

REASONED OPINION

Review of the existing maximum residue levels (MRLs) for ethalfluralin according to Article 12 of Regulation (EC) No 396/2005¹

European Food Safety Authority^{2, 3}

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SUMMARY

A decision not to include ethalfluralin in Annex I to Directive 91/414/EEC entered into force on 12 December 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(1) of Regulation (EC) No 396/2005. Considering that the use of ethalfluralin is no longer authorised within the European Union and that no import tolerances were notified by the designated rapporteur Member State Greece, EFSA based its assessment mainly on the conclusions derived by Greece in the framework of Directive 91/414/EEC.

On 10 March 2011 EFSA issued a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 13 May 2011 were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of ethalfluralin was evaluated by Greece in the framework of Directive 91/414/EEC. Based on the available information, Greece proposed an ADI of 0.042 mg/kg bw/d. An ARfD was not considered necessary. EFSA emphasizes that these toxicological reference values have never been peer reviewed, neither by Member States, nor by EFSA.

Considering that the use of ethalfluralin is no longer authorised within the EU, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of ethalfluralin are not expected to occur in any plant commodity. Nevertheless, primary crop metabolism of ethalfluralin was investigated for four different crop groups (root vegetable, pulses and oilseeds, fruits and cereals). A number of metabolites were formed but all occurred at low levels and were mainly associated with natural constituents of the plant. None of the metabolites in edible commodities were considered to be relevant. Consequently, parent ethalfluralin is considered to be the only relevant residue for enforcement of a potential illegal use. There are indications that this residue may be enforced with a LOQ of 0.01 mg/kg in high water and high oil content commodities.

Residues of ethalfluralin are also not expected to occur in livestock. Moreover, studies on the metabolism of ethalfluralin in lactating goats, lactating cow and laying hens demonstrated that,

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despite a high dosing rate, negligible residues are present in the edible tissues, eggs and milk. No validated analytical methods for enforcement of residues in product of animal origin are available.

A risk assessment is in principle not required considering that the use is no longer authorised in the EU and that no import tolerances have been notified but, assuming the ADI proposed by the RMS, the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer.

Consequently the existing EU MRLs in plants commodities, exceeding the default MRL of 0.01 mg/kg are in principle no longer required. Considering however that the enforcement of potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, should apply or whether the setting of a specific LOQ is necessary. Available data indicate that the default MRL of 0.01 mg/kg could be enforced in practice, although this was only demonstrated in high water and high oil content commodities.

KEY WORDS

ethalfluralin, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, 2,6-dinitroaniline, herbicide.

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting as well as the review of pesticide MRLs at Community level. Article 12(1) of that regulation lays down that EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC a reasoned opinion on the review of the existing MRLs for that active substance. As a decision not to include ethalfluralin in Annex I to Directive 91/414/EEC entered into force on 12 December 2008, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00046 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 the few representative uses evaluated in the framework of that directive might no longer be relevant because the use of active substances that are not included in Annex I is not allowed within the EU. Moreover, non-included substances might still be authorised in third countries requiring the establishment of import tolerances in Regulation (EC) No 396/2005.

In order to have an overview on the pesticide residues data that have been considered for the setting of import tolerances, 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.

Greece, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for ethalfluralin and to prepare a supporting evaluation report. An evaluation report was submitted on 30 March 2010 confirming that no import tolerances for this active substance were notified to the RMS. Submission of a PROFile was therefore not considered relevant.

A draft reasoned opinion was issued by EFSA on 10 March 2011 and submitted to Member States (MS) for commenting. All MS comments received by 13 May 2011 were considered by EFSA for finalization of the reasoned opinion.

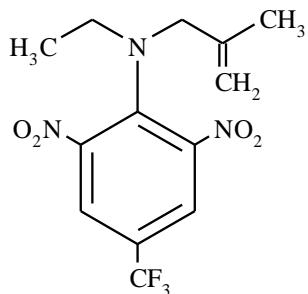
TERMS OF REFERENCE

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

Ethalfluralin is the ISO common name for N-ethyl- α,α,α -trifluoro-N-(2-methylallyl)-2,6-dinitro-p-toluidine (IUPAC). Ethalfluralin is a fat soluble compound ($\text{Log } P_{\text{OW}}=5.11$ at $22 \pm 2^\circ\text{C}$).



