SCIENTIFIC REPORT OF EFSA

Scientific support for preparing an EU position in the 44th Session of the Codex Committee on Pesticide Residues (CCPR) [1]

European Food Safety Authority[2]

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SUMMARY

In preparation of the 44th session of the Codex Committee on Pesticide Residues (CCPR meeting) the European Commission requested EFSA to provide comments on the recommendations of the 2011 Joint FAO/WHO Meeting on Pesticide Residues (JMPR) and pesticide MRLs at step 3 and 6 of the Codex procedure.

In 2011, JMPR evaluated 12 active substances regarding the setting of toxicological reference values to be used in consumer risk assessment (acetamiprid, dichlorvos, dicofol, emamectin benzoate, etofenprox, flutriafol, glyphosate, isopyrazam, penthiopyrad, propylene oxide, saflufenacil and sulfoxaflor). EFSA compared the ADI and ARfD values derived by JMPR with the values derived at EU level and, in case differences were identified, EFSA provided further explanations for the reasons of the differences. In conclusion, EFSA expressed a reservation for the proposed toxicological reference values for dichlorvos, diflubenzuron, isopyrazam, propylene oxide and sulfoxaflor. EFSA is in agreement with the JMPR conclusion that for the propylene oxide related metabolites that the toxicological data are not sufficient to derive reference values. EFSA also expressed a reservation for the ADI/ARfD for acephate and methamidophos, assessed by JMPR in 2005 and 2002, respectively.

JMPR assessed 24 substances regarding the setting of Maximum Residue Limits (CXLs) (acephate, acetamiprid, azoxystrobin, clothianidin, cypermethrins (including alpha- and zeta-cypermethrin), dicamba, diflubenzuron, emamectin benzoate, etofenprox, etoxazole, flutriafol, glyphosate, hexythiazox, isopyrazam, methamidophos, profenofos, propylen oxide, pyraclostrobin, saflufenacil, spinosad, spirotetramat, sufloxaflor, tebuconazole and thiamethoxam). Potential consumer concerns were identified for the CXL proposals for diflubenzuron, profenofos, tebuconazole and acetamiprid. Regarding achephate/methamidophos and cypermethrin a potential risk was identified which are mainly attributed to uncertainties in the risk assessment. According to the EU policy for setting MRLs the data would not be sufficient in some cases where JMPR derived CXL proposals. This finding refers to diflubenzuron in peppers, peaches and plums, spinosad in blackberries and dewberries, acetamiprid in spring onions, plums and beans, hexythiazox in strawberries, etofenprox in grapes, flutriafol in grapes and dicamba in soybeans. Based on the dataset assessed by JMPR MRLs at a different level would be proposed at EU level for pyraclostrobin in citrus, oilseeds and papaya,

[1] On request from European Commission, Question No from EFSA-Q-2012-00028 to EFSA-Q-2012-00054, approved on 23 July 2012

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Suggested citation: European Food Safety Authority; Scientific support for preparing an EU position in the 44th Session of the Codex Committee on Pesticide Residues (CCPR). EFSA Journal 2012;10(7):2859. [155 pp.] doi:10.2903/j.efsa.2012.2859. Available online:www.efsa.europa.eu/efsajournal

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etofenprox in meat, spirotetramat in edible offal, legume vegetables and milks, etoxazole in pome fruit and emamectin benzoate in aubergines. EFSA also identified concerns regarding the residue definitions derived by JMPR for hexythiazox, ethofenprox and tebuconazole.

KEY WORDS

Consumer risk assessment, toxicological evaluation, residue definitions, MRL setting, CCPR meeting 2012

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BACKGROUND

Manufacturers of pesticides submitted data to the JMPR (Joint Meeting on Pesticide Residues) for assessment with view of establishing new Codex maximum residue limits (CXLs). The recent JMPR evaluations of the toxicological data and the residue studies are summarised in the JMPR Report 2011 (WHO/FAO, 2012). It comprises 27 active substances, 3 of them (dichlorvos, dicofol, penthiopyrad) were assessed to derive toxicological reference values only, 15 active substances were assessed in view of setting new CXLs and 9 active substances were assessed for both, toxicology and residues. In preparation of the 44th session of the Codex Committee on Pesticide Residues (CCPR meeting) the European Commission requested EFSA on 9 December 2011 to review the JMPR evaluations of the active substances which will be discussed in the upcoming CCPR meeting in April 2012 and which are reported in the JMPR Report 2011. EFSA should provide comments regarding the acceptability of the CXL proposals and the toxicological reference values. The comments of EFSA should be considered to derive a common EU position for the Codex Committee on Pesticide Residues (CCPR) and to obtain an agreement of the Council before presenting the EU position in the CCPR.

For reasons of transparency and traceability, EFSA has created separate questions for each of the active substances covered by the mandate in the EFSA Register of Questions with the following reference numbers and subjects:

Question number	Subject
EFSA-Q-2012-00028	Acephate- EFSA comments on draft CXLs evaluated by JMPR in 2011
EFSA-Q-2012-00029	Acetamiprid- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00030	Azoxystrobin- EFSA comments on draft CXLs evaluated by JMPR in 2011
EFSA-Q-2012-00031	Clothianidin- EFSA comments on draft CXLs evaluated by JMPR in 2011
EFSA-Q-2012-00032	Cypermethrin (including alpha- and zeta-cypermethrin- EFSA comments on draft CXLs evaluated by JMPR in 2011
EFSA-Q-2012-00033	Dicamba- EFSA comments on draft CXLs evaluated by JMPR in 2011
EFSA-Q-2012-00034	Dichlorvos- EFSA comments on proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00035	Dicofol- EFSA comments on proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00036	Diflubenzuron- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-0037	Emamectin benzoate- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00038	Ethofenprox- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00039	Etoxazole- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00040	Flutriafol- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00041	Glyphosate- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00042	Hexythiazox- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00043	Isopyrazam- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011

Question number	Subject
EFSA-Q-2012-00044	Methamidophos- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00045	Penthiopyrad- EFSA comments on proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00046	Profenofos- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00047	Propylene oxid- - EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00048	Pyraclostrobin- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00049	Saflufenacil- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00050	Spinosad- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00051	Spirotetramat- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00052	Sulfoxaflor- EFSA comments on draft CXLs and proposed toxicological reference values evaluated by JMPR in 2011
EFSA-Q-2012-00053	Tebuconazole- EFSA comments on draft CXLs evaluate by JMPR in 2011
EFSA-Q-2012-00054	Thiamethoxam- EFSA comments on draft CXLs evaluate by JMPR in 2011

On 31 January 2012 the draft scientific report of EFSA was submitted for commenting to EU Member State experts and the European Commission for a Member State consultation. Comments were submitted by Austria, Belgium, Finland, Germany, Ireland, Italy, the Netherlands, Sweden and the United Kingdom and have been taken into account in the final report.

TERMS OF REFERENCE

The European Commission requested EFSA to prepare a contribution for the 44th session of the Codex Committee on Pesticide Residues (CCPR) which will be held on 23 – 28 April 2012 in Shanghai (China).

For all active substances under discussion, EFSA provides background information regarding the status of the active substance at EU level (approval status of the active substance, availability of EFSA conclusions and availability of EFSA reasoned opinions on MRL applications or MRL review.

In case new toxicological reference values were proposed by JMPR in the JMPR Report 2011, EFSA addresses the following questions:

1. Are the proposed toxicological reference values different from the agreed EU reference values?

2. What are the reasons for the differences?

3. Are the toxicological reference values the proposed by JMPR acceptable?

In case CXL proposals were derived by JMPR in the JMPR report 2011, EFSA provided responses on the following questions:

4. Are the residue definitions derived by JMPR comparable with the existing EU residue definitions?

5. Are the proposed CXLs comparable with the residue levels?

6. Are the CXL proposals sufficiently supported by data?

7. Are the levels of the proposed CXLs appropriate?

8. Are the proposed CXLs safe for European consumers with regard to chronic and, where relevant, for acute exposure?

EFSA agreed with the European Commission to respond to this request with a scientific report which will be adopted and published by 15 July 2012.

ASSESSMENT

1. Introduction

EFSA provides the requested background information regarding the toxicological reference values (question 1, 2 and 3 of the Terms of Reference) by comparing the assessments performed by JMPR with the assessments performed at EU level in the framework of the peer review under Regulation (EC) No 1107/2009[3]. The sources of information used are the EFSA conclusions available for the active substances under consideration, the Review Reports, Draft Assessment Reports prepared by the Rapporteur Member States and other sources of information if available.

For deriving the comments on question 4 (Are the residue definitions derived by JMPR comparable with the existing EU residue definitions?) and 5 (Are the proposed CXLs comparable with the residue levels?), EFSA compared the levels of the CXL proposals/MRLs and the enforcement residue definition derived by JMPR with the residue definition established in the EU legislation (Regulation (EC) No 396/2005[4]) or the legislation under preparation. The EU residue definitions for risk assessment were retrieved from the EFSA conclusions, EFSA reasoned opinions on MRL review under Art. 12 of Regulation 396/2005 or, where these documents are not available, the reports prepared by the European Commission in the framework of the peer review of active substances or Member State evaluations in Draft Assessment Reports (DARs).

For assessing whether the CXLs are sufficiently supported by data (question 6) EFSA took into account the currently valid EU guidance documents for consumer risk assessment and the agreed EU policies (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2004, 2008, 2010, 2011 OECD 2011). It is noted that due to the different data requirements and policies in JMPR (FAO, 2009), the assessment of identical residue data sets submitted in support of a EU MRL and CXL request may result in different recommendations at EU level and by JMPR. In this report EFSA provides background information on the reasons for these differences. For calculating the numerical MRL value (question 7), EFSA used the same methodology as JMPR (OECD calculator).

For the assessment of the safety of the CXL proposals (question 8), EFSA used the EFSA PRIMo rev. 2 (EFSA, 2007). For assessing the acute consumer risk, EFSA applied the standard EU methodology, including the agreed EU variability factors and the ARfD agreed at EU level. In those cases where a potential acute intake concern could not be excluded, EFSA calculated additional scenarios, aiming to provide risk managers with more information to decide on the acceptability of the CXL proposal. For the assessment of the long-term consumer risk, EFSA calculated the exposure resulting from the existing EU MRLs, including the risk assessment values (HR or STMR, where appropriate) for the proposed CXLs where the proposed CXLs are higher than the existing EU MRLs. It is noted that this approach overestimates the actual exposure, because it is not likely that each food item consumed contains residues at the maximum level allowed in the European legislation. The contribution of the individual crops under consideration in the CCPR meeting was calculated separately. In case the first conservative risk assessment indicated a potential consumer health risk EFSA performed more refined intake calculations, using appropriate data from other sources (e.g. STMR values instead of the EU MRL where available). The exposure assessments are usually based on the toxicological reference values, unless it was concluded that the toxicological reference values derived by JMPR are preferable. For some active substances, the exposure is calculated for both options.

For CXL proposals for food of animal origin, EFSA focussed mainly on the consumer risk assessment and the validity of feeding studies and animal metabolism studies. For the CXLs for animal

[3] Regulation (EC) No 1107/2009 of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50
[4] Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.

commodities a full assessment of the expected dietary burden at EU level will not possible because relevant information may not be available to EFSA.

2. Comments on the individual substances assessed

2.1. Dichlorvos (025) (T, periodic review)

Dichlorvos was evaluated under Directive 91/414/EEC[5], repealed by Regulation (EC) No 1107/2009 with Italy as Rapporteur Member State. A decision not to approve the active substance (Decision 2007/387/EC[6]) was taken in 2007. An EFSA conclusion is available (EFSA, 2006).

2.1.1. Toxicological endpoints - Dichlorvos

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-1: Comparison of toxicological reference values derived by JMPR and at EU level

Dichlorvos	JMPR evaluation 2011			EU evaluation 2006		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.004 mg/kg bw/d	Human, 21-day oral dosing study	10		No final value could be derived	
Comments ADI	ADI based on the NOAEL of 0.04 mg/kg bw/day for the inhibition of erythrocyte AChE activity in a 21-day study in male volunteers and using a 10-fold intraspecies SF.			A tentative ADI of 0.00008 mg/kg bw/d was derived in an EPCO meeting based on the NOAEL of 0.008 mg/kg bw/day from the 2-year dog study, for AChE inhibition at 0.08 mg/kg bw/day, 100 SF. However, EFSA concluded that based on the available opinion of the PPR Panel neither the reference value nor the safety factor can be confirmed in the light of the uncertainties on the overall picture of the toxicological properties (namely, genotoxicity and carcinogenicity) and the data requirement for a combined long-term and carcinogenicity study.		
ARfD	0.1 mg/kg bw	Human, acute oral toxicity study	10		No final value could be derived	
Comments ARfD	ARfD based on the NOAEL of 1 mg/kg bw for erythrocyte AChE inhibition in the acute oral study in male volunteers and using a 10-fold intraspecies SF. The NOAEL is supported by observations in two other volunteer studies in which no erythrocyte AChE inhibition occurred 1 day after dosing at 0.5 and 0.1 mg/kg bw, respectively.			A tentative ARfD of 0.002 mg/kg bw was derived in an EPCO meeting based on the NOAEL of 0.25 mg/kg bw/day for AChE inhibition, from developmental toxicity studies in rat & rabbit, 100 SF applied. However, EFSA concluded that based on the available opinion of the PPR Panel, as there are still uncertainties and data requirements identified, neither the reference value nor the safety factor are confirmed in the light of uncertainties on the overall picture of the toxicological properties and the data requirement for a long-term study.		
Conclusion	Currently no legally adopted EU toxicological reference values are available for dichlorvos, as the EU assessment considered the toxicological data package insufficient to address the genotoxic and carcinogenic potential of dichlorvos. Considering that the setting of toxicological reference values on the basis of human studies would not be acceptable at the EU level and that the tentative values proposed during the EPCO meeting are the more conservative, they would be the preferred ones to be used for a provisional risk assessment.					

[5] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32
[6] Commission Decision 2007/387/EC of 6 June 2007, OJ L 145, 7.6.2007, p. 16-17

2.2. Dicofol (026) (T, periodic review)

Dicofol was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Spain as Rapporteur Member State. A decision not to approve the active substance (Commission Decision 2008/764/EC[7]) was taken in 2008. For dicofol no EFSA conclusion is available. EFSA recently issued a reasoned opinion on the MRL review under Art. 12 of Regulation (EC) No 396/2005.

2.2.1. Toxicological endpoints - Dicofol

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-1: Comparison of toxicological reference values derived by JMPR and at EU level

Dicofol	**JMPR evaluation 2011**			**EU evaluation**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.002 mg/kg bw/d	2 yr rat	100	No value was derived		
Comments ADI	Based on the NOAEL of 0.22 mg/kg bw/day for histopathological changes in the liver and adrenal gland from the 2-yr rat study, supported by the NOAEL of 0.2 mg/kg bw/day from the 90-day neurotoxicity study in rats. There is a margin of 20.000 between the maximum ADI and the LOAEL for liver adenomas in the male mouse					
ARfD	0.2 mg/kg bw	Acute neurotoxicity rat	100	No value was derived		
Comments ARfD	Based on the NOAEL of 15 mg/kg bw in the acute neurotoxicity study in rats for decreased body weight and decreased feed intake at 75 mg/kg bw. This ARfD was supported by the NOAEL of 15 mg/kg bw in a single-dose oral toxicity study in rats, based on decreased feed intake and hypertrophy of adrenal zona fasciculata at 75 mg/kg bw.					
Conclusion	Currently no EU toxicological reference values are available for dicofol. For a tentative consumer risk assessment, the JMPR values are acceptable.					

[7] Commission Decision 2008/764/EC of 30 September 2008, OJ L 262, 1.10.2008, p. 40-41.

2.3. Acephate (095) (R)

Acephate was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Italy as Rapporteur Member State. A decision not to approve the active substance (Commission Decision 2003/219/EC[8]) was taken in 2003. For acephate no EFSA conclusion is available. The metabolite methamidophos is also not approved at EU level.

2.3.1. Toxicological endpoints -Acephate

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-2: Comparison of toxicological reference values derived by JMPR and at EU level

Acephate	JMPR evaluation 2005			EU evaluation (ECCO 93)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.03 mg/kg bw/d	Human, 28-day study	10	0.0025 mg/kg bw (proposal of the ECCO meeting)	2 yr rat	100
Comments ADI	Based on the NOAEL of 0.25 mg/kg bw/day from the study of repeated doses in humans. Overall safety factor of 10 was derived by dividing the default value of 10 by 2 (because inhibition of acetylcholinesterase activity depends on the C_{max}) and by multiplying by 2 (because some uncertainty remains with respect to the *in vivo* sensitivity to inhibition of human brain acetylcholinesterase activity relative to that of erythrocyte acetylcholinesterase activity, since brain acetylcholinesterase may be more sensitive than erythrocyte acetylcholinesterase).			For acephate, an ADI of 0.0025 mg/kg bw/day was proposed at the ECCO meeting (ECCO 93, 2000) based on the NOAEL of 0.25 mg/kg bw/day from the 2 yr rat study, 100 SF applied. The AChE in the rat brain was more sensitive to inhibition by acephate than erythrocyte AChE or BchE, therefore it seems justified to derive the ADI (and ARfD) from NOAELs for inhibition of brain AChE in animal studies rather than from human data for inhibition of erythrocyte AChE or BChE. The RMS supported the approach taken by the JMPR.		
ARfD	0.1 mg/kg bw	Human, single dose study	10	0.005 mg/kg bw (proposal of the ECCO meeting)	28 d rat	100
Comments ARfD	Based on the NOAEL of 1.2 mg/kg bw from the study of single doses in humans and overall SF of 10.			For acephate, an ARfD of 0.005 mg/kg bw was proposed at the ECCO meeting (ECCO 93, 2000) based on a NOAEL of 0.5 mg/kg bw/day from a 28-day study in rats. The RMS supported the approach taken by th eJMPR.		
Conclusion	Currently no legally adopted EU toxicological reference values are available for acephate. However, during an ECCO meeting, in 2000, the setting of reference values was agreed. At EU level the setting of toxicological reference values on the basis of human studies would not be acceptable, furthermore taking into consideration the reasoning for using animal data instead of human data due to the uncertainties regarding brain AchE inhibition in humans, a more conservative approach is considered appropriate and the reference values proposed at the ECCO meeting are supported.					

[8] Commission Decision 2003/219/EC of 25 March 2003, OJ L 082, 29.03.2003, p. 40-41

2.3.2. Residue definitions - Acephate

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-3: Comparison of the residue definitions derived by JMPR and at EU level

Acephate	Commodity group	JMPR evaluation 2006	EU evaluation
RD enf	Plant commodities	Acephate	Acephate
	Animal commodities		
RD RA	Plant commodities	Acephate + 7.5* methamidophos (for long-term dietary intake) Acephate + 10* methamidophos (for short-term dietary intake)	For the risk assessment the residues of methamidophos need to be considered. EFSA proposes the following residue definition is proposed as: Methamidophos + acephate/2.5 (for chronic-dietary intake) Methamidophos + acephate/1.7 (for short-term dietary intake Tox. equivalence factor of 2.5 and 1.7 are calculated from EU ADI/ARfD for methamidophos and EU ADI/ARfD for acephate, respectively.
	Animal commodities		
Conclusion	RD for enforcement is comparable. For risk assessment the residues of methamidophos and acephate have to be considered, taking into account the toxicological potencies. EFSA proposes a RA residue definition based on methamidophos, including acephate (taking into account the toxicological equivalence).		

2.3.3. CXL proposals - Acephate

In the table below the CXL proposal is compared with the EU MRL.

Table 2-4: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Rice, husked	1	0.02*	**CXL proposal is sufficiently supported by data.** The CXL proposal is derived from 8 Chinese trials (compliance with the GAP cannot be checked from the JMPR report).
Rice, polished			JMPR proposed a mean processing factors of 0.63. From the JMPR report it cannot be checked how the value was derived.
Rice straw and fodder, dry	0.3		No MRLs established at EU level.
The CXL proposals are acceptable.			

2.3.4. Consumer risk assessment - Acephate

The result for the consumer risk assessment is presented in the next section (2.4. Methamidophos).

2.4. Methamidophos (100) (R)

Methamidophos was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Italy as Rapporteur Member State. In 2006 a decision was taken to include methamidophos in Annex I of Directive 91/414/EEC for a limited period until 30 June 2008. After expiry of the Annex I inclusion[9], the authorisations had to be withdrawn at EU level. For methamidophos no EFSA conclusion is available.

2.4.1. Toxicological endpoints - Methamidophos

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-5: Comparison of toxicological reference values derived by JMPR and at EU level

Methamido-phos	JMPR evaluation JMPR 2002			EU evaluation Directive 2006/131		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.004 mg/kg bw/d	2 yr rat supported by 1yr dog, 21 d human volunteers and multigeneration in rats	25	0.001 mg/kg bw/d	2 yr rat	100
Comments ADI	Based on the NOAEL of 0.1 mg/kg bw/day for inhibition of erythrocyte and brain cholinesterase activity in the 2 yr rat study. Use of a safety factor of 25 supported by the information provided by the 21-day study in volunteers, by the finding of negligible species differences in inhibition of cholinesterase activity in rats, dogs and humans in vitro, by the absence of differences in inhibition of erythrocyte and brain cholinesterase activity in various animal species and because the effect was dependent on the Cmax.			No review report available on COM database.		
ARfD	0.01 mg/kg bw	Acute neurotoxicity study rats	25	0.003 mg/kg bw	Acute neurotoxicity study rats	100
Comments ARfD	Based on the NOAEL of 0.3 mg/kg bw for inhibition of erythrocyte and brain cholinesterase activity in the study of neurotoxicity in rats. Use of a safety factor of 25 for the same reasons as those given above for the ADI.			No review report available on COM database.		
Conclusion	At EU level lower toxicological reference values have been established. The agreed EU values are to be used for the consumer risk assessment and to calculate the toxicological equivalence factor.					

2.4.2. Residue definitions - Methamidophos

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[9] Commission Directive 2006/131/EC of 11 December 2011, OJ L 349, 12.12.2006, p 17-21

Table 2-6: Comparison of the residue definitions derived by JMPR and at EU level

Methamidophos	Commodity group	JMPR evaluation	EU evaluation
RD enf	Plant commodities	Methamidophos	Methamidophos
	Animal commodities		
RD RA	Plant commodities	Acephate + 10* methamidophos (for long-term dietary intake) Acephate + 7.5* methamidophos (for short-term dietary intake)	For the risk assessment the residues of acephate need to be considered. EFSA proposes the following residue definition is proposed as: Methamidophos + acephate/2.5 (for chronic-dietary intake) Methamidophos + acephate/1.7 (for short-term dietary intake Tox. equivalence factor of 2.5 and 1.7 are calculated from EU ADI/ARfD for methamidophos and EU ADI/ARfD for acephate, respectively.
	Animal commodities		
Conclusion	RD for enforcement is comparable. At EU level no residue definitions are set for risk assessment. EFSA proposes a RA residue definition based on methamidophos, including acephate (taking into account the toxicological equivalence).		

2.4.3. CXL proposals - Methamidophos

In the following table the CXL proposals are compared with the existing EU MRLs.

Table 2-7: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Rice, husked	0.6[a]	0.01*	**The CXL proposal is sufficiently supported** by data.
Rice, polished			JMPR proposed a mean processing factors of 0.85. From the JMPR report it cannot be checked how the value was derived.
Rice straw and fodder, dry	0.1[b]	-	No MRL established at EU level.
The MRL proposal for rice, husked is sufficiently supported by data.			

[a] Arising from the use of acephate on rice.

[b] for the calculation of animal dietary burden

2.4.4. Consumer risk assessment - Methamidophos

The consumer risk assessment calculated on the basis of the existing MRLs established at EU level for achphate and methamidophos. The input values were calculated to reflect the proposed residue definition (MRL(methamidophos) + MRL(acephate)/2.5 for long-term dietary exposure assessment respectively). This calculation accommodates for the different toxicity of the two active substances and the different molecular weights of acephate and methamidophos. For husked rice the input value for the long-term exposure assessment is calculated as the STMR of 0.047 mg/kg, for the short-term exposure assessment, using the toxicological equivalence factor derived from the ARfD values for methamidophos and acephate, the input value is 0.057 mg/kg.

Table 2-8: Summary of the consumer risk assessment for **methamidophos** (for detailed calculation see Appendix A)

Chronic risk	Chronic exposure resulting from residues of methamidophos and acephate on rice is calculated to account for **max. 3.7% of the ADI.** The total long-term exposure is 125% of the ADI, mainly driven by the EU MRLs set at the level of the LOQ (contribution of up to 120% of the ADI). More refined calculations need to be performed.
Acute risk	Husked rice: 24% of the EU ARfD
Conclusion	**The CXL proposal for rice is only a minor contributor to the total chronic exposure.**

2.5. Cypermethrins (including alpha – and zeta – cypermethrin) (118) (R)

Cypermethrin was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Belgium as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2005/53/EC[10]) was taken in 2005. For zeta-cypermethrin an EFSA conclusion is available (EFSA, 2008b). The assessment of cypermethrin and alpha-cypermethrin was performed before EFSA was involved in the process and the toxicological reference values were included in the respective review reports on cypermethrin[11] and alpha-cypermethrin[12]. EFSA recently issued an opinion regarding the modification of MRLs in various crops[13]. The MRL review is in an early stage.

