European Food Safety Authority

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REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flutriafol according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance flutriafol. In order to assess the occurrence of flutriafol residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the import tolerances and European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still require further consideration by risk managers.

KEY WORDS

flutriafol, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazole, fungicide

[1] On request from EFSA, Question No EFSA-Q-2009-00057, approved on 05 May 2014.

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SUMMARY

Flutriafol was included in Annex I to Directive 91/414/EEC on 01 June 2011, which is after 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(1) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked United Kingdom, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 23 December 2011 and, after having considered several comments made by EFSA, the RMS provided on 13 December 2012 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 28 October 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 10 January 2014 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of flutriafol was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.01 mg/kg bw per d and 0.05 mg/kg bw, respectively.

Metabolism of flutriafol in primary crops was investigated for foliar application on fruits, root and tuber vegetables, oilseeds and cereals crop groups. Metabolic patterns in the different studies were shown to be similar, with the parent compound being the main compound of the TRR in all crops investigated, except in cereal grain, where the cleavage of flutriafol occurred, with the formation of triazole alanine and triazole acetic acid (TDMs). Based on these studies, EFSA proposes parent flutriafol as the residue definition for enforcement and risk assessment purpose pending a harmonized approach on how to consider TDMs in the risk assessment. The proposed residue definitions apply to foliar treatment in all plant commodities. Validated analytical methods for enforcement of the proposed residue definition are available.

Regarding the magnitude of residues in crops reported by the RMS, a sufficient number of residues trials is available for most of the GAPs reported by the RMS, which allowed EFSA to derive appropriate MRLs in the relevant plant commodities. However, for beetroot, tomatoes, melons, watermelons and rice grain, only tentative MRLs could be derived, while for strawberries, sweet corn, beet leaves, fresh lentils, asparagus, dry pulses, maize and oats grain the available data were insufficient to derive tentative MRLs.

Studies investigating the effects of processing on the nature of flutriafol were not provided and are required especially for pome fruits, tomatoes and wine grapes which are the main contributors to the exposure. Several processing studies investigating the magnitude of the residues of flutriafol in processed commodities are available. A robust processing factor for enforcement and risk assessment was derived only for peeled bananas; the processing factors for the other processed commodities were derived on a tentative basis. If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

The potential incorporation of soil residues into rotational crops was investigated in confined studies with lettuce, sugar beet, radish, peas, rape seed and wheat grown in rotation. It can be concluded that a specific residue definition in rotational crops is not necessary. In addition, several rotational crop field trials on root and tuber vegetables, cereals, oilseeds and leafy crops were evaluated. Based on these studies and considering the high persistence of flutriafol in soil, it can be concluded that, after one or several years of application of flutriafol in compliance with the authorised GAPs in Europe, flutriafol and the TDMs residue levels in the edible parts of the rotational crops are expected to exceed 0.01 mg/kg. EFSA therefore concludes that Member States granting authorisations for flutriafol should take the appropriate risk mitigation measures in order to avoid the presence of flutriafol and TDMs

residues in rotational crops. EFSA is also of the opinion that the maximum plateau concentration in soil should be revised in accordance with the authorised uses in Europe and it should be assessed whether the available rotational crops field trials cover this plateau concentration, in order to conclude on the actual residue levels of flutriafol and of the TDMs in the edible parts of the rotated crops.

Based on the uses reported by the RMS, significant exposures to flutriafol residues are expected for dairy, meat ruminants and pigs. The available ruminant metabolism data are not appropriate to derive robust residue definitions. Pending the availability of new metabolism data, the residue in ruminant and pig commodities is tentatively defined as parent flutriafol only, both for enforcement and risk assessment. Validated analytical methods for enforcement are available, except for fat. The available feeding study on lactating ruminants demonstrates that residues of flutriafol are not expected in quantifiable amounts in ruminant and pig meat, kidney and fat and in ruminant milk; MRLs in these commodities can be set at the LOQ. For ruminant and pig liver, MRLs of respectively 0.3 mg/kg and 0.1 mg/kg are proposed. All these MRLs are derived on a tentative basis only due to the identified data gaps, in particular regarding ruminant metabolism data. For poultry products, no residue definition needs to be set and no MRLs are proposed.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for the WHO Cluster diet B (33 % of the ADI) and the highest acute exposure was calculated for peppers (52 % of the ARfD).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for flutriafol. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure was then calculated for WHO Cluster diet B (34 % of the ADI) and the highest acute exposure, for table grapes (80 % of the ARfD).

Based on the above assessment, EFSA does not recommend the inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are 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 summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- An ILV and a confirmatory method for the enforcement of flutriafol residues in fat;
- 8 residue trials supporting the southern outdoor GAP on strawberries and 8 residue trials supporting the indoor GAPs on strawberries;
- 8 and 4 residue trials supporting respectively the northern and southern outdoor GAPs on beetroot;
- 8 residue trials supporting the indoor GAP on tomatoes and 8 residue trials supporting the southern outdoor GAP on tomatoes;
- 8 residue trials on melons supporting the indoor GAP on melons and watermenlons and 8 residue trials on melons supporting the southern outdoor GAP on melons and watermelons;
- 4 residue trials supporting the northern outdoor GAP on sweet corn;
- 4 residue trials supporting the northern outdoor GAP on beet leaves (chard) and 4 residue trials supporting the southern outdoor GAP on beet leaves (chard);
- 5 and 7 additional residue trials supporting respectively the northern and southern outdoor GAPs on fresh peas (without pods);
- 4 residue trials supporting the southern outdoor GAP on lentils (fresh);

- clarifications on the southern outdoor GAP (number of applications, PHI, application rate in g a.s./ha) on asparagus and 4 residue trials supporting that GAP;
- 8 residue trials on dry beans or dry peas supporting the northern outdoor GAP on dry pulses;
- 8 residue trials on barley supporting the southern outdoor GAP on barley and oats (mainly to support the MRL in oats because the MRL for barley is derived from the northern GAP and fully supported by data);
- 8 residue trials supporting the northern outdoor GAP on maize and 8 residue trials supporting the southern outdoor GAP on maize;
- 8 residue trials supporting the southern outdoor GAP on rice grain;
- data investigating the effect of processing on the nature of flutriafol residues in plant commodities (especially for pome fruits, tomatoes and wine grapes);
- an appropriate ruminant metabolism study with radiolabelling of both the carbinol and triazolyl moieties of flutriafol;
- storage conditions of the samples from the feeding studies.

It is highlighted that some of the MRLs derived result 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 MRLs derived but which might have an impact on national authorisations:

- 8 residue trials compliant with the southern outdoor GAP on apples;
- 8 residue trials supporting the southern outdoor GAP on peppers;
- 4 residue trials compliant with the southern outdoor GAP on rape seed;
- recalculation of the maximum plateau concentration of flutriafol residues in soil in accordance with the authorised European uses and assessment whether the available rotational crops field trials cover the maximum plateau concentration.

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 MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- information on the sample storage conditions of the residue trials performed on sugar beet (root), peppers, fresh peas (without pods), barley grain, rice grain and wheat grain (northern trials only).

It is noted by EFSA that the above assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above assessment does not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: flutriafol					
0130000	Pome fruit	0.4	0.3	0.4	Further consideration needed [a]
0140020	Cherries	1.5	-	1	Recommended [b]
0140030	Peaches	0.6	-	0.6	Recommended [b]
0140040	Plums	0.4	-	0.4	Recommended [b]
0151010	Table grapes	0.8	0.8	0.8	Recommended [c]
0151020	Wine grapes	1	0.8	1.5	Further consideration needed [a]
0152000	Strawberries	0.5	-	0.5	Further consideration needed [d]
0163020	Bananas	0.3	0.3	0.3	Recommended [e]
0213010	Beetroot	0.05*	-	0.06	Further consideration needed [f]
0231010	Tomatoes	0.3	-	0.6	Further consideration needed [f]
0231020	Peppers	1	1	1	Recommended [e]
0233010	Melons	0.3	-	0.2	Further consideration needed [f]
0233030	Watermelons	0.3	-	0.2	Further consideration needed [f]
0234000	Sweet corn	0.05*	-	0.05	Further consideration needed [d]
0252030	Beet leaves (chard)	0.05*	-	0.05	Further consideration needed [d]
0255000	Witloof	0.05*	-	0.01*	Recommended [b]
0260040	Peas (fresh, without pods)	0.1	-	0.1	Further consideration needed [d]
0260050	Lentils (fresh)	0.05*	-	0.05	Further consideration needed [d]
0270010	Asparagus	0.05*	-	0.05	Further consideration needed [d]
0300000	Pulses, dry	0.05*	-	0.05	Further consideration needed [d]
401020	Peanuts	0.2	0.15	0.15	Recommended [c]
0401060	Rape seed	0.2	-	0.5	Recommended [b]
0401070	Soya bean	0.4	0.4	0.4	Recommended [e]
0401080	Mustard seed	0.2	-	0.5	Recommended [b]
0401130	Gold of pleasure	0.2	-	0.5	Recommended [b]
0500010	Barley grain	0.5	-	0.15	Recommended [b]
0500030	Maize grain	0.5	-	0.5	Further consideration needed [d]
0500050	Oats grain	0.5	-	0.5	Further consideration needed [d]
0500060	Rice grain	0.5	-	1.5	Further consideration needed [f]
0500070	Rye grain	0.5	-	0.15	Recommended [b]
0500090	Wheat grain	0.5	0.15	0.15	Recommended [e]
0620000	Coffee beans	0.15	0.15	0.15	Recommended [c]
0900010	Sugar beet (root)	0.1	-	0.06	Recommended [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011010	Swine muscle	0.01*	-	0.01*	Further consideration needed (f)
1011020	Swine fat	0.01*	-	0.01*	Further consideration needed (f)
1011030	Swine liver	0.01*	-	0.1	Further consideration needed (f)
1011040	Swine kidney	0.01*	-	0.01*	Further consideration needed (f)
1012010	Bovine muscle	0.01*	-	0.01*	Further consideration needed (f)
1012020	Bovine fat	0.01*	-	0.01*	Further consideration needed (f)
1012030	Bovine liver	0.01*	-	0.3	Further consideration needed (f)
1012040	Bovine kidney	0.01*	-	0.01*	Further consideration needed (f)
1013010	Sheep muscle	0.01*	-	0.01*	Further consideration needed (f)
1013020	Sheep fat	0.01*	-	0.01*	Further consideration needed (f)
1013030	Sheep liver	0.01*	-	0.3	Further consideration needed (f)
1013040	Sheep kidney	0.01*	-	0.01*	Further consideration needed (f)
1014010	Goat muscle	0.01*	-	0.01*	Further consideration needed (f)
1014020	Goat fat	0.01*	-	0.01*	Further consideration needed (f)
1014030	Goat liver	0.01*	-	0.3	Further consideration needed (f)
1014040	Goat kidney	0.01*	-	0.01*	Further consideration needed (f)
1020010	Cattle milk	0.01*	-	0.01*	Further consideration needed (f)
1020020	Sheep milk	0.01*	-	0.01*	Further consideration needed (f)
1020030	Goat milk	0.01*	-	0.01*	Further consideration needed (f)
-	Other products of plant and animal origin	See App C1	-	-	Further consideration needed (g)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(e): 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; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(1) of that regulation stipulates that EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[5] a reasoned opinion on the review of the existing MRLs for that active substance. As flutriafol was included in Annex I to the above mentioned directive on 01 June 2011, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00057 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 all uses authorised within the EU, and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

United Kingdom, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for flutriafol and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 23 December 2011 and subsequently checked for completeness. On 13 December 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 28 October 2013 and submitted to Member States (MS) for commenting. All MS comments received by 10 January 2014 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.

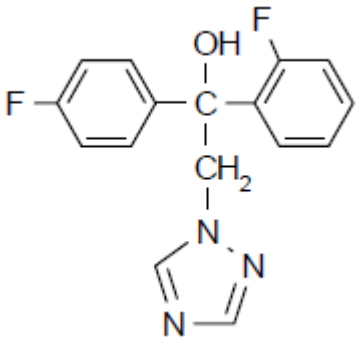
TERMS OF REFERENCE

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

Flutriafol is the ISO common name for (*RS*)-2,4′-difluoro-α-(1*H*-1,2,4-triazol-1-ylmethyl)benzhydryl alcohol (IUPAC).



Flutriafol belongs to the group of triazole compounds which are used as fungicide. It is a systemic compound which is absorbed by the foliage and translocated acropetally in the xylem. This broad spectrum fungicide has eradicant and protective action against leaf and cereal ear diseases, particularly embryo borne diseases such as bunts and smuts. By inhibiting the steroid demethylation step of ergosterol biosynthesis, it leads to fungal cell wall collapse and inhibition of hyphal growth.

Flutriafol was evaluated in the framework of Directive 91/414/EEC with the United Kingdom being the designated rapporteur Member State (RMS). The representative use initially supported for the peer review process was the outdoor foliar spraying treatment of wheat, with 2 applications at 0.125 kg a.s./ha until BBCH 55, in northern and southern Europe. However, the applicant voluntarily withdrew, in accordance with Article 11e of Regulation (EC) No 1490/2002[6], the support for the inclusion of flutriafol in Annex I to Directive 91/414/EEC. Consequently, a first decision on non-inclusion of the active substance was published by means of Commission Decision 2008/934/EC[7], which entered into force on 31 December 2008. In accordance with the provisions laid down in Chapter III of Regulation (EC) No 33/2008[8], flutriafol was subject to a resubmission procedure. The representative use supported was the same; i.e. on winter and spring wheat but restricted to a single application, between BBCH 40 and 55. Following the peer review, which was carried out by EFSA, a decision on inclusion

[6] Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000. OJ L 224, 21.8.2002, p.23-48.

[7] Commission Decision 2008/934/EC of 5 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances. OJ L 333, 11.12.2008, p11-14.

[8] Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I. OJ L 15, 18.01.2008, p.5-12.

of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2011/42/EU[9], which entered into force on 01 June 2011. According to Regulation (EU) No 540/2011[10], flutriafol is deemed to have been approved under Regulation (EC) No 1107/2009[11]. This approval is restricted to uses as fungicide only.

The EU MRLs for flutriafol are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for the import tolerances on apples, wine grapes and bananas (EFSA, 2010a) which were legally implemented in Regulation (EU) No 893/2010/EC[12]. In the same resoned opinion, EFSA did not recommend the modification of the MRLs for soya beans and table grapes. Nevertheless, the modification of the MRL for soya bean was legally implemented in Regulation No 978/2011/EU[13]. Finally, EFSA recommended the modification of the existing MRLs for the import tolerances on pome fruits, cherries, peaches and plums (EFSA, 2013) which were already approved by the meeting of the Standing Committee on the Food Chain and Animal Health held on 24-25 February 2014 but not yet legally implemented. CXLs for flutriafol were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. CXLs of flutriafol for pome fruits, soya bean and coffee beans were included by Regulation No 293/2013/EU[14]. A new MRL for honey (change of the LOQ value) was also implemented in that Regulation. In addition, the CXL for table grapes was already approved by the meeting of the Standing Committee on the Food Chain and Animal Health held on 18-19 November 2013 but not yet legally implemented. All existing EU MRLs, which are established for the parent compound only, are summarised in Appendix C.1 to this document. The CXLs refer to parent compound only.