Ethalfluralin belongs to the group of 2,6-dinitroaniline compounds which are used as herbicide with contact action. In practice, sensitive seedlings treated with ethalfluralin often do not emerge. Ethalfluralin inhibits mitotic cell division in the tips of roots and shoots.

Ethalfluralin was evaluated in the framework of Directive 91/414/EEC with Greece being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was pre-sowing or pre-planting soil application on cotton, sunflower and tomatoes. Following the draft assessment report submission, however, the notifier voluntarily withdrew, in accordance with Article 11e of Regulation (EC) No1490/2002⁴, its support for the inclusion of ethalfluralin in Annex I to Directive 91/414/EEC. Consequently, a decision on non-inclusion of the active substance was published by means of Commission Decision 2008/934/EC⁵, entering into force on 12 December 2008. According to this Commission Decision, any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC shall expire on 31 December 2011 at the latest.

EU MRLs for ethalfluralin in products of plant and animal origin have been set for the first time in 2008 by means of Commission Regulation (EC) No 149/2008⁶ establishing Annexes II, III and IV of Regulation (EC) No 396/2005. These temporary MRLs were derived from the MRLs that have been set at national level before Regulation (EC) No 396/2005 entered into force. All existing EU MRLs, which are established for the parent compound only, are summarized in Appendix B to this document. CXLs for ethalfluralin are not available.

According to the decision of non-inclusion in the Annex I of Directive 91/414/EEC, plant protection products containing ethalfluralin are not authorised in EU Member States. For the purpose of this MRL review, the RMS did not report any use authorised in third countries that might have a significant impact on international trade

⁴ Commission Regulation (EC) No 1490/2002 of 14 August 2002. OJ L 224, 21.8.2002, p. 23-48.

⁵ Commission Decision 2008/934/EC of 5 December 2008, O.J.L 333, 11.12.2008, p11-14

⁶ Commission Regulation (EC) No 149/2008 of 29 January 2008. OJ L 58, 1.3.2008, p. 1-398.

ASSESSMENT

Considering that the use of ethalfluralin is no longer authorised within the EU, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, European consumers are not expected to be exposed to residues of this active substance and a consumer risk assessment is, in principle, not required. Risk managers might have the interest, however, to enforce the potential illegal use of ethalfluralin within the EU as well as the presence of illegitimate residue levels in imported products. In order to assist risk managers in applying the most appropriate enforcement measures, EFSA assessed the available data with particular attention for the analytical methods, the toxicological reference values and the nature of residues in plants and livestock. The assessment of EFSA is mainly based on the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Greece, 2007).

1. Methods of analysis

During the peer review under Directive 91/414/EC, an analytical method using GC-ECD for determination of parent ethalfluralin and its ILV were evaluated and validated in plant matrices with a LOQ of 0.01 mg/kg for high water (tomatoes) and high oil (cotton seed, sunflower seed) content commodities (Greece, 2007). A confirmatory method has been provided but it is not fully validated (linearity and precision are not reported).

Hence there are clear indications that parent ethalfluralin can be enforced in high water and high oil content commodities with a LOQ of 0.01 mg/kg.

Analytical methods for enforcement of residues in commodities of animal origin were not reported.

2. Mammalian toxicology

The toxicological assessment of ethalfluralin was not peer reviewed due to the voluntary withdraw by the notifier under Directive 91/414/EEC but toxicological reference values were established by Greece (2007). 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
ethalfluralin					
ADI	DAR	2007	0.042 mg/kg bw/d	2-year dietary study in the Fischer 344 rat	100
ARfD	DAR	2007	n.n.	n.n.	n.n.

n.n.: not necessary

3. Residues

3.1. Nature and magnitude of residues in plant

Considering that the use of ethalfluralin is no longer authorised within the EU, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of ethalfluralin are not expected to occur in any plant commodity. Nevertheless, metabolism of ethalfluralin was investigated for soil application on various crops, using

[U-phenyl-¹⁴C] radio-labelled ethalfluralin (Greece, 2007). Validated metabolism studies are summarized in table 3-1.

