalin prepared by the rapporteur Member State (Spain) in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 15 July 2009. Last updated on 08 September 2010.

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## 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	Number		Interval (days)		Min. rate			Max. rate	Rate Unit
							Conc.	Unit				Min.	Max.	Min.	Max.					
Almonds	<i>Prunus dulcis</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha	n.a.	Application time: before bud burst
Brazil nuts	<i>Bertholletia excelsa</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56						1.59	kg a.i./ha	n.a.	
Cashew nuts	<i>Anacardium occidentale</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Chestnuts	<i>Castanea sativa</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha	n.a.	Application time: before bud burst
Coconuts	<i>Cocos nucifera</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Hazelnuts	<i>Corylus avellana</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha	n.a.	Application time: before bud burst
Macadamia	<i>Macadamia ternifolia</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56						1.59	kg a.i./ha	n.a.	
Pecans	<i>Carya illinoensis</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Pine nuts	<i>Pinus pinea</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56						1.59	kg a.i./ha	n.a.	
Pistachios	<i>Pistachia vera</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Walnuts	<i>Juglans regia</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha	n.a.	Application time: before bud burst
Apples	<i>Malus domestica</i>	NEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		15		1			1.60	2.40	kg a.i./ha	n.a.	
Pears	<i>Pyrus communis</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		15		1			1.60	2.00	kg a.i./ha	n.a.	
Quinces	<i>Cydonia oblonga</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha	n.a.	Application time: before bud burst
Apricots	<i>Prunus armeniaca</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.60	2.00	kg a.i./ha	n.a.	Application time: before bud burst
Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.60	2.00	kg a.i./ha	n.a.	Application time: before bud burst
Peaches	<i>Prunus persica</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.60	2.00	kg a.i./ha	n.a.	Application time: before bud burst
Plums	<i>Prunus domestica</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.60	2.00	kg a.i./ha	n.a.	Application time: before bud burst
Wine grapes	<i>Vitis vulpitis</i>	NEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.64	2.40	kg a.i./ha	n.a.	
Strawberries	<i>Fragaria x ananassa</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying				1			1.32	2.00	kg a.i./ha	n.a.	Application time: from post-planting until flower initiation but before flower truss emergence
Blackberries	<i>Rubus fruticosus</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.32	2.00	kg a.i./ha	n.a.	
Dewberries	<i>Rubus ceasius</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.36	kg a.i./ha	n.a.	
Raspberries	<i>Rubus idaeus</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.32	2.00	kg a.i./ha	n.a.	
Blueberries	<i>Vaccinium corymbosum</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Cranberries	<i>Vaccinium macrocarpon</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Currants (red, black and white)	<i>Ribes nigrum, rubrum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.32	2.00	kg a.i./ha	n.a.	
Gooseberries	<i>Ribes uva-crispa</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1			1.32	2.00	kg a.i./ha	n.a.	
Rose hips	<i>Rosa canina</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Mulberries	<i>Morus spp.</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Azarole (mediterranean median)	<i>Crataegus azarolus</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Elderberries	<i>Sambucus nigra</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		56		1				1.59	kg a.i./ha	n.a.	
Potatoes	<i>Tuber form Solanum Spp</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			0.80	2.00	kg a.i./ha	n.a.	Application time: pre-emergence
Carrots	<i>Daucus carota</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1			0.80	2.00	kg a.i./ha	90	PHI=90 days, only in Denmark
Celeriac	<i>Apium graveolens var. rapaceum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1				1.60	kg a.i./ha	60	PHI=60 days, only in Germany
Horseradish	<i>Ammoracia rusticana</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1				1.60	kg a.i./ha	n.a.	Application time: post-planting of rhizomes but pre-emergence of shoots
Parsnips	<i>Pastinaca sativa</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1				2.00	kg a.i./ha	n.a.	Application time: pre-emergence
Parsley root	<i>Petroselinum crispum</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha	n.a.	Method: conventional hydraulic spray; Application time: pre-emergence
Salsify	<i>Tragopogon portifolius</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1				0.80	kg a.i./ha	n.a.	Application time: pre-emergence
Garlic	<i>Allium sativum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1			0.80	2.00	kg a.i./ha	56	PHI=56 days, only in Denmark