2.5.1. Toxicological endpoints – Cypermethrins (including alpha – and zeta – cypermethrin)

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-9: Comparison of toxicological reference values derived by JMPR and at EU level

Cypermethrins	JMPR evaluation (JMPR Report, 2006)			EU evaluation (Review report SANCO/4333/2000 – 15/02/2005)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.02 mg/kg bw/d	Dog, 3-month dietary study with *alpha-cypermethrin*	100	0.05 mg/kg bw/d	2 yr rat study with *cypermethrin*	100
Comments ADI	The ADI established for alpha-cypermethrin applied also for cypermethrin and zeta-cypermethrin since all 3 cypermethrins are qualitatively similar in their toxicity and metabolism.			Different ADI values were established respectively for alpha-cypermethrin and zeta-cypermethrin: -ADI for *alpha-cypermethrin*: **0.015** mg/kg bw/d (dog 1 year study, SF 100) (Review report, SANCO/4335/2000) . -ADI for *zeta-cypermethrin*: **0.04** mg/kg bw/d is derived from studies performed with cypermethrin (dog, 2 yr and 1 yr studies (overall NOAEL)), SF 200) (EFSA Scientific report (2008)).		
ARfD	0.04 mg/kg bw	Rat, acute neurotoxicity study with *alpha-cypermethrin*	100	0.2 mg/kg bw	Rat, acute neurotoxicity study with *cypermethrin*	100
Comments ARfD	Same remark as for the ADI.			Different ARfD values were established respectively for alpha-cypermethrin and zeta-cypermethrin: -ARfD for *alpha-cypermethrin*: 0.04 mg/kg bw (rat acute neurotoxicity study, SF 100) (Review report, SANCO/4335/2000). -ARfD for *zeta-cypermethrin*: 0.125 mg/kg bw (rat, developmental study and acute neurotoxicity study, SF 100) (EFSA Scientific report (2008)).		

[10] Commission Directive 2005/53/EC of 16 September 2005, OJ L 241, 17.9.2005, p. 51-56

[11] Review report for the active substance cypermethrin in view of the inclusion of cypermethrin in Annex I of Directive 91/414/EEC (SANCO/4333/2000 final) – 15 February 2005

[12] Review report for the active substance alpha-cypermethrin in view of the inclusion of cypermethrin in Annex I of Directive 91/414/EEC (SANCO/4335/2000 final) – 13 February 2004

[13] http://www.efsa.europa.eu/en/efsajournal/doc/2280.pdf

Cypermethrins	JMPR evaluation (JMPR Report, 2006)			EU evaluation (Review report SANCO/4333/2000 – 15/02/2005)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
Conclusion	EU conclusion: The difference in toxicity between the different cypermethrins was assessed and different toxicological reference values were derived respectively for cypermethrin, alpha-cypermethrin and zeta-cypermethrin. JMPR evaluation: Since the racemic cypermethrin includes a substantial proportion of alpha- and zeta-cypermethrin and since all 3 cypermethrins are qualitatively similar in their toxicity and metabolism, the derived ADI and ARfD established for alpha-cypermethrin could apply for all 3 substances.					

2.5.2. Residue definitions – Cypermethrins

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-10: Comparison of the residue definitions derived by JMPR and at EU level

Cypermethrins	Commodity group	JMPR evaluation (JMPR report 2008)	EU evaluation (EFSA Scientific Report, 2008)
RD enf	Plant commodities	Cypermethrin (sum of isomers)	Cypermethrin, including other mixtures of constituent isomers (sum of isomers)
	Animal commodities	Cypermethrin (sum of isomers), The residue is fat soluble	Cypermethrin, including other mixtures of constituent isomers (sum of isomers). The residue is fat soluble
RD RA	Plant commodities	Cypermethrin (sum of isomers)	Cypermethrin, including other mixtures of constituent isomers (sum of isomers)
	Animal commodities	Cypermethrin (sum of isomers) The residue is fat soluble	Cypermethrin, including other mixtures of constituent isomers (sum of isomers). The residue is fat soluble
Conclusion	The residue definitions are identical.		

2.5.3. CXL proposals – Cypermethrins (including alpha – and zeta – cypermethrin)

In the following table the CXL proposals are compared with the existing EU MRLs.

Table 2-11: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR report 2011)	EU MRL (Reg.(EU) No 520/2011)	Comment
Asparagus	0.4 *a, C*	0.1	**The CXL proposal is sufficiently supported by data.**
Citrus fruits (except shaddocks or pomelos)	0.3 *a, Z*	2	CXL proposal covered by EU MRL.
Eggs	0.01*	0.05*	CXL proposal is acceptable
Poultry fats	0.1	0.1	CXL proposal is acceptable
Poultry meat	0.1 (fat)	0.1 (fat)	CXL proposal is acceptable
Poultry, Edible offal of	0.05*	0.05*	CXL proposal is acceptable
Shaddocks or pomelos	0.5 *a, C, Z*	2	CXL proposal is sufficiently supported (by 6 trials).

Commodity	CXL proposal derived by JMPR report 2011)	EU MRL (Reg.(EU) No 520/2011)	Comment
Tea, Green, Black (black, fermented and dried)	15 *a, C*	0.5	CXL proposal is supported by 6 trials reflecting the Chinese GAP for cypermethrin. The calculated unrounded MRL using the OECD calculator tool exceeds only slightly 10 mg/kg (10.6 mg/kg) and therefore it would be more appropriate to derive a CXL proposal by rounding down to 10 mg/kg.
Tree nuts	0.05* *a, Z*	0.05*	The CXL proposal is based on trials on almonds and pecans and was extrapolated to the whole group of tree nuts. The extrapolation is acceptable.
Overall conclusion: The proposed CXLs are lower than the existing EU MRLs except the proposals for asparagus and tea. The proposed CXLs are sufficiently supported. However, **for tea a lower CXL of 10 mg/kg would be sufficient**.			

[c] Source of data supporting the proposed MRLs: *a: alpha-cypermethrin. c: cypermethrin. z: zeta-cypermethrin*. Capital letters show the source of data responsible for the MRL estimate. Small letters show the sources of other data for that commodity.

2.5.4. Consumer risk assessment - Cypermethrins (including alpha – and zeta – cypermethrin)

The chronic consumer exposure is based on the calculations performed by EFSA in the framework of the recent MRL application (EFSA, 2011c), including the STMR values for asparagus and tea. Since at the moment the information whether the EU MRL is based on a use of cypermethrin/zeta-cypermethrin or on the use of the more toxic alpha-cypermethrin is not available, the calculations are affected by uncertainties. EFSA calculated two scenarios, applying the EU ADI for cypermethrin (optimistic assumption) and the EU ADI for alpha-cypermethrin (pessimistic assumption), respectively. The contribution of the two crops for which JMPR proposed higher MRLs compared with the EU MRLs (asparagus and tea) are reported separately. For sugar beet it is assumed that the residues do not exceed 0.01 mg/kg ("realistic" STMR value). Further refinements are proposed by BE.

The acute risk assessment was performed only for the crops where the CXL proposals are higher than the existing EU MRLs, using the EU ARfD for cypermethrin. Since both CXL proposals are related to GAPs for cypermethrin, only one scenario was calculated using the ARfD for cypermethrin.

Table 2-12: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Scenario 1 (optimistic scenario):** It is assumed that the existing EU MRLs are based on the use of cypermethrin only. **Highest TMDI: 83% ADI (UK toddler)** The contribution of **asparagus** is insignificant (max. **0.02% of the ADI**). For **tea**, the contribution accounts for **max. 1% of the ADI.** **Scenario 2 (pessimistic scenario):** It is assumed that the existing EU MRLs are based on the use of alpha-cypermethrin only. Since asparagus and tea CXL proposal are based on a GAP for cypermethrin these CXLs will not have an impact on the exposure assessment for alpha-cypermethrin. Thus, for these two crops the existing EU MRLs are used as input values. Highest TMDI: 276% ADI (UK toddler) This exposure assessment is overestimating the consumer risk as not all the EU MRLs result from the use of alpha-cypermethrin. The main contributors are sugar beet, wheat, oranges and apples. Thus, the calculation could be further refined by deletion of sugar beet (assuming that there is not transfer into sugar), using a PF for wheat flour (PF=0.43, JMPR), extrapolation of the PF of wheat to rye, inclusion of PF for grapes (PF for wine: 0.08 (JMPR)), and the deletion of all crops for which only cypermethrin uses were notified (blackberries, horse radish,

	parsnip, etc), deletion of asparagus (post-harvest use), use of STMR for alpha-cypermethrin where available (table and wine grapes, strawberries, animal commodities). cypermethrin STMR for apple, pears, peaches, potatoes, carrots, tomatoes, water melons, lettuce. Under these conditions (refined pessicimstic scenario) the highest TMDI was estimated to be 83% of the ADI.
Acute risk	**Scenario 1:** **1.7% ARfD (tea); .0.5% of ARfD for asparagus** Since the CXL proposals are related to the use of cypermethrin, the contribution to the dietary intake of alpha-cypermethrin is not relevant.
Conclusion	The CXL proposals do **not pose an acute consumer risk**. The chronic risk assessment is affected by uncertainties due to lack of information regarding the source of the EU MRLs. The calculations of scenario 2 are probably overly conservative. The crops for which CXL proposals are higher than the EU MRLs (asparagus and tea) are not contributing significantly to the dietary intake. Before the proposed CXLs for asparagus and tea are taken over in the EU legislation the MRL review under Art. 12 of Regulation (EC) No 396/2005 should be completed in order to have the necessary background information which would allow a refined intake calculation taking into account the actual uses at EU level and in third countries.

2.6. Diflubenzuron (130) (R)

Diflubenzuron was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Sweden as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2010/39/EU[14]) was taken in 2010. For diflubenzuron an EFSA conclusion is available (EFSA, 2009a). The MRL review under Art. 12 of Regulation (EC) No 396/2005 has not yet been initiated.

2.6.1. Toxicological endpoints - Diflubenzuron

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-13: Comparison of toxicological reference values derived by JMPR and at EU level

Diflubenzuron	JMPR evaluation (JMPR, 2001)			EU evaluation (EFSA, 2009a)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.02 mg/kg bw/d	Rat, 2 year & 52 week	100	0.1 mg/kg bw/d	Dog, 1 year	100
Comments ADI	Based on a NOAEL of 2 mg/kg bw/d in both studies for haematological effects.			Based on a NOAEL of 10 mg/kg bw/d for haematological effects.		
ARfD	Not necessary			Not necessary		
Comments ARfD	-			-		
Conclusion	For the derivation of the ADI, the 2 year rat study was considered as not acceptable during the EU evaluation because of several limitations. Additionally, for the 1 year dog study, a different interpretation of the haematological findings led to a NOAEL of 10 mg/kg bw/d (versus 2 mg/kg bw/d in the JMPR evaluation). For the metabolite 4-chloroaniline (PCA), confirmatory data were provided for the EU evaluation and are still under peer-review. It is currently considered as a genotoxic carcinogen. Additionally, PCA has a legal classification as Carcinogen Cat 2 (R45 May cause cancer) according to Directive 67/548/EEC (Annex I, Adaptation to the Technical Progress 24). For the metabolite 4-chlorophenylurea (CPU), an assessment of its toxicological relevance was provided after the peer review (not peer reviewed), but insufficient data are available to derive reference values for CPU (or to conclude that the reference values of the parent are also applicable). In the framework of the biocide evaluation, metabolism studies in pigs, goat and hens have been provided. From these studies it cannot be excluded that PCA is formed. Thus, the formation of PCA in humans cannot be excluded.					

2.6.2. Residue definitions - Diflubenzuron

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[14] Commission Directive 2010/39/EU of 22 June 2010, OJ L 156, 23.6.2010, p. 7-11

Table 2-14: Comparison of the residue definitions derived by JMPR and at EU level

Diflu-benzuron	Commodity group	JMPR evaluation 2002	EU evaluation EFSA conclusion (EFSA, 2009a)
RD enf	Plant commodities	Diflubenzuron	Diflubenzuron (for **fruit crops** after foliar application) 2,6-diflubenzoic acid (for **mushrooms** after soil application) For crop groups others than fruits and mushrooms no metabolism studies have been assessed at EU level. In Regulation (EC) No 396/2005 (Annex III) the RD is diflubenzuron for all crops.
	Animal commodities	Diflubenzuron The residue is fat soluble	Sum of diflubenzuron and 4-chlorophenylurea expressed as diflubenzuron (The residue is fat soluble)
RD RA	Plant commodities	Diflubenzuron	For **fruit crops** after foliar application (provisional): diflubenzuron; pending further information on the nature of the residues in processed fruit For **mushrooms** after soil application (provisional): (1) 2,6-difluorobenzoic acid (2) Sum of diflubenzuron + 4-chlorophenylurea + 4-chloroaniline expressed as 4-chloroaniline; pending the finalisation of the toxicological evaluation of the metabolites. For crop groups others than fruits and mushrooms no metabolism studies have been assessed at EU level.
	Animal commodities	Diflubenzuron The residue is fat soluble	Sum of diflubenzuron + 4-chlorophenylurea + 4-chloroaniline + 4-chloroacetanilide expressed as 4-chloroaniline
Conclusion	The EU residue definitions for animal commodities comprise metabolites which were not considered relevant by JMPR. The toxicological evaluation of metabolites 4-chlorophenylurea (CPU) and 4-chloroaniline (PCA) is still pending in EU. In the peer review metabolism studies were only assessed for fruit crops (apples) and for mushrooms. Parent compound was the only relevant residue after foliar applications. Other routes of exposure (uptake via soil, surface water, compost and casing treatment) feature the presence of pertinent metabolites 2,6-diflubenzoic acid (DFBA) and CPU while parent is hardly or not at all present. Hence, in the EU review, parent was not deemed suitable for enforcement and RA purposes regarding the latter type of uses. It is noted hat at EU level no conclusion regarding the residue definition for other crop groups is available. The JMPR residue definition was derived on studies on maize, soybean, cabbage, apple, cotton, orange, mushrooms, rice, wheat and beans (different modes of application of the radio labelled active substance). As the proposed CXLs base merely on foliar treatments, the RD enf is acceptable in this context. The RD RA might be acceptable, too. However, data on the nature of residues in processed fruit are still to be provided on EU level since significant degradation of parent into DFBA and CPU/PCA is expected. **Nature of residues in processed commodities was not assessed by JMPR.**		

2.6.3. CXL proposals - Diflubenzuron

EFSA assessed whether the draft CXLs recommended by JMPR are adequately supported by data.

Table 2-15: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR	EU MRL	Comment
Barley	0.05*	0.1	**CXL proposal is adequately supported** by data. MRL based on MS notification. National GAP is likely to be different.
Hay or fodder (dry) of grasses	3		No MRLs for fodder. CXL proposal is adequately supported by data.
Mustard greens	10	1 (Chinese cabbage)	**CXL proposal is adequately supported** by data. However, it is noted that trials from one season only were available. EU MRL is based on MS notification in the framework of temporary MRLs. National GAP is likely to be different.
Nectarine	0.5	1	MRL for peach is applicable to nectarine.
Oats	0.05*	0.1	**CXL proposal is adequately supported** by data. MRL based on MS notification. National GAP is likely to be different.
Peach	0.5	1	CXL proposal based on merged residue data in plums (3) and peaches (5). Individual data sets are not sufficiently robust to conclude data were from similar populations. Plum and peach data cannot be merged according to EU extrapolation rules, 3 more trials in peaches/ apricots would be required. EU MRL based on MS notification (temporary MRL). National GAP is likely to be different.
Peanut	0.15	0.05*	For peanuts 9 residue trials were provided, using the OECD calculator a CXL proposal of 0.08 mg/kg is derived. The JMPR proposal of 0.15 mg/kg refers to peanut meal, not to peanuts. The reason for using a processing factor of 2 for peanut meal needs to be further explained. It would be expected that diflubenzuron residues are lower in peanut meal as it is fat soluble.
Peanut fodder	40		No MRLs for fodder. Draft CXL is adequately supported by data.
Peppers Chili, dried	20	1*10	Peppers (chili peppers), fresh, *dehydration factor 10 CXL proposal based on Peppers (chili peppers), fresh, *default dehydration factor 7
Peppers, Chili	3	1	CXL proposal based on 3 trials. According to EU rules data on both sweet and chili peppers are considered to derive MRL for peppers if GAP is identical. Since the residues on chilli peppers are significantly higher than the residues in sweet peppers, it needs to be decided how these CXLs should be implemented in EU legislation. EU MRL based on MS notification (temporary MRL). National GAP is likely to be different.

Commodity	CXL proposal derived by JMPR	EU MRL	Comment
Peppers, Sweet (including pimento or pimiento)	0.7	1	CXL proposal based on 6 trials. 6 trials would not be enough for deriving a MRL for a major crop like peppers at EU level. According to EU rules data on both sweet and chili peppers are considered to derive MRL for peppers if GAP is identical. See also comment on peppers, chili.
Plum (including Prunes)	0.5	1	CXL proposal based on merged residue data in plums (3) and peaches (5). Individual data sets are not sufficiently robust to conclude data were from similar populations. Merging not acceptable according to EU extrapolation rules, 5 more trials in plums are required. MRL based on MS notification. National GAP is likely to be different.
Straw and fodder (dry) of cereal grain	1.5		No MRLs for fodder. **CXL proposal is adequately supported** by data.
Tree nuts	0.2	1.0 (pine nuts) 0.1 (almonds) 0.05* (other tree nuts)	**CXL proposal is adequately supported** by data. MRL based on MS notification. National GAP is likely to be different.
Triticale	0.05*	0.1	MRL for wheat is applicable to triticale
Wheat	0.05*	0.1	**CXL proposal is adequately supported** by data. MRL based on MS notification. National GAP is likely to be different.
General comments: Apart from mustard greens, peanut, chilli peppers and tree nuts (except pine nuts) proposed CXLs are lower than EU MRLs. The CXL proposals for peppers (sweet), plums and peaches are based on a data set that is not sufficiently robust. The MRL proposal for peanuts should be clarified (the proposal refers to peanut meal and not to peanuts).			

2.6.4. Consumer risk assessment - Diflubenzuron

Consumer intake calculations were carried out using revision 2 of the EFSA PRIMo. In order to provide a comprehensive risk assessment, in particular with regard to the chronic exposure, the EU MRLs (European Commission MRL database, 12/01/2012) were compared with the draft CXLs recommended by JMPR. Where the draft CXL was higher than the proposed EU MRL, STMR values derived by JMPR were used. For further refinement, the EU MRL (adopted CXL) for pome fruit was replaced by the STMR derived for pome fruit (JMPR, 2002).

Table 2-16: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	The highest chronic exposure to parent diflubenzuron was calculated for German children representing **93.5% of the ADI** of 0.02 mg/kg bw/day set by JMPR. The STMRs derived by JMPR for mustard greens (1.4), peanut (0.05), chilli peppers (0.92, used for the sweet pepper intake calculation) and tree nuts (0.05) and used in the RA are in the same order as the current EU MRLs. Therefore, it can be concluded that the CXL proposals do not have a significant impact on the chronic exposure of European consumers to residues of diflubenzuron. However, the assessment is affected by uncertainties regarding metabolites, degradation products which may be formed during processing or by uptake in rotational crops. The two highest contributors in the chronic assessment are **apples and oranges**, for which there might be significant consumption as processed commodities. It is noted

	that the issue of the nature of residues upon processing has not been addressed in terms of (potentially) relevant metabolites. This fact was also noted by JMPR (page 226 of JMPR evaluation) and according to the EU rules this is a data gap which does not allow a comprehensive risk assessment.
Acute risk	Not applicable.
Conclusion	The proposed CXLs, if added to the existing EU MRLs, do not lead to an unacceptable exposure of the European population regarding parent diflubenzuron. However, **the potential formation of metabolites/degradation products during processing should be assessed by JMPR**. In particular formation of **DFBA and CPU/PCA** and consumer exposure to these substances should be considered.

2.7. Glyphosate (158) (T, R)

Glyphosate was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Germany as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2001/99/EC[15]) was taken in 2001. For glyphosate no EFSA conclusion is available. In 2009, EFSA issued a reasoned opinion regarding the need to modify the residue definition (EFSA, 2009b). In 2012, EFSA prepared a reasoned opinion regarding the modification of MRL for lentils (EFSA, 2012b). The MRL review under Article 12 of Regulation (EC) No 396/2005 is in an early stage.

2.7.1. Toxicological endpoints – Glyphosate

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-17: Comparison of toxicological reference values derived by JMPR and at EU level

Glyphosate	JMPR evaluation (JMPR, 2004, 2011)			EU evaluation (EC, 2002) (EFSA, 2009b)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-1 mg/kg bw/d	Rat, 2 year study	100	0.3 mg/kg bw/d	Rat, 2 year study	100
Comments ADI	Based on the 2-year rat study (Atkinson, 1993). 2011 JMPR concluded that the group ADI of 0-1 mg/kg bw established for glyphosate and AMPA may also be applied to N-acetyl-glyphosate and N-acetyl-AMPA.			Based on the overall assessment of all available long-term studies in rats (Lankas, 1981, Stout and Ruecker, 1990, Atkinson, 1993 and Suresh (1996). Taking into account a different evaluation of the Atkinson study (1993), the EU review has used the NOAEL of 31 mg/kg bw/d in the Lankas study (1981) to derive the ADI. Also applicable to AMPA, N-acetyl-glyphosate and N-acetyl-AMPA.		
ARfD	Not necessary	-	-	Not necessary	-	-
Comments ARfD	Also applicable to AMPA, N-acetyl-glyphosate and N-acetyl-AMPA.			Also applicable to AMPA, N-acetyl-glyphosate and N-acetyl-AMPA.		
Conclusion	For the ADI, the EU and the JMPR assessments differ regarding the interpretation of the 2-yr rat study (Atkinson, 1993), as the JMPR established a NOAEL at 100 mg/kg bw/d versus 10 mg/kg bw/d in the EU assessment. Therefore in the EU evaluation, a lower ADI is based on an overall assessment of the available long-term studies in rats.					

2.7.2. Residue definitions - Glyphosate

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[15] Commission Directive 2001/99/EC of 20 November 2001, OJ L 304, 21.11.2001, p. 14-16

Table 2-18: Comparison of the residue definitions derived by JMPR and at EU level

Glyphosate	Commodity group	JMPR evaluation	EU evaluation
RD enf	Plant commodities (for soya and maize)	sum of glyphosate and N-acetylglyphosate, expressed as glyphosate	Glyphosate (MRL Regulation)
	for other plant commodities	glyphosate	Glyphosate (MRL Regulation)
	Animal commodities	sum of glyphosate and N-acetylglyphosate, expressed as glyphosate	Glyphosate (MRL Regulation)
RD RA	Plant commodities	glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate	Sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl-AMPA,calculated as glyphosate (EFSA RO, 2009)
	Animal commodities	glyphosate, N-acetylglyphosate, AMPA and N-acetyl AMPA, expressed as glyphosate	Sum of glyphosate, N-acetyl-glyphosate, AMPA and N-acetyl-AMPA, calculated as glyphosate (EFSA RO 2009).
Conclusion	Residue definitions are similar, except RD for enforcement for soybeans, maize and animal commodities where JMPR proposed to include metabolites resulting from GMO crops. At EU level it was decided that the existing residue definition is sufficient for enforcement practice, also for import of GM crops containing the GAT gene.		

2.7.3. CXL proposals - Glyphosate

In the following table the proposed CXLs are compared with the existing EU MRLs.

Table 2-19: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR	EU MRL	Comment
Lentils (dry)	5	10 (voted in SCFCAH on 3 February 2012)	**The CXL proposal is sufficiently supported by residue data** (lentils and peas) and supports CAN GAP. The EFSA proposal which was recently published is higher due to a more critical residue trials available (on peas), supporting the same CAN GAP.
Maize flour		-	-
Maize meal		-	-
Sugar beet (transgenic (EPSPS))	15	1	**The CXL proposal is supported by residue data regarding glyphosate** (combined data set reflecting US and CAN GAP). It is noted that at EU level the MRLs would be derived without merging the data sets for different GAPs.
Sweet corn (corn-on-the-cob) (transgenic (EPSPS))	3	0.1*	**The CXL proposal is sufficiently supported by data**. For import of transgenic sweet corn to Europe, an approval is needed at EU level.
General comments: The processing factor of <0.01 was derived for sugar indicating a significant reduction of residues. No detailed information on processing studies available in the JMPR report.			

2.7.4. Consumer risk assessment - Glyphosate

The consumer RA is based on the last RA performed in the framework of Art.10 MRL application on the modification of existing MRLs for glyphosate in lentils (EFSA 2012a). In addition, the STMR and HR values derived by JMPR for the crops under consideration were included.