For the purpose of this MRL review, the critical uses of flutriafol currently authorised within the EU as well as uses authorised in third countries that might have a significant impact on international trade, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). These GAPs include up to 3 foliar spray applications in northern and southern Europe on several categories of crops (fruits, and fruiting vegetables, root vegetables, pulses and oilseeds, cereals and sugar/fodder beet), at dose rates of 30-310 g a.s./ha and PHIs ranging between 1 and 35 days. Import tolerance uses were also reported including up to 8 foliar spray applications on fruits and soya bean, at dose rates of 61-128 g a.s./ha and PHIs ranging between 0 and 21 days.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the evaluation report accompanying the PROFile (United Kingdom, 2011), the Draft Assessment Report (DAR), the

[9] Commission Implementing Directive 2011/42/EU of 11 April 2011 amending Council Directive 91/414/EEC to include flutriafol as active substance and amending Commission Decision 2008/934/EC. OJ L 97, 12.4.2011, p. 42-45.

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

[11] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

[12] Commission Regulation (EU) No 893/2010 of 8 October 2010 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, bentazone, carbendazim, cyfluthrin, fenamidone, fenazaquin, flonicamid, flutriafol, imidacloprid, ioxynil, metconazole, prothioconazole, tebufenozide and thiophanate-methyl in or on certain products. OJ L 266, 9.10.2010, p. 10-38.

[13] Regulation (EU) No 978/2011 of 3 October 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, biphenyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, dithiocarbamates, epoxiconazole, ethephon, flutriafol, fluxapyroxad, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil and spirotetramat in or on certain products. OJ L 258, 4.10.2011, p. 12-69.

[14] Regulation (EU) No 293/2013 of 20 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, phosmet, pyraclostrobin, spinosad and spirotetramat in or on certain products. OJ L 96, 5.4.2013, p. 1-30.

additional report and its addendum prepared under Council Directive 91/414/EEC (United Kingdom, 2006, 2010a, 2010b), the conclusion on the peer review of the pesticide risk assessment of the active substance flutriafol (EFSA, 2010b), the JMPR Evaluation report (FAO, 2011), the previous reasoned opinions on flutriafol (EFSA, 2010a, 2013) as well as the evaluation report submitted during the consultation of Member States (Spain, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[15] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a-b, 2011 and OECD, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS/MS, confirmed by GC-TID and its ILV were evaluated and validated for the determination of flutriafol in plant matrices with an LOQ of 0.01 mg/kg in high water content (wheat whole plant, sugar beet root and foliage) and in dry commodities (wheat grain and dry pea) and with an LOQ of 0.05 mg/kg in wheat straw (United Kingdom, 2006).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for analysis of parent flutriafol with an LOQ of 0.01 mg/kg in high oil content and acidic commodities. For high water content and dry commodities, validation data were not evaluated in detail because a validated analytical method is reported above (Table 1-1).

Table 1-1: Recovery data for the analysis of flutriafol in different crop groups using the QuEChERS method in combination with LC-MS/MS (EURL, 2013)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Acidic (lemon)	0.01 0.1	95 94	7 5	20 10	2
High oil content (olive oil)	0.01 0.1	93 91	7 4	10 10	2

Hence, it is concluded that flutriafol can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities and with an LOQ of 0.05 mg/kg in straw.

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

During the peer review under Directive 91/414/EEC, an analytical method using LC-MS/MS, confirmed by a second mass transition and its ILV were evaluated and validated for the determination of flutriafol in food of animal origin with an LOQ of 0.01 mg/kg in milk, muscle, liver, kidney, fat and eggs (United Kingdom, 2010a). Nevertheless, a confirmatory method and an ILV are missing for fat.

In addition, the RMS also evaluated a GC-MS method which was validated for the determination of flutriafol with an LOQ of 0.01 mg/kg in fat (United Kingdom, 2010a). Nevertheless, a confirmatory method and an ILV are not available.

[15] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

Hence it is concluded that flutriafol can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, eggs, muscle, liver and kidney. Moreover, there are indications that flutriafol can be enforced in fat with an LOQ of 0.01 mg/kg but an ILV and a confirmatory method are missing and are still required.

2. Mammalian toxicology

The toxicological assessment of flutriafol was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2010b). These toxicological reference values are summarised in Table 2-1.

Metabolism studies in both mammalians and plants have shown that active substances belonging to the chemical class of triazoles are metabolized to common metabolites known as triazole derivative metabolites (TDMs), the major ones being the metabolites 1,2,4-triazole[16], triazole alanine[17], triazole lactic acid[18] and triazole acetic acid[19]. The toxicological properties of TDMs were discussed by the EFSA Pesticide Risk Assessment Peer Review Expert Meeting on mammalian toxicology of January 2007 (PRAPeR 14); the agreed toxicological reference values are compiled in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Flutriafol					
ADI	EFSA	2010b	0.01 mg/kg bw per d	2-year rat study	100
ARfD	EFSA	2010b	0.05 mg/kg bw	90-day and 1-year dog studies	100
1,2,4-triazole, triazole acetic acid and triazole lactic acid [(a)]					
ADI	PRAPeR 14	2007	0.02 mg/kg bw per d	Rat, multigeneration study	1000
ARfD	PRAPeR 14	2007	0.06 mg/kg bw	Rat, developmental study	500
Triazole alanine					
ADI	PRAPeR 14	2007	0.1 mg/kg bw per d	Rat, developmental study	1000
ARfD	PRAPeR 14	2007	0.1 mg/kg bw	Rat, developmental study	1000

(a): EFSA PRAPeR Expert Meeting 14 agreed to apply the same toxicological reference values as for 1,2,4 triazole in absence of reproductive toxicity data.

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

During the peer review under Directive 91/414/EEC, metabolism of flutriafol was investigated for foliar application on cereals (barley, wheat), pulses and oilseeds (rape seed) and root and tuber vegetables (sugar beet), using [^{14}C]-triazolyl and [^{14}C]-carbinol labelled flutriafol (EFSA, 2010b; United Kingdom, 2006, 2010b). In addition, a metabolism study on fruits (apple) was assessed by the

[16] 1,2,4-triazole: 1H-[1,2,4]triazole. See Appendix E.
[17] triazole alanine: 3-(1H-1,2,4-triazol-1-yl)-DL-alanine. See Appendix E.
[18] triazole lactic acid: (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid. See Appendix E.
[19] triazole acetic acid: 1*H*-1,2,4-triazol-1-ylacetic acid. See Appendix E.

RMS in the framework of a previous MRL application (EFSA, 2010a). The characteristics of these studies are summarised in Table 3-1.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Apple	[^{14}C]-triazolyl and [^{14}C]-carbinol	Foliar spray, F [(b)]	0.118	1	64 (mature fruits, leaves)	Sources: EFSA, 2010a; FAO, 2011
Root and tuber vegetables	Sugar beet	[^{14}C]-triazolyl and [^{14}C]-carbinol	Foliar spray, F [(c)]	0.125	1	0, 16 and 21 (root and leaves)	Sources: EFSA, 2010b; United Kingdom, 2010b; FAO, 2011
Pulses and oilseeds	Rape seed	[^{14}C]-triazolyl and [^{14}C]-carbinol	Foliar spray, F [(d)]	0.125	1	0, 7, 14, 21 and 42 (at harvest: seeds, plant) [(e)]	Sources: EFSA, 2010b; United Kingdom, 2010b; FAO, 2011
Cereals	Barley, Wheat	[^{14}C]-triazolyl and [^{14}C]-carbinol	Foliar spray, F or G [(f)]	0.081 – 0.105	1	44 to 94 (grain, straw)	Sources: EFSA, 2010b; United Kingdom, 2006; FAO, 2011

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G).
(b): Application at BBCH 74.
(c): Application at BBCH 49.
(d): Application at BBCH 71.
(e): Analysis was performed only on samples from DAT 0, 14 and 42.
(f): Application at various growth stages (BBCH 51-59).

In mature apple fruits, total radioactive residues (TRR) accounted for 0.041 - 0.065 mg eq/kg, depending on the position of the radiolabel. Metabolites identification revealed that parent flutriafol accounted for a major part of the total radioactive residues (50 %–56 % TRR, 0.023-.032 mg/kg), along with several unknown metabolites, the largest fractions corresponding to 2.8 %-4.6 % TRR (0.001-0.003 mg eq/kg), depending on the radiolabel. In apple leaves, for the triazole labelling form, parent flutriafol represented also the predominant compound of the total radioactive residues (47.9 % TRR, 2 mg/kg) along with several unknown metabolites, the major one corresponding to 10.6 % of the TRR (0.442 mg eq/kg). Attempts to identify the triazole derivate metabolites (TDMs), were made in fruits and leaves but 1,2,4-triazole, triazole alanine and triazole acetic acid were detected at a trace level (< 0.001 mg eq/kg) suggesting limited cleavage of the parent molecule.

In sugar beet at harvest (21 DAT), the total radioactive residues accounted for 0.596 - 0.747 mg eq/kg in foliage and 0.005 - 0.009 mg eq/kg in root, for the carbinol and triazolyl radiolabels, respectively. Flutriafol was the major component of the total residue in foliage samples, accounting for 69.2 % - 70.8 % of the TRR (0.412 - 0.519 mg/kg) whilst no other compound accounted for more than 5.4 % of the TRR (0.038 mg eq/kg). No cleavage of the parent molecule was observed. No further identification was attempted in the root due to the very low recovered residue levels.

In rape seed at harvest (42 DAT), total radioactive residues accounted for 0.729 - 1.320 mg eq/kg in seeds and 0.355 - 0.246 mg eq/kg in the remaining whole plant, for the carbinol and triazolyl radiolabel, respectively. In seeds, flutriafol was the major component of the TRR, accounting for 34.7 % – 36.1 % of the TRR (0.254 - 0.474 mg/kg). Other compounds accounted for less than 10 % of the TRR, among them defluorinated flutriafol[24] (up to 7.6 % TRR, 0.098 mg eq/kg) and hexose conjugated flutriafol[25] (up to 3 % TRR, 0.039 mg eq/kg). No cleavage of the parent molecule occurred. In the remaining plant, a similar metabolic pattern as in the seeds was observed.

For the carbinol and triazolyl radiolabels, the total radioactive residues accounted for up to 0.02 mg eq./kg and 0.41 mg eq/kg, respectively, in cereal grain and for up to 0.72 mg eq/kg and 2.1 mg eq./kg, respectively, in cereal straw. Flutriafol remained the major component of the total residues in straw (38 % - 63 % TRR, 0.27 – 1.32 mg/kg) for both radiolabels, and in grain (36 % TRR, 0.002 mg/kg) for the carbinol label only. Indeed, in grain treated with triazolyl radiolabeled flutriafol, apart from the parent compound (up to 24 % TRR, 0.02 mg eq/kg), residues were mainly composed of triazole derivative metabolites (TDMs): triazole alanine (TA) found at levels up to 58 % TRR, 0.015 mg eq/kg and triazole acetic acid (TAA) found at levels up to 26 % TRR, 0.04 mg eq/kg. In all samples, the remaining radioactivity was either unextractable (up to 40 % TRR in barley straw) or unidentified (up to 38 % TRR in barley grain).

Therefore, the metabolism studies showed that parent flutriafol is the predominant compound of the TRR in all crops investigated, except in cereal grain where the cleavage of the parent molecule at the triazole bound occurred, with the formation of the triazole alanine and triazole acetic acid as the predominant compounds of the total residues.

Consequently, the residue for enforcement and risk assessment in all plant commodities after foliar treatment is defined as flutriafol only. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). The conclusions reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2011).

In addition, EFSA notes that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of flutriafol and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA emphasises that the above residue definitions do not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance flutriafol is authorised in northern and southern Europe for foliar treatment in a large number of crops (fruits, beet root, fruiting vegetables, leafy vegetables, pulses, oilseeds, cereals and sugar/fodder beet), both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of flutriafol residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile and by the RMS in its evaluation report (United Kingdom, 2011), including residue trials evaluated in the framework of the peer review (EFSA, 2010b; United Kingdom, 2006) or in the framework of previous MRL applications (EFSA, 2010a, 2013) and additional data submitted during the consultation of Member States (Spain, 2013). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

[24] defluorinated flutriafol: see appendix E.
[25] hexose conjugated flutriafol: see appendix E.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). For some of the reported GAPs, no residue trials are available or the available data are insufficient for MRL calculations. Consequently, neither MRLs nor risk assessment values can be derived for the crops listed below and the following data gaps were identified:

- Strawberries: considering that it is a major crop in Europe, 8 residue trials compliant with the southern outdoor GAP and 8 residue trials compliant with the indoor GAP are required.
- Sweet corn: considering that it is a minor crop in northern Europe, 4 residue trials compliant with the northern outdoor GAP are required.
- Beet leaves (chard): considering that it is a minor crop in northern and southern Europe, 4 residue trials compliant with the northern GAP and 4 residue trials compliant with the southern outdoor GAP are required.
- Lentils (fresh): considering that it is a minor crop in southern Europe, 4 residue trials compliant with the southern outdoor GAP are required.
- Asparagus: as asparagus is a minor crop in southern Europe, 4 residue trials compliant with the southern outdoor GAP are required. Moreover the southern outdoor GAP was not properly reported (number of applications, PHI, application rate expressed in g a.s./hL instead of g a.s./ha) and should be further clarified.
- Peas, fresh (without pods): the number of residue trials supporting the northern and southern outdoor GAPs is not compliant with the data requirements for this major crop (3 and 1 residue trials instead of 8 were submitted supporting the northern and southern outdoor GAPs, respectively). Therefore, 5 and 7 additional residue trials covering respectively the northern and southern outdoor GAPs are still required.
- Pulses, dry (beans, lentils, peas and lupins): considering that dry beans and dry peas are major crops in northern Europe, 8 residue trials on dry beans or dry peas compliant with northern outdoor GAPs on dry pulses are required.
- Maize grain: considering that it is a major crop both in northern and southern Europe, 8 residue trials compliant with the northern outdoor GAP and 8 residue trials compliant with the southern outdoor GAPs are required.
- Oats: according to the current guidelines, the extrapolation from the requested 8 residue trials on barley covering the southern outdoor GAP is possible (see below).

For the remaining GAPs, sufficient trials are available to derive (tentative) MRLs and risk assessment values. The following considerations were made by EFSA:

- Apples: no residue trials compliant with the southern outdoor GAP are available. Although appropriate MRL and risk assessment values can be derived from the import tolerance, 8 trials compliant with the southern outdoor GAP are still required.
- Pears: the residue trials supporting the southern outdoor GAP are not compliant with the data requirements with regard to the number of applications (3 applications instead of 2). Nevertheless, as the data package from the import tolerance is more critical and allows to derive appropriate MRL and risk assessment values, no additional southern residue trials are required.

- Beetroot: since trials were performed with a PHI of 21 days instead of 28 days, the extrapolation from the northern and southern outdoor residue trials on sugar beet (root) is proposed on a tentative basis only. Consequently, 8 and 4 residue trials compliant respectively with the northern and southern outdoor GAPs on beetroot are still required.

- Tomatoes: no residue trials are available to support the southern outdoor use and the indoor residue trials do not comply with the indoor GAP as they were performed at a PHI of 3 days instead of 1 day. In addition, the number of indoor trials is not compliant with the data requirements for this major crop (6 trials instead of 8) (Spain, 2013). Although tentative MRL and risk assessment values can be derived from the indoor data, 8 residue trials compliant with the indoor GAP and 8 residue trials compliant with the southern outdoor GAP are still required.

- Peppers: no residue trials compliant with the southern outdoor GAP are available. Although appropriate MRL and risk assessment values can be derived from the indoor data, 8 residue trials compliant with the southern outdoor GAP are still required.

- Melons and watermelons: no residue trials are available to support the southern outdoor use and the indoor residue trials do not comply with the indoor GAP as they were performed with a PHI of 7 days instead of 10 days and were underdosed (within the 25 % variation). Furthermore, the number of indoor trials is not compliant with the data requirements for these crops (4 trials instead of 8) (Spain, 2013). Although tentative MRL and risk assessment values can be derived from the indoor residue data, 8 residue trials on melons compliant with the indoor GAP on melons and watermelons and 8 residue trials on melons compliant with the southern outdoor GAP on melons and watermelons, are still required.