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application						Application rate			PHI or waiting period (days)	Comments (max. 250 characters)	
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate			Rate Unit
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Onions	<i>Allium cepa</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1			0.80	2.00	kg a.i./ha	56	PHI=56 days, only in Denmark
Shallots	<i>Allium ascalonicum</i> ( <i>Allium cepa</i> var. <i>aggregatum</i> )	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1			0.80	2.00	kg a.i./ha	56	PHI=56 days, only in Denmark
Spring onions	<i>Allium cepa</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying		10		1				2.00	kg a.i./ha	n.a.	Application time: post-emergence
Tomatoes	<i>Lycopersicon esculentum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	1.64	kg a.i./ha	n.a.	Application time: pre-emergence
Peppers	<i>Capsicum annuum</i> , var <i>grossum</i> and var. <i>longum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	1.64	kg a.i./ha	n.a.	Application time: pre-emergence
Cucumbers	<i>Cucumis sativus</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - general (see also comment field)		18		1			0.40	1.60	kg a.i./ha	n.a.	Application method: row application with umbrella Application time: pre and post- emergence, after planting
Gherkins	<i>Cucumis sativus</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - general (see also comment field)		18		1			0.40	1.60	kg a.i./ha	n.a.	Application method: row application with umbrella Application time: pre and post- emergence, after planting
Courgettes	<i>Cucurbita pepo</i> var. <i>melopepo</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - general (see also comment field)		18		1			0.40	1.60	kg a.i./ha	n.a.	Application method: row application with umbrella Application time: pre and post- emergence, after planting
Melons	<i>Cucumis melo</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - general (see also comment field)				1			1.59	kg a.i./ha	n.a.	Application time: pre-emergence.	
Pumpkins	<i>Cucurbita maxima</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - general (see also comment field)		18		1			0.40	1.60	kg a.i./ha	n.a.	Application method: row application with umbrella Application time: pre and post- emergence, after planting
Watermelons	<i>Citrullus lanatus</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - general (see also comment field)				1			1.59	kg a.i./ha	n.a.	Application time: pre-emergence.	
Sweet corn	<i>Zea mays</i> var. <i>sacharata</i>	NEU	Outdoor	UK	Weeds	CS	455.0	g/L	Soil treatment - spraying				1			2.00	kg a.i./ha	n.a.	Application time: pre-emergence	
Broccoli	<i>Brassica oleracea</i> var. <i>italica</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			0.80	1.64	kg a.i./ha	n.a.	Application time: before transplanting / 5-7 days post- transplanting
Cauliflower	<i>Brassica oleracea</i> var. <i>botrytis</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			0.80	1.64	kg a.i./ha	n.a.	Application time: before transplanting / 5-7 days post- transplanting
Brussels sprouts	<i>Brassica oleracea</i> var. <i>gemmifera</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			0.80	1.64	kg a.i./ha	n.a.	Application time: before transplanting / 5-7 days post- transplanting
Head cabbage	<i>Brassica oleracea</i> convar <i>capitata</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			0.80	1.64	kg a.i./ha	n.a.	Application time: before transplanting / 5-7 days post- transplanting
Chinese cabbage	<i>Brassica pekinensis</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying				1			1.59	kg a.i./ha	56	Application time: before transplanting / EFSA Journal 2011;9(10):2400	
Kale	<i>Brassica oleracea</i> convar. <i>Acephalea</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			1.59	kg a.i./ha	56	EFSA Journal 2011;9(10):2400	
Kohlrabi	<i>Brassica oleracea</i> convar. <i>acephala</i> , var. <i>gongylodes</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying				1			1.59	kg a.i./ha	21	Application time: before transplanting / EFSA Journal 2011;9(10):2400	
Lamb's lettuce	<i>Valerianella locusta</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying	n.a.			1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Cress	<i>Lepidium sativum</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying	n.a.			1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Rocket, Rucola	<i>Eruca sativa</i> ( <i>Diplotaxis</i> <i>spec.</i> )	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying	n.a.			1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Leaves and sprouts of Brassica spp	<i>Brassica spp</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying	n.a.			1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Chervil	<i>Anthriscus cerefolium</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1			0.50	1.64	kg a.i./ha	n.a.	
Chives	<i>Allium schoenoprasum</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying		12		1			1.14	kg a.i./ha	42	EFSA Journal 2011;9(10):2400	
Celery leaves	<i>Apium graveolens</i> var. <i>seccalinum</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying				1			1.37	kg a.i./ha	42	EFSA Journal 2011;9(10):2400	
Parsley	<i>Petroselinum crispum</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying		15		1			1.59	kg a.i./ha	28	EFSA Journal 2011;9(10):2400	
Sage	<i>Salvia officinalis</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying				1			1.59	kg a.i./ha	28	EFSA Journal 2011;9(10):2400	
Rosemary	<i>Rosmarinus officinalis</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying	n.a.			1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	