In maize, rape seed and soybean the residues of AMPA are included in the consumer RA. In the EFSA opinion 2009 the contribution of N-acetyl-glyphosate, AMPA and N-acetyl-AMPA to the total consumer exposure was considered. However, it was found that the EPSPS maize and soybeans are more critical for the consumer exposure. Therefore the contribution of N-acetyl-glyphosate and N-acetyl-AMPA was not included.

Table 2-20: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	No chronic consumer intake concerns were identified (max. **47.2% of the ADI**, WHO Cluster diet B).
Acute risk	**Not necessary** as no ARfD established.
Conclusion	The CXL proposals for glyphosate in lentils, sugar beet and sweet corn are sufficiently supported by data with no consumer intake concerns identified.

2.8. Profenofos (171) (R)

Profenofos is no longer used at European level. Since no manufacturer supported the active substance it was not evaluated under Directive 91/414/EEC. A non-inclusion decision was taken in 2002 (Commission Regulation 2002/2076/EC[16]). For profenofos no EFSA conclusion is available. The European Commission has included in Regulation (EC) No 396/2005 the CXLs proposed for profenofos in the JMPR evaluation report 2008 and adopted by the Codex Alimentarius Commission (CAC) on July 2009 (Commission Regulation 2010/459/EC[17]). It is noted that EU MRLs have been established in 2002 (Directive 2002/79/EC) following an evaluation prepared by Germany. In this evaluation toxicological reference values have been derived.

2.8.1. Toxicological endpoints -Profenofos

The following toxicological reference values have been derived by JMPR. At EU level a toxicological evaluation was performed in the framework of setting MRLs under the MRL Directive 90/642 with Germany acting as Rapporteur Member State.

Table 2-21: Comparison of toxicological reference values derived by JMPR and at EU level

Profenofos	**JMPR evaluation 2007**			**Germany, 2001**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.03 mg/kg bw/d	Dog: 90 days, 6 months and 1 year studies	100	0-0.005 mg/kg bw/d	Dog, 1 year study	200
Comments ADI	Based on the overall NOAEL for the inhibition of brain cholinesterase activity is 2.9 mg/kg bw/d.			Based on the LOAEL 1 mg/kg bw/d where only slight effects are observed, and considering that NOAEL is 20 times lower. Additional SF of 2 because of the use of the LOAEL.		
ARfD	1.0 mg/kg bw	Rat acute neurotoxicity	100	0.01 mg/kg bw	Dog, 1 year study	100
Comments ARfD	Based on the NOAEL for the inhibition of brain cholinesterase activity.			Based on the NOAEL for the inhibition of brain cholinesterase activity.		
Conclusion	The results of the 1 year dog study have been interpreted differently by Germany (in 2001) and by JMPR (in 2007). A slight and not significant inhibition of brain cholinesterase activity (lower than 20%) has been considered as an acute adverse effect in the German assessment, and minimal to moderate liver effects have triggered a chronic NOAEL of 0.05, whereas JMPR considered that the highest dose of 12.5 was the NOAEL. Based on limited details available in the JMPR Report and the German evaluation, a final conclusion on the acceptability of the toxicological reference values derived by the two bodies cannot be made.					

2.8.2. Residue definitions – Profenofos

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[16] Commission Regulation (EC) No 2076/2002 of 20 November 2002. OJ L 319, 23.11.2002, p. 3-11.
[17] Commission Regulation (EU) No 459/2010 of 27 May 2010. OJ L 129, 28.05.2010, p. 3-49.

Table 2-22: Comparison of the residue definitions derived by JMPR and at EU level

Profenofos	Commodity group	JMPR evaluation (JMPR, 2008)	EU evaluation
RD enf	Plant commodities	Profenofos	Profenofos Regulation (EC) No 396/2005
	Animal commodities	Profenofos The residue is **not fat-soluble**	Profenofos The residue is **fat-soluble**
RD RA	Plant commodities	Profenofos	No evaluation at EU level
	Animal commodities	Profenofos	No evaluation at EU level
Conclusion	The enforcement residue definitions are comparable. Since no EU evaluation was performed at EU level, no EU residue definitions for risk assessment were established. It is noted that in 2003 JMPR defined the residues as fat soluble whereas in the current version of the JMPR database it is classified as not fat soluble. Further clarifications would be desirable.		

2.8.3. CXL proposals - Profenofos

Table 2-23: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR (JMPR, 2011)	EU MRL	Comment
Peppers, Chilli	3	0.05*	**The CXL proposal is sufficiently supported** by data.
Pepper chilli, dried	20	-	The commodity is not currently listed in Annex I of Regulation (EC) No 396/2005. The CXL proposal was estimated using the default dehydration factor of 7.
General comments: See consumer risk assessment.			

2.8.4. Consumer risk assessment - Profenofos

The long-term consumer exposure was estimated using the median residue value as derived from the residue trials on peppers and the median residue values for mangos, tomatoes and cotton seeds reported in a previous JMPR evaluation report (JMPR, 2008). The acute exposure assessment was performed only with regard to chilli peppers, but only for adults. EFSA calculated 2 scenarios: in scenario 1 the German toxicological reference values were used, whereas in scenario 2 the calculation is performed on the basis of the ADI and ARfD established by JMPR.

Table 2-24: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Scenario 1: 137 % of the German ADI** Pepper (fresh): max. 14.2 % (WHO Cluster diet B). **Scenario 2: Max. 22.8 % of the JMPR ADI.** Pepper (fresh): max. 2.4 % (WHO Cluster diet B).
Acute risk	**No consumption data for chilli peppers available in the PRIMo.** No calculation for children, since chilli peppers are not a relevant food item in the diet of children. **Scenario 1: 491% of the German ARfD for adults, using the consumption data reported for sweet peppers.** **Scenario 2: 4.9 %** (adults) of the JMPR ARfD**.**

Conclusion	**The CXL proposal is acceptable with regard to consumer safety only if the toxicological reference values derived by the JMPR are used**. Using the more conservative ADI / ARfD derived by Germany in 2001, a potential consumer risk cannot be excluded. However, the contribution of the crop under consideration (pepper, chilli) is considered as low.

2.9. Hexythiazox (176) (R)

Hexythiazox was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Finland as Rapporteur Member State. A decision to approve the active substance (Commission Decision 2011/46/EU[18]) was taken in 2011. For hexythiazox an EFSA conclusion is available (EFSA, 2010c). EFSA recently issued a reasoned opinion on an import tolerance request for tea (EFSA, 2012a). The MRL review under Article 12 of Regulation (EC) No 396/2005 has not yet been initiated.

2.9.1. Toxicological endpoints - Hexythiazox

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-25: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation 1991;			**EU evaluation (EFSA, 2010c)**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.03 mg/kg bw/d			0.03 mg/kg bw/d	2 yr rat	100
Comments ADI						
ARfD	unnecessary			Not allocated		
Comments ARfD						
Conclusion	The toxicological reference values are similar. However, the peer review requested toxicological information to address the toxicity of the metabolite PT-1-3 which is possibly present in significant levels in processed commodities. JMPR considered the toxicological data on parent hexythiazox as sufficient for hazard characterisation.					

2.9.2. Residue definitions - Hexythiazox

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-26: Comparison of the residue definitions derived by JMPR and at EU level

Hexythiazox	**Commodity group**	**JMPR evaluation**	**EU evaluation (EFSA, 2010c)**
RD enf	Plant commodities	Hexythiazox	Hexythiazox
	Animal commodities	Sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox; The residue is fat soluble	Hexythiazox

[18] Commission Decision 2011/46/EU of 14 April 2011, OJ L 101, 15.4.2011, p. 20-23

Hexythiazox	Commodity group	JMPR evaluation	EU evaluation (EFSA, 2010c)
RD RA	Plant commodities	Sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox	Hexythiazox
	Animal commodities	Sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3), expressed as hexythiazox; The residue is fat soluble	In the peer review no RD for animal commodities was discussed, because the supported uses did not refer to feed commodities. Fat solubility was also not discussed. Log $P_{o/w}$ = 2.67
Conclusion	The EU residue definition for risk assessment does not comprise the metabolites. However, the peer review identified data gaps regarding the possible presence of this metabolite in processed commodities. The peer review also noted that the metabolite has a higher acute toxicity than parent compound and therefore asked for additional toxicological information to elucidate the toxicological relevance of the metabolite.		

2.9.3. CXL proposals - Hexythiazox

In the following table the proposed CXLs are compared with the existing EU MRLs.

Table 2-27: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Beer			No detailed information is available on the studies according to which processing factors were derived. More details regarding the formation of the metabolite/degradation product PT-1-3 should be reported.
Fermented tea infusion			The calculated processing factors for tea infusions range from 0.01 to 0.34. Since the results are very inhomogeneous, the median processing factors would probably not be used in a EU risk assessment. However, taking into account the high safety margin, the open questions regarding the processing study would not be a reason to reject CXL proposal for tea.
Green tea infusion			
Hops, dry	3	20	**The CXL proposal is sufficiently supported by data** (compliance with GAP could not be estimated). The data on which the higher EU MRL is based are not available to EFSA (temporary MRL in Annex III of Reg. 396/2005, set on the basis of a MS MRL).
Strawberry	6	0.5	Insufficient residue data had been provided to support the US GAP (5). The JMPR used proportionality principle to derive 9 data points for deriving the CXL proposal. The proportionality principle is not yet common practice in the EU. To decide whether the proportionality principle is applicable, the other trial parameters should not contribute to the variation. Thus, more information would be required regarding the location of the trials, the water amount etc.

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Strawberry jam			No detailed information is available on the studies according to which processing factors were derived. It is noted that a study on the effect of processing on the residue levels of hexythiazox in fruit crops was evaluated in the DAR. The residue levels of PT-1-3 were below the LOD of 0.015 mg/kg in strawberry jam and citrus marmalade. It is also noted that in the framework of the Inclusion Directive confirmatory data on the toxicological relevance of this metabolite were requested. The information shall be submitted by 31 May 2013.
Strawberry, canned			No detailed information is available on the studies according to which processing factors were derived. More details regarding the formation of the metabolite/degradation product PT-1-3 should be reported.
Tea, Green, Black (black, fermented and dried)	15	4	The EU and CXL proposals reflect an Indian GAP with seemingly the same application rate. However, EU MRL was derived for the same Indian GAP where a PHI of 3 days was notified (EFSA, 2012a)[19]. The JMPR had no information on the PHI interval but used more critical values for CXL proposal. The discrepancy of GAPs reported to JMPR and in the framework of import tolerances should be avoided in the future. If the PHI of 0 days is confirmed, the data are sufficient to derive a CXL proposal.
General comments: More details regarding the formation of the metabolite/degradation product PT-1-3 in processed commodities should be reported. According to the JMPR evaluation, all the residue data were reported as sum of hexythiazox and all metabolites hydrolysable to trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine (PT-1-3), expressed as hexythiazox. Considering that the residue definition for the setting of MRLs comprises only the parent compound, the CXL proposals are probably set at levels higher than necessary. The use of the proportionality approach for deriving a CXL proposal for strawberries is not acceptable.			

2.9.4. Consumer risk assessment - Hexythiazox

The risk assessment is based on the existing EU MRLs, including the STMRs for the crops under consideration.

Table 2-28: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	No consumer intake concerns were identified with refined RA calculation. The total calculated intake accounted for a maximum of **93.9% of the ADI** (DE child diet). The contribution to the total consumer intake (% of the ADI) was 2% for tea, <1.5% for strawberries and <0.5% for hops. The exposure to the metabolite/degradation product PT-1-3 could not be estimated.
Acute risk	Not necessary.
Conclusion	Taking into account the exposure to the parent compound, the proposed CXLs are acceptable. However, the formation of the degradation product and its contribution to the exposure should be further assessed.

[19] Reasoned opinion on the modification of the existing MRL for hexythiazox in tea, EFSA Journal 2012;10(1):2514

2.10. Etofenprox (184) (T, R, periodic review)

Etofenprox was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Italy as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2009/77/EC[20]) was taken in 2009. For etofenprox an EFSA conclusion is available (EFSA, 2008c). The MRL review under Art. 12 of Regulation (EC) No 396/2005 has not yet been initiated.

2.10.1. Toxicological endpoints - Etofenprox

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-29: Comparison of toxicological reference values derived by JMPR and at EU level

Etofenprox	JMPR evaluation 2011			EU evaluation 2008		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.03 mg/kg bw/d	2 yr mouse, supported by 2 yr rat	100	0.03 mg/kg bw/d	2 yr mouse, supported by 2 yr rat	100
Comments ADI	Based on the NOAEL of 3.1 mg/kg bw/day for renal toxicity (an increased incidence of dilated and basophilic renal tubules) in the 2 yr mouse study, which is supported by the 2 yr rat study with a NOAEL of 3.7 mg/kg bw/day for an increase in foci or areas of eosinophilic hepatocytes in males and vacuolated hepatocytes in females and reduced body weight gain in males.			Based on the NOAEL of 3.1 mg/kg bw/day for renal toxicity (an increased incidence of dilated and basophilic renal tubules) in the 2 yr mouse study, which is supported by the 2-yr rat study with a NOAEL of 3.7 mg/kg bw/day for an increase in foci or areas of eosinophilic hepatocytes in males and vacuolated hepatocytes in females and reduced body weight gain in males.		
ARfD	1 mg/kg bw	Rabbit developmental study	100	1 mg/kg bw	Rabbit developmental study	100
Comments ARfD	Based on of the overall NOAEL of 100 mg/kg bw/day from the two developmental toxicity studies in rabbits, based on the occurrence of reduced maternal body weight gain and feed consumption during the early dosing period (gestation day 6) and increased post-implantation loss, which could occur after a single exposure.			Based on the occurrence of reduced maternal bodyweight gain and food consumption, abortions, mortality and slightly increased post-implantation loss and intrauterine growth retardation in the developmental toxicity study in rabbit with a NOAEL of 100 mg/kg bw/day.		
Conclusion	The toxicological reference values derived by JMPR are identical with the EU values and based on the same relevant study and endpoints.					

2.10.2. Residue definitions - Etofenprox

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[20] Commission Directive 2009/77/EC of 1 July 2009, OJ L 172, 2.7.2009, p. 23-33

Table 2-30: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation 2011	EU evaluation
RD enf	Plant commodities	Etofenprox	Etofenprox (Reg. 396/2005); Etofenprox plus α-CO (2-(4-ethoxyphenyl)-2-methylpropyl 3-phenoxybenzoate), expressed as etofenprox (EFSA conclusion)
	Animal commodities	Etofenprox (The residue is fat soluble)	Etofenprox (The residue is fat soluble) (Reg. 396/2005)
RD RA	Plant commodities	Etofenprox	Etofenprox plus α-CO, expressed as etofenprox (EFSA conclusion)
	Animal commodities	Etofenprox The residue is fat soluble	Etofenprox The residue is fat soluble (log Pow = 6.9)
Conclusion	The EU RA and enforcement residue definition for plant commodities proposed by the Peer review include the metabolite α-CO which was found in residue trials in higher concentrations than expected from metabolism studies. The EU residue definitions for animal matrices are provisional, lacking metabolism studies with α-CO metabolite.		

The plant metabolism studies assessed by the JMPR and EFSA were the same, with the exception of the study on rice (foliar and soil application), which was assessed by the JMPR. In all crops, except rice, metabolite a-CO was below 10% TRR. In rice it accounted for 16% TRR in whole rice and for 12% in brown rice. The JMPR did not include this metabolite in the residue definitions for plants because they considered that under practical conditions (residue trials) low levels of α-CO are present in the treated crops (14-19% of the parent). The peer review, in contrary, considered that this metabolite occurs at significant levels under practical conditions (residue trials) and included this metabolite in the residue definitions for plants since in residue trials higher concentrations than expected form metabolism studies were found.

Adequate studies on the nature of etofenprox in livestock are available and are performed with parent etofenprox. This was considered insufficient by the peer review experts, which were of the opinion that the nature of α-CO in livestock has to be investigated, given its occurrence in feed crops. The peer review requested a study on the nature of α-CO in livestock and consequently the residue definitions (parent etofenprox) in animal matrices were set on a provisional basis.

2.10.3. CXL proposals - Etofenprox

Analytical methods are available to monitor residues of etofenprox and α-CO residues in plant matrices (high acid, high water content).

In the following table the existing EU MRLs are compared with the proposed CXLs.

Table 2-31: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL (Annex III of Reg. 396/2005)	Comment
Apple	0.6	1	**The CXL proposal is sufficiently supported** by residue data. The EU MRL (temporary MRL Annex III) is higher.

Commodity	CXL proposal derived by JMPR 2011	EU MRL (Annex III of Reg. 396/2005)	Comment
Apple juice	-	-	The median processing factor of <0.06 was derived, based on 3 studies. According to EU guidance documents, at least 4 processing studies are required. No detailed information is available on the studies according to which processing factor was derived.
Apple purée	-	-	The processing factor of 0.3 was derived, based on 3 studies (mean of two highest values). According to EU guidance documents, at least 4 processing studies are required. No detailed information is available on the studies according to which processing factor was derived.
Beans (dry)	**0.05**	0.01*	7 GAP compliant residue trials on beans are available. According to EU guidance beans (dry) is a major crop and therefore at least 8 GAP compliant residue trials are required. However, the residues in beans in all trials were below the LOQ (either 0.01 or 0.05 mg/kg). Thus EFSA considers that CXL proposal is **sufficiently supported** by residue data.
CANNED APPLES	-	-	The processing factor of <0.09 was derived, based on 1 study only and is thus considered as insufficiently supported by data.
CANNED PEACHES	-	-	The processing factor of <0.11 was derived, based on 1 study only and is thus considered as insufficiently supported by data.
DRIED GRAPES (=CURRANTS,RAISINS AND SULTANAS)	8	-	The MRL proposal was derived on the basis of the HR for grapes (2.6 mg/kg) applying a mean processing factor (2.1) derived from two trials. A more robust data set for processing would be desirable (at least 4 processing studies).
Edible offal (Mammalian)	0.05	0.05	According to EU food classification the derived CXL refers also to liver and kidney. The CXL proposal was derived for the cattle dietary burden from the intake of apple pomace and rice straw. As residues in other feed crops under consideration are below the LOQ, the calculated livestock dietary burden properly reflects the livestock exposure.
Eggs	0.01*	0.01*	Poultry dietary burden not triggered.
Grape juice			The median processing factor of <0.03 was derived, based on 5 studies. However, no detailed information is available on the studies according to which processing factor was derived.

Commodity	CXL proposal derived by JMPR 2011	EU MRL (Annex III of Reg. 396/2005)	Comment
Grapes	4	5	No trials compliant with the Italian GAP have been provided. 10 residue trials supporting a less critical GAP (>25% deviation) on grapes were available. JMPR used proportionality principle to adjust the data for Italian GAP. The proportionality principle is not yet common practice in the EU. To decide whether the proportionality principle is applicable, the other trial parameters should not contribute to the variation. Thus, more information would be required regarding the location of the trials, the water amount etc. The EU MRL (temporary MRL in Annex III) is higher.
Maize	0.05*	0.5	There are 6 residue trials on maize matching Brazilian GAP; residues in all trials were below the LOQ of 0.01 or 0.05 mg/kg. Additional 2 overdosed trials (1.5N) were available with residues below the LOQ of 0.01 mg/kg. Thus, it is considered that the CXL proposal is supported by residue data. The EU MRL is higher.
Meat (from mammals other than marine mammals)	0.5 (fat)	0.5 (fat)	The CXL proposal was derived for the cattle dietary burden from the intake of apple pomace and rice straw. As residues in other feed crops under consideration are below the LOQ, the calculated livestock dietary burden properly reflects the livestock exposure. Basically the CXL proposal is acceptable, but a lower value of 0.3 mg/kg would also be considered as sufficient.[21]
Milks	0.02	0.05	The CXL proposal was derived for the cattle dietary burden from the intake of apple pomace and rice straw. As residues in other feed crops under consideration are below the LOQ, the calculated livestock dietary burden properly reflects the livestock exposure.
Nectarine	**0.6**	0.5	The CXL proposal is sufficiently supported by residue data. The CXL proposal is derived by extrapolating residue data from peaches. Nectarines fall under peaches classification according to Reg.600/2010.
Peach	**0.6**	0.5	The CXL proposal is sufficiently supported by residue data.

[21] In the feeding study which was performed with a dose rate of 0.5 ppm, the residues in fat accounted for 0.54 mg/kg. Considering that the dietary burden is only 0.277 ppm (ca. 50% of the dose tested in the feeding study) EFSA is of the opinion that a MRL of 0.3 mg/kg would be sufficient.

Commodity	CXL proposal derived by JMPR 2011	EU MRL (Annex III of Reg. 396/2005)	Comment
PEACH JUICE	-	-	The median processing factor of <0.05 was derived, based on 3 studies. According to EU guidance documents, at least 4 processing studies are required. No detailed information is available on the studies according to which processing factor was derived.
Pear	0.6	1	**The CXL proposal is sufficiently** supported by residue data. Extrapolation from apples.
Poultry meat	0.01*	0.01*	Poultry dietary burden not triggered.
Poultry, Edible offal of	0.01*	0.01*	Poultry dietary burden not triggered.
Rape seed	0.01*	0.05	**The CXL proposal is sufficiently** supported by residue data.
Rice	0.01*	0.5	There are 7 residue trials on rice matching US GAP; residues in all trials were below the LOQ of 0.01 mg/kg. Additional 2 overdosed trials (5N) were available with residues below the LOQ of 0.01 mg/kg. Thus, it is considered that **the CXL proposal is supported** by residue data. The EU MRL is higher.
Rice straw and fodder, dry	0.05	-	The CXL proposal based on 6 GAP compliant residue trials on rice. Currently there are no EU rules in place for deriving the maximum residue limits in animal feeding stuffs.
Wine	-	-	The median processing factor of <0.04 was derived, based on 4 studies. However, no detailed information is available on the studies according to which processing factor was derived.
General comments: Only in few crops (beans, peaches/nectarines) the derived CXL proposals are higher than the EU MRLs. Although, when discussing the residue definition in plants (to include or not the α-CO metabolite), the JMPR refers to residue trials data on pome fruit, stone fruit, grapes, in the residue trials section no information is provided on the actual levels of this metabolite in the crops treated with etofenprox according to the reported GAPs. The MRL was derived by applying the proportionality approach. This approach is not acceptable for major crops.			

2.10.4. Consumer risk assessment - Etofenprox

The chronic risk assessment is based on the existing EU MRLs, including those CXLs proposals (or relevant STMR values) which are higher than existing EU MRLs. For wine grapes the processing factor for wine was included.

The acute risk assessment was performed only for the commodities where JMPR proposed higher CXLs compared to the existing EU MRLs.

It is noted that the existing EU MRLs for plant commodities are set for the enforcement residue definition as parent etofenprox. Residue definition conversion factors for the EU MRLs or CXL proposals to convert them into the residue definition proposed in the peer review are not available.

Table 2-32: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	No chronic consumer intake concerns have been identified (m**aximum of 79.4% of the ADI**). Regarding the crops under consideration for CXL modification, residues in peaches (0.3% of the ADI) and beans (<0.2% of the ADI) contribute insignificantly to the overall consumer exposure.
Acute risk	No acute consumer intake concerns identified. (**max. ARfD** consumption calculated for peaches **2.2% of ARfD**).
Conclusion	The proposed CXLs do not pose a chronic or acute consumer concern regarding the parent compound etofenprox. However, for meat/fat a lower CXL value could be considered.

2.11. Tebuconazole (189) (R, periodic review)

Tebuconazole was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Denmark as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2008/125/EC[22]) was taken in 2008. For tebuconazole an EFSA conclusion is available (EFSA, 2008a). In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 EFSA has issued a reasoned opinion (EFSA, 2011e). The implementation of the EFSA recommendations in the EU MRL legislation is under preparation (SANCO 12786/2011). In addition, several MRL applications are under preparation (DE, ES) or have been submitted to EFSA to be finalised within the next weeks (ES).

2.11.1. Toxicological endpoints - Tebuconazole

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-33: Comparison of toxicological reference values derived by JMPR and at EU level

Tebuconazole	**JMPR evaluation 2010 (ARfD), 2003 (ADI)**			**EU evaluation**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.03 mg/kg bw/d	1 yr dog	100	0.03 mg/kg bw/d	1 yr dog supported by developmental mouse study (LOAEL)	100/300
Comments ADI	-			-		
ARfD	0.3 mg/kg bw	Developmental toxicity in rats and rabbits	100	0.03 mg/kg bw	Developmental mouse study (LOAEL)	300
Comments ARfD	The JMPR based the ARfD on the maternal and developmental NOAEL from the studies is in rats and rabbits.			The ARfD established at EU level is based on an increased incidence of malformations in a mouse study at the LOAEL. Thus, an increased uncertainty factor was applied.		
Conclusion	The ADI values are derived from the same studies. The difference in the ARfD values is because the two bodies considered different critical effects.					