- Witloof: the authorized northern outdoor GAP refers to the use on chicory roots for the production of witloof (leafy vegetables) after forcing. Although 2 residue trials instead of the requested 4 residue trials were submitted, a no residue situation is expected in chicory root based also on the outcome of the metabolism data on sugar beet root conducted at a similar GAP (see also section 3.1.1.1). It is therefore also assumed that no residues above the LOQ will be expected in the witloof leaves and EFSA proposes to set the MRL at the LOQ of the validated analytical method (0.01 mg/kg) in witloof leaves. Consequently, appropriate MRL and risk assessment value can be derived from the northern outdoor data and no additional residue trials on witloof are required.

- Rape seed, mustard seeds and gold of pleasure: the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for these crops (4 trials instead of 8). Although appropriate MRL and risk assessment values can be derived from the northern outdoor data, 4 additional residue trials on rapeseed compliant with the southern outdoor GAP on rapeseed, mustard seeds and gold of pleasure, are still required.

- Barley (grain and straw): no residue trials are available to support the southern outdoor use. Although appropriate MRL and risk assessment values can be derived from the northern residue dataset, 8 residue trials on barley compliant with the southern outdoor GAP are still required. It is noted that these trials would also support the southern use on oats.

- Rice grain: the submitted residue trials do not comply with the southern outdoor GAP as they were performed with a more critical PHI (21 days instead of 28 days). In addition, the number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this major crop (4 trials instead of 8). Although tentative MRL and risk assessment values can be derived, 8 residue trials compliant with the southern outdoor GAP are still required.

The potential degradation of flutriafol residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of flutriafol residues was demonstrated for a period of 12 months at -23°C in commodities with high water content (wheat whole plant), dry commodities (wheat grain) and straw (EFSA, 2010a, 2010b; United Kingdom, 2006). Additional storage stability data were also assessed in the framework of an MRL application demonstrating that flutriafol residues are stable for a period of 12 months at -18°C both in high water (apple) and high oil content matrices (rape seed) (EFSA, 2010a). Furthermore, storage stability of flutriafol residues was also demonstrated for a period of 23 months at frozen temperatures in commodities with high acid content (grapes) (FAO, 2011). The storage conditions for the submitted residue trials performed on sugar beet (root), peppers, fresh peas (without pods), barley grain, rice grain and wheat grain (northern trials only) were not reported by the RMS. However, since the storage stability has been demonstrated for at least 12 months, a degradation of the residues in these samples is not expected to had occurred and this information is only desirable.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for beetroot, tomatoes, melons, watermelons and rice grain, where tentative MRLs are derived and for strawberries, sweet corn, beet leaves (chard), peas (fresh, without pods), lentils (fresh), asparagus, pulses (dry beans, lentils, peas and lupins), maize grain, oats grain and oats straw where the available data were insufficient to derive tentative MRLs (see also Table 3-2). Where several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. Tentative MRLs were also derived for feed crops (cereals straw, sugar and fodder beet tops, fodder beet root) in view of the future need to set MRLs in feed items.

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

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Pome fruit	Import	Outdoor	2x 0.02; 0.03; 2x 0.04; 3x 0.05; 4x 0.06; 2x 0.08; 0.09; 2x 0.10; 0.11; 2x 0.12; 0.16; 0.18; 0.21; 0.24	2x 0.02; 0.03; 2x 0.04; 3x 0.05; 4x 0.06; 2x 0.08; 0.09; 2x 0.10; 0.11; 2x 0.12; 0.16; 0.18; 0.21; 0.24	**0.07**	**0.24**	**0.4**	**1.00**	Combined data set on apples (20) and pears (4) compliant with GAP. Extrapolation to the whole group of pome fruits possible (EFSA, 2013). MRL_{OECD} = 0.32 R_{ber} = 0.24 R_{max} = 0.22
	SEU (apples)	Outdoor	-	-	-	-	-	-	No trials available.
	SEU (pears)	Outdoor	3x <0.01; 4x 0.01; 2x 0.02; 0.05	3x <0.01; 4x 0.01; 2x 0.02; 0.05	0.01	0.05	0.07 (tentative)	1.00	Trials on apples overdosed (3 applications instead of 2). MRL_{OECD} = 0.07 R_{ber} = 0.04 R_{max} = 0.05
Cherries	Import	Outdoor	0.17; 0.24; 0.25; 0.26; 2x 0.30; 0.32; 0.33; 0.34; 0.38; 0.39; 0.40; 0.42; 0.46; 0.47; 0.59	0.17; 0.24; 0.25; 0.26; 2x 0.30; 0.32; 0.33; 0.34; 0.38; 0.39; 0.40; 0.42; 0.46; 0.47; 0.59	0.34	0.59	1	1.00	Trials on sweet and sour cherries compliant with GAP (EFSA, 2013). MRL_{OECD} = 1.05 R_{ber} = 0.83 R_{max} = 0.61
Peaches	Import	Outdoor	0.05; 0.12; 0.13; 2x 0.15; 0.17; 2x 0.18; 0.19; 2x 0.24; 0.41	0.05; 0.12; 0.13; 2x 0.15; 0.17; 2x 0.18; 0.19; 2x 0.24; 0.41	0.18	0.41	0.6	1.00	Trials compliant with GAP (EFSA, 2013). MRL_{OECD} = 0.55 R_{ber} = 0.46 R_{max} = 0.42

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Plums	Import	Outdoor	0.02; 0.03; 0.04; 0.07; 0.09; 0.11; 0.12; 0.23	0.02; 0.03; 0.04; 0.07; 0.09; 0.11; 0.12; 0.23	0.08	0.23	0.4	1.00	Trials compliant with GAP (EFSA, 2013). MRL_{OECD} = 0.36 R_{ber} = 0.24 R_{max} = 0.31
Wine grapes	Import	Outdoor	0.15; 2x 0.21; 0.27; 0.30; 0.33; 0.34; 0.39; 0.41; 0.44; 0.45; 0.61; 0.89	0.15; 2x 0.21; 0.27; 0.30; 0.33; 0.34; 0.39; 0.41; 0.44; 0.45; 0.61; 0.89	0.34	0.89	1.5	1.00	Trials on grapes compliant with GAP (EFSA, 2010a). MRL_{OECD}= 1.16 R_{ber}= 0.89 R_{max}= 0.90
Strawberries	SEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	-	-	-	-	-	-	No trials available.
Bananas	Import	Outdoor	0.01; 2x 0.02; 2x 0.07; 0.08; 0.09; 2x 0.1; 0.14; 2x 0.17	0.01; 2x 0.02; 2x 0.07; 0.08; 0.09; 2x 0.1; 0.14; 2x 0.17	0.09	0.17	0.3	1.00	Trials on ubagged bananas compliant with GAP (EFSA, 2010a). MRL_{OECD} = 0.3 R_{ber} = 0.26 R_{max} = 0.24

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Tomatoes	SEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	0.13; 2x 0.15; 0.16; 0.19; 0.24	0.13; 2x 0.15; 0.16; 0.19; 0.24	0.16	0.24	0.6 (tentative)	1.00	Trials on tomatoes performed with a less critical PHI (3d instead of 1d) (Spain, 2013). MRL_{OECD} = 0.51 R_{ber} = 0.41 R_{max} = 0.32
Peppers	SEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	0.15; 0.19; 0.24; 0.26; 0.29; 0.32; 2x 0.41	0.15; 0.19; 0.24; 0.26; 0.29; 0.32; 2x 0.41	0.28	0.41	1	1.00	Trials on peppers compliant with GAP (FAO, 2011). MRL_{OECD} = 0.85 R_{ber} = 0.78 R_{max} = 0.58
Melons, watermelons	SEU	Outdoor	-	-	-	-	-	-	No trials available.
	EU	Indoor	0.03; 0.04; 0.05; 0.08	0.03; 0.04; 0.05; 0.08	0.05	0.08	0.2 (tentative)	1.00	Trials on melons performed with a PHI of 7d instead of 10d (Spain, 2013). Extrapolation to watermelons possible. MRL_{OECD} = 0.15 R_{ber} = 0.15 R_{max} = 0.16
Sweet corn	NEU	Outdoor	-	-	-	-	-	-	No trials available.
Beet leaves (chard)	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	SEU	Outdoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Witloof	NEU	Outdoor	2x <0.04	2x <0.04	0.01	0.01	0.01*	1.00	Trials compliant with GAP. MRL_{OECD}= - R_{ber}= - R_{max}= -
Peas, fresh (without pods)	NEU	Outdoor	2x <0.04; 0.06[e]	2x <0.04; 0.06[e]	-	-	-	-	Trials on peas without pods compliant with GAP. Number of trials not sufficient to derive an MRL proposal.
	SEU	Outdoor	<0.04	<0.04	-	-	-	-	Trials on peas without pods compliant with GAP. Number of trials not sufficient to derive an MRL proposal.
Lentils (fresh)	SEU	Outdoor	-	-	-	-	-	-	No trials available.
Asparagus	SEU	Outdoor	-	-	-	-	-	-	No trials available.
Pulses, dry (Beans, Lentils, Peas, Lupins)	NEU	Outdoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Rape seed, Mustard seed, Gold of pleasure	NEU	Outdoor	0.03; 0.04; 0.07; 2x 0.08; 0.13; 0.15; 0.31	0.03; 0.04; 0.07; 2x 0.08; 0.13; 0.15; 0.31	0.08	**0.31**	**0.5**	**1.00**	Trials on rape seed compliant with GAP on rape seed, mustard seed and gold of pleasure. MRL_{OECD}= 0.47 R_{ber}= 0.29 R_{max}= 0.40
	SEU	Outdoor	0.03; 0.05; 0.13; 0.15	0.03; 0.05; 0.13; 0.15	**0.09**	0.15	0.4 (tentative)	1.00	Trials on rape seed compliant with GAP on rape seed, to mustard seed and gold of pleasure. MRL_{OECD}= 0.33 R_{ber}= 0.29 R_{max}= 0.39
Soya bean	Import	Outdoor	<0.01; 0.01; 2x 0.02; 2x 0.03; 0.04; 0.05; 2x 0.06; 2x 0.07; 2x 0.08; 2x 0.09; 0.13; 0.19; 0.20; 0.31	<0.01; 0.01; 2x 0.02; 2x 0.03; 0.04; 0.05; 2x 0.06; 2x 0.07; 2x 0.08; 2x 0.09; 0.13; 0.19; 0.20; 0.31	0.07	0.31	0.4	1.00	Trials on soya bean compliant with GAP (EFSA, 2010a). MRL_{OECD}= 0.38 R_{ber}= 0.18 R_{max}= 0.26
Barley grain	NEU	Outdoor	0.02; 0.03; 3x 0.04; 0.05; 0.06; 0.07	0.02; 0.03; 3x 0.04; 0.05; 0.06; 0.07	0.04	0.07	0.15	1.00	Trials on barley compliant with GAP. MRL_{OECD}= 0.13 R_{ber}= 0.12 R_{max}= 0.09
	SEU	Outdoor	-	-	-	-	-	-	No trials available.
Maize grain	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	SEU	Outdoor	-	-	-	-	-	-	No trials available.
Oats grain	SEU	Outdoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Rice grain	SEU	Outdoor	0.29; 0.36; 0.42; 0.47	0.29; 0.36; 0.42; 0.47	0.39	0.47	1.5 (tentative)	1.00	Trials on husked rice performed with a more critical PHI (21d instead of 28d). MRL_{OECD}= 1.16 R_{ber}= 0.92 R_{max}= 0.80
Wheat grain, Rye grain	NEU	Outdoor	2x <0.01; 2x 0.01; 0.02; 2x 0.03; 0.06; 0.09	2x <0.01; 2x 0.01; 0.02; 2x 0.03; 0.06; 0.09	0.02	0.09	0.15	1.00	Trials on wheat compliant with GAP on wheat and rye. MRL_{OECD}= 0.14 R_{ber}= 0.09 R_{max}= 0.11
	SEU	Outdoor	2x <0.01; 2x 0.01; 2x 0.02; 0.04; 0.10	2x <0.01; 2x 0.01; 2x 0.02; 0.04; 0.10	**0.02**	**0.10**	**0.15**	**1.00**	Trials on wheat compliant with GAP on wheat and rye. MRL_{OECD}= 0.15 R_{ber}= 0.07 R_{max}= 0.13
Barley straw	NEU	Outdoor	2x 0.39; 0.80; 1.20; 1.40; 4.00	2x 0.39; 0.80; 1.20; 1.40; 4.00	1.00	4.00	7 (tentative)	1.00	Trials on barley compliant with GAP. MRL_{OECD}= 6.79 R_{ber}= 4.10 R_{max}= 6.40
	SEU	Outdoor	-	-	-	-	-	-	No trials available.
Oats straw	SEU	Outdoor	-	-	-	-	-	-	No trials available.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Wheat straw, Rye straw	NEU	Outdoor	2x 0.14; 2x 0.48; 1.20; 1.50; 2.10; 2x 2.60	2x 0.14; 2x 0.48; 1.20; 1.50; 2.10; 2x 2.60	1.20	2.60	6 (tentative)	1.00	Trials on wheat compliant with GAP on wheat and rye. MRL_{OECD}= 5.27 R_{ber}= 4.70 R_{max}= 4.30
	SEU	Outdoor	0.15; 0.35; 0.55; 1.41; 1.50; 1.87; 3.56; 4.08	0.15; 0.35; 0.55; 1.41; 1.50; 1.87; 3.56; 4.08	**1.46**	**4.08**	**8** (tentative)	**1.00**	Trials on wheat compliant with GAP on wheat and rye. MRL_{OECD}= 7.50 R_{ber}= 6.28 R_{max}= 6.32
Beetroot, Sugar beet (root), Fodder beet (root)	NEU	Outdoor	6x <0.01; 2x 0.01; 0.02; 0.03	6x <0.01; 2x 0.01; 0.02; 0.03	0.01	0.03	0.04 (tentative for beetroot)	1.00	Trials on sugar beet compliant with GAPs on sugar and fodder beet. Extrapolation to beetroot tentatively possible (trials performed with a PHI of 21d instead of 28d). MRL_{OECD} = 0.04 R_{ber} = 0.03 R_{max} = 0.03
	SEU	Outdoor	3x <0.01; 0.01; 3x 0.02; 0.04	3x <0.01; 0.01; 3x 0.02; 0.04	**0.02**	**0.04**	**0.06** (tentative for beetroot)	**1.00**	Trials on sugar beet compliant with GAPs on sugar and fodder beet. Extrapolation to beetroot tentatively possible (trials performed with a PHI of 21d instead of 28d). MRL_{OECD} = 0.06 R_{ber} = 0.04 R_{max} = 0.05

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (flutriafol)	Risk assessment (flutriafol)					
Sugar beet (tops), Fodder beet (tops)	NEU	Outdoor	0.14; 0.15; 0.27; 0.28; 0.32; 0.33; 0.38; 0.64	0.14; 0.15; 0.27; 0.28; 0.32; 0.33; 0.38; 0.64	0.30	0.64	1 (tentative)	1.00	Trials on sugar beet compliant with GAP on sugar and fodder beet. MRL_{OECD} = 0.94 R_{ber} = 0.74 R_{max} = 0.81
	SEU	Outdoor	0.05; 0.15; 0.29; 0.33; 0.34; 0.36; 0.46; 0.84	0.05; 0.15; 0.29; 0.33; 0.34; 0.36; 0.46; 0.84	**0.34**	**0.84**	**1.5** (tentative)	**1.00**	Trials on sugar beet (tops) compliant with GAP on sugar and fodder beet. MRL_{OECD} = 1.29 Rber = 0.87 Rmax = 1.10

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011a).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Residues measured in mechanically harvested peas.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of flutriafol residues was not investigated in the framework of the peer review. However, flutriafol is authorised on numerous crops where residues of flutriafol exceed 0.1 mg/kg and the chronic exposure exceeds 10 % of the ADI (see also section 4). Therefore, data investigating the effect of industrial and/or household processing on the nature of flutriafol residues in plant commodities are required especially for pome fruits, wine grapes and tomatoes, which are the main contributors to the overall exposure. Consequently the MRL proposals for these commodities are considered tentative only.