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	Number	Interval (days)		Min. rate	Max. rate			Rate Unit	
							Conc.	Unit					Min.	Max.						
Thyme	<i>Thymus spp.</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying		n.a.		1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Basil	<i>Ocimum basilicum</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying		n.a.		1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Bay leaves (laurel)	<i>Laurus nobilis</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying		n.a.		1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Tarragon	<i>Artemisia dracunculus</i>	NEU	Outdoor	UK	Weeds	CS	400.0	g/L	Foliar treatment - spraying		n.a.		1			1.50	kg a.i./ha	42	Method: conventional hydraulic spray (ground)	
Beans (with pods)	<i>Phaseolus vulgaris</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		0.40	2.00	kg a.i./ha	n.a.		
Beans (without pods)	<i>Phaseolus vulgaris</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		0.40	2.00	kg a.i./ha	n.a.		
Peas (with pods)	<i>Pisum sativum</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			2.00	kg a.i./ha	n.a.		
Peas (without pods)	<i>Pisum sativum</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Soil treatment - spraying		10		1			2.00	kg a.i./ha	n.a.		
Lentils (fresh)	<i>Lens culinaris</i> syn. <i>L. esculenta</i>	NEU	Outdoor	FR	Weeds	EC	250.0	g/L	Soil treatment - spraying		8		1			0.55	kg a.i./ha	63		
Asparagus	<i>Asparagus officinalis</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.60	kg a.i./ha	21	PHI=21 days, only in Germany	
Celery	<i>Apium graveolens</i> var. <i>dulce</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1		1.32	1.64	kg a.i./ha	60	PHI=60 days, only in Germany	
Fennel	<i>Foeniculum vulgare</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			1.60	kg a.i./ha	60	PHI=60 days, only in Germany	
Globe artichokes	<i>Cynara scolymus</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			1.60	kg a.i./ha	70	PHI=70 days, only in Germany	
Leek	<i>Allium porrum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1		0.80	2.00	kg a.i./ha	56	PHI=56 days, only in Denmark	
Rhubarb	<i>Rheum x hybridum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1			1.60	kg a.i./ha	n.a.	Application time: post planting before shooting	
Beans (dry)	<i>Phaseolus vulgaris</i>	NEU	Outdoor	DE, DK	Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1		0.40	2.00	kg a.i./ha	42	PHI=42 days, only in Denmark	
Peas (dry)	<i>Pisum sativum</i>	NEU	Outdoor	DE, DK	Weeds	CS	455.0	g/L	Foliar treatment - spraying		18		1		0.40	2.00	kg a.i./ha	42	PHI=42 days, only in Denmark	
Lupins	<i>Lupinus spp.</i>	NEU	Outdoor	DE, UK	Weeds	CS	455.0	g/L	Foliar treatment - spraying		CS		1			1.18	kg a.i./ha	n.a.	Application time: pre-emergence	
Sunflower seed	<i>Helianthus annuus</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1		0.23	2.00	kg a.i./ha	n.a.		
Rape seed	<i>Brassica napus</i>	NEU	Outdoor	DE	Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			0.91	kg a.i./ha	n.a.		
Soya bean	<i>Glycine max</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1		0.23	2.00	kg a.i./ha	n.a.		
Barley	<i>Hordeum spp.</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		30		1			2.00	kg a.i./ha	n.a.		
Maize	<i>Zea mays</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			2.00	kg a.i./ha	90	PHI=90 days, only in Denmark. France has an outdoor GAP on maize forage: 1x1,12 kg a.i./ha, PHI=90 days and application time: pre-emergence BBCH 07	
Millet	<i>Panicum spp.</i>	NEU	Outdoor	FR	Weeds	CS	400.0	g/L	Foliar treatment - spraying		16		1			1.20	kg a.i./ha	120	Application time: pre or post-emergence	
Rye	<i>Secale cereale</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		30		1			2.00	kg a.i./ha	n.a.		
Sorghum	<i>Sorghum bicolor</i>	NEU	Outdoor	FR	Weeds	CS	400.0	g/L	Foliar treatment - spraying		16		1			1.20	kg a.i./ha	120	Application time: pre or post-emergence	
Wheat	<i>Triticum aestivum</i>	NEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		30		1			2.00	kg a.i./ha	n.a.		
Herbal infusions (flowers)	<i>Not specified</i>	NEU	Outdoor	BE	Weeds	CS	455.0	g/L	Foliar treatment - spraying	1	8		1			0.91	kg a.i./ha			
Spices (seeds)	<i>Not specified</i>	NEU	Outdoor	BE	Weeds	CS	455.0	g/L	Foliar treatment - spraying	1	8		1			0.91	kg a.i./ha			
Spices (fruits and berries)	<i>Not specified</i>	NEU	Outdoor	BE	Weeds	CS	455.0	g/L	Foliar treatment - spraying	1	8		1			0.91	kg a.i./ha			
Alfalfa	<i>Medicago Sativa</i>	NEU	Outdoor	FR	Weeds	EC	250.0	g/L	Foliar treatment - spraying		11	1	2		0.50	1.00	kg a.i./ha	n.a.	Method: broadcast spray; Application time: early post-emergence. Every two years.	
Maize (for forage)	<i>Zea mays</i>	NEU	Outdoor	FR	Weeds	EC	250.0	g/L	Foliar treatment - spraying		7		1			1.12	kg a.i./ha	90	Method: broadcast spray.	