2.11.2. Residue definitions - Tebuconazole

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-34: Comparison of the residue definitions derived by JMPR and at EU level

Tebuconazole	**Commodity group**	**JMPR evaluation 2011**	**EU evaluation** (EFSA, 2011e)
RD enf	Plant commodities	Tebuconazole	Tebuconazole
	Animal commodities	Tebuconazole The residue is fat soluble	Sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole (fat soluble)

[22] Commission Directive 2008/125/EC of 19 December 2008, OJ L 344, 20.12.2008, p. 78-88

Tebuconazole	Commodity group	JMPR evaluation 2011	EU evaluation (EFSA, 2011e)
RD RA	Plant commodities	Tebuconazole	Tebuconazole (Reg. 396/2005); An additional residue definition is needed for TDMs (triazole, triazole alanine, triazole acetic acid and triazole lactic acid) harmonised for all active substances of the triazole group.
	Animal commodities	Tebuconazole The residue is fat soluble	Sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole (fat soluble) An additional residue definition is needed for TDMs (triazole, triazole alanine, triazole acetic acid and triazole lactic acid) harmonised for all active substances of the triazole group.
Conclusion	As already highlighted during the latest MRL review for tebuconazole, residue for enforcement and risk assessment defined by JMPR for commodities of animal origin only includes the parent compound but according to EFSA the conjugates of tebuconazole and hydroxy-tebuconazole cannot be excluded from the residue definition because they significantly contribute to the total residue of tebuconazole and hydrolysis of these conjugates in the human intestinal tract cannot be excluded. This is particularly true for edible offals where residues exceeding the LOQ are expected. On the other hand, the differences in residue definition are not expected to impact comparability of EU MRLs and CXLs because, although not explicitly reported in the residue definition, the livestock feeding studies considered by JMPR seem to include residue levels for hydroxyl-tebuconazole and conjugates.		

2.11.3. CXL proposals - Tebuconazole

EFSA assessed whether the draft CXLs recommended by JMPR are adequately supported by data. In addition, a comparison was made with the outcome of the latest tebuconazole MRL review carried out at EU level (EFSA, 2011e) providing more insight on the differences between both assessments. An overview of the findings is provided in the table below.

Table 2-35: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR	EU MRL/proposed MRLs under MRL review.	Comment (The MRL proposals after the dash refer to the proposals of the EFSA RO on the MRL review)
Apple	**1**	1 / 0.3	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Apple juice			
Apple sauce			
Apricot	**2**	1 / 0.6	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Artichoke, globe	0.6	0.5 / 0.6	CXL is already covered by the latest EU MRL review.
Banana	0.05	0.05* / 0.05	CXL is already covered by the latest EU MRL review.

Commodity	**CXL proposal derived by JMPR**	**EU MRL/proposed MRLs under MRL review.**	**Comment** (The MRL proposals after the dash refer to the proposals of the EFSA RO on the MRL review)
Barley	2	2 / 2	CXL is already covered by the latest EU MRL review.
Barley straw and fodder, dry	40		
Beans (dry)	**0.3**	0.2 / 0.2	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Beans, cooked			
Beer			
Broccoli	**0.2**	1 / 0.15	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Brussels sprout	0.3	0.5 / 0.7	CXL is already covered by the latest EU MRL review.
Cabbage, cooked			
Cabbages, Head	**1**	1 / 0.7	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Carrot	0.4	0.5 / 0.4	CXL is already covered by the latest EU MRL review.
Cauliflower	0.05*	1 / 0.05	CXL is already covered by the latest EU MRL review.
Cherries	**4**	5 / 1	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Coffee beans	0.1	0.1 / 0.1	CXL is already covered by the latest EU MRL review.
Cotton oil, edible			
Cotton seed	2	0.05* / no proposal	**CXL proposal is adequately supported** by data. No authorisation reported within the EU.
Cucumber	0.15	0.5 / 0.2	CXL is already covered by the latest EU MRL review.
Dried grapes (=currants, Raisins and Sultans)	7		
Edible offal (Mammalian)	**0.2**	0.1 / 0.1* except ruminant liver (0.2)	Draft CXL is higher due to the different approaches in deriving MRLs for edible offal. JMPR takes the highest result for all offals while at EU level liver and kidney are assessed separately.
Egg plant	0.1	0.5 / 0.4	CXL is already covered by the latest EU MRL review.
Eggs	0.05*	0.1 / 0.1*	CXL is already covered by the latest EU MRL review.

Commodity	**CXL proposal derived by JMPR**	**EU MRL/proposed MRLs under MRL review.**	**Comment** (The MRL proposals after the dash refer to the proposals of the EFSA RO on the MRL review)
Elderberries	1.5	2 / 1.5	CXL is already covered by the latest EU MRL review.
Garlic	**0.1**	0.1 / 0.06	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Grapes	**6**	Table: 2 / 0.5 Wine: 2/ 1 with further consideration needed	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Hops, dry	**40**	30 / 30	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Leek	**0.7**	1 / 0.6	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Maize fodder	6		
Mango	0.05	0.1 / 0.1	CXL is already covered by the latest EU MRL review.
Meat (from mammals other than marine mammals)	0.05*	0.1 / 0.1*	CXL is already covered by the latest EU MRL review.
Melons, except Watermelon	0.15	0.2 / 0.2	CXL is already covered by the latest EU MRL review.
Milks	0.01*	0.05* / 0.02*	CXL is already covered by the latest EU MRL review.
Nectarine	**2**	1 / 0.6	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Oats	2	2 / 2	CXL is already covered by the latest EU MRL review.
Olives	0.05*	0.05* / 0.05	CXL is already covered by the latest EU MRL review.
Onion, bulb	**0.1**	0.05* / 0.06	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Papaya	2	2 / 2	CXL is already covered by the latest EU MRL review.
Passion fruit	0.1	1 / 1	CXL is already covered by the latest EU MRL review.
Peach	**2**	1 / 0.6	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.

Commodity	**CXL proposal derived by JMPR**	**EU MRL/proposed MRLs under MRL review.**	**Comment** (The MRL proposals after the dash refer to the proposals of the EFSA RO on the MRL review)
Peach jam			
Peach juice			
Peach preserve			
Peanut	**0.15**	0.05* / 0.05	**CXL proposal is adequately supported** by data (based on US GAP). EU GAP was reported but is not supported by data. EU GAP will be withdrawn.
Peanut fodder	40		
Pear	**1**	1 / 0.3	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Peppers Chili, dried	10		See comment on peppers, sweet
Peppers, Sweet (including pimento or pimiento)	**1**	0.5 / 0.6	**CXL proposal is adequately supported** by data but an acute consumer risk cannot be excluded (see below). At EU level a fall-back MRL was derived based on a less critical GAP/dataset.
Plum preserve			
Plums (including Prunes) [except prunes]	**1**	0.5 / 0.6	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Poultry meat	0.05*	0.1 / 0.1*	CXL is already covered by the latest EU MRL review.
Poultry, Edible offal of	0.05*	Poultry liver: 0.1 / 0.1* Other poultry edible offal: 0.1 / no proposal	Draft CXL is covered for liver but not for the other edible offals since these are usually not assessed at EU level.
Prunes	3	0.5 / 0.6 plums	The processing factor of 3 for prunes is derived from 2 studies only. However, since it corresponds to the expected dehydration factor it is acceptable.
Rape seed	0.3	0.5 / 0.5	CXL is already covered by the latest EU MRL review.
Rice	1.5	2 / 1	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Rye	**0.15**	0.2 / 0.1	**CXL proposal is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Rye straw and fodder, Dry	40		

Commodity	CXL proposal derived by JMPR	EU MRL/proposed MRLs under MRL review.	Comment (The MRL proposals after the dash refer to the proposals of the EFSA RO on the MRL review)
Soya bean (dry)	**0.15**	0.1 / 0.07	**CXL proposal is adequately supported** by data. Although EU review is based on the same US GAP, MRL resulting from the EU review is lower due to a different dataset and a different calculation method of the MRL.
Soya bean oil, refined			
Squash, Summer	0.2	0.2 / 0.2	CXL is already covered by the latest EU MRL review (courgette).
Sweet corn (corn-on-the-cob)	0.6	0.2 / no proposal	**CXL proposal is adequately supported** by data. No authorisation reported within the EU.
Tomato	0.7	1 / 0.9	CXL is already covered by the latest EU MRL review.
Tree nuts	0.05*	0.05* / 0.05	CXL is already covered by the latest EU MRL review.
Triticale	0.15	0.2 / 0.2	CXL is already covered by the latest EU MRL review.
Wheat	0.15	0.2 / 0.2	CXL is already covered by the latest EU MRL review.
General comments: -			

2.11.4. Consumer risk assessment - Tebuconazole

Consumer intake calculations were carried out using revision 2 of the EFSA PRIMo. In order to provide a comprehensive risk assessment, in particular with regard to the chronic exposure, the MRLs resulting from the latest review on tebuconazole (EFSA, 2011e) were compared with the draft CXLs recommended by JMPR. Where the draft CXL was higher than the proposed EU MRL, STMR and HR values derived by JMPR were used.

Table 2-36: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	The highest chronic exposure, taking into consideration the latest EU MRL proposals and the draft CXLs proposed by JMPR, is calculated for German children accounting for **23.8% of the ADI**.
Acute risk	EFSA identified acute intake concerns for the draft CXLs on **table grapes** (1004%, VF 5), **peaches** (198%; includes nectarines at EU level), **apples** (163%), **pears** (152%), **peppers** (130%), **cherries** (126%) and **apricots** (103%). For table grapes, peaches and cherries, the exceedance of the ARfD is mainly attributed to the lower ARfD established at EU level. For apples, pears, peppers and apricots, the exceedance of the ARfD is partially also attributed to the use of a higher variability factor at EU level. By applying the lower VF of 5 an exceedance of the ARfD would still be calculated for **apples (120%), pears (109%), peaches (145%**). For **table grapes and cherries** no "refinement of the calculation" with alternative VF is possible. Thus, the identified concern still remains. No exceedances of the ARfD were identified for any other draft CXL.
Conclusion	The **CXL proposals are not acceptable** from a consumer safety point of view for

	apples, pears, cherries, peaches and table grapes. For **apricots and peppers** a consumer risk is identified if the exposure is calculated with the currently agreed EU methodology. If the lower variability factor of 5 is used, the exposure for apricots and peppers is below 100% of the ARfD.

2.12. Spinosad (203) (R)

Spinosad was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with the Netherlands as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2007/6/EC[23]) was taken in 2007. For spinosad no EFSA conclusion is available. In 2010 and 2011 EFSA issued several reasoned opinions on MRL applications. In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 is ongoing. EFSA has circulated the draft a reasoned opinion for Member State consultation. The reasoned opinion will be adopted in February 2012.

2.12.1. Toxicological endpoints - Spinosad

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-37: Comparison of toxicological reference values derived by JMPR and at EU level

Spinosad	JMPR evaluation 2001			EU evaluation Peer review		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.02 mg/kg bw/d	2 yr rat	100	0.024 mg/kg bw/d	2 yr rat	100
Comments ADI						
ARfD	unnecessary			Not needed		
Comments ARfD						
Conclusion	The different ADI values result from different rounding practices.					

2.12.2. Residue definitions - Spinosad

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-38: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation	EU evaluation
RD enf	Plant commodities	sum of spinosyn A and spinosyn D	Spinosad: sum of spinosyn A and spinosyn D
	Animal commodities	sum of spinosyn A and spinosyn D The residue is fat soluble	Spinosad: sum of spinosyn A and spinosyn D The residue is fat soluble
RD RA	Plant commodities	sum of spinosyn A and spinosyn D	Spinosad: sum of spinosyn A and spinosyn D (MRL review under Art. 12 identified a minor deficiency regarding the some unknown n compounds occurring in metabolism studies. Further data to be provided to take decision that these metabolites are not relevant for consumer exposure.)

[23] Commission Directive 2007/6/EC of 14 February 2007, OJ L 43, 15.2.2007, p. 13-18

	Commodity group	JMPR evaluation	EU evaluation
	Animal commodities	sum of spinosyn A and spinosyn D The residue is fat soluble	For poultry liver and eggs: Spinosad: sum of spinosyn A, spinosyn D, *O*-demethylated spinosyn D and *N*-demethylated spinosyn D Other animal commodities: Spinosad: sum of spinosyn A and spinosyn D The residue is fat soluble
Conclusion	The residue definitions are comparable with the exception of poultry liver and eggs where at EU level additional metabolites were included in the residue definition.		

2.12.3. CXL proposals - Spinosad

In the following table the proposed CXLs are compared with the existing EU MRLs.

Table 2-39: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR	EU MRL	Comment
Blackberries	**1**	0.3	The CXL proposal was extrapolated from raspberries. However, the data base is not very robust (4 trials only). For extrapolations from raspberries to dewberries and blackberries at least 8 trials would be required.
Blueberries	**0.4**	0.3	**The CXL proposal is sufficiently supported** by data.
Cranberry	0.02	0.02*	**The CXL proposal is sufficiently supported** by data.
Dewberries (including Boysenberry and Loganberry)	**1**	0.02*	The CXL proposal was extrapolated from raspberries. However, the data base is not very robust (4 trials only). For extrapolations from raspberries to dewberries and blackberries at least 8 trials would be required.
Onion, Bulb	0.1	0.2	**The CXL proposal is sufficiently supported** by data
Passion fruit	**0.7**	0.5	**The CXL proposal is sufficiently supported** by data
Raspberries, Red, Black	**1**	0.3	The CXL proposal was derived for a Belgian GAP which is supported by 4 trials. It is noted that this GAP was not notified under the MRL review (art. 12) to EFSA. The **CXL proposal however, is sufficiently supported** by data.
Spring onion	**4**	0.2	The CXL proposal is based on 3 trials reflecting the US GAP. At EU level at least 4 trials would be required.
Tree nuts	**0.07**	1 0.05	Almonds Other tree nuts

Commodity	CXL proposal derived by JMPR	EU MRL	Comment
General comments: It is noted that the GAPs notified to the JMPR have not always be reported in the framework of the MRL review under Art. 12. In addition, some of the more critical EU MRLs which were assessed at EU level have not been notified to JMPR. The CXL proposal for blackberries and dewberries was derived from raspberries by extrapolation. The database is not robust enough to perform extrapolations.			

[d] The recommendation for almond hulls is withdrawn as the commodity is not traded.

[e] The recommendation for almonds is withdrawn to be replaced by a recommendation for Tree nuts

2.12.4. Consumer risk assessment – Spinosad

The consumer risk assessment is based on the most recent risk assessment performed in the framework of an MRL application, replacing the input values with the appropriate STMR/HR for the crops where the CXL proposals are higher than the EU MRLs.

Table 2-40: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	No long-term consumer concern was identified (max. **86% of the ADI**).
Acute risk	Not needed.
Conclusion	The proposed CXLs do not pose a consumer concern.

2.13. Pyraclostrobin (210) (R)

Pyraclostrobin was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009, with Germany as Rapporteur Member State. A decision to approve the active substance was taken in 2004 (Commission Directive 2004/30/EC[24]). No EFSA conclusion is available. Since 2009 pyraclostrobin is authorised to be used also as a plant growth regulator (Commission Directive 2009/25/EC[25]). For pyraclostrobin no EFSA conclusion is available. Between 2009 and 2011, EFSA issued six reasoned opinions on MRL applications and additional two opinions are in progress. EFSA also issued a reasoned opinion in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011f) however EFSA conclusion and recommendations are not yet implemented in the EU MRL legislation.

2.13.1. Toxicological endpoints – Pyraclostrobin.

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-41: Comparison of toxicological reference values derived by JMPR and at EU level

Pyraclostrobin	JMPR evaluation (JMPR, 2003)			EU evaluation (EC, 2004)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.03 mg/kg bw/d	Rat, 2-yr study	100	0.03 mg/kg bw/d	Rat, chronic study	100
Comments ADI				COM Review report		
ARfD	0.05 mg/kg bw	Rabbit, developmental toxicity study	100	0.03 mg/kg bw	Rabbit, developmental toxicity study	100
Comments ARfD	The JMPR considered foetal toxicity as the relevant effect for setting the ARfD.			Based on maternal toxicity appearing from the first day of dosing.		
Conclusion	For the ARfD, a lower value has been chosen in the EU evaluation. With the use of the same study, the JMPR evaluation took into account the foetal toxicity whereas the EU evaluation considered the maternal toxicity occurring already on the first day of dosing. JMPR concluded that the maternal effects (transient reduction in food intake and body-weight gain on the first days of dosing) were likely to be caused by local gastrointestinal effects related to high pyraclostrobin concentrations, or to taste disturbances resulting from regurgitation or leaking of the gavaging solution.					

2.13.2. Residue definitions – Pyraclostrobin.

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-42: Comparison of the residue definitions derived by JMPR and at EU level

Pyraclostrobin	Commodity group	JMPR evaluation (JMPR, 2004)	EU evaluation (EC, 2002, 2004)
RD enf	Plant commodities	Pyraclostrobin	Pyraclostrobin Regulation (EC) No 396/2005

[24] Commission Directive 2004/30/EC of 10 March 2004. OJ L 77, 13.03.2004, p. 50-53.
[25] Commission Directive 2009/25/EC of 2 April 2009, OJ L 91, 3.4.2009, p. 20-22.

Pyraclostrobin	Commodity group	JMPR evaluation (JMPR, 2004)	EU evaluation (EC, 2002, 2004)	
	Animal commodities	Pyraclostrobin In the CL the residues are reported as being **not fat-soluble.** However, in the 2004 JMPR report the residue is classified as **fat-soluble**.	Pyraclostrobin The residue is **fat-soluble**	
RD RA	Plant commodities	Pyraclostrobin	Pyraclostrobin	
	Animal commodities	Pyraclostrobin	Sum of pyraclostrobin and its metabolites containing the 1-(4-chlorophenyl)-1*H*-pyrazole moiety or the 1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazole moiety, expressed as pyraclostrobin	*CF RD enf to RD RA* 4 (ruminant liver) 1 (all other commodities)
Conclusion	The residue definition for enforcement for products of plant and animal origin established in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement set by JMPR. The residue definition for risk assessment for products of plant origin in EU is identical to the residue definition set by JMPR. The residue definition for risk assessment for products of animal origin in EU is different than the residue definition established by JMPR; it was confirmed during the review of the existing MRLs for pyraclostrobin performed under Article 12 of Regulation (EC) No 396/2005. It is noted that EFSA proposed to set the conversion factor from enforcement to risk assessment only for mammalian liver (at 4), thus meaning that the contribution of the metabolites to the total residues in the other products of animal origin was not relevant (EFSA, 2011f). It is recommended to update the database CX/PR 12/44/5-Add.1 regarding the fat solubility of the residues in animal commodities.			

2.13.3. CXL proposals - Pyraclostrobin

Table 2-43: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR (JMPR, 2011)	EU MRL (EFSA, 2011f) (existing/proposed)	Comment
Alfalfa fodder	30	-	**The CXL is sufficiently supported** by data. Alfalfa fodder was included in a revised livestock dietary burden and JMPR considered not necessary to propose new CXLs for pyraclostrobin in animal commodities.
Artichoke, globe	2	0.02 / 2	The CXL proposal is equal to the EU MRL proposed under Article 12 review.
Barley	1	0.3 / 0.5	The CXL proposal was derived combining the results from trials on barley (4) and oats (12) and extrapolating the CXL to both crops. The proposed CXL based on barley and oats is acceptable..
Beer	PF <0.67	PF 0.7	Processing factors are comparable.

Commodity	**CXL proposal derived by JMPR (JMPR, 2011)**	**EU MRL (EFSA, 2011f)** (existing/proposed)	**Comment**
Blackberries	3	1 / 2	**The CXL proposal is sufficiently supported** by combined results from trials on blackberries (4) and raspberries (9). The difference to the proposed EU MRL is a consequence of the calculation methodology.
Blueberries	4	0.5 / 3	**The CXL proposal is sufficiently supported** by data. The difference to the proposed EU MRL is primarily a consequence of the calculation methodology.
Brewing malt	PF 1.17	PF 1.2	Processing factors are comparable.
Cherries	3	0.3 /2	**The CXL proposal is sufficiently supported** by data. The difference to the proposed EU MRL is primarily a consequence of the calculation methodology.
Cherry juice	PF 0.16	PF 0.17	Processing factors are comparable.
Citrus fruits	2	1 / 1	The proposed group CXL was based on the more critical residue situation resulted from 8 trials on oranges in line with the Spanish GAP for oranges extrapolated to the whole group. According to the EU guidance document this extrapolation would not be acceptable, because the GAP on this crop differs from the citrus fruit GAP and the number of trials is not sufficient to support the extrapolation (EC, 2011). Thus, for the Spanish GAP on oranges (*4 x 0.225 kg a.s./ha; PHI 7 days*) sufficient data would be available to derive the **MRL value of 2 mg/kg for oranges**. It is noted that the Spanish GAP and the relevant trial results are not reported in the PROFile (EFSA, 2011f). For other citrus, except oranges a CXL of **1.5 mg/kg** would be derived from the combined dataset of oranges (13), grapefruit (6) and lemons (5) compliant with the cGAP for citrus fruits (*3 x 0.225 kg a.s./ha; PHI 0 days)*. This extrapolation would be in line with the extrapolation rules discussed last year in CCPR. The JMPR evaluation report is needed to conclude on the proposed peeling factor of 0.08. The peeling factor of 0.14 was proposed by EU during the Article 12 review (EFSA, 2011f).

Commodity	CXL proposal derived by JMPR (JMPR, 2011)	EU MRL (EFSA, 2011f) (existing/proposed)	Comment
Currants	2	2 / 3	The CXL proposal (based on German GAP: 3*0.067 kg/ha, PHI 3 d) is lower than the EU MRL proposed under Article 12 review which is based on trials reflecting a different GAP (import tolerance is based on a US/CAN GAP (4*0.21 kg/ha, 0 d PHI). For the most critical EU GAP (UK GAP: 2*0.1 kg/ha, 3 d PHI) a MRL of 2 mg/kg would be required. **There seems to be a discrepancy regarding the GAPs reported to JMPR and to EFSA.** It is noted that the CXL of 2 mg/kg is proposed (see JMPR report p. 216) but not listed in the overview table.
Fruiting vegetables, Cucurbits	0.5	0.02* / 0.5	The group CXL proposal is equal to the individual EU MRLs proposed under Article 12 review. The median peeling factor of 0.5 for cucurbits with inedible peel is proposed by both JMPR and EU.
Garlic	0.15	0.2 / 0.3	The **CXL proposal is sufficiently supported** by data. It is lower than the EU MRL proposed under Article 12 review.
Malt germ	PF 2.33	-	The JMPR evaluation report is needed to conclude on the PF proposal.
Nectarine	0.3	0.2 / 0.2	See peaches
Oats	1	0.3 / 0.5	The CXL proposal was derived combining the results from trials on barley (4) and oats (12). The CXL proposal is acceptable.
Oil seed except peanut	0.4	sunflower seed: 0.3 / 0.3	The proposed group CXL was based on the more critical residue situation resulted from residue trials on sunflowers and extrapolated to the whole group (except peanuts). This extrapolation is acceptable at EU level, but confirmation that the GAP authorised in US on the other members of the oilseed group is comparable to the GAP reported for sunflowers and rapeseeds is needed.
		rapeseed: 0.02 / 0.02	
		soy bean: 0.02*/0.05	
		Other oilseeds: 0.02 / 0.02 0.02* / 0.02*	
		cotton seed: 0.3 / 0.02*	For cotton seeds, the extrapolation is theoretically not possible as the GAP is not comparable. Provided that the samples from the residue trials were harvested 21 days after last application (to be confirmed), sufficient data would be available to derive for **cotton seeds a lower MRL value of 0.2 mg/kg**. The ALARA (as low as reasonable acceptable) principle should be considered.
Onion, bulb	1.5	0.2 / 0.3	The **CXL proposal is sufficiently supported** by data.

Commodity	CXL proposal derived by JMPR (JMPR, 2011)	EU MRL (EFSA, 2011f) (existing/proposed)	Comment
Orange oil	PF 6.24	-	JMPR evaluation report is needed to conclude on the PF proposal.
Papaya	0.15	0.05*/ 0.05	The CXL proposal is sufficiently supported by data; however the residue trial dataset justifies a **lower MRL of 0.07 mg/kg**.
Peach	0.3	0.2 / 0.2	The **CXL proposal is sufficiently supported** by data and is based on an alternative GAP.
Pearl barley	PF <0.67	PF 0.7	Processing factors are comparable.
Pecan	W[f]	0.02*/0.02*	See tree nuts
Plum puree	PF 1.87	-	JMPR evaluation report is needed to conclude on the PF proposal.
Plums (including Prunes)	0.8	0.2 / 1	The **CXL proposal is sufficiently supported**, reflecting a US GAP. It is lower than the EU MRL proposed under Article 12 review reflecting a French GAP which seems to be less critical than the US GAP.
Prunes	PF 4.59	PF 4.7	Processing factors are comparable.
Rape seed oil, edible	PF 1.33	-	JMPR evaluation report is needed to conclude on the PF proposal.
Raspberries, Red, Black	3	1 / 2	The **CXL proposal is sufficiently supported** by combined results from trials on blackberries (4) and raspberries (9).
Rye	0.2	0.1 / 0.1	The proposed CXL was extrapolated from the existing CXL on wheat (derived by JMPR in 2004) acknowledging that the critical German GAP for rye is identical with the German GAP for wheat. This extrapolation would be also allowed at EU level.
Sorghum	0.5	0.02* / 0.02*	The **CXL proposal is sufficiently supported** by data.
Spring onion	1.5	0.02* / 1	The **CXL proposal is sufficiently supported** by data.
Strawberry	1.5	0.5 / 1	The **CXL proposal is sufficiently supported** by data. The difference to the proposed EU MRL is primarily a consequence of the calculation methodology.
Strawberry jam	PF 0.21	-	JMPR evaluation report is needed to conclude on the PF proposal.
Tree nuts (except pistachios)	0.02*	Other tree nuts 0.02* / 0.02*	The group CXL proposal is equal to the EU MRL proposed under Article 12

Commodity	CXL proposal derived by JMPR (JMPR, 2011)	EU MRL (EFSA, 2011f) (existing/proposed)	Comment
		Pistachios: 1/1	review. It is noted that **JMPR recommended to maintain** the **CXL of 1 mg/kg for pistachios** (see JMPR report p. 220). Thus, the modification of the crop description is needed, as highlighted in the first column.
Triticale (wheat)	0.2	0.1 / 0.2	The CXL proposal is equal to the EU MRL proposed under Article 12 review.
General comments: Reservation expressed for CXL proposals for citrus fruits, cotton seeds, and papaya.			