Studies investigating the magnitude of residues of flutriafol in processed commodities of several crops. An overview of these processing studies is given in Table 3-3. Since the effect of the processing on the nature of the residues has not been investigated, a robust processing factor for enforcement and risk assessment was derived only for peeled bananas. For the other processed commodities, no robust processing factors for enforcement and risk assessment could be derived as they were not sufficiently supported by studies (a minimum of 3 processing studies is normally required) and the effect of processing on the nature of flutriafol was not investigated. Therefore, the processing factors reported in Table 3-3 for these commodities should be considered as indicative only.

If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: flutriafol				
Processing factors recommended (sufficiently supported by data)				
Bananas, peeled	12	0.76	1.00	PF derived from residue trials on bananas. Source: United Kingdom, 2009
Indicative processing factors (limited dataset and tentative residue definition)				
Apples, juice	1	0.48	1.00	Source: United Kingdom, 2009.
Apples, dry pomace	1	9.20	1.00	Source: United Kingdom, 2009.
Apples, wet pomace	1	1.88	1.00	Source: United Kingdom, 2009.
Wine grapes, juice	1	0.63	1.00	Source: United Kingdom, 2009.
Soya bean, refined oil	1	1.25	1.00	Source: United Kingdom, 2009.
Soya bean, meal	1	1.30	1.00	Source: United Kingdom, 2009.
Wheat, white flour	1	0.33	1.00	Source: FAO, 2011.
Wheat, bran	1	2.10	1.00	Source: FAO, 2011.

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration, except permanent crops (apples and pears), may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of flutriafol range between 1051 - 13583 days which is far higher than the trigger value of 100 days (EFSA, 2010b). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of flutriafol in rotational crops – lettuce, sugar beet, radish, pea, oilseed rape, wheat - has been evaluated (EFSA, 2010b; FAO, 2011; United Kingdom, 2006, 2010a). Two confined rotational crop studies investigating the nature of residues at different plant-back intervals are available. The characteristics of these studies are summarised in Table 3-4.

In the first confined rotational crop study reported in the DAR (United Kingdom, 2006), TRR values were generally higher for triazolyl label than for carbinol label, except in wheat straw, for which the residue levels were in the same order of magnitude.

TRR in wheat grain were 1.04 - 0.04 mg eq/kg at 30 DAT, 1.22 - 0.02 mg eq/kg at 120 DAT and 0.3-< 0.01 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. In the 120 and 365 DAT samples from the triazolyl label, flutriafol was not detected whilst triazole alanine accounted respectively for 48.5 % of the TRR (0.59 mg/kg) and 50.5 % of the TRR (0.15 mg/kg); triazole acetic acid accounted respectively for 18.8 % of the TRR (0.23 mg eq/kg) and 14.2 % of the TRR (0.04 mg eq/kg). No further identification of the metabolites was attempted in wheat grain after treatment with the carbinol labelled flutriafol.

TRR in sugar beet roots were 0.08 - 0.02 mg eq/kg at 30 DAT, <0.01 - 0.09 mg eq/kg at 120 DAT and 0.03 - <0.01 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. In the 120 DAT samples from the triazolyl label, triazole alanine accounted for 19.6 % of the TRR (0.02 mg eq/kg) and 1,2,4-triazole for 17.3 % of the TRR (0.02 mg eq/kg). Flutriafol and triazole acetic acid accounted respectively for 4.7 and 2.7 % of the TRR (<0.01 mg eq/kg). No further characterisation of the metabolites was attempted in the sugar beet roots after treatment with the carbinol-labelled flutriafol.

Table 3-4: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Lettuce	[^{14}C]-triazolyl or [^{14}C]-carbinol	Spraying (bare soil)	0.26	30, 120, 365	130, 220, 449	EFSA, 2010b; UK, 2010a; FAO, 2011
Root and tuber vegetables	Sugar beet	[^{14}C]-triazolyl or [^{14}C]-carbinol	Spraying (bare soil), G	0.25	30, 120, 365	At maturity	EFSA, 2010b; UK, 2006; FAO, 2011
	Radish	[^{14}C]-triazolyl or [^{14}C]-carbinol	Spraying (bare soil)	0.26	30, 120, 365	130, 220, 409	EFSA, 2010b; UK, 2010a; FAO, 2011

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Cereals	Wheat	[^{14}C]-triazolyl or [^{14}C]-carbinol	Spraying (bare soil), G	0.25	30, 120, 365	At maturity	EFSA, 2010b; UK,, 2006; FAO, 2011
		[^{14}C]-triazolyl or [^{14}C]-carbinol	Spraying (bare soil)	0.26	30, 120, 365	130[(b)], 220[(b)], 409[(b)] 197[(c)], 287[(c)], 512[(c)] 219[(d)], 231[(d)], 309[(d)], 321[(d)], 570[(d)]	EFSA, 2010b, UK, 2010a; FAO, 2011

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Sampling of forage
(c): Sampling of hay
(d): Sampling of grain and straw

TRR in wheat straw were 6.47 - 10.46 mg eq/kg at 30 DAT, 1.32 - 0.93 mg eq/kg at 120 DAT and 0.20 - 0.13 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. In the 120 and 365 DAT wheat straw samples from the triazolyl label, parent flutriafol was the major compound, accounting respectively for 38.2 % of the TRR (0.5 mg/kg) and 30.7 % of the TRR (0.06 mg/kg); triazole acetic acid accounted respectively for 15.5 % of the TRR (0.21 mg eq/kg) and 22.2 % of the TRR (0.04 mg eq/kg). In the 120 DAT sample from the carbinol label, only parent flutriafol was identified, accounting for 43.3 % of the TRR (0.4 mg/kg).

TRR in sugar beet foliage were 0.60 - 0.20 mg eq/kg at 30 DAT, 0.57 - 0.19 mg eq/kg at 120 DAT and 0.35 - 0.13 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. In the 120 DAT samples from the triazolyl label, triazole acetic acid was the major compound, accounting for 21 % of the TRR (0.12 mg eq/kg) and parent flutriafol accounted for 17 % of the TRR (0.10 mg/kg). In the 120 DAT sample from the carbinol label, only parent flutriafol was identified, accounting for 25.7 % of the TRR (0.05 mg/kg).

In the second metabolism study submitted in the additional report (United Kingdom, 2010a), TRR were determined for both labels, but metabolites identification was only detailed for triazolyl label.

TRR in lettuce were 0.076 - 0.048 mg eq/kg at 30 DAT, 0.075 - 0.05 mg eq/kg at 120 DAT and 0.123-0.019 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. In the 30- and 120 DAT samples, parent flutriafol was the major compound (49.3 - 50.6 % TRR ; 0.035 - 0.039 mg/kg), and triazole lactic acid accounted for 15.6 - 16.9 % of the TRR (0.012 mg eq/kg in both samples). In the 365 DAT sample, triazole lactic acid was the major compound, accounting for 45.7 % of the TRR (0.06 mg eq/kg) whilst parent flutriafol and triazole alanine were detected at 16.5 % of the TRR and 15.7 % of the TRR (0.02 mg eq/kg), respectively. No other compound was detected at levels above 0.01 mg eq/kg.

TRR in radish tops were 0.177 - 0.060 mg eq/kg at 30 DAT, 0.084 - 0.048 mg eq/kg at 120 DAT and 0.107 - 0.071 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. Parent flutriafol

was the major compound in all samples, accounting for 52 - 55 % of the TRR (0.05 - 0.10 mg/kg), triazole alanine accounted for 25 - 28 % of the TRR (0.02 - 0.05 mg eq/kg). No other compound was detected at levels above 0.01 mg eq/kg.

TRR in radish roots were 0.066 - 0.023 mg eq/kg at 30 DAT, 0.051 - 0.020 mg eq/kg at 120 DAT and 0.059 - 0.008 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. Triazole alanine was the major compound of the total residues in all samples, accounting for 47.1, 41.7 and 73.1 % of the TRR (0.02 to 0.04 mg eq/kg), respectively at 30, 120 and 365 DAT. Parent flutriafol accounted for 21 - 25 % of the TRR (0.01 and 0.02 mg/kg) in the 30 and 120 DAT samples, respectively. No other compound was detected at levels above 0.01 mg eq/kg.

TRR in wheat forage were 0.23 - 0.13 mg eq/kg at 30 DAT, 0.24 - 0.13 mg eq/kg at 120 DAT and 0.075 - 0.061 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. TRR in wheat hay were 0.668 - 0.357 mg eq/kg at 30 DAT, 0.497 - 0.290 mg eq/kg at 120 DAT and 0.191- 0.083 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. TRR in wheat straw were 1.749 - 1.129 mg eq/kg at 30 DAT, 1.395 - 1.220 mg eq/kg at 120 DAT and 0.798 - 0.480 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. Parent flutriafol was the major compound of the total residues in all samples at all plant back intervals (except in the 365 DAT wheat hay sample) and accounted for up to 58 % of the TRR in forage (0.14 mg/kg) and 32 % of the TRR in hay and straw (0.15 - 0.23 mg/kg). Triazole lactic acid, triazole acetic acid and triazole alanine were detected in forage, hay and straw at significant levels, mainly in the 365 DAT samples.

TRR in wheat grain were 0.648 - 0.032 mg eq/kg at 30 DAT, 0.528 - 0.028 mg eq/kg at 120 DAT and 0.440 - 0.011 mg eq/kg at 365 DAT, respectively for the triazolyl and carbinol labels. At all plant back intervals, the 1,2,4-triazole and the triazole lactic acid metabolites were never detected whilst triazole alanine and triazole acetic acid metabolites were the major compounds, accounting respectively for 30 - 59 % of the TRR (0.14 - 0.39 mg eq/kg) and for 28 - 46 % of the TRR (0.16 - 0.2 mg eq/kg).

Consequently, metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary.

3.1.2.3. Magnitude of residues

In addition to the confined rotational crop studies, several rotational crop field trials were evaluated in the framework of the peer review (EFSA, 2010b; United Kingdom, 2006, 2010b) and by the JMPR (FAO, 2011).

Rotational crops field trials were conducted after a foliar spray treatment on cereals at 0.19 kg a.s./ha the first year and each subsequent year at a dose of 0.25 kg a.s./ha. After five consecutive years of application, with a total rate applied of 1.19 kg a.s./ha, sugar beet, fodder beet, potato, carrot and spring barley, as rotational crops, were sown/planted on the test sites and grown up to maturity. Flutriafol residues were detected in sugar beet and fodder beet roots, potatoes and carrots at levels of < 0.01 – 0.02 mg/kg, in sugar beet and fodder beet tops at levels of < 0.01 – 0.08 mg/kg and in barley grain and straw at levels of 0.05 mg/kg and 0.38 mg/kg, respectively.

Additional rotational crop field trials were assessed by the JMPR (FAO, 2011). Three plots in three different sites in the United Kingdom were treated with an exaggerated dose of 4.0 kg a.s./ha, applied on bare soil. Several crops (potato, carrot, sugar beet, sunflower, oilseed rape, pea, maize, spring barley and wheat, cabbage) were sown three years after treatment. Representative samples of the different crops were taken at harvest and analysed for residues of flutriafol and its major metabolites triazole alanine and triazole acetic acid. Residues of flutriafol were below 0.05 mg/kg in the potato tuber, sunflower seed, maize grain, rape seed and pea. Residues of flutriafol were found in barley grain (< 0.03 – 0.07 mg/kg), wheat grain (< 0.03 – 0.03 mg/kg), cabbage heads (< 0.05 – 0.12 mg/kg), carrot roots (< 0.05 – 0.13 mg/kg), sugar beet roots (< 0.01 – 0.03 mg/kg), maize straw (0.16 – 0.31 mg/kg) and sugar beet foliage (0.03 – 0.42 mg/kg). Significant residue levels of flutriafol were found in barley straw (0.24 – 1.5 mg/kg), wheat straw (0.29 – 2.5 mg/kg) and pea haulm (0.28 – 3.8 mg/kg) whilst

residues of triazole alanine were found in wheat grain (0.28 – 3.0 mg/kg), rape seed (0.59 – 17 mg/kg) and pea (0.15 – 7.7 mg/kg).

Based on the available rotational crop field trials and considering that the total seasonal application rates of flutriafol within the EU range between 125 – 930 g a.s./ha, there is clear evidence that flutriafol and the triazole derivative metabolites residues are expected to be present at levels above 0.01 mg/kg in all the edible parts of the crops grown in rotation with crops treated in compliance with the authorized uses. EFSA is therefore of the opinion that considering the high persistence of flutriafol, the predicted maximum concentration of flutriafol in soil should be revised in accordance with the authorized uses within the EU (See Appendix A) and it should be assessed whether the available rotational crops field trials cover the maximum plateau concentration, in order to conclude on the actual residue levels of flutriafol and of the triazole derivative metabolites in the edible parts of the rotated crops. Meanwhile, EFSA concludes that Member States granting authorisations for flutriafol should take the appropriate risk mitigation measures in order to avoid the presence of flutriafol and the triazole derivative metabolites residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Flutriafol is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-5. The indicative processing factors derived in section 3.1.1.3 were used for the relevant commodities. Moreover, for rape seed meal, the default processing factor of 2 has been included in the calculation in order to consider the potential concentration of residues in this commodity. It is highlighted that for several feed items, no residue data were available (pulses, maize grain, oats grain and straw, see also section 3.1.1.2). The animal intake of flutriafol residues via these commodities has therefore not been assessed and may have been underestimated. However, this is not expected to have a major impact on the outcome of the dietary burden considering the high contribution of sugar beet and wheat straw.

Table 3-5: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: flutriafol				
Apple pomace	0.13	Median residue x PF	0.13	Median residue x PF
Wheat and rye grain	0.02	Median residue	0.02	Median residue
Barley grain	0.04	Median residue	0.04	Median residue
Wheat and rye bran	0.04	Median residue x PF	0.04	Median residue x PF
Wheat and rye straw	1.46	Median residue	4.08	Highest residue
Barley straw	1.00	Median residue	4.00	Highest residue
Sugar and fodder beet roots	0.02	Median residue	0.04	Highest residue
Sugar and fodder beet tops	0.34	Median residue	0.84	Highest residue
Rape seed meal	0.18	Median residue x 2	0.18	Median residue x 2
Soya bean	0.07	Median residue	0.07	Median residue

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Soya bean meal	0.09	Median residue x PF	0.09	Median residue x PF

The results of the calculations are reported in Table 3-6. The calculated dietary burdens for dairy ruminants, meat ruminants and pigs were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore only required in these groups of livestock.

Table 3-6: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition : flutriafol					
Dairy ruminants	0.038	0.096	Sugar beet leaves	2.63	Y
Meat ruminants	0.065	0.171	Wheat straw	3.98	Y
Poultry	0.004	0.006	Sugar beet root	0.09	N
Pigs	0.024	0.059	Sugar beet leaves	1.46	Y

3.2.2. Nature of residues

The nature of flutriafol residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (EFSA, 2010b; United Kingdom, 2006, 2010a) and by the JMPR (FAO, 2011). Reported metabolism studies include one study in lactating cow using [^{14}C-triazol]-labelled flutriafol and one study in laying hens, although not required, using respectively [^{14}C-carbinol] and [^{14}C-triazol]-labelled flutriafol. The characteristics of these studies are summarised in Table 3-7.