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		Growth stage	Number		Interval (days)		Min. rate	Max. rate			Rate Unit	
							Conc.			Unit	From BBCH	Until BBCH	Min.						Max.
Grapefruit	<i>Citrus paradisi</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Oranges	<i>Citrus sinensis</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Lemons	<i>Citrus limon</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Limes	<i>Citrus aurantifolia</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Mandarins	<i>Citrus reticulata</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Almonds	<i>Prunus dulcis</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Brazil nuts	<i>Bertholletia excelsa</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Cashew nuts	<i>Anacardium occidentale</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Chestnuts	<i>Castanea sativa</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Coconuts	<i>Cocos nucifera</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Hazelnuts	<i>Corylus avellana</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Macadamia	<i>Macadamia ternifolia</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Pecans	<i>Carya illinoensis</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Pine nuts	<i>Pinus pinea</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Pistachios	<i>Pistachia vera</i>	SEU	Outdoor	IT	Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Walnuts	<i>Juglans regia</i>	SEU	Outdoor		Weeds	CS	365.0	g/L	Soil treatment - spraying		0		1		0.91	1.10	kg a.i./ha	n.a.	
Apples	<i>Malus domestica</i>	SEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.00	2.40	kg a.i./ha	n.a.	Application time: winter
Pears	<i>Pyrus communis</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.00	2.00	kg a.i./ha	n.a.	Application time: winter
Quinces	<i>Cydonia oblonga</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Medlar	<i>Mespilus germanica</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Loquat	<i>Eriobotrya japonica</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Apricots	<i>Prunus armeniaca</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.00	2.00	kg a.i./ha	n.a.	Application time: winter
Cherries	<i>Prunus cerasus</i> , <i>Prunus avium</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Peaches	<i>Prunus persica</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.00	2.00	kg a.i./ha	n.a.	Application time: winter
Plums	<i>Prunus domestica</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.00	kg a.i./ha	n.a.	
Table grapes	<i>Vitis evitis</i>	SEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.32	2.40	kg a.i./ha	n.a.	
Wine grapes	<i>Vitis evitis</i>	SEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		7		1		1.00	2.40	kg a.i./ha	n.a.	Application time: winter
Strawberries	<i>Fragaria x ananassa</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		0		1		1.32	2.00	kg a.i./ha	n.a.	Application time: pre-planting or post-planting at the end of winter stop
Potatoes	<i>Tuber form Solanum Spp</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		1.00	2.00	kg a.i./ha	n.a.	Application time: pre-emergence
Carrots	<i>Daucus carota</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		1.32	1.98	kg a.i./ha	n.a.	Application time: pre-emergence
Garlic	<i>Allium sativum</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1		1.00	2.00	kg a.i./ha	75	PHI=75 days, only in Italy
Onions	<i>Allium cepa</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		13		1		1.00	2.00	kg a.i./ha	75	PHI=75 days, only in Italy
Tomatoes	<i>Lycopersicon esculentum</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		0.40	2.00	kg a.i./ha	75	PHI=75 days, only in Italy
Peppers	<i>Capsicum annuum</i> , var <i>grossum</i> and var. <i>longum</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		0.40	2.00	kg a.i./ha	75	PHI=75 days, only in Italy
Aubergines (egg plants)	<i>Solanum melongena</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1		0.40	2.00	kg a.i./ha	75	PHI=75 days, only in Italy
Melons	<i>Cucumis melo</i>	SEU	Outdoor	FR	Weeds	CS	400.0	g/L	Soil treatment - spraying		19		1		1.32		kg a.i./ha	n.a.	Application time: post planting pre-emergence
Broccoli	<i>Brassica oleracea</i> var. <i>italica</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1		1.00	2.00	kg a.i./ha	100	Application time: pre-transplanting PHI=100 days, only in Italy
Cauliflower	<i>Brassica oleracea</i> var. <i>botrytis</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1		1.00	2.00	kg a.i./ha	100	Application time: pre-transplanting PHI=100 days, only in Italy
Head cabbage	<i>Brassica oleracea</i> <i>convar capitata</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1		1.00	2.00	kg a.i./ha	100	Application time: pre-transplanting PHI=100 days, only in Italy
Lettuce	<i>Lactuca sativa</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1		0.50	1.65	kg a.i./ha	n.a.	Application time: pre-transplanting