[f] The recommendations for almonds and pecan are withdrawn to be replaced by a recommendation for Tree nuts.
[g] The recommendation for almond hulls is withdrawn as the commodity is not traded.
[h] The recommendations for cucumber, melons and squash are withdrawn to be replaced by a recommendation for Fruiting vegetables, Cucurbits
[i] The recommendation for sunflower seed is withdrawn to be replaced by a recommendation for Oilseed except peanut.

2.13.4. Consumer risk assessment – Pyraclostrobin

The long-term consumer exposure calculation was based on the conclusions and recommendations derived in the review of the existing EU MRLs for pyraclostrobin under Article 12 of Regulation (EC) No 396/2005. The previous assessment was updated using the median residue values derived from the results of the residue trials supporting CXL proposals higher than the recommended EU MRLs. For citrus and cucurbits with inedible peel the peeling factors were included) The acute exposure assessment was performed only with regard to the commodities for which the CXL proposals were higher than the recommended EU MRLs.

Table 2-44: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Max. 14 % of the ADI** (DE child diet) Highest contributor commodities**:** barley: 1. 4 %; wheat 0.4 %.
Acute risk	**Maximum 82.3 % of the ARfD** (onions); oranges: 69.9 %.; cherries: 64 %; blackberries: 47.2 %; grapefruits (47 %)
Conclusion	The CXLs proposal are acceptable with regard to consumer risk (**max. 82.3% of the ARfD** for **onions**).

2.14. Azoxystrobin (229) (R)

Azoxystrobin was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with The United Kingdom as Rapporteur Member State. A decision to approve[26] the active substance (Commission Directive 2010/55/EU[27]) was taken in 2010. For azoxystrobin an EFSA conclusion is available (EFSA. 2010). Since 2008, several reasoned opinions have been issued for azoxystrobin, currently two additional applications are under preparation (CZ, DE). In addition, the MRL review under Art. 12 is in an advanced stage (draft RO should be available in Feb. 2012).

2.14.1. Toxicological endpoints - Azoxystrobin

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-45: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation 2008			EU evaluation 2010		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0.2 mg/kg bw/d	2 yr rat	100	0.2 mg/kg bw/d	2 yr rat	100
Comments						
ARfD	unnecessary			unnecessary		
Comments						
Conclusion	The same toxicological end points have been derived by JMPR and EU peer review					

2.14.2. Residue definitions - Azoxystrobin

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-46: Comparison of the residue definitions derived by JMPR and at EU level

Azoxystrobin	**Commodity group**	**JMPR evaluation 2008**	**EU evaluation 2010**
RD enf	Plant commodities	Azoxystrobin	Azoxystrobin
	Animal commodities	Azoxystrobin Residues fat soluble (borderline)	Azoxystrobin Not considered fat soluble
RD RA	Plant commodities	Azoxystrobin	Azoxystrobin
	Animal commodities	Azoxystrobin Residues fat soluble	Azoxystrobin (provisional) Not considered fat soluble

[26] Approval renewed as from 1 January 2012 with Commission Implementing Regulation 2011/703/EU of 20 July 2011. OJ L 190, 21.7.2011, p. 33-37

[27] Commission Directive 2010/55/EU of 20 August 2010, OJ L 220, 21.8.2010, p. 67.70

Azoxystrobin	Commodity group	JMPR evaluation 2008	EU evaluation 2010
Conclusion	**Similar plant and animal residue definitions**, except for the fat solubility property where JMPR states "fat soluble". However it should be noted the following JMPR comment on the fat solubility *"The Meeting noted that azoxystrobin represents a borderline case of fat solubility"*. This may explain the difference in the EU and JMPR conclusions.		

2.14.3. CXL proposals - Azoxystrobin

The 2011 JMPR meeting recommended new CXLs for ginseng and coffee beans.

Table 2-47: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal JMPR 2011	EU MRL 2011[a]	Comment
Ginseng	0.1	50	CXL proposal covered by EU MRL
Coffee beans	0.02	0.1*	CXL proposal covered by EU MRL
General comments: CXLs proposed for ginseng and coffee are sufficiently supported by data. The CXL proposal for okra was included in the risk assessment of JMPR but it is not included in the CL. Clarifications would be desirable whether this CXL is supported by JMPR.			

a: Sanco/12225/2011

2.14.4. Consumer risk assessment - Azoxystrobin

EFSA calculated a chronic consumer risk assessment based on the existing EU MRLs. The results are summarised in the table below.

Table 2-48: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Highest TMDI: 52% ADI (DE child)** Consumer risk assessment conducted using the MRL values currently into force at EU level and covering the CXLs proposed for okra (derived in 2008 JMPR), ginseng and coffee beans.
Acute risk	**Not relevant, ARfD not necessary**
Conclusion:	The proposed CXLs for ginseng and coffee beans are acceptable.

2.15. Spirotetramat (234) (R)

Spirotetramat was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Austria as Rapporteur Member State. The decision on the approval of the active substance has not yet been taken. For spirotetramat no EFSA conclusion is available. Between 2009 and 2011 EFSA issued five reasoned opinions regarding MRL applications.

2.15.1. Toxicological endpoints - Spirotetramat

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-49: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation 2008			**EU evaluation: DAR (AT), 2008**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.5 mg/kg bw/d			0.05 mg/kg bw/d	1 yr dog	100
Comments ADI	-			-		
ARfD	1.0 mg/kg bw			1 mg/kg bw	Acute rat neurotoxicity	100
Comments ARfD	-			-		
Conclusion	The toxicological reference values are identical.					

2.15.2. Residue definitions - Spirotetramat

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-50: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation 2008**	**EU evaluation DAR (AT), 2008**
RD enf	Plant commodities	Spirotetramat and its enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one (BYI08330-enol), expressed as spirotetramat .	Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat
	Animal commodities	Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one (BYI08330-enol), expressed as spirotetramat.	Spirotetramat and its metabolite BYI08330-enol expressed as spirotetramat

	Commodity group	JMPR evaluation 2008	EU evaluation DAR (AT), 2008
RD RA	Plant commodities	*Spirotetramat, enol metabolite* 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, *ketohydroxy metabolite* 3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione,*monohydroxy metabolite* cis-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan -2-one, and *enol glucoside* metabolite glucosideof 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.	BYI08330 and the 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as BYI08330.
	Animal commodities	Spirotetramat enol metabolite, 3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one, expressed as spirotetramat.	Spirotetramat (BYI08330), BYI08330-enol and BYI08330-enolglucuronide, expressed as BYI08330.
Conclusion	The EU RD enforcement for plant commodities comprises three additional metabolites which were not included in the JMPR residue definition. Because of this difference, the levels of the EU MRL are not directly comparable with the CXL proposals. The RDs enforcement for animal commodities are identical. The RDs RA for plant commodities are identical. The EU RD RA for animal commodities comprises additional compounds (parent spirotetramat and BYI08330-enolglucuronide). It is noted that parent spirotetramat was not found in any metabolism studies. It was included only for editorial reasons. The BYI08330-enolglucuronide was included in the EU RD because it was found in significant amounts (14-37% of TRR).		

2.15.3. CXL proposals - Spirotetramat

Since the enforcement residue definitions set by Codex and at EU level are different, a direct comparison of the levels of CXLs and EU MRLs is hampered. However, EFSA assessed whether the CXL proposals are acceptable. In case they should be taken over in the EU legislation, it needs to be checked if the CXL levels need to be adapted to the EU residue definition.

Table 2-51: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Brussels sprouts	No CXL proposal derived	0.3	JMPR concluded that the trials are not sufficient to support the critical GAP because the trials were overdosed (3 applications were performed in the supervised field trials whereas the critical GAP allows only 2 applications). At EU level these trials were considered acceptable.
Cotton seed	**0.4**	0.3	**The CXL proposal is sufficiently supported** by data. The difference to the EU MRL is a consequence of the calculation methodology and the residue definition.
Cotton seed meal	1		**The CXL proposal is sufficiently supported**.
Cotton seed oil, edible			

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Edible offal (Mammalian)	**1**	0.03	The highest residue resulting from the calculated maximum dietary burden is calculated to be 0.55 mg/kg (cattle kidney). Thus, **0.7 mg/kg would be a sufficient CXL** for edible offal (mammalian)
Eggs	0.01	0.01*	**The CXL proposal is sufficiently supported**.
Kiwifruit	0.02*	0.3	**The CXL proposal is sufficiently supported**. The difference to the EU MRL is a consequence of the calculation methodology and the different residue definitions.
Legume animal feeds	30		
Legume vegetables	1.5	1.5 beans and peas (with pods), 0.7 beans without pods, 0.01* other leg. Veg.	The residue trials from beans with pods were extrapolated to all legume vegetables, although the data for beans and peas without pods would allow to set a **lower CXL at a lower level (0.8 mg/kg** calculated with OECD calculator).
Litchi	15	15	**The CXL proposal is sufficiently supported.**
Mango	**0.3**	0.2	**The CXL proposal is sufficiently supported**. The difference to the EU MRL is a consequence of the calculation methodology, the different residue definitions and a different PHI.
Meat (from mammals other than marine mammals)	**0.05**	0.01*	**The CXL proposal is sufficiently supported**.
Milks	**0.01**	0.005*	Validated analytical methods are available for a LOQ of 0.005 mg/kg. Since in the feeding studies at the expected dietary burden is below the LOQ of 0.005 mg/kg, the CXL should be set at this level (**0.005 mg/kg)**.
Onion, Bulb	**0.4**	0.3	**The CXL proposal is sufficiently supported.** The different EU MRL results for a different GAP.
Papaya	0.4	0.4	**The CXL proposal is sufficiently supported.**
Poultry meat	0.01*	0.01*	**The CXL proposal is sufficiently supported.**
Poultry, Edible offal of	0.01	0.01*	**The CXL proposal is sufficiently supported.**
Pulses [except soya bean (dry)]	**2**	1.5 beans, peas, 0.1* other pulses	**The CXL proposal is sufficiently supported**. The difference to the EU MRL is a consequence of the calculation methodology and the different residue definitions.

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Soya bean (dry)	**4**	3	**The CXL proposal is sufficiently supported**. The difference to the EU MRL is a consequence of the calculation methodology, the different residue definitions and a different PHI.
Soya bean flour (defatted)			
Soya bean oil, refined			
General comments: Reservastions are expressed regarding the levels of the proposed CXLs for edible offal (mammalian), legume vegetables and milks where lower MRLs than the proposed values of the JMPR would be sufficient**.**			

2.15.4. Consumer risk assessment - Spirotetramat

The chronic exposure assessment performed in the framework of the most recent reasoned opinion in the context of a MRL application was updated by replacing the EU risk assessment input values with the STMR/HR values derived by JMPR for crops where the CXL proposal exceeds the EU MRL (unless EU STMR is higher).

The acute exposure assessment was performed only for the crops under consideration for which the CXL proposal exceeds the existing EU MRL (unless the EU STMR/HR is higher).

Table 2-52: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Max. 32.9% of the ADI** contribution of the crops for which CXL proposals are higher than EU MRLs: lyche: 0.16%; beans without pods: 0.25%, peas without pods: 0.56%; swine meat: 0.22%;bovine meat: 0.2%; milk: 0.4%; all other: <0.1% of ADI
Acute risk	**Maximum 2% of the ARfD (mangoes), onions: 1.1%, beans (with pods): 1%, all other crops: < 1%.**
Conclusion	The CXL proposals are all acceptable with regard to consumer safety. However, lower CXLs would be appropriate for **edible offal (mammalian), legume vegetables and milks.**

2.16. Clothianidin (238) (R)

Clothianidin was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Belgium as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2006/41/EC[28]) was taken in 2006. For clothianidin no EFSA conclusion is available. EFSA issued a reasoned opinion on clothianidin in 2010, additional applications are under preparation (ES). The MRL review is in an advanced stage (draft RO expected for Feb. 2012).

2.16.1. Toxicological endpoints - Clothianidin

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-53: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation (2010 JMPR report)			**EU evaluation** (EU Review Report, SANCO/10533/2005-rev. final 18 January 2005)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.1 mg/kg bw/d	2yr rats	100	0.097 mg/kg bw/d	2 yr rat	100
Comments ADI	Based on the NOAEL in the 2-yr rat study of 9.7 mg/kg bw/day for decreased body weight and food consumption.			Based on the NOAEL of 9.7 mg/kg bw/day in the 2-yr rat study		
ARfD	0.6 mg/kg bw	Rat acute neurotoxicity	100	0.1 mg/kg bw	Developmental toxicity rat and rabbit	100
Comments ARfD				Review report		
Conclusion	With regard to the ADI, both EU and JMPR based their assessment on the same relevant study and endpoint and the slight difference relates to the rounding of the final value. Regarding the ARfD a different study and endpoint have been identified relevant by the JMPR and EU assessments, the ARfD proposed in the EU is appropriate as it reflects an early effect on the first days of treatment at lower doses than in the JMPR proposal.					

2.16.2. Residue definitions - Clothianidin

Upon request of the manufacturer, JMPR reviewed the residue definition derived in 2010[29]. According to the manufacturer, the Z-isomer should not be included in the residue definition since it cannot be isolated as such. In the following table the revised JMPR residue definitions for risk assessment and enforcement purpose derived in 2011 are compared with the current EU residue definitions.

[28] Commission Directive 2006/41/EC of 7 July 2006, OJ L 187, 8.7.2006, p. 24-27

[29] Definition of the residue for compliance with the MRL or for estimation of the dietary intake for plant commodities: ***sum of clothianidin and its Z-isomers***
Definition of the residue for compliance with the MRL or for estimation of the dietary intake for animal commodities: ***sum of clothianidin and its Z-isomer***

Table 2-54: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation** (2011 Report)	**EU evaluation** -Regulation (EC) No 396/2005 -Peer review
RD enf	Plant commodities	clothianidin	-Clothianidin and, thiamethoxam (sum of thiamethoxam and clothianidin, expressed as thiamethoxam)(1). -Clothianidin (Peer review)
	Animal commodities	clothianidin	-Clothianidin and, thiamethoxam (sum of thiamethoxam and clothianidin, expressed as thiamethoxam)(1) -Not required (Peer review)
RD RA	Plant commodities	clothianidin	Clothianidin – (Peer review) See also thiamethoxam
	Animal commodities	clothianidin	Not required (Peer review) See also thiamethoxam
Conclusion	EFSA agrees with the JMPR recommendation not to include the Z-isomers in the residue definitions for enforcement and risk assessment purposes for plant and animal commodities. The proposed residue definitions for enforcement purposes and dietary risk assessment do not impact on the recommendations for clothianidin as well as for the dietary risk assessment made by the 2010 JMPR. Clarification are required regarding the status of the CXL proposals advanced by the CCPR 43 (based on the JMPR evaluation 2010) to step 5. It seems that CAC of 2011 did not advance those daft CXLs to step 6. These proposals are not included in the Circular Letter CL2011/22-PR. The EU reservation made in the 43rd CCPR Meeting on the proposed CXLs fro root and tuber vegetables is unchanged: The extrapolation of residues found on potatoes (following treatment with thiamethoxam) to the whole group of root and tuber vegetables is not acceptable. There are sufficient data to set individual MRLs for carrots, potatoes, radishes, sugar been. EFSA reiterates the recommendations made already in the framework of MRL applications (EFSA, 2010b) to **amend the EU residue definition for thiamethoxam** in order to avoid an overlap with the MRLs established for clothianidin and also in view of the different toxicological end points allocated respectively to clothianidin and thiamethoxam (See thiamethoxam (245) assessment). It is noted that the EU reservation expressed in the 43rd CCPR on the CXL proposal for root and tuber vegetables is maintained for the following reason (EU position paper 43rd CCPR): "Root and tuber vegetables (including sugar beet roots): GAPs were reported for carrots, potatoes, radishes and sugar beet (in addition, GAPs for clothianidin were reported for carrots, chicory roots, tuberous and corm vegetable and sugar beet, but they were less critical than the use of thiamentoxam.) The GAPs were not comparable: seed treatment for sugar beets, foliar application for the other crops, different application rate for carrots and radishes compared with potatoes "		

2.17. Dicamba (240) (R)

Dicamba was evaluated under Directive 91/414/EEC[30], repealed by Regulation (EC) No 1107/2009 with Denmark as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2008/69/EC[31]) was taken in 2008. For dicamba an EFSA conclusion is available (EFSA, 2011a). EFSA recently received an application regarding the modification of an MRL (DK). The MRL review under Article 12 is in an early stage.

2.17.1. Toxicological endpoints - Dicamba

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-55: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation 2010			EU evaluation 2011		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0.3 mg/kg bw/d	Developmental toxicity rabbit	100	0.3 mg/kg bw/d	Rat, 2-generation	100
Comments ADI						
ARfD	0.5 mg/kg bw	13 week dog	100	0.3 mg/kg bw	Rabbit, teratology	100
Comments ARfD				The lower ARfD reflects an early effect on the first days of treatment. This effect was not considered by JMPR.		
Conclusion	The same ADI value was derived by JMPR and by EU, but based on different toxicological endpoints. The ARfD of 0.3 mg/kg proposed at EU level and derived from the teratology rabbit study is slightly lower than the JMPR proposal.					

2.17.2. Residue definitions – Dicamba

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-56: Comparison of the residue definitions derived by JMPR and at EU level

Dicamba	**Commodity group**	**JMPR evaluation 2010**	**EU evaluation**
RD enf	Plant commodities	dicamba	Dicamba (Reg. 396/2005) Dicamba and its salts and conjugated , expressed as dicamba (EFSA, 2011a)
	Animal commodities	Sum of dicamba and 3,6-dichlorosalicylic acid (DCSA) expressed as dicamba	Dicamba (Reg. 396/2005) Dicamba (free and conjugated) (EFSA, 2011a)
RD RA	Plant commodities	Sum of dicamba and 5-OH dicamba expressed as dicamba	Dicamba + 5-OH-dicamba, free and conjugated (EFSA, 2011a)
	Animal commodities	Sum of dicamba and 3,6-dichlorosalicylic acid (DCSA) expressed as dicamba	Dicamba (free and conjugated) (EFSA, 2011a)

[30] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32
[31] Commission Directive 2008/69/EC of 1 July 2008, OJ L 172, 2.7.2008, p. 9-14

Dicamba	Commodity group	JMPR evaluation 2010	EU evaluation
Conclusion	The inclusion of the conjugates in the residue definition should be considered (justification see below). It should be clarified whether the metabolism studies were performed on Dicamba resistant soybeans (genetically modified crop).		

The following comments were done last year on the residue definition for plant and animal products derived by the JMPR 2010. These comments remain valid:

Plant residue definitions

The JMPR proposal for the plant residue definitions differ from the EU proposals as conjugates were included in the definitions set at EU level. The inclusion of the conjugates are supported by the following:

- Dicamba conjugates were observed in higher/similar amounts than free dicamba in the metabolism studies conducted on wheat and sugar cane (8%, 18% and 9% vs 2%, 11% and 13% TRR in forage and leaves 12, 18 and 28 days after application).

- 5-OH dicamba conjugates were also quantified in significant proportions in these same matrices (65%, 8% and 11% versus 0.1%, 39% and 9% TRR).

- As it is mentioned in the JMPR report, the analytical methods developed for determining the residues of dicamba and its metabolites in plant matrices, start with an extraction step that includes an hydrolysis (95°C, >1 hours, 1M HCl). Conjugates are therefore released by this hydrolysis step (totally or partially) and consequently, dicamba and 5-OH dicamba conjugates were taken into when samples were analysed for in the residue trials.

Considering the points above, EFSA remains of the opinion that ***plant residue definitions must include the dicamba and 5-OH dicamba conjugates*** *and should be expressed as following*

- Monitoring: Dicamba ***(free and conjugates)****,*

- Risk assessment: Dicamba and 5-OH dicamba ***(free and conjugates)*** *expressed as dicamba.*

Animal residue definition

The EU and JMPR assessment relies on the same animal metabolism studies conducted on cow, goat and poultry. The JMPR proposes to define the residues definition for monitoring and risk assessment as the sum of Dicamba and DCSA, whereas the definitions were limited to dicamba alone at EU level. The inclusion of DCSA in the residue definition was intensively discussed in the course of the EU peer review, as DCSA was allocated with a lower ADI than dicamba (0.01 vs. 0.30 mg/kg bw/d). DCSA was finally not included having regard to the following points:

- DCSA was not identified as a significant metabolite in plants (mostly <2% TRR), and animals are therefore not exposed to significant DCSA residues.

- DCSA was not identified in poultry matrices (excreta only). It was not identified in fat, muscle and in the cow and goat metabolism study but represented ca. 10% of the TRR in kidney, up to 20% in cow liver.

- A worst case calculation based on the ADI of 0.01 mg/kg bw/d proposed at EU level for DCSA and the animal intakes resulting from the use on pasture, shows its contribution to be less than 1% of the ADI.

Therefore, as the contribution of DCSA to the consumer intake was considered negligible and since dicamba was shown to constitute an appropriate marker in poultry and ruminant matrices (accounting for 50% to 95% TRR), the animal residue definition for monitoring and risk assessment was limited to the parent dicamba only.

2.17.3. CXL proposals – Dicamba

In the table below the CXLs are compared with the existing EU MRLs. However, due to the different residue definitions, a direct comparison is impeded.

Table 2-57: Comparison of CXL proposals derived by JMPR and EU MRLs s

Commodity (JMPR classification)	CXL proposal JMPR 2011	EU MRL	Comment
Soya bean	5	0.05* (default LOQ)	The CXL proposal is derived from trials which were overdosed, applying the proportionality approach which is not acceptable at EU level, in particular for herbicide use and for major crops. Clarifications should be provided whether the residue trials were performed on genetically modified soybeans or on conventional crops.
General comments: CXL for products of animal origin was not reconsidered by JMPR 2011 since no changes in the animal intakes to those calculated by JMPR 2010			

2.17.4. Consumer risk assessment – Dicamba

The consumer risk assessment was performed with the EFSA PRIMo model rev.2 and:

- The CXL proposed by JMPR 2010 on asparagus, barley, sorghum, wheat and sugar cane and animal products (except bovine meat).
- The CXL of 5 mg/kg proposed for soya bean by JMPR 2011,
- The EU MRL currently into force on sweet corn, other cereals and bovine meat.
- value "0" for the other inputs.

Table 2-58: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Highest TMDI: 9% ADI** (WHO Cluster B)
Acute risk	**Highest IESTI: 10% ARfD for wheat (**EU ARfD value of 0.3 mg/kg bw, EFSA 2011**),**
Conclusion	**The CXL proposal does not pose a consumer health risk.**

2.18. Etoxazole (241) (R)

Etoxazole was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with France as Rapporteur Member State. A decision to approve the active substance was taken in 2005 (Commission Directive 2005/34/EC[32]). For etoxazole no EFSA conclusion is available. EFSA has provided comments and recommendations on the acceptability of the CXLs proposed for etoxazole in the JMPR evaluation report 2010 and adopted by the Codex Alimentarius Commission (CAC) on July 2011 but a decision on the inclusion of these CXLs in Regulation (EC) No 396/2005 has not yet been taken. An MRL application on banana, cherries and plums is under preparation in Spain. The MRL review is ongoing; a first draft Reasoned Opinion is expected in April 2012.

2.18.1. Toxicological endpoints – Etoxazole

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-59: Comparison of toxicological reference values derived by JMPR and at EU level

Etoxazole	**JMPR evaluation (JMPR, 2010)**			**EU evaluation (EC, 2004)**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.05 mg/kg bw/d	Dog, 90 d and 1 yr study	100	0.04 mg/kg bw/d	2 yr rat	100
Comments ADI	JMPR report: JMPR concluded on an overall NOAEL of 5.33 mg/kg bw/day based on liver effects from two dog studies.			Review report: the peer review under Directive 91/414/EEC concluded on a NOAEL of 4.0 mg/kg bw/day based on liver effects from a rat study.		
ARfD	Not necessary			Not necessary		
Comments ARfD						
Conclusion	The ADI values derived by JMPR and at EU level are slightly different. Although the liver is recognized as the target organ of etoxazole by both assessments, it is not possible to thoroughly comment on the most appropriate ADI. However, having the EU assessment selected a longer term study than the JMPR, the EU ADI is supported. Considering the low acute toxicity of etoxazole, both assessments considered not necessary to allocate an ARfD.					