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

Group	Crop	Label position	Type(F) or (G) or (I) ^(a)	Application details			
				Rate	No	Sampling	Remarks
Root and tuber vegetables	potatoes	[U phenyl ¹⁴ C] ethalfluralin	early post-emergence when the plants were on average 15 cm high (F)	8.96 and 18.0 kg a.s./ha	1	control and treated tubers were harvested 68 DAT	mixture with non-radiolabelled ethalfluralin two treatment rates with specific activities of 5.16 and 1.77 µCi/mg
Pulses and oilseed	peanuts	[U phenyl ¹⁴ C] ethalfluralin	incorporated into the soil before sowing (F)	1.12 kg a.s./ha	1	142 DAT	
	cotton	[U phenyl ¹⁴ C] ethalfluralin	incorporated into the top 7.5 cm before sowing (F)	0.56 kg a.s./ha or 1.12 kg a.s./ha	1	6 and 12 weeks or 11 and 15 weeks immature crops in 1973 and 1974 respectively 5 months after treatment (mature crops)	
	green beans	[U phenyl ¹⁴ C] ethalfluralin	incorporated to a depth of 7 to 8 cm before sowing (F)	1.68 kg a.s./ha	1	39 , 53 (immature whole plants), 59 (whole plant and edible pods) and 81 DAT (mature dry seed, pods and stems).	

Group	Crop	Label position	Type/(F) or (G) or (I) ^(a)	Application details			
				Rate	No	Sampling	Remarks
Pulses and oilseed	peas	[U phenyl ¹⁴ C] ethalfluralin	incorporated to a depth of 7 to 8 cm before sowing (F)	1.00 kg a.s./ha	1	39 (immature whole plants), 59 (whole plant, edible pods and edible seed) and 81 DAT (mature dry seed, pods and stems).	
	dry beans	[U phenyl ¹⁴ C] ethalfluralin	incorporated to a depth of 7 to 8 cm before sowing (F)	1.68 kg a.s./ha	1	39 (immature whole plants), 59 (immature whole plants) and 87 DAT (mature dry seeds, pods and stems).	
Cereals	corn	[U phenyl ¹⁴ C] ethalfluralin	incorporated into the top 7.5 cm before sowing (F)	0.56 kg a.s./ha or 1.68 kg a.s./ha	1	5 and 12 weeks (immature crops) and 5 month after treatment (mature crops)	
	corn	[U phenyl ¹⁴ C] ethalfluralin	sprayed onto the soil surface Immediately before sowing (F)	1.25 kg a.s./ha	1	66 (forage samples), 109 (silage samples) and 136 DAT (mature samples)	mixture with non-radiolabelled technical ethalfluralin to a specific radioactivity of 1.74 µCi/mg
Fruits and fruiting vegetables	cucumber	[U phenyl ¹⁴ C] ethalfluralin	spread onto the soil surface, then watered in, prior to sowing (F)	1.68 kg a.s./ha	1	Haulm: 26, 32, and 50 DAT Fruits: 60, 70, 75, 76, 104 DAT	

(a): Outdoor or field use (F), glasshouse application (G) or indoor application (I)

The metabolism of ethalfluralin has been investigated in four different crop groups (root vegetable, pulses and oilseeds, fruits and cereals). In plants, parent ethalfluralin was absent or present at very low levels in all treated commodities. A number of metabolites were formed but all occurred at low

levels and were associated with natural constituents of the plant. None of the metabolites in edible commodities exceeded 10% of the total radioactive residues or 0.01 mg/kg, and none are considered to be relevant.