Critical Outdoor Gaps for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application						Application rate			PHI or waiting period (days)	Comments (max. 250 characters)	
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate			Rate Unit
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Scarole (broad-leaf endive)	<i>Cichorium endiva</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1			0.50	1.65	kg a.i./ha	n.a.	Application time: pre-transplanting
Witloof	<i>Cichorium intybus</i> . var. <i>Foliosum</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1			0.50	1.65	kg a.i./ha	n.a.	Application time: pre-transplanting
Beans (with pods)	<i>Phaseolus vulgaris</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			0.80	2.00	kg a.i./ha	n.a.	
Beans (without pods)	<i>Phaseolus vulgaris</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			0.80	2.00	kg a.i./ha	n.a.	
Peas (with pods)	<i>Pisum sativum</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	2.00	kg a.i./ha	n.a.	
Peas (without pods)	<i>Pisum sativum</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	2.00	kg a.i./ha	n.a.	
Lentils (fresh)	<i>Lens culinaris</i> syn. <i>L. esculenta</i>	SEU	Outdoor	FR	Weeds	EC	250.0	g/L	Soil treatment - spraying		8		1			0.55		kg a.i./ha	63	Method: Broadcast spray; Time application: pre-emergence
Asparagus	<i>Asparagus officinalis</i>	SEU	Outdoor	IT	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.00	2.00	kg a.i./ha	60	Application time: pre-transplanting, pre-sprouting
Celery	<i>Apium graveolens</i> var. <i>dulce</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.00	2.00	kg a.i./ha	n.a.	Application time: pre-transplanting, pre-sprouting
Fennel	<i>Foeniculum vulgare</i>	SEU	Outdoor	IT	Weds	CS	365.0	g/L	Soil treatment - spraying	0	13		1			0.45	0.73	kg a.i./ha	75	Other application time (limited to 1 application per season): pre-emergence (BBCH 00-03) 920 g/ha, pre-transplanting (on bare soil after tillering) 920 g/ha
Globe artichokes	<i>Cynara scolymus</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.00	2.00	kg a.i./ha	60	Application time: pre-transplanting, pre-sprouting PHI=60 days, only in Italy
Beans (dry)	<i>Phaseolus vulgaris</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	2.00	kg a.i./ha	n.a.	
Peas (dry)	<i>Pisum sativum</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	2.00	kg a.i./ha	n.a.	
Lupins	<i>Lupinus spp.</i>	SEU	Outdoor	FR	Weeds	CS	400.0	g/L	Foliar treatment - spraying		11		1				1.20	kg a.i./ha	90	Application Time: pre or post-emergence
Peanuts	<i>Arachis hypogaea</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		0		1			1.32	1.98	kg a.i./ha	n.a.	Application time: pre-plant incorporated
Sunflower seed	<i>Helianthus annuus</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying	0	9		1				2.00	kg a.i./ha	n.a.	Application time: pre-emergence
Soya bean	<i>Glycine max</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Soil treatment - spraying	0	9		1				2.00	kg a.i./ha	n.a.	Application time: pre-emergence
Cotton seed	<i>Gossypium spp.</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Soil treatment - spraying		8		1			1.32	2.00	kg a.i./ha	n.a.	Application time: pre-emergence
Barley	<i>Hordeum spp.</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			1.00	2.00	kg a.i./ha	90	PHI=90 days, only in Italy
Maize	<i>Zea mays</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			1.00	1.98	kg a.i./ha	90	PHI=90 days, only in Italy. France has an outdoor GAP on maize forage: 1x1,12 kg a.i./ha, PHI=90 days and application time: pre-emergence BBCH 07.
Millet	<i>Panicum spp.</i>	SEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		16		1			1.20		kg a.i./ha	120	ES GAP: 1x1,35 kg a.s./ha; BBCH 08 (pre-emergence) equivalent
Oats	<i>Avena fatua</i>	SEU	Outdoor	ES	Weeds	EC	250.0	g/L	Soil treatment - spraying		9		1			1.14	1.35	kg a.i./ha	n.a.	
Rice	<i>Oryza sativa</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Foliar treatment - spraying		9		1			1.14	1.35	kg a.i./ha	n.a.	PHI=90 days, only in Italy
Rye	<i>Secale cereale</i>	SEU	Outdoor		Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			1.00	2.00	kg a.i./ha	90	PHI=90 days, only in Italy
Sorghum	<i>Sorghum bicolor</i>	SEU	Outdoor	FR	Weeds	CS	455.0	g/L	Soil treatment - spraying		16		1			1.20		kg a.i./ha	120	ES GAP: 1x1,35 kg a.s./ha; BBCH 08 (pre-emergence) equivalent
Wheat	<i>Triticum aestivum</i>	SEU	Outdoor	ES	Weeds	CS	455.0	g/L	Foliar treatment - spraying		16		1			1.00	2.00	kg a.i./ha	90	PHI=90 days, only in Italy
Alfalfa	<i>Medicago Sativa</i>	SEU	Outdoor	FR	Weeds	EC	250.0	g/L	Foliar treatment - spraying		11	1	2			0.50	1.00	kg a.i./ha	n.a.	Method: broadcast spray; Application time: early post-emergence. Every two years.
Maize (for forage)	<i>Zea mays</i>	SEU	Outdoor	FR	Weeds	EC	250.0	g/L	Foliar treatment - spraying		7		1			1.12		kg a.i./ha	90	Method: broadcast spray.

## Review of the existing MRLs for pendimethalin

<b>Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)</b>																				
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			Growth stage	Number		Interval (days)		Min. rate	Max. rate	Rate Unit			
							Conc.	Unit			From BBCH	Until BBCH	Min.	Max.				Min.		
Melons	<i>Cucumis melo</i>	NEU/SEU	Indoor	FR	Weeds	CS	400.0	g/L	Soil treatment - spraying		19		1				1.32	kg a.i./ha	n.a.	Application time: post-planting, pre-emergence

<b>Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments)</b>																				
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			Growth stage	Number		Interval (days)		Min. rate	Max. rate	Rate Unit			
							Conc.	Unit			From BBCH	Until BBCH	Min.	Max.				Min.		
Sugar cane	<i>Saccharum officinarum</i>	non-EU	Outdoor	FR	Weeds	SC	400.0	g/L	Soil treatment - spraying				1				2.00	kg a.i./ha		Method: broadcast spray; Application time: before transplanting; PHI: 8 months

## APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

<b>Pendimethalin</b>								
Status of the active substance:			<b>Included</b>		Code no.:			
LOQ (mg/kg bw):					proposed LOQ:			
Toxicological end points								
ADI (mg/kg bw/day):			<b>0,125</b>		ARfD (mg/kg bw):		<b>n.n</b>	
Source of ADI:			<b>EC</b>		Source of ARfD:		<b>EC</b>	
Year of evaluation:			<b>2003</b>		Year of evaluation:		<b>2003</b>	
Chronic risk assessment - refined calculations								
			TMDI (range) in % of ADI minimum - maximum 0                      1					
			<b>No of diets exceeding ADI:</b>					
			---					
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)
1,3	DE child	0,5	Apples	0,2	Wheat	0,1	Milk and milk products: Cattle	
1,3	NL child	0,3	Apples	0,2	Potatoes	0,2	Milk and milk products: Cattle	
1,3	WHO Cluster diet B	0,3	Wheat	0,1	Tomatoes	0,1	Potatoes	
0,9	IE adult	0,1	Maize	0,1	Maize	0,1	Potatoes	
0,9	DK child	0,2	Wheat	0,2	Rye	0,1	Potatoes	
0,9	WHO cluster diet D	0,3	Wheat	0,2	Potatoes	0,0	Tomatoes	
0,8	WHO cluster diet E	0,2	Wheat	0,2	Potatoes	0,1	Wine grapes	
0,8	FR toddler	0,2	Potatoes	0,1	Apples	0,1	Apples	
0,8	FR infant	0,2	Milk and milk products: Cattle	0,2	Potatoes	0,1	Carrots	
0,8	PT General population	0,2	Potatoes	0,2	Wheat	0,1	Wine grapes	
0,7	SE general population 90th percentile	0,2	Potatoes	0,1	Wheat	0,1	Milk and milk products: Cattle	
0,7	WHO regional European diet	0,2	Potatoes	0,1	Wheat	0,0	Tomatoes	
0,7	WHO Cluster diet F	0,1	Wheat	0,1	Potatoes	0,0	Milk and milk products: Cattle	
0,7	ES child	0,2	Wheat	0,1	Milk and milk products: Cattle	0,1	Potatoes	
0,6	UK Toddler	0,2	Wheat	0,1	Potatoes	0,1	Apples	
0,6	UK Infant	0,1	Potatoes	0,1	Wheat	0,1	Apples	
0,5	NL general	0,1	Potatoes	0,1	Wheat	0,1	Milk and milk products: Cattle	
0,5	FR all population	0,2	Wine grapes	0,1	Wheat	0,0	Potatoes	
0,5	IT kids/toddler	0,3	Wheat	0,1	Tomatoes	0,0	Potatoes	
0,4	ES adult	0,1	Wheat	0,0	Milk and milk products: Cattle	0,0	Potatoes	
0,4	LT adult	0,1	Potatoes	0,1	Apples	0,0	Rye	
0,4	IT adult	0,2	Wheat	0,0	Tomatoes	0,0	Apples	
0,4	PL general population	0,1	Potatoes	0,1	Apples	0,0	Tomatoes	
0,4	DK adult	0,1	Wheat	0,1	Potatoes	0,1	Wine grapes	
0,4	UK vegetarian	0,1	Wheat	0,1	Potatoes	0,0	Wine grapes	
0,3	UK Adult	0,1	Wheat	0,1	Potatoes	0,0	Wine grapes	
0,2	FI adult	0,0	Potatoes	0,0	Wheat	0,0	Rye	

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

## APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 03/04/2012 14:22))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, 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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
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 cloudberries)	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), pommerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
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 mammy 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	
210000	(i) Root and tuber vegetables	
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	

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
	vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,2
213030	Celeriac	0,1
213040	Horseradish	0,2
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,2
213070	Parsley root	0,2
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	Tumips	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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
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*
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	0,5 <sup>(a)</sup>
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,5 <sup>(a)</sup>
243020	Kale (Borecole (curly kale), collards)	0,5 <sup>(a)</sup>
243990	Others	0,5 <sup>(a)</sup>
244000	(d) Kohlrabi	0,3 <sup>(a)</sup>
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,05*
251010	Lamb's lettuce (Italian comsalad)	0,05*
251020	Lettuce (Head lettuce, lollo 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,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
	sorrel, glasswort)	
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	0,6*
256020	Chives	0,6 <sup>(a)</sup>
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,6 <sup>(a)</sup>
256040	Parsley	2 <sup>(a)</sup>
256050	Sage (Winter savory, summer savory, )	2 <sup>(a)</sup>
256060	Rosemary	0,6 <sup>(a)</sup>
256070	Thyme ( marjoram, oregano)	0,6 <sup>(a)</sup>
256080	Basil (Balm leaves, mint, peppermint)	0,6 <sup>(a)</sup>
256090	Bay leaves (laurel)	0,6 <sup>(a)</sup>
256100	Tarragon (Hyssop)	0,6 <sup>(a)</sup>
256990	Others	0,6 <sup>(a)</sup>
260000	(vi) Legume vegetables (fresh)	0,2
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,2
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,2
260030	Peas (with pods) (Mangetout (sugar peas))	0,2
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,2
260050	Lentils	0,2
260990	Others	0,2
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,1
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
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	
300000	3. PULSES, DRY	0,2
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,2
300020	Lentils	0,2
300030	Peas (Chickpeas, field peas, chickling vetch)	0,2
300040	Lupins	0,2
300990	Others	0,2
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
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*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomile 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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
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*
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	Tumeric (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*