2.18.2. Residue definitions - Etoxazole

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-60: Comparison of the residue definitions derived by JMPR and at EU level

Etoxazole	**Commodity group**	**JMPR evaluation (JMPR, 2010)**	**EU evaluation**
RD enf	Plant commodities	Etoxazole	Etoxazole Regulation (EC) No 396/2005
	Animal commodities	Etoxazole The residue is fat-soluble	Not established

[32] Commission Directive 2005/34/EC of 17 May 2005, OJ L 125, 18.05.2005, p. 5-7

Etoxazole	Commodity group	JMPR evaluation (JMPR, 2010)	EU evaluation
RD RA	Plant commodities	Etoxazole	Etoxazole (DAR, FR 2001)
	Animal commodities	Etoxazole The residue is fat-soluble	Not established (DAR, FR 2001)
Conclusion	The residue definition for enforcement for products of plant origin established in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement set by JMPR. The residue definition for risk assessment for products of plant origin established during the peer review is identical to the residue definition for risk assessment for products of plant origin set by JMPR. Since no significant residues of etoxazole (≥ 0.1 mg/kg) occurred in crops or crop parts fed to animals, no residue definition for enforcement and risk assessment were derived for commodities of animal origin at time of the peer review. However, the residue was classified as fat-soluble.		

2.18.3. CXL proposals – Etoxazole

In the following table the CXL proposal is compared with the existing EU MRL.

Table 2-61: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR (JMPR, 2011)	EU MRL	Comment
Pome fruits	0.07	0.02*	**The proposed group CXL is sufficiently supported by data** and complies with the EU guidance document for extrapolation (EC, 2011). However the combined residue dataset (9 apple plus 4 pear trials) justifies the **lower MRL of 0.05 mg/kg.**
Comment: A lower MRL for pome fruit would be sufficient.			

2.18.4. Consumer risk assessment - Etoxazole

The long-term consumer exposure calculation included EFSA recommendations on the acceptability of the CXLs for etoxazole adopted by Codex Alimentarius Commission (CAC) on July 2011 and was using the STMR for pome fruits.

Table 2-62: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**Max. 6 % of the ADI** Pome fruits: max 0.3 % (DE child diet).
Acute risk	Not necessary since no ARfD was established.
Conclusion	**The CXL proposal is acceptable with regard to consumer risk.**

2.19. Thiamethoxam (245) (R)

Thiametoxam was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Spain as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2007/6/EC[33]) was taken in 2007. For thiamethoxam no EFSA conclusion is available. In 2009 and 2010 EFSA issued reasoned opinions regarding MRL applications. The MRL review under Article 12 of Regulation (EC) No 396/2005 is in an advanced stage (draft reasoned opinion should be available in February 2012).

2.19.1. Toxicological endpoints - Thiamethoxam

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-63: Comparison of toxicological reference values derived by JMPR and at EU level

Thiamethoxam	**JMPR evaluation** (2010 Report)			**EU evaluation** (EU Review Report, SANCO/10390/2002-rev. final 14 July 2006)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.08 mg/kg bw/d	90-day toxicity study in dogs	100	0.026 mg/kg bw/d	Long-term mouse study	100
Comments ADI	Based on a NOAEL of 8.23 mg/kg bw/day in a 90-day study in dogs, for prolonged thromboplastin time. This ADI is protective of the hepatotoxic and hepatocarcinogenic effects observed in mice, which were not observed in rats because of a marked species difference in metabolism. It is also protective of the marginally toxic effects observed in a multigeneration study in rats at 46 mg/kg bw/day.			Based on the NOAEL of 2.6 mg/kg bw/day for hepatotoxicity (liver hypertrophy, inflammation, necrosis) in an 18-month study in mice.		
ARfD	1 mg/kg bw	Single-dose neurotoxicity study in rats	100	0.5 mg/kg bw	Rabbit developmental toxicity study	100
Comments ARfD	Based on a NOAEL of 100 mg/kg bw in a single-dose neurotoxicity study in rats, supported by a single-dose toxicity study in mice, in which clinical signs of toxicity were observed at 500 mg/kg bw, the lowest dose tested. The transient functional changes in rats appeared to be mild signs of overt toxicity rather than neurotoxicity.			Based on the developmental NOAEL of 50 mg/kg bw/day for reduced foetal body weight, delayed ossification and increased post-implantation loss.		
Conclusion	With regard to the ADI, the EU assessment is supported as it is considering a relevant species (mouse), study and endpoint for the purpose of long term assessment. Regarding the ARfD, the neurotoxicity study used by the JMPR is considered relevant to an acute exposure, the absence of a detailed knowledge of the developmental toxicity study in rabbits and the related discussions during the EU assessment does not allow a sound opinion.					

2.19.2. Residue definitions - Thiamethoxam

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[33] Commission Directive 2007/6/EC of 14 February 2007, OJ L 43, 15.2.2007, p. 13-18

Table 2-64: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation** (2011 Report)	**EU evaluation** -Regulation (EC) No 396/2005 -Peer review, EFSA Reasoned opinions
RD enf	Plant commodities	Thiamethoxam	-Clothianidin and, -Thiamethoxam (sum of thiamethoxam and clothianidin, expressed as thiamethoxam) (**Reg. 396/2005**) -Thiamethoxam + N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N"-nitro-guanidine (CGA 322704) expressed as thiamethoxam (**Peer review – LoEPs, 2006**)
	Animal commodities	Thiamethoxam	-Clothianidin and, -Thiamethoxam (sum of thiamethoxam and clothianidin, expressed as thiamethoxam) (**Reg. 396/2005**) -Thiamethoxam + N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N"-nitro-guanidine (CGA 322704) expressed as thiamethoxam (**Peer review– LoEPs, 2006**)
RD RA	Plant commodities	Thiamethoxam and clothianidin (considered separately)	-Thiamethoxam + N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N"-nitro-guanidine (CGA 322704) expressed as thiamethoxam (**Peer review– LoEPs, 2006**)
	Animal commodities (except poultry)	Thiamethoxam and clothianidin (considered separately)	-Thiamethoxam + N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N"-nitro-guanidine (CGA 322704) expressed as thiamethoxam (**Peer review– LoEPs, 2006**)
	Animal commodities (for poultry)	Sum of thiamethoxam, CGA 265307 and MU3, expressed as thiamthoxam; and clothanidin (clothianidin to be considered separately from thiamethoxam)	-Thiamethoxam + N-(2-chloro-thiazol-5-ylmethyl)-N'-methyl-N"-nitro-guanidine (CGA 322704) expressed as thiamethoxam (**Peer review– LoEPs, 2006**)
Conclusion	EFSA agrees with the JMPR residue definitions. See also conclusions on residue definition for clothianidin (238).		

2.20. Acetamiprid (246) (T, R, new compound)

Acetamiprid was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with Greece as Rapporteur Member State. A decision to approve the active substance (Commission Directive 2004/99/EC[34]) was taken in 2004. For acetamiprid no EFSA conclusion is available. Since 2009, EFSA issued several reasoned opinions for acetamiprid. In the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 EFSA has issued a reasoned opinion (EFSA, 2011d) The recommendations of EFSA are not yet implemented in the EU MRL legislation.

2.20.1. Toxicological endpoints - Acetamiprid

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-65: Comparison of toxicological reference values derived by JMPR and at EU level

Acetamiprid	JMPR evaluation 2011			EU evaluation 2004		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.07 mg/kg bw/d	2 yr rat study and 2-generation reproduction study	100	0.07 mg/kg bw/d	2 yr rat study and 2-generation reproduction study	100
Comments ADI	Based on the NOAEL of 7.1 mg/kg bw/day for clinical signs and hepatocyte vacuolation seen at 17.5 mg/kg bw/day from the 2 yr study in rats, supported by the NOAEL of 6.67 mg/kg bw/day for decreased parental bw gain and feed consumption and hepatocyte vacuolation at 18.9 mg/kg bw/day observed in a multigeneration study in rats.			Based on the NOAEL of 7 mg/kg bw/day from the 2-yr rat study showing liver and kidney toxicity, supported by the NOAEL of 6.5 mg/kg bw/day from the multigeneration study in rats.		
ARfD	0.1 mg/kg bw	Rat, acute neurotoxicity study	100	0.1 mg/kg bw	Rat, acute neurotoxicity study	100
Comments ARfD	Based on the NOAEL of 10 mg/kg bw in an acute neurotoxicity study in rats, presenting evidence of neurotoxicity, decreased locomotor activity and increased urination frequency, supported by the NOAEL for maternal toxicity in the developmental neurotoxicity study of 10 mg/kg bw/day, for reduced bw gain in dams during the first 3 days of dosing (gestation days 6–9).			Based on the NOAEL of 10 mg/kg bw for reduced motor activity in an acute neurotoxicity study in rats.		
Conclusion	The toxicological reference values derived by JMPR are identical with the EU values and based on the same relevant studies and endpoints, although a developmental neurotoxicity study was apparently not available to the EU assessment.					

2.20.2. Residue definitions - Acetamiprid

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[34] Commission Directive 2004/99/EC of 1 October 2004, OJ L 309, 6.10.2004, p. 6-8

Table 2-66: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation 2011	EU evaluation
RD enf	Plant commodities	acetamiprid	acetamiprid
	Animal commodities	sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid	sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid
RD RA	Plant commodities	acetamiprid	acetamiprid
	Animal commodities	sum of acetamiprid and N-desmethyl-acetamiprid, expressed as acetamiprid	sum of acetamiprid and N-desmethyl-acetamiprid (IM-2-1), expressed as acetamiprid
Conclusion	Residue definitions derived by JMPR and EFSA (2011) are the same. (The residue definition for animal commodities reported in the circular letter was not correct and conflicting with the JMPR report.)		

2.20.3. CXL proposals - Acetamiprid

EFSA assessed whether the draft CXLs recommended by JMPR are adequately supported by data. In addition, a comparison was made with the outcome of the latest acetamiprid MRL review carried out at EU level (EFSA, 2011d) providing more insight on the differences between both assessments. An overview of the findings is provided in the table below.

Table 2-67: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Apple juice			A similar processing factor was derived at EU level but it was not considered to be sufficiently robust as only 2 trials were available. It is not clear how many trials were considered by JMPR.
Beans, except broad bean and soya bean	**0.4**	0.01* / 0.06 beans (fresh, with pods)	Draft CXL is based on 6 trials only; 2 additional trials would be needed to make the dataset more robust. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Beans, shelled	**0.3**	0.06/0.06	**Draft CXL is adequately supported** by data. No authorisation reported within the EU.
Berries and other small fruit (except grapes and strawberries)	**2**	0.01*/1.5 blueberries, LOQ other berries	**Draft CXL is adequately supported** by data. Within the EU, import tolerance was only reported for blueberries with a smaller data set.
Cabbages, Head	**0.7**	0.01*/ 0.6	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Celery	**1.5**	0.01*/1	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Cherries	**1.5**	0.5/0.5	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Citrus fruits	0.8	1/0.9	Draft CXL is covered by the recent EU MRL review.
Citrus juice			A similar processing factor was derived at EU level but it was not considered to be sufficiently robust as only 1 trial was available. It is not clear how many trials were considered by JMPR.
Citrus oil			No data reported at EU level. It is also not clear how many trials were considered by JMPR.
Citrus peel			No data reported at EU level. It is also not clear how many trials were considered by JMPR.
Cotton seed	**0.7**	0.02/0.5	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Cotton seed oil, edible			A similar processing factor was derived at EU level but it was not considered to be sufficiently robust as only 1 trial was available. It is not clear how many trials were considered by JMPR.
DRIED GRAPES (=CURRANTS, RAISINS AND SULTANAS)			No data reported at EU level. It is also not clear how many trials were considered by JMPR.
Edible offal (Mammalian)	0.05	0.1 swine liver, 0.2 swine kidney, 1 ruminant liver, kidney,	Draft CXL is covered by the recent EU MRL review noting however that the EU assessment was limited to liver and kidney of ruminants and pigs only (no horses or other edible offal).
Eggs	0.01*	0.05*/0.01*	Draft CXL is covered by the recent EU MRL review.
Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower)	**0.4**	0.01*/0.3 broccoli, 0.15 cauliflower	**Draft CXL is adequately supported by data.** MRL resulting from recent EU review is lower due to a different dataset/GAP for cauliflower.
Fruiting vegetables, Cucurbits	0.2	0.3/0.3 cucurbits, edible peel, 0.01*/0.01* melons, watermelons	Although pooling of data for all cucurbits is normally not supported at EU level, draft CXLs are not impacted in this case. They are therefore considered to be adequately supported by data. MRLs resulting from recent EU review are different due to different datasets and GAPs.

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Fruiting vegetables, other than Cucurbits (except sweet corn &mushrooms)	**0.2**	0.1/0.15 tomatoes, aubergines 0.3/0.3 peppers	Although pooling of data for all solanacea is normally not supported at EU level, draft CXLs are not impacted in this case. They are therefore considered to be adequately supported by data. MRLs resulting from recent EU review are different due to different datasets and GAPs.
Garlic	**0.02**	0.01*/0.01*	**Draft CXL is adequately supported** by data. No authorisation reported within the EU.
Grapes	**0.5**	0.01*/0.2	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Leafy vegetables (except spinach)	3	5/3 lettuce, lamb's lettuce, rucola, leaves and sprouts of Brassica spp 3/3 cress, land cress, red mustard, chard, fresh herbs 0.01*/0.5 purslane 5/1.5 scarole	**Draft CXL is adequately supported** by data but an acute consumer risk for scarole and kale cannot be excluded (see below). At EU level the same dataset was used but extrapolated to other crops (based on the authorisations reported at EU level).
Mammalian fats (except milk fats)	0.02	0.05*/0.2	Draft CXL is covered by the recent EU MRL review noting however that the EU assessment was limited to fats of ruminants and pigs only (no horses).
Meat (from mammals other than marine mammals)	0.02	0.05*/0.5	Draft CXL is covered by the recent EU MRL review noting however that the EU assessment was limited to meat of ruminants and pigs only (no horses).
Milks	0.02	0.05*/0.3	Draft CXL is covered by the recent EU MRL review noting however that the EU assessment was limited to ruminant milk only (no horses).
Nectarine	**0.7**	0.1/0.1	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Onion, Bulb	0.02	0.01*/0.02	**Draft CXL is adequately supported** by data and corresponds to the recent review carried out by EFSA.
Peach	**0.7**	0.1/0.1	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Peas, shelled (succulent seeds)	0.3	0.01*/0.01*	**Draft CXL is adequately supported** by data. No authorisation reported within the EU.

Commodity	CXL proposal derived by JMPR 2011	EU MRL	Comment
Peppers Chili, dried	**2**	0.3/0.3 peppers (fresh)	**Draft CXL is adequately supported** by data.
Plums (including Prunes)	**0.2**	0.02/0.03	Draft CXL is based on 6 trials and 2 additional trials would normally be required at EU level for this major crop. MRL resulting from recent EU review is lower due to a different dataset/GAP.
Pome fruits	**0.8**	0.1/0.7	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to a different dataset.
Poultry meat	0.01*	0.05*/0.02*	Draft CXL is covered by the recent EU MRL review.
Poultry, Edible offal of	0.05*	0.1/0.1* poultry liver	Draft CXL is covered by the recent EU MRL review noting however that the EU assessment was limited to poultry liver only.
Spinach	5[l]	3/5	**Draft CXL is adequately supported** by data and corresponds to the recent review carried out by EFSA. According to EU risk assessment, this MRL is not of concern for consumers. However, JMPR identified an acute intake concern for children (180% of the ARfD) (see below).
Spring onions	**5**	0.01*/0.01*	Draft CXL is based on 3 trials and 1 additional trial would normally be required at EU level for this minor crop. No authorisation reported within the EU.
Strawberry	0.5	0.01*/0.5	**Draft CXL is adequately supported** by data and corresponds to the recent review carried out by EFSA.
Tomato paste			No data reported at EU level. It is also not clear how many trials were considered by JMPR.
Tomato purée			No data reported at EU level. It is also not clear how many trials were considered by JMPR.
Tree nuts	**0.06**	0.01*/0.01*	**Draft CXL is adequately supported** by data. No authorisation reported within the EU.
General comments: The number of trials is not sufficient to derive a reliable CXL for spring onions, plums and beans (except broad bean and soya bean)			

[l] On the basis of information provided to the JMPR it was not possible to conclude from the estimate of short-term intake for acetamiprid that the consumption of spinach was less than the ARfD

2.20.4. Consumer risk assessment - Acetamiprid

Consumer intake calculations were carried out using revision 2 of the EFSA PRIMo. In order to provide a comprehensive risk assessment, in particular with regard to the chronic exposure, the MRLs resulting from the latest review on acetamiprid (EFSA, 2011d) were compared with the draft CXLs recommended by JMPR. Where the draft CXL was higher than the proposed EU MRL, STMR and HR values derived by JMPR were used. It should be noted however that the refinement of the risk

assessment for head cabbage by considering the removal of outer leaves, as proposed by JMPR, was not considered appropriate by EFSA[35]. An overview of the findings is provided below.

Table 2-68: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	The highest chronic exposure was calculated for German children represent ting **6.1% of the ADI.** Considering that for the EU review of MRLs a chronic exposure of 6.0% of the ADI was calculated, it can be concluded that the draft CXLs proposed by JMPR are not significantly impacting on the chronic exposure of European consumers to acetamiprid residues.
Acute risk	Although JMPR identified a potential acute intake concern for the draft CXL on **spinach**, EFSA did not identify a risk related to this crop (**58%**). The reason for this discrepancy is that at EU level it was agreed to assume that spinach is consumed after bulking and blending of leaves which have a unit weight of less than 25 g, thus no variability factor is applied. JMPR uses a VF of 3 for spinach (bunch). In contrast to JMPR, EFSA identified an **acute intake concern for scarole (166%)** and **kale (128%),** using the EU VF of 5 for scarole and 7 for kale. Applying a VF of 5 for kale, the exposure would be acceptable (91%). No exceedances of the ARfD were identified for any other draft CXL.
Overall conclusion	Using the EU methodology a potential acute consumer health risk is identified for **scarole and kale** (leafy vegetables except spinach). For kale the exposure would be below 100% if the calculation is performed with the less conservative variability factor of 5.

[35] According to the EU food classification the MRL would be applicable to head cabbage (whole plant after removal of roots and decayed leaves). JMPR derived the MRL from the results referring to cabbage head with wrapper leaves, whereas the STMR and HR were derived for the results corresponding to the cabbage heads without wrapper leaves. EFSA performed the risk assessment with the HR and STMR derived from the whole plant, including the wrapper leaves. Since this more conservative approach did not identify a potential acute or chronic risk, no further refinements were considered necessary (e.g. using input values for cabbage head without wrapper leaves).

2.21. Emamectin benzoate (247) (T, R, new compound)

Emamectin benzoate evaluation under Directive 91/414/EEC (repealed by Regulation (EC) No 107/2009) with the Netherlands as Rapporteur Member State is still ongoing. The EU peer review of the active substance is only at a very early stage and an EFSA conclusion for emamectin benzoate is not expected before late 2012/early 2013. However, EFSA issued in 2009 and 2011 reasoned opinions regarding an MRL application for emamectin.

2.21.1. Toxicological endpoints – Emamectin benzoate

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-69: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation (JMPR, 2011)			**Provisional EU evaluation (NL, 2011)**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.0005 mg/kg bw/d	Rat, 1 year & 2 year Dog, 14 wk & 1 year	500	(0.0025) **provisional**	Rat, 104 week Dog, 14 wk & 1 year	100
Comments ADI	Additional SF of 5 based on steep dose-response curves in mice, rats and dogs; and irreversible histopathological effects in neural tissues of dogs at the LOAEL.			No additional SF is proposed by the RMS (NL) in the DAR. EU peer review is ongoing.		
ARfD	0.03 mg/kg bw	Rat, acute neurotoxicity study	200	(0.05) **provisional**	Rat, acute neurotoxicity study	100
Comments ARfD	Additional SF of 2 based on degeneration of neurons in brain, spinal cord and sciatic nerve at 25 mg/kg bw.			No additional SF is proposed by the RMS (NL) in the DAR. EU peer review is ongoing.		
Conclusion	EU and JMPR proposals for the ADI and ARfD values seem to be derived from the same toxicological studies for which the same NOAELs have been derived (0.25 mg/kg bw/d and 5 mg/kg bw, respectively for the ADI and the ARfD). In the JMPR evaluation, additional safety factors were considered. However, the EU evaluation is ongoing and concerns were raised by MSs in relationship with the neurotoxic effects (triggering an increased SF in the JMPR evaluation) and the establishment of reference values. Pending on the completion of the EU evaluation, the reference values proposed by JMPR seem to be acceptable based on the available evaluation.					

2.21.2. Residue definitions – Emamectin benzoate

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-70: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation 2011**	**EU evaluation (Ongoing, not finalised)**
RD enf	Plant commodities	Emamectin B1a benzoate	Emamectin benzoate B1a, expressed as emamectin (DAR, NL, 2011)
	Animal commodities	Emamectin B1a benzoate	**No proposal** (studies not submitted, as not relevant for the supported uses)
RD RA	Plant commodities	Emamectin B1a benzoate	**Pending** (EU peer review ongoing)

	Commodity group	JMPR evaluation 2011	EU evaluation (Ongoing, not finalised)
	Animal commodities	Emamectin B1a benzoate	**No proposal** (studies not submitted, as not relevant for the supported uses)
Conclusion	Similar plant residue definition **for enforcement** at EU and JMPR levels, but EU definition **for risk assessment** not finalised (inclusion of avermectin-like metabolites under discussion). In the framework of MRL applications under Art. 10 of Regulation (EC) No 396/2005, the risk assessment was based on the parent compound only, noting that this might be modified in the light of the outcome of the peer review. The justification for the inclusion of the avermectin-like metabolites is given below.		

The exclusion of the avermectin-like metabolites from the residue definition for enforcement is questionable for the following reasons (especially for the leafy crop plant group):

- Considering the low toxicological reference values proposed for emamectin B1a (ADI 0.0005 mg/kg bw/d) and the uncertainty on the toxicological profile of the avermectin-like metabolites, not identified in the rat metabolism.

- In the metabolism studies conducted on lettuce and cabbage, although present individually at low levels and proportions, when summed up together avermectin-like metabolites are present in higher levels than the parent B1a (ratio "avermectin-likes/parent B1a" = 1.2/1.7, 1.6/1.9, 1.8/2.5 and 2.1/2.8 after PHI 1, 3, 7 and 10 days respectively).

- The presence of 4 of these 13 avermectin-like metabolites (8,9-ZMa, AB1a, MFB1a and FAB1a) is confirmed in the supervised residue trials conducted on lettuce. These 4 avermectin-likes in addition to emamectin B1b also analysed for, represent *ca.* 20% of the total residues in the indoor trials at PHI 3 and 7 days (mean total residues 0.262/0.156 mg/kg, n = 13) and 45% of the total residues at PHI 3 days in the outdoor residue trials conducted in northern and southern EU on summer period (mean total residues: 0.012 mg/kg, n = 7).

2.21.3. CXL proposals – Emamectin benzoate

Although JMPR and EU evaluations have been performed on the same residue datasets (mostly EU trials conducted in FR, IT, SP, UK and SW according to EU GAPs), differences are noted in the CXL/MRL, STMR and HR values derived by JMPR and at EU level. These noticeable inconsistencies are mainly related to the followings:

- Use of different MRL calculators (OECD calculator by JMPR, R_{max}/R_{ber} calculator at EU level),

- Different crop grouping at EU and JMPR level (fruiting vegetables, leafy crops),

- Additional residues trials available at EU levels but not submitted to JMPR (grapes)

- STMR and HR derived by JMPR from residue levels in the edible part of the commodity, in contrast, from the whole commodity at EU level (stone fruits, cucurbits inedible peel).

- Default LOQ of 0.01* mg/kg applied at EU level, whereas an LOQ of 0.001* or 0.002* was taken into account by JMPR (HPLC-MS/MS analytical method fully validated at the LOQ of 0.001 mg/kg)

EFSA Note: The LOQ of 0.01* mg/kg currently adopted at EU level under Reg. (EC) No 396/2005 seems no longer appropriate if the toxicological reference values proposed by JMPR are confirmed under the EU peer review, since such a value represents a too significant default intake for certain plant or animal commodities (*e.g.* 79% for milk, FR toddler in PRIMo model). EU would have to adopt similar LOQs as JMPR (0.001 or 0.002* mg/kg depending on the plant or animal commodities).