Based on the results of the metabolism studies, EFSA concludes that parent ethalfluralin is the only relevant residue for enforcement of a potential illegal use. There are indications that this residue could be enforced with a LOQ of 0.01 mg/kg in high water and high oil content commodities (see section 1).

3.2. Nature and magnitude of residues in livestock

Residues of ethalfluralin are also not expected to occur in livestock. In addition, studies on the metabolism of ethalfluralin in lactating goats, lactating cow and laying hens were submitted and evaluated in the framework of Directive 91/414/EEC. In these studies, despite a high dosing rate, negligible residues were present in the edible tissues, eggs and milk (Greece, 2007). No validated analytical methods for enforcement of residues in product of animal origin are available (see also section 1).

4. Consumer risk assessment

A risk assessment is in principle not required considering that the use is no longer authorised in the EU and that no import tolerances have been notified. In order to assess whether the default MRL of 0.01 mg/kg as defined by Regulation (EC) No 396/2005 is sufficiently protective for European consumers, chronic intake calculations assuming the toxicological reference values proposed by the RMS and a LOQ of 0.01 mg/kg for all products of plant and animal origin were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Acute intake calculations were not carried out because and ARfD was not deemed necessary by the RMS.

The detailed results of the chronic intake calculations are reported in Appendix A to this document. The highest chronic exposure was calculated for UK infants, French toddlers and Dutch children representing 1.6 % of the ADI. EFSA highlights that the above calculation does not reflect real exposure of consumers to ethalfluralin residues; it is a theoretical calculation indicating that the default MRL of 0.01 mg/kg provides a satisfactory level of protection for the European consumer.

CONCLUSIONS AND RECOMMENDATIONS

The toxicological profile of ethalfluralin was evaluated by Greece in the framework of Directive 91/414/EEC. Based on the available information, Greece proposed an ADI of 0.042 mg/kg bw/d. An ARfD was not considered necessary. EFSA emphasizes that these toxicological reference values have never been peer reviewed, neither by Member States, nor by EFSA.

Considering that the use of ethalfluralin is no longer authorised within the EU, that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of ethalfluralin are not expected to occur in any plant commodity. Nevertheless, primary crop metabolism of ethalfluralin was investigated for four different crop groups (root vegetable, pulses and oilseeds, fruits and cereals). A number of metabolites were formed but all occurred at low levels and were mainly associated with natural constituents of the plant. None of the metabolites in edible commodities were considered to be relevant. Consequently, parent ethalfluralin is considered to be the only relevant residue for enforcement of a potential illegal use. There are indications that this residue may be enforced with a LOQ of 0.01 mg/kg in high water and high oil content commodities.

Residues of ethalfluralin are also not expected to occur in livestock. Moreover, studies on the metabolism of ethalfluralin in lactating goats, lactating cow and laying hens demonstrated that, despite a high dosing rate, negligible residues are present in the edible tissues, eggs and milk. No validated analytical methods for enforcement of residues in product of animal origin are available.

A risk assessment is in principle not required considering that the use is no longer authorised in the EU and that no import tolerances have been notified but, assuming the ADI proposed by the RMS, the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, provides a satisfactory level of protection for the European consumer.

Consequently the existing EU MRLs in plants commodities, exceeding the default MRL of 0.01 mg/kg are in principle no longer required. Considering however that the enforcement of potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend whether the default MRL of 0.01 mg/kg, as defined by Regulation (EC) No 396/2005, should apply or whether the setting of a specific LOQ is necessary. Available data indicate that the default MRL of 0.01 mg/kg could be enforced in practice, although this was only demonstrated in high water and high oil content commodities.

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- EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007.
- Greece, 2007. Draft assessment report on the active substance ethalfluralin prepared by the rapporteur Member State Greece in the framework of Council Directive 91/414/EEC, August 2007.