Table 3-7: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Cow	[^{14}C]-triazolyl	1	0.08, twice daily	7	Milk	Twice daily
						Urine and faeces	
						Tissues	At sacrifice
Laying poultry	Hens	Group 1: [^{14}C]-triazolyl; Group 2: [^{14}C]-carbinol	Group 1: 12 ; Group 2: 6	1.13-1.45; (Group 1) 0.97-1.24 (Group 2) Single daily dose	7	Eggs	Twice daily
						Excreta	Daily
						Tissues	At sacrifice

The ruminant metabolism study was underdosed (0.47 N rate). Most of the administered radioactivity was excreted in the urine and faeces (45 % and 33 % of the applied dose, respectively). A total of 0.1 % of the radioactivity administered to the cow was secreted in milk over the 7 days dosing period.

Low levels of flutriafol and 4-hydroxyflutriafol[26] were identified in milk (< 3 % TRR). Most of the radioactivity in the milk (75 % TRR) was characterized as polar, water soluble metabolites which were converted to organo soluble fractions by harsh hydrolysis conditions but without any further identification. In liver, only flutriafol was identified (29 % TRR). In kidney, only 4-hydroxyflutriafol was identified (23 % TRR). For both matrices, no individual compound accounted for more than 10 % of the TRR. In muscle and fat, the radioactive residues were too low for further metabolites identification.

In laying hens, 91.6 % and 92.6 % of the applied dose were recovered in the excreta, respectively for the triazole and the carbinol labels. The total radioactive residues in eggs reached a plateau concentration at the end of the dosing period and ranged from 0.134 mg eq./kg (carbinol label) to 0.204 mg eq./kg (triazole label). The highest total radioactive residues were recovered in liver (0.36-0.41 mg eq./kg) and to a minor extent in muscle (0.01 – 0.06 mg eq./kg) and in fat (0.011-0.016 mg eq./kg). In eggs, parent flutriafol was the predominant compound of the total radioactive residues with up to 75 % of the TRR (0.119 mg/kg) and 50.5 % of the TRR (0.103 mg/kg) for the carbinol and triazole labellings, respectively. The 1,2,4-triazole metabolite was also detected in eggs (up to 29.3 % TRR, 0.060 mg eq./kg) and muscle (75.0 % TRR, 0.048 mg eq./kg). Flutriafol was detected in liver at low concentrations (up to 3.2 % TRR, 0.013 mg/kg) whilst the metabolite 1,2,4-triazole was present at a level of 13.9 % of the TRR (0.057 mg eq./kg). Flutriafol was found in fat at levels of up to 80 % of the TRR (0.028 mg/kg) but no flutriafol was detected in muscle.

The cow metabolism study is considered not appropriate to derive a robust residue definition, since only a small part of the radioactivity was identified in the different matrices and no metabolism study was conducted with the radiolabel on the carbinol moiety of the parent molecule. Furthermore, this study is underdosed compared to the maximum dietary burden of meat ruminants (0.47 N). Therefore, a new ruminant metabolism study is required, with radiolabel on both the carbinol and triazolyl moieties of the parent compound. Meanwhile the residue for enforcement and risk assessment in ruminant commodities is tentatively defined as parent flutriafol only. It is assumed that metabolism in rat and ruminants would be comparable; therefore the same tentative residue definition can be extrapolated to pigs. Validated analytical methods for enforcement of the tentative residue definition are available, except for fat, for which an ILV and a confirmatory method are required (see also section 1.2).

For poultry commodities, no residue definition is required and no MRLs are proposed, as calculated dietary burden did not triggered the value of 0.1 mg/kg DM.

The conclusions reached by EFSA do not reflect the views of the JMPR (FAO, 2011), who defined, based on the same metabolism studies, residue definitions for enforcement and risk assessment in livestock matrices as parent flutriafol only. However, EFSA considered these residue definitions not appropriate, taking into account the data gaps identified in the metabolism studies.

Log $P_{o/w}$ of flutriafol is lower than 3 (EFSA, 2010b). EFSA concludes that the tentative residue definition in commodities of animal origin is not fat soluble.

In addition, EFSA highlighetd that the above studies do not investigate the possible impact of plant metabolism on the isomer ratio of flutriafol and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA emphasises that the above tentative residue definitions in ruminant matrices do not yet take into consideration triazole derivative metabolites (TDMs) whilst these metabolites were shown to represent a major part of the residues in cereal grains and in rotational crops. Since these metabolites may be

[26] 4-hydroxyflutriafol: 1-(2-fluoro-4-hydroxyphenyl)-1-(4-fluorophenyl)-2-(1,2,4 triazol-1-yl) ethanol. See Appendix E.

generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

3.2.3. Magnitude of residues

During the peer review under Directive 91/414/EEC, the magnitude of flutriafol residues in ruminants was investigated in a feeding study with lactating cows (EFSA, 2010b; United Kingdom, 2010a). This study was also assessed by the JMPR (FAO, 2011). Three groups of lactating cows, each consisting of three animals, were dosed for 29 consecutive days with flutriafol at levels of 0.5, 1.5, and 5 mg/kg in the diet (equivalent to 0.018, 0.054 and 0.180 mg/kg bw per d). The samples were analysed for parent flutriafol. Results of the ruminant livestock feeding study are summarised in Table 3-8.

The storage conditions of the samples from the cow feeding study were not reported by the RMS. Considering that storage stability of futriafol in animal commodities was demonstrade only for 4 months (JMPR, 2011), this information is required in order to confirm the results from the livestock feeding studies.

MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009) and are summarised in Table 3-8. Quantifiable residues in liver of pigs and ruminants are expected and tentative MRLs for these commodities can be proposed. However, significant residues in meat, fat, kidney and milk are not expected and MRLs for these commodities can be established at the LOQ. Considering the data gaps identified for the metabolism in ruminants, for the sample storage conditions of the livestock feeding study and for the validation of the analytical method in fat, these MRLs are considered as tentative only (see also sections 1.2, 3.1.1.2, 3.2.1 and 3.2.2).

Table 3-8: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	MRL proposal (mg/kg)[(d)]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[(a)]	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: flutriafol												
Ruminant muscle	0.065	0.171	0.02	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	3	<0.01	<0.01	<0.01	<0.01				
			0.18	3	<0.01	<0.01	<0.01	<0.01				
Ruminant fat	0.065	0.171	0.02	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	3	<0.01	<0.01	<0.01	<0.01				
			0.18	3	<0.01	<0.01	<0.01	<0.01				
Ruminant liver	0.065	0.171	0.02	3	0.03	0.03	0.03	0.03	0.11	0.27	0.3 (tentative)	1.00
			0.05	3	0.09	0.09	0.09	0.09				
			0.18	3	0.28	0.28	0.28	0.28				
Ruminant kidney	0.065	0.171	0.02	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	3	<0.01	<0.01	<0.01	<0.01				
			0.18	3	<0.01	<0.01	<0.01	<0.01				
Milk	0.038	0.096	0.02	30	<0.01 [(e)]	n.a.	<0.01 [(e)]	n.a.	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	30	<0.01 [(e)]	n.a.	<0.01 [(e)]	n.a.				
			0.18	30	<0.01 [(e)]	n.a.	<0.01 [(e)]	n.a.				
Pig muscle	0.024	0.059	0.02	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	3	<0.01	<0.01	<0.01	<0.01				
			0.18	3	<0.01	<0.01	<0.01	<0.01				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[b]	Highest residue (mg/kg)[c]	MRL proposal (mg/kg)[d]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[a]	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Pig fat	0.024	0.059	0.02	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	3	<0.01	<0.01	<0.01	<0.01				
			0.18	3	<0.01	<0.01	<0.01	<0.01				
Pig liver	0.024	0.059	0.02	3	0.03	0.03	0.03	0.03	0.04	0.10	0.1 (tentative)	1.00
			0.05	3	0.09	0.09	0.09	0.09				
			0.18	3	0.28	0.28	0.28	0.28				
Pig kidney	0.024	0.059	0.02	3	<0.01	<0.01	<0.01	<0.01	<0.01	<0.01	0.01* (tentative)	1.00
			0.05	3	<0.01	<0.01	<0.01	<0.01				
			0.18	3	<0.01	<0.01	<0.01	<0.01				

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk
(a): Based on a 635 kg animal consuming 23 kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(*): Indicates that the MRL is set at the limit of analytical quantification.

4. Consumer risk assessment

In the framework of this review, only the uses of flutriafol reported by the RMS in Appendix A were considered, however the use of flutriafol was previously also assessed by the JMPR (FAO, 2011). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The (tentative) median and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The peeling factor of 0.76 derived for banana was also used (see also section 3.1.1). 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 GAP was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: flutriafol				
Pome fruits	0.07	Median residue (tentative) [a]	0.24	Highest residue (tentative) [a]
Cherries	0.34	Median residue [b]	0.59	Highest residue [b]
Peaches	0.18	Median residue [b]	0.41	Highest residue [b]
Plums	0.08	Median residue [b]	0.23	Highest residue [b]
Wine grapes	0.34	Median residue (tentative) [a]	0.89	Highest residue (tentative) [a]
Strawberries	0.50	EU MRL [c]	0.50	EU MRL [c]
Bananas	0.06	Median residue x PF [b]	0.13	Highest residue x PF [b]
Beetroot	0.02	Median residue (tentative) [a]	0.04	Highest residue (tentative) [a]
Tomatoes	0.16	Median residue (tentative) [a]	0.24	Highest residue (tentative) [a]
Peppers	0.28	Median residue [b]	0.41	Highest residue [b]
Melons	0.05	Median residue (tentative) [a]	0.08	Highest residue (tentative) [a]
Watermelons	0.05	Median residue (tentative) [a]	0.08	Highest residue (tentative) [a]
Sweet corn	0.05	EU MRL [c]	0.05	EU MRL [c]
Beet leaves (chard)	0.05	EU MRL [c]	0.05	EU MRL [c]
Witloof	0.01*	Median residue [b]	0.01*	Highest residue [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peas (fresh, without pods)	0.10	EU MRL (c)	0.10	EU MRL (c)
Lentils (fresh)	0.05	EU MRL (c)	0.05	EU MRL (c)
Asparagus	0.05	EU MRL (c)	0.05	EU MRL (c)
Pulses (dry)	0.05	EU MRL (c)	0.05	EU MRL (c)
Rape seed, Mustard seed, Gold of pleasure	0.09	Median residue (b)	0.31	Highest residue (b)
Soya bean	0.07	Median residue (b)	0.31	Highest residue (b)
Barley grain	0.04	Median residue (b)	0.07	Highest residue (b)
Maize and oat grain	0.50	EU MRL (c)	0.50	EU MRL (c)
Rice grain	0.39	Median residue (tentative) (b)	0.47	Highest residue (tentative) (b)
Wheat and ry grain	0.02	Median residue (b)	0.10	Highest residue (b)
Sugar beet (root)	0.02	Median residue (b)	0.04	Highest residue (b)
Swine meat	0.01	Median muscle (tentative) (d)	0.01	Highest muscle (tentative) (d)
Swine fat (free of lean meat)	0.01	Median residue (tentative) (d)	0.01	Highest residue (tentative) (d)
Swine liver	0.04	Median residue (tentative) (d)	0.10	Highest residue (tentative) (d)
Swine kidney	0.01	Median residue (tentative) (d)	0.01	Highest residue (tentative) (d)
Ruminant meat	0.01*	Median muscle (tentative) (d)	0.01*	Highest muscle (tentative) (d)
Ruminant fat	0.01*	Median residue (tentative) (d)	0.01*	Highest residue (tentative) (d)
Ruminant liver	0.11	Median residue (tentative) (d)	0.27	Highest residue (tentative) (d)
Ruminant kidney	0.01*	Median residue (tentative) (d)	0.01*	Highest residue (tentative) (d)
Ruminant milk	0.01*	Median residue (tentative) (d)	0.01*	Highest residue (tentative) (d)

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(b): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(c): Use reported by the RMS is not supported by data; the existing EU MRL multiplied by a conversion factor for risk assessment 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 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 values derived for flutriafol (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1.

The highest chronic exposure was calculated for the WHO Cluster diet B, representing 33 % of the ADI, and the highest acute exposure was calculated for peppers, representing 52 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of flutriafol on crops fully supported by data (footnote (b) in Table 4-1) is acceptable with regard to consumer exposure. For the other crops and livestock commodities, major uncertainties remain due to the data gaps identified in section 3, in particular with regard to the residue definitions in ruminant and pig matrices, but considering the proposed tentative MRLs or the existing EU MRLs in the exposure calculation did not indicate a risk to consumers.

EFSA notes that the above studies do not investigate the possible impact of plant and livestock metabolism on the isomer ratios in the flutriafol residues to which the consumers are exposed to and in view of the unknown relative toxicity of each isomer, further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarised in Table 4-2.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: flutriafol				
Pome fruits	0.07	Median residue (tentative) [a]	0.24	Highest residue (tentative) [a]
Cherries	0.34	Median residue [b]	0.59	Highest residue [b]
Peaches	0.18	Median residue [b]	0.41	Highest residue [b]
Plums	0.08	Median residue [b]	0.23	Highest residue [b]
Table grapes	0.21	Median residue (CXL) [c]	0.61	Highest residue (CXL) [c]
Wine grapes	0.34	Median residue (tentative) [a]	0.89	Highest residue (tentative) [a]
Strawberries	0.50	EU MRL [d]	0.50	EU MRL [d]
Bananas	0.06	Median residue x PF [b]	0.13	Highest residue x PF [b]
Beetroot	0.02	Median residue (tentative) [a]	0.04	Highest residue (tentative) [a]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Tomatoes	0.16	Median residue (tentative) [a]	0.24	Highest residue (tentative) [a]
Peppers	0.28	Median residue [b]	0.41	Highest residue [b]
Melons	0.05	Median residue (tentative) [a]	0.08	Highest residue (tentative) [a]
Watermelons	0.05	Median residue (tentative) [a]	0.08	Highest residue (tentative) [a]
Sweet corn	0.05	EU MRL [d]	0.05	EU MRL [d]
Beet leaves (chard)	0.05	EU MRL [d]	0.05	EU MRL [d]
Witloof	0.01*	Median residue [b]	0.01*	Highest residue [b]
Peas (fresh, without pods)	0.10	EU MRL [d]	0.10	EU MRL [d]
Lentils (fresh)	0.05	EU MRL [d]	0.05	EU MRL [d]
Asparagus	0.05	EU MRL [d]	0.05	EU MRL [d]
Pulses (dry)	0.05	EU MRL [d]	0.05	EU MRL [d]
Peanuts	0.02	Median residue (CXL) [c]	0.08	Highest residue (CXL) [c]
Rape seed, Mustard seed, Gold of pleasure	0.09	Median residue [b]	0.31	Highest residue [b]
Soya bean	0.07	Median residue [b]	0.31	Highest residue [b]
Barley grain	0.04	Median residue [b]	0.07	Highest residue [b]
Maize grain	0.50	EU MRL [d]	0.50	EU MRL [d]
Oats grain	0.50	EU MRL [d]	0.50	EU MRL [d]
Rice grain	0.39	Median residue (tentative) [a]	0.47	Highest residue (tentative) [a]
Wheat grain, Rye grain	0.02	Median residue [b]	0.10	Highest residue [b]
Coffee beans	0.05	Median residue (CXL) [c]	0.10	Highest residue (CXL) [c]
Sugar beet (root)	0.02	Median residue [b]	0.04	Highest residue [b]
Swine meat	0.01*	Median muscle (tentative) [e]	0.01*	Highest muscle (tentative) [e]
Swine fat (free of lean meat)	0.01*	Median residue (tentative) [e]	0.01*	Median residue (tentative) [e]
Swine liver	0.04	Median residue (tentative) [e]	0.10	Median residue (tentative) [e]
Swine kidney	0.01*	Median residue (tentative) [e]	0.01*	Median residue (tentative) [e]
Ruminant meat	0.01*	Median muscle (tentative) [e]	0.01*	Highest muscle (tentative) [e]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Ruminant fat	0.01*	Median residue (tentative) [(e)]	0.01*	Median residue (tentative) [(e)]
Ruminant liver	0.11	Median residue (tentative) [(e)]	0.27	Median residue (tentative) [(e)]
Ruminant kidney	0.01*	Median residue (tentative) [(e)]	0.01*	Median residue (tentative) [(e)]
Ruminant milk	0.01*	Median residue (tentative) [(e)]	0.01*	Median residue (tentative) [(e)]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(b): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(c): CXL is supported by data; the corresponding risk assessment values are used for the exposure calculations.
(d): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative 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.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference values derived for flutriafol (see Table 2-1); detailed results of the calculations are presented as the EU/Codex scenario in Appendix B.2. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 34 % of the ADI, and the highest acute exposure was calculated for table grapes, representing 80 % of the ARfD.