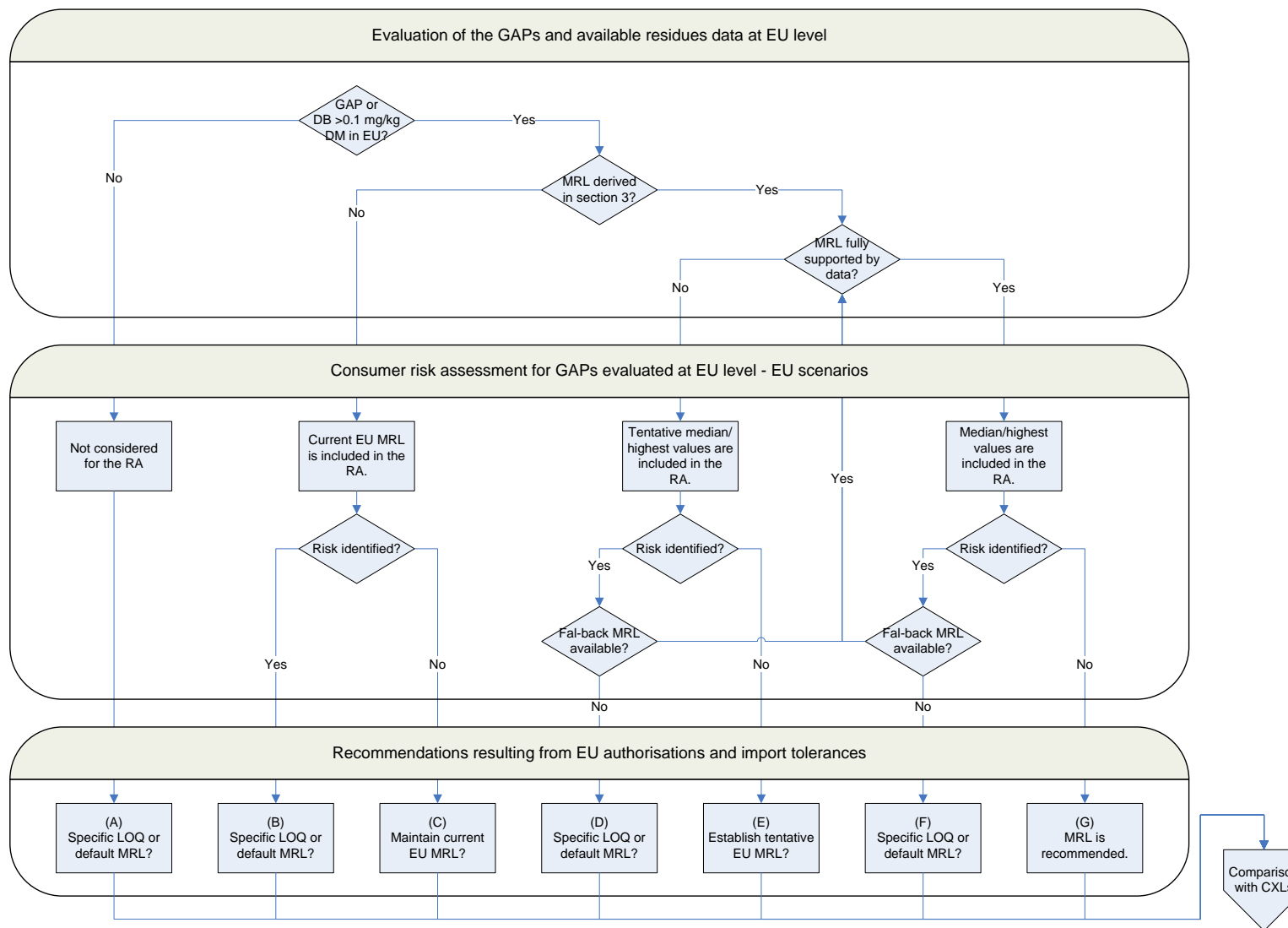
Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing	0,05*