APPENDIX A – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

ethafluralin						
Status of the active substance:		Code no.				
LOQ (mg/kg bw):		0,01 proposed LOQ:				
Toxicological end points						
ADI (mg/kg bw/day):	0,042	ARID (mg/kg bw):	n.n.			
Source of ADI:	DAR	Source of ARID:	DAR			
Year of evaluation:	2007	Year of evaluation:	2007			

Explain choice of toxicological reference values.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations								
			TMDI (range) in % of ADI minimum - maximum 0 2					
No of diets exceeding ADI:			---					
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
1,6	UK Infant	0,9	Milk and cream,	0,2	Sugar beet (root)	0,1	Potatoes	1,6
1,6	FR toddler	0,9	Milk and cream,	0,1	Potatoes	0,1	Apples	1,6
1,6	NL child	0,7	Milk and cream,	0,2	Apples	0,1	Potatoes	1,6
1,5	UK Toddler	0,5	Sugar beet (root)	0,5	Milk and cream,	0,1	Wheat	1,5
1,3	DE child	0,3	Milk and cream,	0,3	Apples	0,1	Wheat	1,3
1,1	WHO Cluster diet B	0,2	Wheat	0,1	Milk and cream,	0,1	Tomatoes	1,1
1,1	FR infant	0,6	Milk and cream,	0,1	Potatoes	0,1	Carrots	1,1
1,0	DK child	0,3	Milk and cream,	0,1	Wheat	0,1	Rye	1,0
0,9	IE adult	0,1	Sweet potatoes	0,1	Milk and cream,	0,1	Maize	0,9
0,8	ES child	0,3	Milk and cream,	0,1	Wheat	0,1	Oranges	0,8
0,8	SE general population 90th percentile	0,3	Milk and cream,	0,1	Potatoes	0,1	Wheat	0,8
0,7	WHO cluster diet E	0,1	Wheat	0,1	Potatoes	0,1	Milk and cream,	0,7
0,7	WHO cluster diet D	0,2	Wheat	0,1	Milk and cream,	0,1	Potatoes	0,7
0,7	WHO regional European diet	0,1	Milk and cream,	0,1	Potatoes	0,1	Wheat	0,7
0,6	WHO Cluster diet F	0,1	Milk and cream,	0,1	Wheat	0,1	Potatoes	0,6
0,5	NL general	0,2	Milk and cream,	0,1	Potatoes	0,0	Wheat	0,5
0,5	PT General population	0,1	Potatoes	0,1	Wheat	0,1	Wine grapes	0,5
0,5	ES adult	0,1	Milk and cream,	0,1	Wheat	0,0	Oranges	0,5
0,4	FR all population	0,1	Wine grapes	0,1	Wheat	0,1	Milk and cream,	0,4
0,4	UK vegetarian	0,1	Sugar beet (root)	0,1	Milk and cream,	0,0	Wheat	0,4
0,4	DK adult	0,1	Milk and cream,	0,0	Wheat	0,0	Potatoes	0,4
0,4	IT kids/toddler	0,2	Wheat	0,0	Other cereal	0,0	Tomatoes	0,4
0,4	UK Adult	0,1	Sugar beet (root)	0,1	Milk and cream,	0,0	Wheat	0,4
0,4	LT adult	0,1	Milk and cream,	0,1	Potatoes	0,0	Apples	0,4
0,3	FI adult	0,1	Milk and cream,	0,0	Potatoes	0,0	Wheat	0,3
0,3	IT adult	0,1	Wheat	0,0	Tomatoes	0,0	Apples	0,3
0,2	PL general population	0,1	Potatoes	0,0	Apples	0,0	Tomatoes	0,2