Based on the above calculations, EFSA concludes that the CXLs, all supported by data (footnote c in Table 4-2), are not expected to be of concern for European consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of flutriafol was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.01 mg/kg bw per d and 0.05 mg/kg bw, respectively.

Metabolism of flutriafol in primary crops was investigated for foliar application on fruits, root and tuber vegetables, oilseeds and cereals crop groups. Metabolic patterns in the different studies were shown to be similar, with the parent compound being the main compound of the TRR in all crops investigated, except in cereal grain, where the cleavage of flutriafol occurred, with the formation of triazole alanine and triazole acetic acid (TDMs). Based on these studies, EFSA proposes parent flutriafol as the residue definition for enforcement and risk assessment purpose pending a harmonized approach on how to consider TDMs in the risk assessment. The proposed residue definitions apply to foliar treatment in all plant commodities. Validated analytical methods for enforcement of the proposed residue definition are available.

Regarding the magnitude of residues in crops reported by the RMS, a sufficient number of residues trials is available for most of the GAPs reported by the RMS, which allowed EFSA to derive appropriate MRLs in the relevant plant commodities. However, for beetroot, tomatoes, melons, watermelons and rice grain, only tentative MRLs could be derived, while for strawberries, sweet corn,

beet leaves, fresh lentils, asparagus, dry pulses, maize and oats grain the available data were insufficient to derive tentative MRLs.

Studies investigating the effects of processing on the nature of flutriafol were not provided and are required especially for pome fruits, tomatoes and wine grapes which are the main contributors to the exposure. Several processing studies investigating the magnitude of the residues of flutriafol in processed commodities are available. A robust processing factor for enforcement and risk assessment was derived only for peeled bananas; the processing factors for the other processed commodities were derived on a tentative basis. If more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

The potential incorporation of soil residues into rotational crops was investigated in confined studies with lettuce, sugar beet, radish, peas, rape seed and wheat grown in rotation. It can be concluded that a specific residue definition in rotational crops is not necessary. In addition, several rotational crop field trials on root and tuber vegetables, cereals, oilseeds and leafy crops were evaluated. Based on these studies and considering the high persistence of flutriafol in soil, it can be concluded that, after one or several years of application of flutriafol in compliance with the authorised GAPs in Europe, flutriafol and the TDMs residue levels in the edible parts of the rotational crops are expected to exceed 0.01 mg/kg. EFSA therefore concludes that Member States granting authorisations for flutriafol should take the appropriate risk mitigation measures in order to avoid the presence of flutriafol and TDMs residues in rotational crops. EFSA is also of the opinion that the maximum plateau concentration in soil should be revised in accordance with the authorised uses in Europe and it should be assessed whether the available rotational crops field trials cover this plateau concentration, in order to conclude on the actual residue levels of flutriafol and of the TDMs in the edible parts of the rotated crops.

Based on the uses reported by the RMS, significant exposures to flutriafol residues are expected for dairy, meat ruminants and pigs. The available ruminant metabolism data are not appropriate to derive robust residue definitions. Pending the availability of new metabolism data, the residue in ruminant and pig commodities is tentatively defined as parent flutriafol only, both for enforcement and risk assessment. Validated analytical methods for enforcement are available, except for fat. The available feeding study on lactating ruminants demonstrates that residues of flutriafol are not expected in quantifiable amounts in ruminant and pig meat, kidney and fat and in ruminant milk; MRLs in these commodities can be set at the LOQ. For ruminant and pig liver, MRLs of respectively 0.3 mg/kg and 0.1 mg/kg are proposed. All these MRLs are derived on a tentative basis only due to the identified data gaps, in particular regarding ruminant metabolism data. For poultry products, no residue definition needs to be set and no MRLs are proposed.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure was calculated for the WHO Cluster diet B (33 % of the ADI) and the highest acute exposure was calculated for peppers (52 % of the ARfD).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for flutriafol. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out. The highest chronic exposure was then calculated for WHO Cluster diet B (34 % of the ADI) and the highest acute exposure, for table grapes (80 % of the ARfD).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend the inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are 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 summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- An ILV and a confirmatory method for the enforcement of flutriafol residues in fat;
- 8 residue trials supporting the southern outdoor GAP on strawberries and 8 residue trials supporting the indoor GAPs on strawberries;
- 8 and 4 residue trials supporting respectively the northern and southern outdoor GAPs on beetroot;
- 8 residue trials supporting the indoor GAP on tomatoes and 8 residue trials supporting the southern outdoor GAP on tomatoes;
- 8 residue trials on melons supporting the indoor GAP on melons and watermenlons and 8 residue trials on melons supporting the southern outdoor GAP on melons and watermelons;
- 4 residue trials supporting the northern outdoor GAP on sweet corn;
- 4 residue trials supporting the northern outdoor GAP on beet leaves (chard) and 4 residue trials supporting the southern outdoor GAP on beet leaves (chard);
- 5 and 7 additional residue trials supporting respectively the northern and southern outdoor GAPs on fresh peas (without pods);
- 4 residue trials supporting the southern outdoor GAP on lentils (fresh);
- clarifications on the southern outdoor GAP (number of applications, PHI, application rate in g a.s./ha) on asparagus and 4 residue trials supporting that GAP;
- 8 residue trials on dry beans or dry peas supporting the northern outdoor GAP on dry pulses;
- 8 residue trials on barley supporting the southern outdoor GAP on barley and oats (mainly to support the MRL in oats because the MRL for barley is derived from the northern GAP and fully supported by data);
- 8 residue trials supporting the northern outdoor GAP on maize and 8 residue trials supporting the southern outdoor GAP on maize;
- 8 residue trials supporting the southern outdoor GAP on rice grain;
- data investigating the effect of processing on the nature of flutriafol residues in plant commodities (especially for pome fruits, tomatoes and wine grapes);
- an appropriate ruminant metabolism study with radiolabelling of both the carbinol and triazolyl moieties of flutriafol;
- storage conditions of the samples from the feeding studies.

It is highlighted that some of the MRLs derived result 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 MRLs derived but which might have an impact on national authorisations:

- 8 residue trials compliant with the southern outdoor GAP on apples;
- 8 residue trials supporting the southern outdoor GAP on peppers;
- 4 residue trials compliant with the southern outdoor GAP on rape seed;
- recalculation of the maximum plateau concentration of flutriafol residues in soil in accordance with the authorised European uses and assessment whether the available rotational crops field trials cover the maximum plateau concentration.

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 MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- information on the sample storage conditions of the residue trials performed on sugar beet (root), peppers, fresh peas (without pods), barley grain, rice grain and wheat grain (northern trials only).

It is noted by EFSA that the above assessment was performed disregarding the possible impact of the isomer ratios due to plant or livestock metabolism and further investigation on this matter would in principle be required. Since guidance on the consideration of isomer ratios in the consumer risk assessment is not yet available, EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA also emphasises that the above assessment does not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: flutriafol					
0130000	Pome fruit	0.4	0.3	0.4	Further consideration needed [a]
0140020	Cherries	1.5	-	1	Recommended [b]
0140030	Peaches	0.6	-	0.6	Recommended [b]
0140040	Plums	0.4	-	0.4	Recommended [b]
0151010	Table grapes	0.8	0.8	0.8	Recommended [c]
0151020	Wine grapes	1	0.8	1.5	Further consideration needed [a]
0152000	Strawberries	0.5	-	0.5	Further consideration needed [d]
0163020	Bananas	0.3	0.3	0.3	Recommended [e]
0213010	Beetroot	0.05*	-	0.06	Further consideration needed [f]
0231010	Tomatoes	0.3	-	0.6	Further consideration needed [f]
0231020	Peppers	1	1	1	Recommended [e]
0233010	Melons	0.3	-	0.2	Further consideration needed [f]
0233030	Watermelons	0.3	-	0.2	Further consideration needed [f]
0234000	Sweet corn	0.05*	-	0.05	Further consideration needed [d]
0252030	Beet leaves (chard)	0.05*	-	0.05	Further consideration needed [d]
0255000	Witloof	0.05*	-	0.01*	Recommended [b]
0260040	Peas (fresh, without pods)	0.1	-	0.1	Further consideration needed [d]
0260050	Lentils (fresh)	0.05*	-	0.05	Further consideration needed [d]
0270010	Asparagus	0.05*	-	0.05	Further consideration needed [d]
0300000	Pulses, dry	0.05*	-	0.05	Further consideration needed [d]
401020	Peanuts	0.2	0.15	0.15	Recommended [c]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
0401060	Rape seed	0.2	-	0.5	Recommended [b]
0401070	Soya bean	0.4	0.4	0.4	Recommended [e]
0401080	Mustard seed	0.2	-	0.5	Recommended [b]
0401130	Gold of pleasure	0.2	-	0.5	Recommended [b]
0500010	Barley grain	0.5	-	0.15	Recommended [b]
0500030	Maize grain	0.5	-	0.5	Further consideration needed [d]
0500050	Oats grain	0.5	-	0.5	Further consideration needed [d]
0500060	Rice grain	0.5	-	1.5	Further consideration needed [f]
0500070	Rye grain	0.5	-	0.15	Recommended [b]
0500090	Wheat grain	0.5	0.15	0.15	Recommended [e]
0620000	Coffee beans	0.15	0.15	0.15	Recommended [c]
0900010	Sugar beet (root)	0.1	-	0.06	Recommended [b]
1011010	Swine muscle	0.01*	-	0.01*	Further consideration needed [f]
1011020	Swine fat	0.01*	-	0.01*	Further consideration needed [f]
1011030	Swine liver	0.01*	-	0.1	Further consideration needed [f]
1011040	Swine kidney	0.01*	-	0.01*	Further consideration needed [f]
1012010	Bovine muscle	0.01*	-	0.01*	Further consideration needed [f]
1012020	Bovine fat	0.01*	-	0.01*	Further consideration needed [f]
1012030	Bovine liver	0.01*	-	0.3	Further consideration needed [f]
1012040	Bovine kidney	0.01*	-	0.01*	Further consideration needed [f]
1013010	Sheep muscle	0.01*	-	0.01*	Further consideration needed [f]
1013020	Sheep fat	0.01*	-	0.01*	Further consideration needed [f]
1013030	Sheep liver	0.01*	-	0.3	Further consideration needed [f]
1013040	Sheep kidney	0.01*	-	0.01*	Further consideration needed [f]
1014010	Goat muscle	0.01*	-	0.01*	Further consideration needed [f]
1014020	Goat fat	0.01*	-	0.01*	Further consideration needed [f]
1014030	Goat liver	0.01*	-	0.3	Further consideration needed [f]
1014040	Goat kidney	0.01*	-	0.01*	Further consideration needed [f]
1020010	Cattle milk	0.01*	-	0.01*	Further consideration needed [f]
1020020	Sheep milk	0.01*	-	0.01*	Further consideration needed [f]
1020030	Goat milk	0.01*	-	0.01*	Further consideration needed [f]
-	Other products of plant and animal origin	See App C1	-	-	Further consideration needed [g]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers was identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(e): 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; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on flutriafol prepared by the rapporteur Member State United Kingdom in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 23 December 2011. Last updated on 13 December 2012.

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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			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
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.					
Beetroot	*Beta vulgaris subsp. Vulgaris*	NEU	Outdoor	FR					Foliar treatment - spraying	39	49		2	20			125.00	g a.i./ha	28	
Sweet corn	*Zea mays var. sacharata*	NEU	Outdoor	FR					Foliar treatment - spraying	30	71		2	15	20		117.50	g a.i./ha	21	20 day PHI is reported
Beet leaves (chard)	*Beta vulgaris*	NEU	Outdoor	FR					Foliar treatment - spraying	39	49		2	20			125.00	g a.i./ha	28	
Witloof	*Cichorium intybus. var. Foliosum*	NEU	Outdoor	FR					Foliar treatment - spraying	39	49		1				125.00	g a.i./ha		Use on chicory root with production of witloof (leaves) after forcing.
Peas (without pods)	*Pisum sativum*	NEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		94.00	g a.i./ha	21	
Beans (dry)	*Phaseolus vulgaris*	NEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		125.00	g a.i./ha	14	
Lentils (dry)	*Lens culinaris syn. L. esculenta*	NEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		125.00	g a.i./ha	14	
Peas (dry)	*Pisum sativum*	NEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		125.00	g a.i./ha	14	
Lupins	*Lupinus spp.*	NEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		125.00	g a.i./ha	14	
Rape seed	*Brassica napus*	NEU	Outdoor	FR					Foliar treatment - spraying	62	80		2	15	20		125.00	g a.i./ha	n.a.	
Mustard seed	*Brassica nigra*	NEU	Outdoor	FR					Foliar treatment - spraying	62	80		2	15	20		125.00	g a.i./ha	n.a.	
Gold of pleasure	*Camelina sativa*	NEU	Outdoor	FR					Foliar treatment - spraying	62	80		2	15	20		125.00	g a.i./ha	n.a.	
Barley	*Hordeum spp.*	NEU	Outdoor	UK		SC	125.0	g/L	Foliar treatment - spraying		73		2				125.00	g a.i./ha	n.a.	
Maize	*Zea mays*	NEU	Outdoor	FR					Foliar treatment - spraying	30	71		2	15	20		117.50	g a.i./ha	n.a.	20 day PHI
Rye	*Secale cereale*	NEU	Outdoor	UK		SC	47.0	g/l	Foliar treatment - spraying		73		2				117.50	g a.i./ha	n.a.	
Wheat	*Triticum aestivum*	NEU	Outdoor	UK		SC	125.0	g/L	Foliar treatment - spraying		73		2				125.00	g a.i./ha	n.a.	
Sugar beet	*Beta vulgaris*	NEU	Outdoor	FR					Foliar treatment - spraying	39	49		2		20		125.00	g a.i./ha	21	
Fodder beet	*Beta vulgaris*	NEU	Outdoor	FR					Foliar treatment - spraying	39	49		2		20		125.00	g a.i./ha	21	