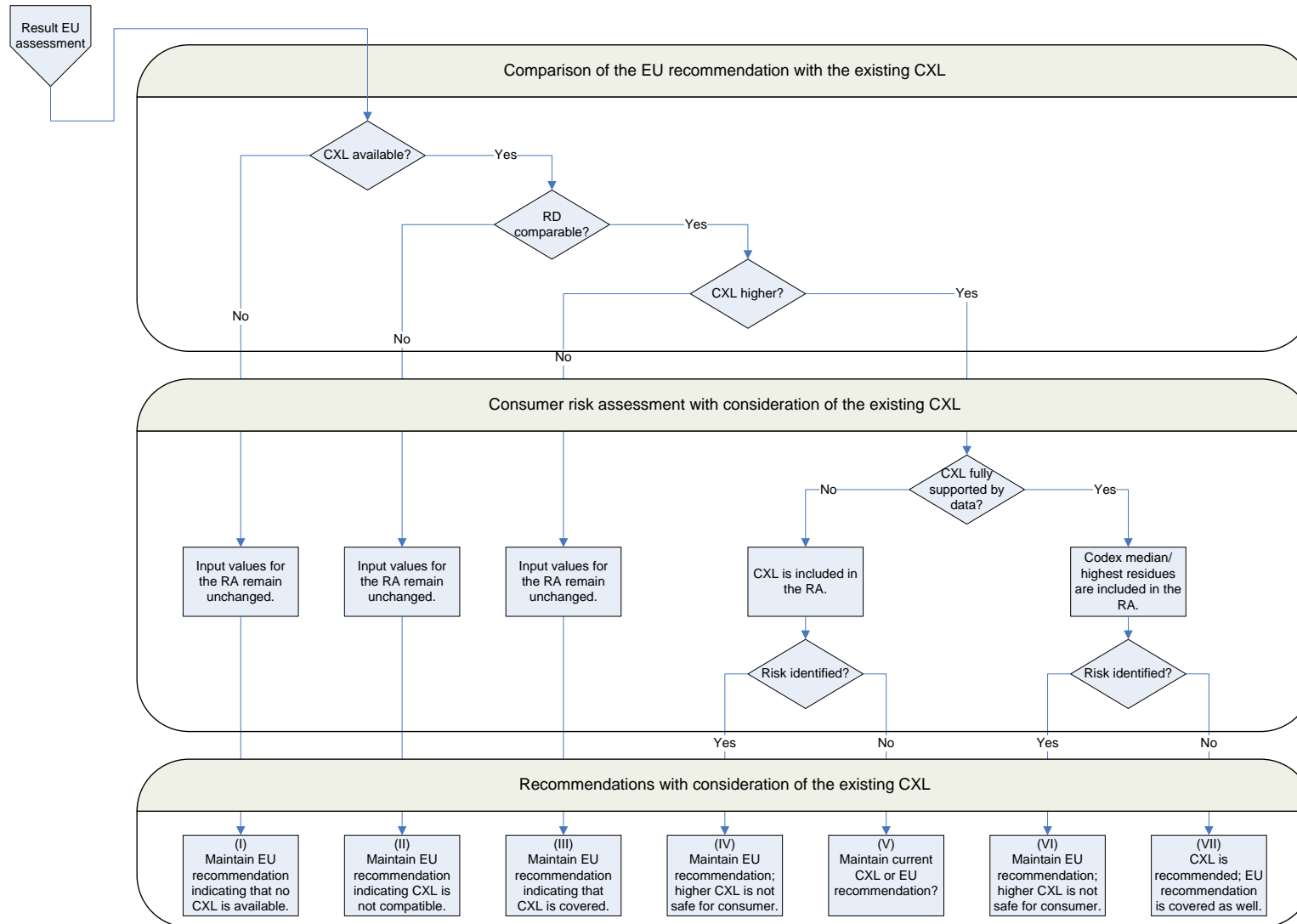
Code number	Groups and examples of individual products to which the MRLs apply (a)	Pendimethalin (F)
	added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(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	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
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  
(a) Value voted during SCFCAH, not yet legally implemented (SANCO/12782/2011)

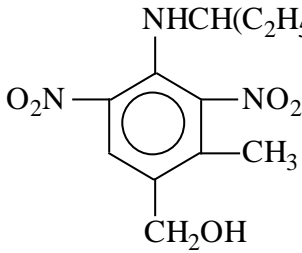
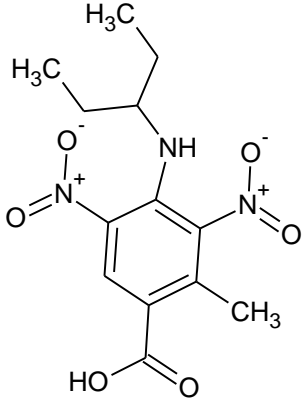
**APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS**







**APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA**

Common name	IUPAC name	Structural formula
4-hydroxymethyl- pendimethalin	4-[(1-ethylpropyl)amino]-2-methyl-3,5-dinitrobenzyl alcohol	
4-carboxylic pendimethalin acid	2-methyl-3,5-dinitro-4-(pentan-3-ylamino)benzoic acid	

## ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
EC	emulsifiable concentrate
EC	European Commission
EFSA	European Food Safety Authority
eq	equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography coupled with electron capture detection
GC-MS	gas chromatography coupled with mass spectrometry detection
GC-MS/MS	gas chromatography with tandem mass spectrometry
GC-NPD	gas chromatography coupled with nitrogen/phosphorous detection
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
L	litre
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
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
Rber	statistical calculation of the MRL by using a non-parametric method
Rmax	statistical calculation of the MRL by using a parametric method
RMS	rappporteur Member State
RSD	relative standard deviation
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
TRR	total radioactive residue