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

APPENDIX B – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 24/01/2011 14:30)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
100000	I. FRUIT FRESH OR FROZEN; NUTS	0,02*
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
120000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
130000	(iii) Pome fruit	0,02*
130010	Apples (Crab apple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage,	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
	mirabelle)	
140990	Others	0,02*
150000	(v) Berries & small fruit	0,02*
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,02*
154020	Cranberries	0,02*
154030	Curants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azazole (mediterranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea swallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) Java apple (water apple), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Bread fruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,02*
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
213000	(c) Other root and tuber vegetables except sugar beet	0,02*
213010	Beetroot	0,02*
213020	Carrots	0,02*
213030	Celeriac	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,02*
213100	Swedes	0,02*
213110	Turnips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silverskin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanaceae	
231010	Tomatoes (Cherry tomatoes,)	0,02*
231020	Peppers (Chilli peppers)	0,05
231030	Aubergines (egg plants) (Pepino)	0,02*
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbits - edible peel	0,02*
232010	Cucumbers	0,02*
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,02*
232990	Others	0,02*
233000	(c) Cucurbits -inedible peel	0,02*
233010	Melons (Kiwano)	0,02*
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,02*
233990	Others	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
234000	(d) Sweet corn	0,02*
239000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	0,02*
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	0,02*
242010	Brussels sprouts	0,02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (ta goo choi), peking cabbage (pe-tsai), cow cabbage)	0,02*
243020	Kale (Borecole (curly kale), collards)	0,02*
243990	Others	0,02*
244000	(d) Kohlrabi	0,02*
250000	(v) Leaf vegetables & fresh herbs	0,02*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,02*
251010	Lamb's lettuce (Italian cosmolad)	0,02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
251990	Others	0,02*
252000	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
252990	Others	0,02*
253000	(c) Vine leaves (grape leaves)	0,02*
254000	(d) Water cress	0,02*
255000	(e) Witloof	0,02*
256000	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet ciley and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory,)	0,02*
256060	Rosemary	0,02*
256070	Thyme (marjoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (laurel)	0,02*
256100	Tarragon (Hyssop)	0,02*
256990	Others	0,02*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,1
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
260990	Others	0,02*
270000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bamboo shoots	0,02*
270090	Palm hearts	0,02*
270990	Others	0,02*
280000	(viii) Fungi	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,02*
280990	Others	0,02*
290000	(ix) Sea weeds	0,02*
300000	3. PULSES, DRY	
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
300990	Others	0,02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,02*
401020	Peanuts	0,05
401030	Poppy seed	0,02*
401040	Sesame seed	0,02*
401050	Sunflower seed	0,02*
401060	Rape seed (Bird rapeseed, turnip rape)	0,02*
401070	Soya bean	0,05
401080	Mustard seed	0,02*
401090	Cotton seed	0,02*
401100	Pumpkin seeds	0,02*
401110	Safflower	0,02*
401120	Borage	0,02*
401130	Gold of pleasure	0,02*
401140	Hempseed	0,02*
401150	Castor bean	0,02*
401990	Others	0,02*
402000	(ii) Oilfruits	0,02*
402010	Olives for oil production	0,02*
402020	Palm nuts (palmoil kernels)	0,02*
402030	Palmfruit	0,02*
402040	Kapok	0,02*
402990	Others	0,02*
500000	5. CEREALS	
500010	Barley	0,02*
500020	Buckwheat	0,02*
500030	Maize	0,1
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
500070	Rye	0,02*
500080	Sorghum	0,02*
500090	Wheat (Spelt Tritcale)	0,02*
500990	Others	0,02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i>)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomile flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Lime (linden)	0,02*
631990	Others	0,02*
632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPPS (dried) , including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Tumeric (Curcuma)	0,02*
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*
860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	0,01*
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	0,01*
1011000	(a) Swine	0,01*
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
1011990	Others	0,01*
1012000	(b) Bovine	0,01*
1012010	Meat	0,01*
1012020	Fat	0,01*
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	0,01*
1013010	Meat	0,01*
1013020	Fat	0,01*
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	0,01*
1014010	Meat	0,01*
1014020	Fat	0,01*
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	0,01*
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk and cream, not	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Ethalfluralin
	concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
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

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
GAP	good agricultural practice
GC-NPD	gas chromatography coupled with nitrogen phosphorous detection
ha	hectare
HPLC	high performance liquid chromatography
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue limit
MS/MS	tandem mass spectrometry
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	Pesticide Residues Overview File
RA	risk assessment

RD	residue definition
RMS	rapporteur Member State
TRR	total radioactive residue