Table 2-71: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity (JMPR classification)	**CXL proposal JMPR 2011**	**EU MRL**	**Comment**
Beans (except broad bean and soya bean)	**0.015**	0.01*	The MRL proposal is based on 8 trials on beans with pods. The CXL proposal for beans (VP 0061 is also applicable to beans without pods. For beans without pods the residue trials would not be accepted at EU level. The same datasets were assessed at EU level to derive a MRL for beans with pods. The different MRL proposals are resulting from different MRL calculators.
Cos lettuce	1	1	See lettuce
Cotton seed	0.002*	Default LOQ (0.01*)	**CXL proposal is sufficiently supported**. No uses or import tolerances at EU level (US GAP: 16.8 g/ha, PHI 21)
Edible offal (Mammalian)	**0.08**	Default LOQ (0.01*)	**CXL proposal is sufficiently supported** No MRL proposed at EU level (default EU LOQ questionable)
Fruiting vegetables **Cucurbits**	0.007	0.01* Melon, Cucumber	**CXL proposal is sufficiently supported by data.** The higher EU MRL is resulting from the same datasets, but using different MRL classes. The setting of EU MRLs at the level proposed by JMPR would be also acceptable.
Fruiting vegetables **other than Cucurbits** (except sweet corn and mushrooms)	0.02 derived from trial on pepper STMR: 0.003 HR: 0.013	0.02 Tomato, Pepper	CXL proposal is acceptable for tomatoes and pepper. The CXL proposal is derived from the trials on peppers, whereas the EU MRL for tomatoes was derived from the indoor trials on cherry tomato. For aubergines the EU MRL was derived from indoor trials on normal tomatoes. Due to the different trials used to derive the EU MRLs, the STMR and HR values are also different Tomato: EU STMR: 0.006, EU HR: 0.008 Pepper: EU STMR: 0.003, EU HR: 0.013
		0.01* Aubergine, Other	For aubergines a lower value of 0.01 mg/kg would be sufficient (based on trials no normal sized tomatoes). JMPR extrapolated the results from peppers to aubergines. This extrapolation is normally not acceptable at EU level. Aubergines: EU STMR 0.002, EU HR: 0.004
Grapes	0.03	0.05	**CXL proposal is sufficiently supported by data**: Same dataset but EU MRL derived from Southern trials whereas form merged Northern and Southern trial at JMPR level.
Lettuce, Head	1	1	**CXL proposal is sufficiently supported.**
Lettuce, Leaf	1		
Mammalian fats (except milk fats)	**0.02**	Default LOQ (0.01*)	**CXL acceptable**. No MRL proposed at EU level (default EU LOQ questionable)
Meat (from mammals other than marine mammals)	0.004	Default LOQ (0.01*)	**CXL acceptable.** No MRL proposed at EU level (default EU LOQ questionable)
Milks	0.002	Default LOQ (0.01*)	**CXL acceptable**. Default EU LOQ of 0.01* should be reconsidered. (0.01 mg/kg in milk represents 79% ADI in PRIMo model)
Mustard greens	**0.2**	Default LOQ (0.01*)	**CXL proposal is sufficiently supported.**

Commodity (JMPR classification)	CXL proposal JMPR 2011	EU MRL	Comment
Nectarine/Peach	**0.03**	0.02	**CXL is sufficiently supported by data.** The difference to the EU MRL is a consequence of the calculation methodology .
Pome fruits	0.02	0.02	**CXL is sufficiently supported with data.** At EU level slightly higher STMR and HR values were derived from the dataset corresponding to the most critical EU GAP (3*37.5 g, 3 d PHI) of 0.005 and 0.015 derived from trials conducted according to the EU GAP. However, the EU GAPs notified to JMPR are different **(details see below).**
General comments: The CXL proposals are acceptable, with the exception of **aubergines** where a **lower value of 0.01 mg/kg** would be **sufficient.** The CXL proposal for beans (VP 0061) which is also applicable to beans without pods is based on trials on beans with pods. This extrapolation is not acceptable at EU level. For beans without pods the residue trials would not be accepted at EU level.			

Apples (STMR and HR proposals)

On "Pome fruit" the CXL of 0.02 mg/kg is acceptable, but the STMR and HR values should be recalculated, taking into account the EU GAP defined with a PHI of 3 days (and not 7 days as proposed in the JMPR evaluation).

EU critical GAP are defined as 3 foliar spray applications (interval 7 days) at 37.5 g a.s./ha and **PHI 3 days**. 8 trials in Northern EU (FR, SW) and 8 trials in Southern EU (SP, IT) conducted over two growing seasons (2005 and 2006) according to the cGAP (3 treatments ranging from 30 to 40 g/ha) and using two different formulations (with 0.25% v/v mineral oil and without oil) are available. The following emamectin B1a benzoate residues were observed:

- Without oil: 3x 0.001*, 3x 0.001, 0.002, 3x 0.003, 0.004, 2x 0.005, 2x 0.006, 0.008
- With oil: 0.001*, 0.001, 2x 0.002, 2x 0.004, 3x 0.005, 2x 0.006, 2x 0.008, 2x 0.009, 0.015

Since both datasets are from different populations (U-test, 5%), a maximum residue level of 0.02 mg/kg was proposed, derived from the dataset "with mineral oil".

STMR	0.005
HR	0.015
OECD calculator:	0.02

2.21.4. Consumer risk assessment – Emamectin benzoate

Consumer risk assessment performed with the EFSA PRIMo model rev. 2, using:

- The toxicological reference values proposed by JMPR,

- The highest STMR and HR proposed by JMPR or EU or the more appropriate (*e.g.* level in pulp proposed by JMPR for "cucurbits inedible peel" and for "peach/nectarine"),

- The STMR and HR proposed by JMPR for the products of animal origin, since the default EU LOQ of 0.01* mg/kg is not longer appropriate when considering the low ADI proposed by JMPR.

- The crop commodities not considered in the JMPR evaluation but for which MRLs have been set under Reg. (EC) No 396/2005 (Citrus, apricot, plum, strawberry, herbs, flowering brassica, head cabbage and artichoke).

- The value "0" for all the other plant or animal commodities not considered by JMPR or at EU level.

- the avermectin-like metabolites were not included.

Table 2-72: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	Highest EIDI**: 35% ADI** (IT Adult)
Acute risk	**56% ARfD lettuce** (if the 4 avermectin-like metabolites and B1b analysed for in the residue trials are considered (HR 0.69 mg.kg instead of 0.62 mg/kg), the exposure would be slightly increased to 62% ARfD) For other crops the expected acute exposure is less than 32 % ARfD.
Conclusion	**The proposed CXLs do not pose a consumer health risk.**

2.22. Flutriafol (248) (T, R, new compound)

Flutriafol was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with the United Kingdom as Rapporteur Member State. A decision to approve the active substance (Commission Implementing Directive 2011/42/EU[36]) was taken in 2011. For flutriafol an EFSA conclusion is available (EFSA, 2010d). In 2010, EFSA issued a reasoned opinion regarding an MRL application (import tolerances). The MRL review under Article 12 of Regulation (EC) No 396/2005 has not yet been initiated.

2.22.1. Toxicological endpoints – Flutriafol

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-73: Comparison of toxicological reference values derived by JMPR and at EU level

Flutriafol	JMPR evaluation 2011			EU evaluation 2010		
	Value	Study relied upon	Safety factor	Value	Study relied upon	Safety factor
ADI	0-0.01 mg/kg bw/d	2 yr rat	100	0.01 mg/kg bw/d	2 yr rat	100
Comments	Based on the NOAEL in the 2 yr rat study of 1.0 mg/kg bw/day for increases in fatty changes and increased weights of the liver in males at 10 mg/kg bw/day, supported by the NOAEL in the carcinogenicity study in mice of 1.2 mg/kg bw/day, based on the increased incidence and severity of hepatic centrilobular fatty change in males at 6 mg/kg bw/day.			Based on the NOAEL of 1.0 mg/kg bw/day in the 2-yr rat study for increased relative liver weight in males and histopathology.		
ARfD	0.05 mg/kg bw	90 d and 1 yr dog	100	0.05 mg/kg bw	90 d and 1 yr dog	100
Comments	Based on the NOAEL of 5 mg/kg bw/day in the 90-day and 1-year toxicity studies in dogs based on reduced body weight gain (males) or body weight loss (females) after 1 week (the first time of measurement) and subsequently reduced body weight gain during the early part of the study, although feed consumption was unaffected by treatment. A safety factor of 100 was applied. This provides a margin of greater than 1000 between the ARfD and the LOAEL for cleft palate in rats (75 mg/kg bw/day).			Based on the NOAEL of 5 mg/kg bw/day in the 90-day and 1-year toxicity studies in dogs based on reduced body weight gain and body weight loss during the first week of the study; the MoS to the teratogenic effects is 1500.		
Conclusion	The toxicological reference values derived by JMPR are identical with the EU values, based on the same relevant studies and endpoints.					

2.22.2. Residue definitions - Flutriafol

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

[36] Commission Implementing Directive 2011/42/EU of 11 April 2011, OJ L 97, 12.4.2011, p. 42-45

Table 2-74: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation 2011	EU evaluation 2010
RD enf	Plant commodities	Flutriafol	Flutriafol
	Animal commodities	Flutriafol The residue is fat soluble	Flutriafol (Reg. 396/2005) Open (EFSA, 2010d)
RD RA	Plant commodities	Flutriafol	Flutriafol (Triazole Derivative Metabolites, TDM)
	Animal commodities	Flutriafol The residue is fat soluble	Open (EFSA, 2010d)
Conclusion	Similar plant residue definition for monitoring and enforcement at EU and JMPR level (parent flutriafol), but EFSA in its evaluation highlighted that a separate risk assessment would have to be conducted for TMD, considering all active substances belonging to the triazole chemical class. For products of animal origin, no proposal was made during the EU peer review. It was concluded that the submitted cattle metabolism study was not appropriate to propose a residue definition for animal products and a new goat/cattle metabolism study was required.		

2.22.3. CXL proposals - Flutriafol

Table 2-75: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal JMPR 2011	EU MRL 2010	Comment
Banana	0.3	0.3	CXL proposal and EU MRL derived from the same dataset. The STMR (0.05 mg/kg) and HR (0.09 mg/kg) proposed by JMPR were derived from the levels measured in pulp.
Coffee beans	**0.15**	0.05* (default LOQ)	**CXL proposal is sufficiently supported.** (8 trials in Brazil, Columbia and Guatemala, matching the Brazil GAP)
Grapes	0.8	1 (wine)	Same dataset was submitted to JMPR and in support of the import tolerance request, but. -EU proposal of 1 mg/kg based US cGAP defined as **7x 125 g/ha, PHI 14 d**, and 13 US trials conducted according to the GAP at the dose rate of 128 g/ha (STMR 0.34, HR 0.86). - In contrast, US cGAP at JMPR level has been reported as **6x 91 g/ha, PHI 14 d**, and therefore the CXL proposal was derived after scaling of the values (91/128) since the trials were conducted at the dose rate of 128 g/ha. The scaling leads to the following proposals: CXL, 0.8 mg/kg, STMR 0.21 (0.34 x 91/128) and HR 0.61 (0.86 x 91/128). The USA have to confirm whether the dose rate of 125 g/ha is still supported at US level. If not EU MRL can be lowered to the CXL proposal of 0.8 mg/kg at EU level.

Commodity	CXL proposal JMPR 2011	EU MRL 2010	Comment
		0.05* (table)	**CXL proposal of 0.8 mg/kg is sufficiently supported.** Since the HR of 0.86 mg/kg resulted in an exceedance of the ARfD (117%), the EU MRL of 1 mg/kg proposed for wine grape was not extrapolated to table grape and LOQ value was proposed. **There is no exceedance when the HR of 0.61 mg/kg derived by scaling is applied (80% ARfD, DE infant).**
Peanut	0.15	0.2	**CXL proposal is sufficiently supported** and covered by EU MRL of 0.2 mg/kg
Peppers, Sweet (including pimento)	1	1	**CXL proposal is sufficiently supported.** (8 indoor trials performed in Spain according Spain GAP)
Pome fruits	**0.3**	0.2 apples	**CXL proposal is sufficiently supported.** JMPR and EU evaluation were performed on the same US dataset based on US GAP. The different proposals result from the use of different MRL calculators.
		0.05* others (default LOQ)	**CXL extrapolation to the whole group "Pome fruit acceptable since supported by a sufficient number of trials (16).** Extrapolation to the pome fruit group was not done by EU in 2010, since the import tolerance has been requested for "apple" only.
Soya bean (dry)	**0.4**	0.3	**CXL proposal is sufficiently supported.** JMPR and EU evaluations were performed on the same US dataset based on US GAP. The different proposals result from the use of different MRL calculators.
Wheat	0.15	0.5	**CXL proposal is sufficiently supported,** and covered by EU MRL of 0.5 mg/kg
General comments: The CXL proposals are acceptable or covered by the existing EU MRLs. US cGAP for grapes should be clarified.			

2.22.4. Consumer risk assessment - Flutriafol

Consumer risk assessment was performed with the EFSA PRIMo model rev. 2, using:

- The STMR/HR values proposed by JMPR for banana, coffee, table grape, pepper, pome fruits and soya,
- The STMR/HR derived for wine grape at EU level in the framework of the import tolerance application, based on US cGAP with an dose rate of 125 g a.i./ha
- The MRLs currently into force at EU level for citrus, strawberry, potato, carrot, tomato, aubergine, cucurbits inedible peel, pea (without pods), oilseeds, cereals and sugar beet.
- The default LOQ value of 0.05* mg/kg for all the other plant commodities and 0.01* mg/kg for animal products.

Table 2-76: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	**98% ADI** (WHO cluster B), but this value has to be considered ads a large overestimate, since no refinement was done, as the MRL value was used for a large number of crops (STMRs not available, active substance not yet review under Article 12 of Regulation (EC) No 396/2005). Using the STMR values proposed for the 8 crops under consideration in the JMPR evaluation, the EIDI is only 24% of the ADI.
Acute risk	**No exceedance of the ARfD** Table grape: 80% ARfD Peppers 52% ARfD Apple 31% ARfD Pear 29% ARfD Banana 15% ARfD

2.23. Isopyrazam (249) (T, R, new compound)

Isopyrazam was evaluated under Directive 91/414/EEC, repealed by Regulation (EC) No 1107/2009 with The United Kingdom as Rapporteur Member State. A decision to approve the active substance has not yet been taken. For isopyrazam an EFSA conclusion has been finalised recently (EFSA, 2012c). In 2010 and 2011, EFSA issued two reasoned opinions on MRL applications (EFSA, 2010c, 2011b).

2.23.1. Toxicological endpoints - Isopyrazam

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-77: Comparison of toxicological reference values derived by JMPR and at EU level

Isopyrazam	JMPR evaluation 2011			EU peer review (EFSA, 2012c)		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.06 mg/kg bw/d	2-yr rat study	100	0.03 mg/kg bw/d	2-yr rat study	200
Comments ADI	Derived from the NOAEL of 5.5 mg/kg bw/day in the 2 yr rat study on the basis of decreased body weight gain in females and foci of eosinophilic hepatocytes and clinical chemistry changes (triglycerides, bilirubin) of equivocal toxicological significance in both sexes at 27.6 mg/kg bw/day, supported by the NOAEL of 9.9 mg/kg bw/day in the mouse 80-week feeding study, based on periportal hepatocellular hypertrophy in females at 500 ppm (equal to 56.2 mg/kg bw/day). The margin between the maximum ADI and the LOAEL at 232.8 mg/kg bw per day for uterine and liver tumours in female rats is approximately 3900.			Derived from the LOAEL of 5.5 mg/kg bw/day in the 2 yr rat study on the basis of liver centrilobular hypertrophy and vacuolation, and bile duct hyperplasia and fibrosis. An increased SF by 2 was used as based on a LOAEL. The ADI covers a ratio *syn*/*anti* isomers up to 60:40 i.e. up to 40% of the more toxic *anti* isomers and is applicable to the metabolites CSCD 656800, CSCD 591489 and CSCD 563692.		
ARfD	0.3 mg/kg bw	Rat, acute neurotoxicity study	100	0.2 mg/kg bw	Rat, developmental toxicity study	100
Comments ARfD	Derived from the NOAEL of 30 mg/kg bw in the rat acute neurotoxicity study, on the basis of nonspecific clinical signs of toxicity (weak appearance and decreased activity) at 250 mg/kg bw. The margin between the ARfD and the LOAEL at 500 mg/kg bw/day for teratogenic effects (microphthalmia) in rabbits is approximately 1700.			Based on the maternal NOAEL of 20 mg/kg bw/day for reduced maternal body weight observed during the first days of dosing in the developmental toxicity study in rat. The ARfD covers a ratio *syn*/*anti* isomers up to 60:40 i.e. up to 40% of the more toxic *anti* isomers and is applicable to the metabolites CSCD 656800, CSCD 591489 and CSCD 563692.		
Conclusion	The derivation of the ADI was based on the same relevant study in the JMPR and EU evaluations, but the LOAEL of the study was defined differently, no NOAEL was identified by the EU evaluation resulting in the use of an increased SF of 200. The JMPR and EU evaluations based the ARfD on different studies and endpoints. The EU reference values are supported.					

2.23.2. Residue definitions - Isopyrazam

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-78: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	JMPR evaluation 2011	EU evaluation (EFSA, 2012c)
RD enf	Plant commodities	isopyrazam (sum of syn-isomer and anti-isomer)	Isopyrazam (sum of isomers)
	Animal commodities	isopyrazam (sum of syn-isomer and anti-isomer) The residue is fat soluble	Isopyrazam (sum of isomers) The residue is fat soluble
RD RA	Plant commodities	sum of isopyrazam and 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]amide* expressed as isopyrazam. *This name covers CSCD459488/ hydroxy-isopyrazam (syn-isomers) and CSCD459489/hydroxy-isopyrazam (anti-isomers), too.	Sum of isopyrazam (sum of isomers) and hydroxyl isopyrazam (CSCD459488, free and conjugated), expressed as isopyrazam
	Animal commodities	isopyrazam (sum of syn-isomer and anti-isomer) The residue is fat soluble	Sum of isopyrazam and all metabolites containing the 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid (CSAA798670) moiety, expressed as isopyrazam
Conclusion	The RD enf for plant and for animal commodities is the same for JMPR and the EU review, i.e. parent alone. The RD RA derived by JMPR and the final RD derived in the EU review differ: both include metabolite **CSCD459488 (**this metabolite has a similar toxicity as isopyrazam and was present in plant commodities (primary and rotational crops) in pertinent amounts). The EU RD also comprises the conjugates of this metabolites. According to EFSA's understanding the JMPR RD also covers the metabolite CSCD459489. According to the CL and the conclusion reported in the JMPR Report p. 180/181 JMPR included metabolite **3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]amide** (this name covers CSCD459488 and CSCD459489)**,** whereas on page 180, 11th paragraph of the JMPR report a different residue definition for dietary intake is mentioned ("*For estimation of dietary intakes, the Meeting decided to include CSCD459488, the major metabolite in the residue definition for plant commodities*"). Clarifications should be provided by JMPR to explain if the CXCD459489 (hydroxyl-isopyrazam anti isomer) is included in the RD. In animal commodities, dihydroxylated isopyrazam was an important residue, however available livestock feeding studies determined residues of total isopyrazam with a method including all metabolites containing the 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid moiety (CSAA798670). Hence, the RD RA for animal commodities was fitted accordingly.		

2.23.3. CXL proposals - Isopyrazam

EFSA assessed whether the draft CXLs recommended by JMPR are adequately supported by data. In addition, a comparison was made with the outcome of the latest isopyrazam MRL reviews carried out at EU level (EFSA, 2010c and EFSA, 2011b). An overview of the findings is provided in the table below.

Table 2-79: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR 2011	EU MRL Annex III of Reg. 396/2005	Comment
Banana	0.06	0.05	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is slightly lower due to different calculation methods for the MRLs.
Barley	0.07	0.6	**Draft CXL is adequately supported** by data. MRL resulting from recent EU review is higher due to a different data set for S-EU.
Barley straw and fodder, dry	2		No MRLs for fodder. Draft CXL is adequately supported by data.
Beer			A similar processing factor was derived at EU level.
Edible offal (Mammalian)	0.02	0.01*	Draft CXL based on residues in liver. MRL resulting from recent EU review is lower since a higher livestock dietary burden estimate (Australia) was considered by JMPR.
Eggs	0.01*	0.01*	No difference
Malt			No processing factor was derived at EU level. It is not clear how many trials were considered by JMPR.
Mammalian fats (except milk fats)	0.01*	0.01*	No difference
Meat (from mammals other than marine mammals)	0.01*	0.01*	No difference
Milk fats	0.02		No MRL is in place at EU level for milk fat. Since the MRL for milk is set at the LOQ, also the MRL for milk fat would be at the same level.
Milks	0.01*	0.01*	No difference
Pot barley			A similar processing factor was derived at EU level.
Poultry fats	0.01*	0.01*	No difference
Poultry meat	0.01*	0.01*	No difference
Poultry, Edible offal of	0.01*	0.01*	No difference
Rye	0.03	0.2	Based on extrapolation from wheat data
Rye straw and fodder, dry	3		Based on extrapolation from wheat data
Triticale	0.03	0.2	Based on extrapolation from wheat data
Triticale straw and fodder, dry	3		Based on extrapolation from wheat data
Wheat	0.03	0.2	Draft CXL is adequately supported by data. MRL resulting from recent EU review is higher due to a different data set for S-EU.
Wheat bran, unprocessed	0.15		No MRLs for processed commodities. A similar processing factor was derived at EU level but was not considered to be sufficiently robust as only 2 trials were available. It is not clear how many trials were considered by JMPR.

Commodity	CXL proposal derived by JMPR 2011	EU MRL Annex III of Reg. 396/2005	Comment
Wheat germ			No processing factor was derived at EU level. It is not clear how many trials were considered by JMPR.
Wheat straw and fodder, dry	3		No MRLs for fodder. Draft CXL is adequately supported by data.
White flour			A similar processing factor was derived at EU level.
Wholemeal bread			A similar processing factor was derived at EU level.
Wholemeal flour			A similar processing factor was derived at EU level.
General comments: The proposed CXLs are acceptable			

2.23.4. Consumer risk assessment - Isopyrazam

Consumer intake calculations were carried out using revision 2 of the EFSA PRIMo. The MRLs resulting from the latest review on isopyrazam were compared with the draft CXLs recommended by JMPR. As only the CXLs for banana and for mammalian edible offal are slightly higher than the MRLs, the impact on the consumer risk assessment is only marginal. Since the residue definitions for risk assessment derived by JMPR and during the EU review are different (they include different metabolites, respectively), a comprehensive risk assessment beyond the screening of the proposed CXLs is not possible.

Table 2-80: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	The highest chronic exposure was calculated for Danish children representing **8.5% of the ADI** of 0.03 mg/kg bw/day. Considering that for the EU MRLs a chronic exposure of also 8.5% of the ADI was calculated, it can be concluded that the draft CXLs are not markedly impacting on the chronic exposure of European consumers to isopyrazam residues.
Acute risk	No acute risk was identified for any of the commodities with the proposed CXLs. The intakes were max. **2.5% of the ARfD** of 0.2 mg/kg bw for the consumer groups of children, adults and the general population, respectively.
Conclusions	The proposed CXL proposals do not pose a consumer health risk.

2.24. Propylene oxide (250) (T, R, new compound)

No dossier for approval has been submitted at EU level for the active substance propylene oxide. Thus, no evaluation and no EFSA conclusion are available.

2.24.1. Toxicological endpoints – Propylene oxide

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-81: Comparison of toxicological reference values derived by JMPR and at EU level

Propylene oxide	JMPR evaluation 2011			EU evaluation		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.04 mg/kg bw/d	Rat, chronic study by inhalation	1000	-	-	-
Comments ADI	An additional factor of 10 was applied to the default SF of 100 to address the limitations in the database. No ADI could be established for propylene chlorohydrin and propylene bromohydrin.			No evaluation at EU level		
ARfD	0.04 mg/kg bw	Rat, chronic study by inhalation	1000	-	-	-
Comments ARfD	Derived on the same basis as the ADI. The meeting concluded that there was inadequate information to support the derivation of a value based on specific acute effects. No ARfD could be established for propylene chlorohydrin and propylene bromohydrin.			No evaluation at EU level		
Conclusion	The JMPR database consists mainly of published papers, often with limited levels of detail and no statements of compliance with good laboratory practice. Pending the availability of the detailed evaluation including the confirmation of GLP compliance, the acceptability of the ADI and the ARfD cannot be concluded. EFSA shares the view of JMPR that for propylene chlorohydrin and propylene bromohydrin a full toxicological evaluation needs to be made. It is also noted that propylene oxide is classified according to EU CLP Regulation (EC) No. 1272/2008 for its mutagenic and carcinogenic properties: - Muta. 1B H340: May cause genetic defects - Carc. 1B H350: May cause cancer					

2.24.2. Residue definitions – Propylene oxide

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-82: Comparison of the residue definitions derived by JMPR and at EU level

Propylene oxide	Commodity group	JMPR evaluation 2011	EU evaluation
RD enf	Plant commodities	Propylene oxide	Not included in Annex II, III or IV of Regulation (EC) No 396/2005
	Animal commodities	no data, no residues anticipated	

Propylene oxide	Commodity group	JMPR evaluation 2011	EU evaluation
RD RA	Plant commodities	Propylene oxide (PPO), and propylene chlorohydrin (PCH) plus propylene bromohydrin (PBH) to be considered separately from propylene oxide	Not approved in EU, no review conducted.
	Animal commodities	no data, metabolism data in rats used for assessment, no RD proposed	
Conclusion	The very brief summary presented in the JMPR report does not permit opinion regarding proposed residue definitions. As for scarce reporting, submitted metabolism data for plants and animals might be insufficient for a sound conclusion. Data in rats alone are usually not considered sufficient to conclude on livestock metabolism.		