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 charachters)
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.					
Apples	*Malus domesticus*	SEU	Outdoor	ES	Powdery mildew, Venturia inaequalis	SC	125.0	g/L	Foliar treatment - spraying	15	87	1	3	10	14	9.00	31.00	g a.i./ha	14	
Pears	*Pyrus communis*	SEU	Outdoor	IT	Scab, powdery mildew	SC	250.0	g/L	Foliar treatment - spraying	n.a.	n.a.		2	10	14	20.00	30.00	g a.i./ha	21	
Strawberries	*Fragaria x ananassa*	SEU	Outdoor	ES	Sphaeroteca macularis (powdery mildew)	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	54.00	190.00	g a.i./ha	3	
Beetroot	*Beta vulgaris subsp. Vulgaris*	SEU	Outdoor	FR					Foliar treatment - spraying	39	49		2	20			125.00	g a.i./ha	28	
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	ES	Leveillula taurica	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	45.00	190.00	g a.i./ha	1	
Peppers	*Capsicum annuum, var grossum and var. longum*	SEU	Outdoor	ES	Leveillula taurica	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	45.00	190.00	g a.i./ha	1	
Melons	*Cucumis melo*	SEU	Outdoor	ES	Powdery mildew	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	125.00	310.00	g a.i./ha	10	
Watermelons	*Citrullus lanatus*	SEU	Outdoor	ES	Powdery mildew	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	125.00	310.00	g a.i./ha	10	
Beet leaves (chard)	*Beta vulgaris*	SEU	Outdoor	FR					Foliar treatment - spraying	39	49		2	20			125.00	g a.i./ha	28	
Peas (without pods)	*Pisum sativum*	SEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		94.00	g a.i./ha	21	
Lentils (fresh)	*Lens culinaris syn. L. esculenta*	SEU	Outdoor	FR					Foliar treatment - spraying	16	69		2	15	20		94.00	g a.i./ha	21	
Asparagus	*Asparagus officinalis*	SEU	Outdoor	ES	Puccinia spp.	SC	125.0	g/L	Foliar treatment - spraying	11						12.00	19.00	g a.i./hL	n.a.	
Rape seed	*Brassica napus*	SEU	Outdoor	FR					Foliar treatment - spraying	62	80		2	15	20		125.00	g a.i./ha	n.a.	
Mustard seed	*Brassica nigra*	SEU	Outdoor	FR					Foliar treatment - spraying	62	80		2	15	20		125.00	g a.i./ha	n.a.	
Gold of pleasure	*Camelina sativa*	SEU	Outdoor	FR					Foliar treatment - spraying	62	80		2	15	20		125.00	g a.i./ha	n.a.	
Barley	*Hordeum spp.*	SEU	Outdoor	IT	Powdery mildew, Rust, Septoria blotch, Head blight	SC	125.0	g/L	Foliar treatment - spraying	29	62		3				125.00	g a.i./ha	35	
Maize	*Zea mays*	SEU	Outdoor	FR					Foliar treatment - spraying	30	71		2	15	20		117.50	g a.i./ha	n.a.	20 day PHI
Oats	*Avena fatua*	SEU	Outdoor	IT	Powdery mildew, Rust, Septoria blotch, Head blight	SC	125.0	g/L	Foliar treatment - spraying	29	62		3				125.00	g a.i./ha	35	
Rice	*Oryza sativa*	SEU	Outdoor	IT	Pyricularia oryzae, Drechslera oryzae	SC	250.0	g/L	Foliar treatment - spraying				2				187.50	g a.i./ha	28	
Rye	*Secale cereale*	SEU	Outdoor	FR		SC	250.0	g/L	Foliar treatment - spraying	30	51		2	20	30		117.50	g a.i./ha	n.a.	
Wheat	*Triticum aestivum*	SEU	Outdoor	IT	Powdery mildew, Rust, Septoria blotch, Head blight	SC	125.0	g/L	Foliar treatment - spraying	29	61		2				125.00	g a.i./ha	35	
Sugar beet	*Beta vulgaris*	SEU	Outdoor	FR					Foliar treatment - spraying	39	49		2		20		125.00	g a.i./ha	21	
Fodder beet	*Beta vulgaris*	SEU	Outdoor	FR					Foliar treatment - spraying	39	49		2		20		125.00	g a.i./ha	21	

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
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.					
Strawberries	*Fragaria x ananassa*	NEU/SEU	Indoor	ES	Sphaeroteca macularis (powdery mildew)	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	54.00	190.00	g a.i./ha	3	
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	ES	Leveillula taurica	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	45.00	190.00	g a.i./ha	1	
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU/SEU	Indoor	ES	Leveillula taurica	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	45.00	190.00	g a.i./ha	1	
Melons	*Cucumis melo*	NEU/SEU	Indoor	ES	Powdery mildew	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	125.00	310.00	g a.i./ha	10	
Watermelons	*Citrullus lanatus*	NEU/SEU	Indoor	ES	Powdery mildew	SC	125.0	g/L	Foliar treatment - spraying	13	89	1	3	10	14	125.00	310.00	g a.i./ha	10	

Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
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.					
Apples	*Malus domesticus*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	71	85	4	6				120.00	g a.i./ha	14	EFSA Journal 2013;11(10):3446
Pears	*Pyrus communis*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	71	85	4	6				120.00	g a.i./ha	14	EFSA Journal 2013;11(10):3446
Quinces	*Cydonia oblonga*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	71	85	4	6				120.00	g a.i./ha	14	EFSA Journal 2013;11(10):3446
Medlar	*Mespilus germanica*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	71	85	4	6				120.00	g a.i./ha	14	EFSA Journal 2013;11(10):3446
Loquat	*Eriobotrya japonica*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	71	85	4	6				120.00	g a.i./ha	14	EFSA Journal 2013;11(10):3446
Cherries	*Prunus cerasus, Prunus avium*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	74	85		4				128.00	g a.i./ha	7	EFSA Journal 2013;11(10):3446
Peaches	*Prunus persica*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	74	85		4				128.00	g a.i./ha	7	EFSA Journal 2013;11(10):3446
Plums	*Prunus domestica*	non-EU	Outdoor	US	Scab (Venturia inaequalis), Powdery mildew (Podosphaera leucotricha)	SC	125.0	g/L	Foliar treatment - spraying	74	85		4				128.00	g a.i./ha	7	EFSA Journal 2013;11(10):3446
Wine grapes	*Vitis euvitis*	non-EU	Outdoor		-	SC	125.0	g/L	Foliar treatment - spraying				7				128.00	g a.i./ha	14	EFSA Journal 2010;8(4):1587
Bananas	*Musa x paradisica*	non-EU	Outdoor		Yellow Sigatoka leaf spot (Mycosphaerella musicola), Black Sigatoka leaf spot (Mycosphaerella fijiensis).	SC	125.0	g/L	Foliar treatment - spraying				8				125.00	g a.i./ha	0	EFSA Journal 2010;8(4):1587
Soya bean	*Glycine max*	non-EU	Outdoor		Soybean rust (Phakospora pachyrizi)	SC	125.0	g/L	Foliar treatment - spraying				3				61.25	g a.i./ha	21	2 applications each at 61.25 g as/ha + 1 application at 122.5 g as/ha - EFSA Journal 2010; 8(4):1587

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario including demonstrated safe EU MRL proposals and all CXLs

APPENDIX B.1 – EU SCENARIO INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Flutriafol			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	4 33
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)
33.3	WHO Cluster diet B	12.4	Maize	6.1	Wine grapes	4.8	Tomatoes	
25.0	IE adult	11.5	Maize	4.3	Wine grapes	1.2	Strawberries	
22.0	DE child	8.4	Apples	2.4	Strawberries	1.5	Tomatoes	
20.0	UK Infant	5.1	Maize	3.9	Milk and cream,	2.5	Rice	
19.5	PT General population	8.5	Wine grapes	3.1	Rice	2.4	Maize	
17.4	FR all population	13.6	Wine grapes	0.7	Tomatoes	0.7	Wheat	
16.4	NL child	4.4	Apples	2.9	Milk and cream,	1.4	Rice	
15.5	WHO cluster diet E	5.5	Wine grapes	2.8	Maize	0.8	Rice	
13.9	UK Toddler	3.4	Sugar beet (root)	2.3	Rice	2.1	Milk and cream,	
13.7	FR toddler	4.0	Milk and cream,	3.1	Strawberries	1.8	Apples	
12.3	WHO cluster diet D	2.7	Maize	2.2	Rice	1.6	Tomatoes	
11.1	DK child	2.0	Oats	1.6	Apples	1.3	Milk and cream,	
11.0	ES child	1.9	Rice	1.5	Tomatoes	1.4	Maize	
9.5	WHO Cluster diet F	2.0	Wine grapes	1.1	Tomatoes	0.8	Rice	
9.3	DK adult	4.7	Wine grapes	0.6	Tomatoes	0.6	Oats	
8.8	SE general population 90th percentile	1.6	Rice	1.2	Milk and cream,	1.2	Tomatoes	
8.7	FR infant	2.6	Milk and cream,	2.4	Strawberries	1.8	Apples	
8.7	WHO regional European diet	1.7	Tomatoes	0.8	Wine grapes	0.8	Rice	
8.7	UK vegetarian	2.8	Wine grapes	1.5	Rice	1.0	Tomatoes	
8.4	UK Adult	3.7	Wine grapes	1.4	Rice	0.7	Tomatoes	
8.0	ES adult	1.4	Wine grapes	1.2	Tomatoes	0.9	Rice	
7.7	IT kids/toddler	2.2	Tomatoes	1.3	Wheat	0.8	Rice	
7.5	NL general	2.1	Wine grapes	0.8	Apples	0.7	Tomatoes	
5.9	IT adult	1.8	Tomatoes	0.8	Wheat	0.7	Rice	
5.2	LT adult	1.3	Apples	1.0	Tomatoes	0.8	Rice	
4.6	FI adult	1.0	Wine grapes	0.7	Tomatoes	0.6	Milk and cream,	
4.0	PL general population	1.4	Apples	1.4	Tomatoes	0.3	Cherries	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
51.6	Peppers	0.41 / -	36.9	Peppers	0.41 / -	42.2	Wine grapes	0.89 / -	42.2	Wine grapes	0.89 / -
48.7	Peaches	0.41 / -	35.7	Peaches	0.41 / -	14.3	Peaches	0.41 / -	11.1	Peaches	0.41 / -
47.0	Apples	0.24 / -	34.7	Apples	0.24 / -	13.4	Peppers	0.41 / -	9.6	Peppers	0.41 / -
43.7	Pears	0.24 / -	31.4	Pears	0.24 / -	10.8	Apples	0.24 / -	9.0	Apples	0.24 / -
27.9	Tomatoes	0.24 / -	24.3	Melons	0.08 / -	10.3	Pears	0.24 / -	7.9	Pears	0.24 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
58.6	Grape juice	0.89 / -		6.9	Wine	0.89 / -	
24.5	Apple juice	0.24 / -		3.2	Apple juice	0.24 / -	
14.7	Peach juice	0.41 / -		1.6	Peach preserved with	0.41 / -	
8.4	Pear juice	0.24 / -		0.9	Tomato (preserved-	0.24 / -	
8.4	Tomato juice	0.24 / -		0.9	Bread/pizza	0.1 / -	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Flutriafol IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.2 – EU/CODEX SCENARIO INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

Flutriafol			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.01**	ARfD (mg/kg bw):	**0.05**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	5 34
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)
34.2	WHO Cluster diet B	12.4	Maize	6.1	Wine grapes	4.8	Tomatoes	
25.6	IE adult	11.5	Maize	4.3	Wine grapes	1.2	Strawberries	
24.7	DE child	8.4	Apples	2.7	Table grapes	2.4	Strawberries	
20.1	PT General population	8.5	Wine grapes	3.1	Rice	2.4	Maize	
20.0	UK Infant	5.1	Maize	3.9	Milk and cream,	2.5	Rice	
18.0	NL child	4.4	Apples	2.9	Milk and cream,	1.6	Table grapes	
17.6	FR all population	13.6	Wine grapes	0.7	Tomatoes	0.7	Wheat	
16.0	WHO cluster diet E	5.5	Wine grapes	2.8	Maize	0.8	Rice	
14.4	UK Toddler	3.4	Sugar beet (root)	2.3	Rice	2.1	Milk and cream,	
14.1	FR toddler	4.0	Milk and cream,	3.1	Strawberries	1.8	Apples	
12.7	WHO cluster diet D	2.7	Maize	2.2	Rice	1.6	Tomatoes	
11.4	DK child	2.0	Oats	1.6	Apples	1.3	Milk and cream,	
11.1	ES child	1.9	Rice	1.5	Tomatoes	1.4	Maize	
9.9	WHO Cluster diet F	2.0	Wine grapes	1.1	Tomatoes	0.8	Rice	
9.5	DK adult	4.7	Wine grapes	0.6	Tomatoes	0.6	Oats	
9.1	WHO regional European diet	1.7	Tomatoes	0.8	Wine grapes	0.8	Rice	
8.9	FR infant	2.6	Milk and cream,	2.4	Strawberries	1.8	Apples	
8.8	UK vegetarian	2.8	Wine grapes	1.5	Rice	1.0	Tomatoes	
8.8	SE general population 90th percentile	1.6	Rice	1.2	Milk and cream,	1.2	Tomatoes	
8.6	UK Adult	3.7	Wine grapes	1.4	Rice	0.7	Tomatoes	
8.2	NL general	2.1	Wine grapes	0.8	Apples	0.7	Tomatoes	
8.1	ES adult	1.4	Wine grapes	1.2	Tomatoes	0.9	Rice	
7.9	IT kids/toddler	2.2	Tomatoes	1.3	Wheat	0.8	Rice	
6.2	IT adult	1.8	Tomatoes	0.8	Wheat	0.7	Rice	
5.2	LT adult	1.3	Apples	1.0	Tomatoes	0.8	Rice	
4.8	FI adult	1.0	Wine grapes	0.7	Tomatoes	0.6	Milk and cream,	
4.7	PL general population	1.4	Apples	1.4	Tomatoes	0.7	Table grapes	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
79.9	Table grapes	0.61 / -	79.9	Table grapes	0.61 / -	42.2	Wine grapes	0.89 / -	42.2	Wine grapes	0.89 / -
51.6	Peppers	0.41 / -	36.9	Peppers	0.41 / -	38.7	Table grapes	0.61 / -	38.7	Table grapes	0.61 / -
48.7	Peaches	0.41 / -	35.7	Peaches	0.41 / -	14.3	Peaches	0.41 / -	11.1	Peaches	0.41 / -
47.0	Apples	0.24 / -	34.7	Apples	0.24 / -	13.4	Peppers	0.41 / -	9.6	Peppers	0.41 / -
43.7	Pears	0.24 / -	31.4	Pears	0.24 / -	10.8	Apples	0.24 / -	9.0	Apples	0.24 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
58.6	Grape juice	0.89 / -		6.9	Wine	0.89 / -	
24.5	Apple juice	0.24 / -		3.2	Apple juice	0.24 / -	
14.7	Peach juice	0.41 / -		1.6	Peach preserved with	0.41 / -	
8.4	Pear juice	0.24 / -		0.9	Tomato (preserved-	0.24 / -	
8.4	Tomato juice	0.24 / -		0.9	Bread/pizza	0.1 / -	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Flutriafol IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs - File created on 27/03/2014 18:41)

Code number	Groups and examples of individual products to which the MRLs apply [a]	Flutriafol
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,2
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,2
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,2
110030	Lemons (Citron, lemon)	0,2
110040	Limes	0,2
110050	Mandarins (Clementine, tangerine and other hybrids)	0,2
110990	Others	0,2
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	0,4 [b]
130010	Apples (Crab apple)	0,4 [b]
130020	Pears (Oriental pear)	0,4 [b]
130030	Quinces	0,4 [b]
130040	Medlar	0,4 [b]
130050	Loquat	0,4 [b]
130990	Others	0,4 [b]
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	1.5 [b]
140030	Peaches (Nectarines and similar hybrids)	0,6 [b]
140040	Plums (Damson, greengage, mirabelle)	0,4 [b]
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	0,8 [a]
151020	Wine grapes	1
152000	(b) Strawberries	0,5
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 (mediteranean 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	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,3
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	0,2
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	0,2
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,3
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	0,3
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply [a]	Flutriafol
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	0,3
233010	Melons (Kiwano)	0,3
233020	Pumpkins (Winter squash)	0,3
233030	Watermelons	0,3
233990	Others	0,3
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb´s lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce,	0,05*
	romaine (cos) lettuce)	
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	
401010	Linseed	0,2
401020	Peanuts	0,2
401030	Poppy seed	0,2
401040	Sesame seed	0,2
401050	Sunflower seed	0,2
401060	Rape seed (Bird rapeseed, turnip rape)	0,2
401070	Soya bean	0,4
401080	Mustard seed	0,2
401090	Cotton seed	0,2
401100	Pumpkin seeds	0,2
401110	Safflower	0,2
401120	Borage	0,2
401130	Gold of pleasure	0,2
401140	Hempseed	0,2
401150	Castor bean	0,2
401990	Others	0,2
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,5
500010	Barley	0,5
500020	Buckwheat	0,5
500030	Maize	0,5
500040	Millet (Foxtail millet, teff)	0,5
500050	Oats	0,5
500060	Rice	0,5
500070	Rye	0,5
500080	Sorghum	0,5
500090	Wheat (Spelt Triticale)	0,5
500990	Others	0,5
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,15
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*

Code number	Groups and examples of individual products to which the MRLs apply [a]	Flutriafol
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,1
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	0,01*
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*
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 concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,01*
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)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,01*
1060000	(vi) Snails	0,01*
1070000	(vii) Other terrestrial animal products	0,01*

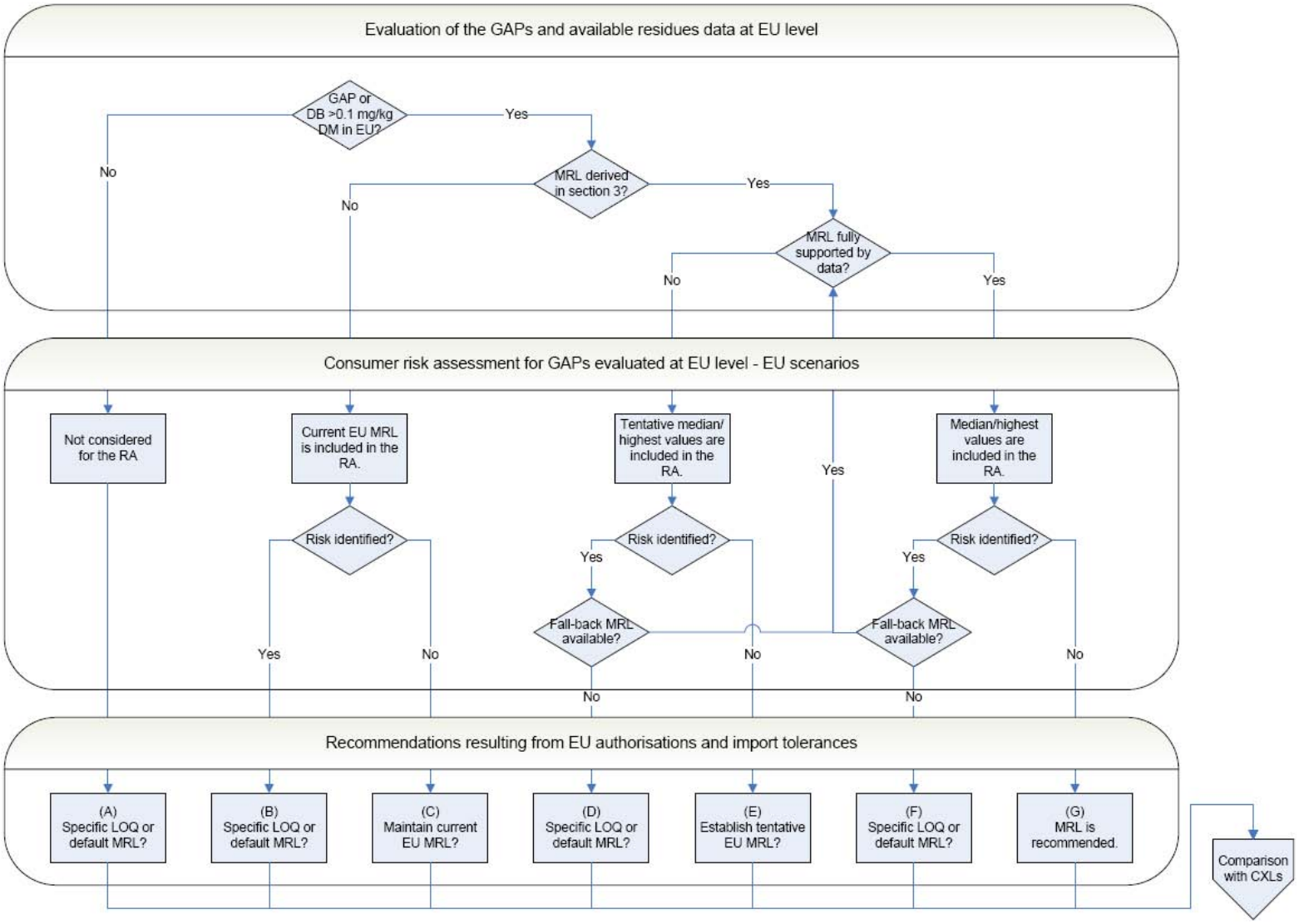
(*) Indicates lower limit of analytical determination
(a): This MRL was already approved by the meeting of the Standing Committee on the Food Chain and Animal Health held on 18-19 November 2013 but not yet legally implemented.
(b): These MRLs were already approved by the meeting of the Standing Committee on the Food Chain and Animal Health held on 24-25 February 2014 but not yet legally implemented.

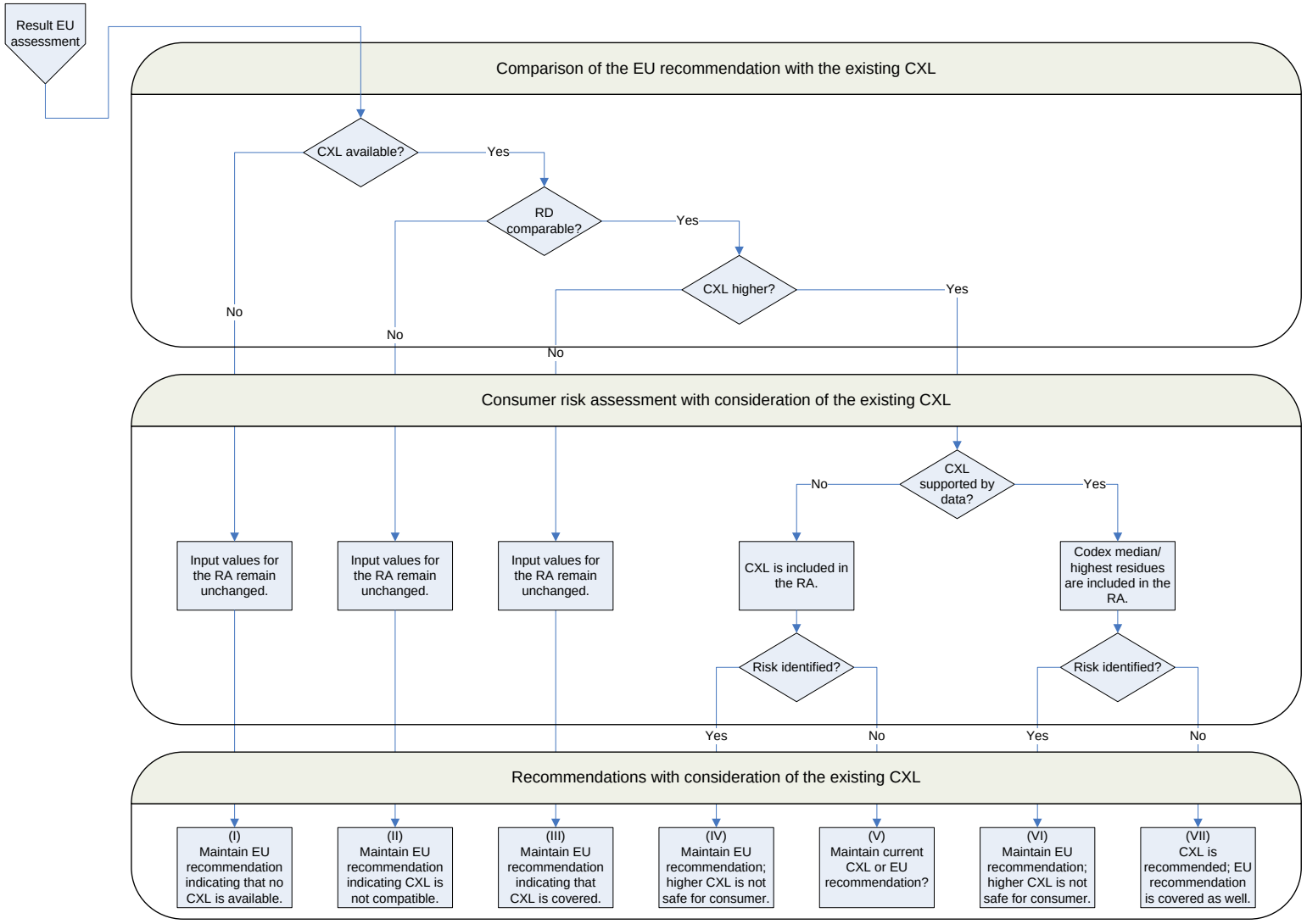
APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for flutriafol in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
130010	Apples	Flutriafol	0.3	Flutriafol	0.07	0.16	3	n.c.	0.07	0.16	n.a.	1	2011	No	CXL based on a total of sixteen (16) trials conducted on apples [extrapolated to pome fruit] in the USA according to GAP.
130020	Pears	Flutriafol	0.3	Flutriafol	0.07	0.16	3	n.c.	0.07	0.16	n.a.	1	2011	No	
130030	Quinces	Flutriafol	0.3	Flutriafol	0.07	0.16	3	n.c.	0.07	0.16	n.a.	1	2011	No	
130040	Medlar	Flutriafol	0.3	Flutriafol	0.07	0.16	1	n.c.	0.07	0.16	n.a.	1	2011	No	
130050	Loquat	Flutriafol	0.3	Flutriafol	0.07	0.16	1	n.c.	0.07	0.16	n.a.	1	2011	No	
151010	Table grapes	Flutriafol	0.8	Flutriafol	0.21	0.61	3	n.c.	0.21	0.61	n.a.	1	2011	No	CXL based on a total of thirteen (13) trials conducted in the USA according to GAP. **N.B.** Since the CXL is underpinned by scaled residues (i.e. using the principle of proportionality; scaling factor: 0.71) the EFSA calculated values (STMR and HR) are also calculated on the basis of these endpoints.
151020	Wine grapes	Flutriafol	0.8	Flutriafol	0.21	0.61	3	n.c.	0.21	0.61	n.a.	1	2011	No	
163020	Bananas	Flutriafol	0.3	Flutriafol	0.05	0.09	3	n.c.	0.08	0.17	0.8	1	2011	No	CXL based on a total of twelve (12) trials conducted in South America according to GAP. **N.B.** Since residues were determined in the whole fruit and pulp it was possible to calculate a mpf.
231020	Peppers	Flutriafol	1	Flutriafol	0.28	0.41	3	n.c.	0.28	0.41	n.a.	1	2011	Yes	CXL based on a total of eight (8) trials conducted in Spain according to GAP.
401020	Peanuts	Flutriafol	0.15	Flutriafol	0.02	n.c.	3	n.c.	0.02	0.08	n.a.	1	2011	No	CXL based on a total of thirteen (13) trials conducted in the USA according to GAP.
401070	Soya bean	Flutriafol	0.4	Flutriafol	0.055	n.c.	3	n.c.	0.06	0.3	n.a.	1	2011	No	CXL based on a total of twenty (20) trials conducted in the USA according to GAP. Could also apply to beans (dry).
500090	Wheat grain	Flutriafol	0.15	Flutriafol	0.015	n.c.	3	n.c.	0.02	0.1	n.a.	1	2011	Yes	CXL based on a total of eight (8) trials conducted in southern France and Spain according to GAP.
620000	Coffee beans	Flutriafol	0.15	Flutriafol	0.05	n.c.	3	n.c.	0.05	0.1	n.a.	1	2011	No	CXL based on a total of eight (8) trials conducted in Brazil, Columbia and Guatemala according to GAP.

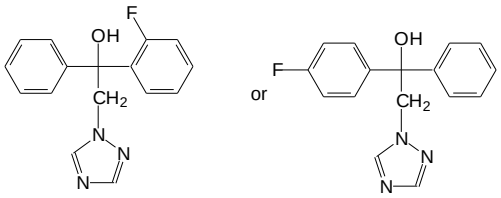
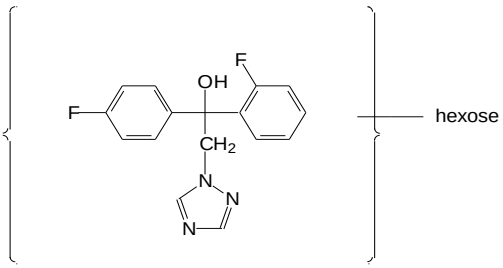
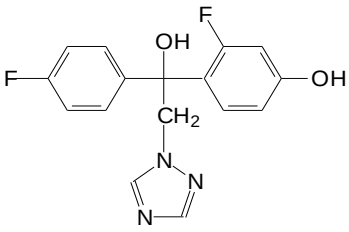
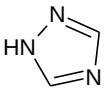
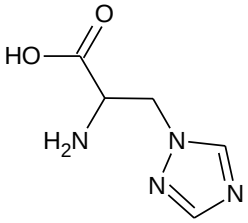
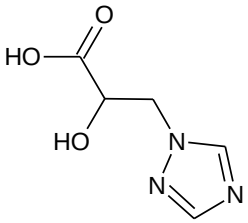
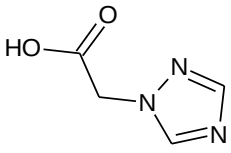
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
defluorinated flutriafol	(1*RS*)-1-(2-fluorophenyl)-1-phenyl-2-(1*H*-1,2,4-triazol-1-yl)ethanol or (1*RS*)-1-(4-fluorophenyl)-1-phenyl-2-(1*H*-1,2,4-triazol-1-yl)ethanol	
hexose conjugated flutriafol	Not available	
4-hydroxyflutriafol	3-fluoro-4-[(1RS)-1-(4-fluorophenyl)-1-hydroxy-2-(1H-1,2,4-triazol-1-yl)ethyl]phenol	
Triazole derivative metabolites (TDMs)		
1,2,4-triazole (free triazole)	1*H*-1,2,4-triazole	
triazole alanine	3-(1*H*-1,2,4-triazol-1-yl)-DL-alanine	
triazole lactic acid	(2*RS*)-2-hydroxy-3-(1*H*-1,2,4-triazol-1-yl)propanoic acid	
triazole acetic acid	1*H*-1,2,4-triazol-1-ylacetic acid	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
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_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organization of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
IESTI	International Estimate Short Term Intake

ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient n-octanol/water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues Overview File
PRAPeR	Pesticide Risk Assessment Peer Review
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RMS	rapporteur Member State
RSD	relative standard deviation
SC	suspension concentrate
SEU	Southern European Union
TDM	triazole derivative metabolite
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organization