2.24.3. Consumer risk assessment – Propylene oxide

Table 2-83: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	No risk assessment conducted due to insufficient data • Agreed that residue trials are insufficient to estimate maximum residue levels according to RD enf. Moreover, trials are insufficient to assess consumer exposure according to RD RA as PBH levels not available. • Neither ARfD nor ADI could be established for metabolites PCH and PBH.
Acute risk	See above

2.25. Sulfoxaflor (252) (T, R, new compound)

For sulfoxaflor a dossier has been submitted with view of getting an approval under Regulation 1107/2009. Ireland is the designated Rapporteur Member State. The completeness decision was taken in September 2011. Since the peer review is in an early stage, an EFSA conclusion is not yet available. Currently, a MRL application is under preparation in Ireland.

2.25.1. Toxicological endpoints - Sulfoxaflor

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-84: Comparison of toxicological reference values derived by JMPR and at EU level

Saflufenacil	JMPR evaluation (Report 2011)			EU evaluation is not yet available; the RMS proposed the following toxicological reference values		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.05 mg/kg bw/d	2 year rat	100	0.04 mg/kg bw/d	2 yr rat carcinogenicity study	100
Comments ADI	Supported by parental and offpsring NOAEL in a two-generation rat study, 23 week rat study, 90 days and 1 year dog studies.			DAR not yet available.		
ARfD	0.3 mg/kg bw	Acute neurotoxicity rat	100	0.25 mg/kg bw	not reported	100
Comments ARfD				Evaluation by the RMS (IE) ongoing. RMS will propose a ARfD of 0.25 mg/kg bw.		
Conclusion	JMPR decided on a ADI value of 0.05 mg/kg bw/day based on liver effects in the female rat at a dose of 750 ppm in the 2 year rat study when the same non-neoplastic liver effects were seen at a lower dose (500ppm) in the males, often with greater severity. According to the EMS the ADI should be set at the level of 0.04 mg/kg bw, based on a NOAEL of 4.24 mg/kg bw/day (100 ppm) in male rats in a 2 year carcinogenicity study and application of a safety factor of 100.					

2.25.2. Residue definitions - Sulfoxaflor

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-85: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation (Report 2011)**	**EU evaluation (Not available)**
RD enf	Plant commodities	sulfoxaflor	Not mentioned in Annex II, III and IV. RMS will propose sulfoxaflor as RD.
	Animal commodities	sulfoxaflor	Not mentioned in Annex II, III and IV. RMS will propose sulfoxaflor as RD.
RD RA	Plant commodities	sulfoxaflor	RMS will propose sulfoxaflor as RD.
	Animal commodities	sulfoxaflor	RMS will propose sulfoxaflor as RD.

	Commodity group	JMPR evaluation (Report 2011)	EU evaluation (Not available)
Conclusion	The proposed JMPR residue definitions are acceptable on a provisional basis, pending a different conclusion will be derived in the EU peer review process.		

Note: Sulfoxaflor recommendations were made as part of the CCPR Pilot project and are not based on official GAPs - (Pilot project in which JMPR conducted an independent and parallel review along with a joint review team from Australia, Canada and the USA and recommended MRLs before national governments or other regional registration authorities). It needs to be discussed whether the global dataset method is acceptable (see also general considerations of the JMPR report).

2.25.3. CXL proposals – Sulfoxaflor

Without prejudice of the decision on the global dataset method, EFSA checked whether the CXL proposals are sufficiently supported by data. The findings are summarised in the following table.

Table 2-86: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	CXL proposal derived by JMPR	EU MRL Art. 18 (1) (b)	Comment
Apple juice			STMR-p reported on page 301 of JMPR report is 0.028 mg/kg (not 0.060 mg/kg as reported in the CL).
Barley	0.6	0.01	CXL proposal based on 6 residue trials from Aus/NZL. Additional trials are available from other zones. A CXL of 0.4 mg/kg would be sufficient based on the merged residue datasets. The same CXL would be derived with the global dataset method (see general considerations, 2.4).
Barley flour			STMR-p reported on page 301 of JMPR report is 0.050 mg/kg (not 0.036 mg/kg as reported in the CL).
Barley straw and fodder, dry	3		Using the global dataset method a CXL proposal of 2 mg/kg would be derived.
Barley, pearled			STMR-p reported on page 301 of JMPR report is 0.044 mg/kg (not 0.032 mg/kg as reported in the CL).
Broccoli	3	0.01	CXL proposal is supported by sufficient residue trials (5). However, using the global dataset method a CXL proposal of 2 mg/kg would be derived.
Cabbages, Head	0.4	0.01	EFSA proposes to merge the residue data sets available from Australia, NE, SE and USA (14) as these are not significantly different and to derive a CXL proposal of **0.5** mg/kg (STMR: **0.07** mg/kg; HR: **0.37** mg/kg). This proposal is in line with the global dataset method.

Commodity	CXL proposal derived by JMPR	EU MRL Art. 18 (1) (b)	Comment
Cauliflower	0.04	0.01	The CXL proposal is acceptable. However, it is noted that the global dataset method would lead to a CXL proposal of 0.07 mg/kg.
Celery	1.5	0.01	CXL based on sufficient residue trials (6).
Cherry, dried			
Citrus fruits	0.9	0.01	CXL derived from 10 residue trials on oranges. An extrapolation to the whole citrus group would not be acceptable at EU level. Instead, it is proposed to set individual CXLs for grapefruit (0.8 mg/kg), oranges (0.8 mg/kg) and lemons (0.5 mg/kg).
Cotton seed	0.4	0.01	CXL based on 6 residue trials. (A CXL of 0.2 mg/kg would be sufficient based on the merged residue datasets).
Dried grapes (= Currants, Raisins, and Sultanas)	6		
Edible offal (Mammalian)	0.6		
Eggs	0.1		
Fruiting vegetables, Cucurbits	0.5		CXL acceptable for outdoor use only (although based on 6 trials only on cantaloupe). It is noted that the CXL proposal derived with the global dataset method is 0.4 mg/kg.
Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)	1.5		CXL based on 11 outdoor residue trials on tomatoes. The extrapolation to the whole group would not be acceptable at EU level, where an extrapolation is only possible to aubergines. However, since no GAP is reported for aubergines, the proposed CXL of 0.7 mg/kg should be applicable only to tomatoes. For peppers the trials are sufficient to derive a CXL proposal of 0.6 mg/kg merging the trials from Australia, Europe and USA.
Garlic	0.01*		No GAP reported for garlic. Therefore usually an extrapolation is not possible. However, since the CXL proposal is at the LOQ, the value might be acceptable.
Grapes	2		CXL acceptable.

Commodity	CXL proposal derived by JMPR	EU MRL Art. 18 (1) (b)	Comment
Leafy vegetables	6		CXL proposal is based on 6 trials on spinach under outdoor conditions. The extrapolation to the whole group of leafy vegetables is not acceptable at EU level. It is preferable to derive separate CXL proposals for the individual crops included in the leafy vegetable group, provided that there are sufficient trials. The proposed CXL of 6 mg/kg is overestimating the residues in mustard greens (HR 0.9 mg/kg), head lettuce (HR 0.49 mg/kg), radish tops (HR 0.48 mg/kg). The following CXL proposals would be appropriate: 3 mg/kg for lettuce, 5 mg/kg for spinach, 2 mg/kg for mustard greens.
Meat (from mammals other than marine mammals)	0.3		
Milks	0.2		
Onion, bulb	0.01*		CXL acceptable (based on 6 trials). No possible extrapolation to garlic as no GAP provided for garlic.
Orange juice			
Peppers, Chili (dried)	15		CXL derived from the CXL set for fruiting vegetables other than cucurbits using the generic factor of 10 (drying). The proposal of 1.5 mg/kg for fruiting vegetables however, is based on the most critical dataset for tomatoes. For peppers the residues were lower (0.6 mg/kg would be sufficient for fresh peppers. Thus, for dried chilli peppers the CXL proposal of 6 mg/kg would be appropriate.
Pome fruits	0.4	-	CXL proposal acceptable.
Poultry meat	0.1		
Poultry, Edible offal of	0.3		
Rape seed	0.15		CXL based on sufficient residue trials (8 US/CAN trials). Using the global dataset method (including the EU trials) a CXL proposal of 0.4 mg/kg would be derived.
Root and tuber vegetables (except carrots)	0.03		CXL proposal based on sufficient residue trials on potatoes (18) and sugar beet root (13). According to the JMPR recommendation on page 294, the proposed CXL of 0.03 mg/kg should apply only to root and tuber vegetables (except carrots) whereas in the CXL was reported for the whole group of root and tuber vegetables. For carrots a CXL of 0.05 mg/kg could be derived, based on the US and EU trials.
Soya bean (immature seeds)	0.3		Using the global dataset method would lead to a CXL proposal of 0.2 mg/kg.

Commodity	CXL proposal derived by JMPR	EU MRL Art. 18 (1) (b)	Comment
Soya bean fodder	3		Using the global dataset method would lead to a CXL proposal of 2 mg/kg.
Spring onion	0.7		CXL acceptable based on sufficient residue trials (5).
Stone fruits (except cherry)	2/3		The reporting of the conclusion for stone fruit is not clear: According to the CL a proposal of 2 mg/kg is derived for stone fruit (except cherries) (STMR 0.13, HR 0.9). However, on page 286 of the JMPR report, in the summary for stone fruit a CLX proposal of 3 mg/kg (it is not clear whether this value is applicable to all stone fruit) is reported (with a STMR 0.91 and HR 21.2) based on the data set on cherry trials from the USA. EFSA is of the opinion that for cherries a MRL of 3 mg/kg is appropriate, whereas for the other stone fruit a lower CXL could be derived, merging the trials for nectarines, apricots and peaches (0.7 mg/kg for peaches, nectarines and apricots, 0.6 mg/kg for plums).
Strawberry	0.5		CXL proposal is based on the US trials only. Using the global dataset method, including the trials form Australia and New Zealand, a CXL proposal of 0.7 mg/kg would be derived.
Tomato juice			
Tomato paste			
Tomato puree			
Tree nuts	0.015		CXL proposal is sufficiently supported (based on 6 residue trials).
Triticale	0.2		CXL extrapolated from the wheat residue dataset.
Watercress	6		The reasoning for the watercress CXL is not reported in the JMPR Report.
Wheat	0.2		CXL based on 6 residue trials reflecting the most critical zone although additional trials from other zones are available. Using the global dataset method a lower CXL of 0.15 mg/kg is derived.
Wheat straw and fodder, dry	3		Using the global dataset method a CXL of 2 mg/kg would be derived.
Wine			
General comments:			

2.25.4. Consumer risk assessment – Sulfoxaflor

The chronic and acute risk assessment is performed with the EFSA PRIMo using the STMR/HR values derived by JMPR on the basis of the toxicological reference values derived by the RMS. Summary of the consumer risk assessment (for detailed calculation see Appendix A). EFSA also

calculated the exposure for the case that the MRLs are derived by the global dataset method (using the STMR and HR from the global dataset).

Chronic risk	No chronic intake concern was identified considering the median residue values for the crops for which a CXL is proposed and the default MRL of 0.01* mg/kg for all the other plant commodities in the EFSA PRIMo Model (**TMDI: 13.3% ADI, NL child**).
Acute risk	No acute intake concern was identified when the highest residue values for the crops for which a CXL is proposed were taken into consideration using the EFSA PRIMo Model (**max. IESTI: 84.5% ARfD, scarole broad-leaf**). It is noted that using the ARfD proposed by the RMS (0.25 mg/kg bw) the exposure related to residues on scarole exceed the ARfD (**101.4% of the ARfD**). In the scenario using the global dataset approach no significant changes in the acute exposure are resulting.

2.26. Penthiopyrad (253) (T, new compound)

No dossier for approval has been submitted at EU level for the active substance penthiopyrad. Thus, no evaluation and no EFSA conclusion are available. Currently, a MRL application is under preparation in the UK.

2.26.1. Toxicological endpoints - Penthiopyrad

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-87: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation (JMPR, 2011)			**EU evaluation (UK, 2012)**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.1 mg/kg bw/d	Rat, multigeneration study	100	0.09 mg/kg	Rat, 2 year study	100
Comments ADI	-			A different NOAEL has been derived in the 2-yr rat study, 9 mg/kg bw/d in the EU evaluation (based on kidney lesions in males) versus 27 mg/kg bw/d in the JMPR evaluation (based on reduced body weight gain and liver changes). It is noted that this proposal has not been peer reviewed yet.		
ARfD	1 mg/kg bw	Rat, acute neurotoxicity study	100	0.75 mg/kg bw	Rabbit, developmental toxicity study	100
Comments ARfD	-			The same NOAELs were proposed in the JMPR and EU evaluations for both studies (rat acute neurotoxicity and rabbit developmental toxicity). In the EU evaluation, it was considered more appropriate to use the lowest NOAEL for acute effects in the rabbit developmental studies. It is noted that this proposal has not been peer reviewed yet.		
Conclusion	Pending on the completion of the EU evaluation, it cannot be predicted what will be the agreed reference values at the EU level. For the metabolite PAM, an ADI of 0.006 mg/kg bw/d is proposed in the EU evaluation, based on the presence of PAM in the rat metabolism (~7% of parent dose) and considering that all of the toxicity of penthiopyrad is due to PAM. No ARfD is proposed, even though there are indications that PAM is more acutely toxic than penthiopyrad.					

2.27. Saflufenacil (251) (T, R, new compound)

For the active substance saflufenacil at EU level, no dossier for approval has been submitted at EU level. Thus, no evaluation and no EFSA conclusion are available. EFSA recently assessed an application for import tolerances (EFSA, 2012d) which also comprised an evaluation of the toxicological reference values and residue definitions.

2.27.1. Toxicological endpoints - Saflufenacil

The following toxicological reference values have been derived at EU level and by JMPR.

Table 2-88: Comparison of toxicological reference values derived by JMPR and at EU level

	JMPR evaluation (JMPR, 2011)			**EU evaluation (EFSA, 2012d)**		
	Value	**Study relied upon**	**Safety factor**	**Value**	**Study relied upon**	**Safety factor**
ADI	0-0.05 mg/kg bw/d	Mouse, 18 month carcinogenicity	100	0.046 mg/kg bw/d	Mouse, 18 month carcinogenicity	100
Comments ADI	Supported by the rat chronic study and the rat developmental study.			MS consultation for the RO was recently finished. No comments on ADI submitted.		
ARfD	unnecessary			0.05 mg/kg bw	Rat, developmental toxicity	100
Comments ARfD	-			MS consultation for the RO was recently finished. No comments on ARfD submitted.		
Conclusion	For the ADI, the same NOAEL from a long term mouse study was used in the JMPR and EU evaluations. However, the value was not rounded in the EU evaluation. For the ARfD, the findings in the rat developmental study were considered relevant in the EU evaluation. Based on the available JMPR evaluation, it is not clear if the same database was available and how the findings were interpreted.					

2.27.2. Residue definitions - Saflufenacil

In the following table the residue definitions for risk assessment and enforcement purpose are compared.

Table 2-89: Comparison of the residue definitions derived by JMPR and at EU level

	Commodity group	**JMPR evaluation 2011**	**EU evaluation EFSA 2012d, EMS UK**
RD enf	Plant commodities	Saflufenacil	The sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil (provisional)
	Animal commodities	Saflufenacil	Saflufenacil (provisional)
RD RA	Plant commodities	Saflufenacil	The sum of saflufenacil, M800H11 and M800H35, expressed as saflufenacil (provisional)
	Animal commodities	Saflufenacil	Saflufenacil (provisional)

	Commodity group	JMPR evaluation 2011	EU evaluation EFSA 2012d, EMS UK
Conclusion	The provisional residue definitions proposed by EFSA in the framework of the import tolerance MRL application are identical to those established by the Environmental Protection Agency (EPA) and are the same as proposed by the applicant and the EMS. In the Member State consultation organised by EFSA for the import tolerance request no comments regarding the residue definition were submitted. Under practical conditions metabolites at quantifiable levels (metabolite M11) are present only in sunflower seed; in the rest of the plants these metabolites are <LOQ or LOD. The actual impact of metabolites to the MRL proposal and consumer exposure is insignificant. However, it must be taken into account that when residues in trials are at the LOQ, the MRL will be 3 x LOQ instead of LOQ by the JMPR.		

2.27.3. CXL proposals - Saflufenacil

Most of the crops for which the CXLs were derived by the JMPR evaluation correspond to the crops assessed under the import tolerance request submitted to EFSA according to Article 10 of Regulation (EC) No 396/2005. Differences in MRL proposals are related to the differences in residue definitions (metabolites <LOQ considered as present at the LOQ) and to the fact that EFSA chose the highest residue value from replicate residue trials whereas the JMPR chose the average residue values.

Table 2-90: Comparison of CXL proposals derived by JMPR and EU MRLs

Commodity	**CXL proposal derived by JMPR 2011**	**EU MRL** (EFSA, 2012d)	**Comment**
Banana	0.01	0.03*	**The CXL proposal sufficiently supported** by residue data.
Barley straw and fodder, dry	0.025	-	**The CXL proposal sufficiently supported** by residue data.
Beans (dry)	0.3	0.5	**The CXL proposal sufficiently supported** by residue data. The differences result from the fact that EFSA chose the highest value from replicate field trials whereas the JMPR selected the average value.
Cereal grains	0.01	0.03* cereals, except buckwheat	**The CXL proposal sufficiently supported** by residue data. The EU MRL proposal derived only for uses for which GAPs were reported.
Citrus fruits	0.01	0.03* oranges, grapefruit, lemons	**The CXL proposal sufficiently supported** by residue data. The EU MRL proposal derived only for crops for which the MRL was requested.
Coffee beans	0.01	No proposal	JMPR merged residue data sets reflecting different use patterns. From the data presented in the JMPR report it is not clear what is the critical GAP and whether the trials are representative for the critical GAP. In the EU import tolerance application EFSA was of the opinion that the critical GAPs notified to EFSA were not sufficiently supported by residue data. Coffee beans are major crop and therefore 8 residue trials are required.
Cotton seed	0.2	0.3	The **CXL proposal sufficiently supported** by residue data.

Commodity	**CXL proposal derived by JMPR 2011**	**EU MRL** (EFSA, 2012d)	**Comment**
Grapes	0.01	0.03*	The **CXL proposal sufficiently supported** by residue data.
Edible offal (mammalian)	0.3	0.6 bovine, sheep, goat liver 0.3 swine liver 0.02 bovine, sheep, goat kidney	The **CXL proposal sufficiently supported** by residue data. Different MRL proposals result from different livestock diets.
Maize fodder	0.05	-	**The CXL proposal sufficiently supported** by residue data.
Mammalian fats (except milk fats)	0.01	0.01*	The **CXL proposal sufficiently supported**.
Meat (from mammals other than marine mammals)	0.01	0.01*	**The CXL proposal supported**.
Milks	0.01	0.01*	The **CXL proposal sufficiently supported**.
Peas (pods and succulent=immature seeds)	0.01	0.03* legume vegetables	CXL proposal refers to peas (with pods) and peas (without pods) according to EU food classification. The JMPR combined residue data on peas (with pods) and peas (without pods), which is not acceptable according to EU extrapolation rules. However, individual data sets were sufficient and residues were below the LOQ and thus the **CXL proposal is considered acceptable**.
Peas, shelled (succulent seeds)	0.01	0.03*	
Peas, dry	0.05	0.1	The **CXL proposal sufficiently supported** by residue data. The differences result from the fact that EFSA chose the highest value from replicate field trials whereas the JMPR selected the average value.
Pome fruits	0.01	0.03* apples, pears	The **CXL proposal sufficiently supported** by residue data. The EU MRL proposal derived only for crops for which the MRL was requested.
Rape seed	0.6	Default LOQ, no import tolerance requested	The **CXL proposal sufficiently supported** by residue data.
Sorghum straw and fodder dry	0.025	-	The **CXL proposal sufficiently supported** by residue data.
Soya bean (immature seeds)	0.01	0.03*	CXL proposal for immature soya beans would correspond to fresh beans (with pods) according to EU food classification since this is the commodity traded. Only after preparation the beans would be shelled, just before consumption.
Soya bean (dry)	0.07	0.07	The **CXL proposal sufficiently supported** by residue data.

Commodity	**CXL proposal derived by JMPR 2011**	**EU MRL** (EFSA, 2012d)	**Comment**
Stone fruits	0.01	0.03* (except apricots)	The **CXL proposal sufficiently supported** by residue data. The EU MRL proposal derived only for crops for which the MRL was requested.
Sunflower seed	0.7	1.0	The **CXL proposal sufficiently supported** by residue data. The differences result from the fact that EFSA chose the highest value from replicate field trials whereas the JMPR selected the average value.
Sweet corn	0.01	0.01*	The **CXL proposal sufficiently supported** by residue data.
Tree nuts	0.01	0.01* almonds, pecan nuts	Residue extrapolation from pecans and almonds to the whole group of nuts depends on whether there are uses authorized on other nuts. The EU MRL proposal derived only for crops for which the MRL was requested.
Wheat straw and fodder, dry	0.025	-	The **CXL proposal sufficiently supported** by residue data.
Sunflower seed oil edible	PF 0.03	PF <0.09	Insufficient information available to comment on the processing factor (PF) EFSA for its assessment had 1 study available.
Soya bean oil, refined	PF 0.25	PF <0.5	Insufficient information available to comment on the processing factor (PF) EFSA for its assessment had 1 study available.
General comments: None			

2.27.4. Consumer risk assessment - Saflufenacil

The chronic consumer risk assessment is based on the calculations performed in the framework of the import tolerance request under Article 10 of Regulation (EC) No 396/2005, including the CXL proposals exceeding the proposed EU import tolerances.

For the acute consumer risk assessment the crops for which higher CXLs compared to the proposed import tolerances were reported in the JMPR report (citrus, except orange, grapefruit and lemon, nuts, except pecan and almonds, apricots, coffee beans and rapeseed, kidney).

Table 2-91: Summary of the consumer risk assessment (for detailed calculation see Appendix A)

Chronic risk	The total refined consumer exposure accounts for **0.4-2.4% of the ADI** (NL child diet). No chronic consumer intake concerns identified.
Acute risk	No acute consumer intake concerns were identified. The maximum exposure is calculated for bovine kidney (**2% of the ARfD**).
Conclusion	For the proposed CXLs no consumer intake concerns have been identified.

CONCLUSIONS AND RECOMMENDATIONS

The recommendation presented in the JMPR report 2011 concerning toxicological reference values, CXLs and the residue definitions for the active substances under consideration were reviewed with view of their acceptability at EU level. For the following active substances EFSA identified issues which should be further considered for deriving the EU position in the CCPR meeting.

Dichlorvos (025):

At EU level, only tentative toxicological reference values have been derived for dichlorvos, as the toxicological data package was considered insufficient to address the genotoxic and carcinogenic potential of dichlorvos. JMPR has set the toxicological reference values on the basis of human studies which would not be acceptable at the EU level. On provisional basis the tentative EU ADI and ARfD values should be used for provisional risk assessments.

Acephate (095) / methamidophos (100):

It is noted that the toxicological reference values derived at EU level for acephate are significantly lower than the values derived by JMPR (ADI 0.0025 mg/kg bw/d, ARfD 0.005 mg/kg bw). Although these values are not formally adopted, they are to be used for EU risk assessments. JMPR derived the toxicological reference values from human studies. This approach is not acceptable in the EU.

Also for methamidophos lower toxicological reference values have been established at EU level compared with the JMPR values (ADI 0.001 mg/kg bw/d, ARfD 0.003 mg/kg bw). The agreed EU values are to be used for the consumer risk assessment at EU level and for the calculation of the toxicological equivalence factor.

In the long-term intake calculation based on the EU ADI values for acephate and methamidophos, the CXL proposal for rice was identified as a minor contributor to the overall chronic intake. However, the existing EU MRLs for acephate and methamidophos are already leading to a dietary exposure exceeding the ADI. Thus, before the proposed CXL for rice is taken over in the EU legislation, one or more of the existing EU MRLs need to be deleted or lowered.

Cypermethrin (118):

The proposed CXLs are lower than the existing EU MRLs except the proposals for asparagus and tea. EFSA is of the opinion that for tea a lower CXL of 10 mg/kg would be sufficient.

The dietary consumer exposure calculations revealed that the CXL proposals do not pose an acute consumer risk. The chronic risk assessment based on the existing EU MRLs and the CXL proposals for asparagus and tea is affected by uncertainties due to lack of information regarding the source of the EU MRLs (currently no conclusive information is available whether the existing EU MRL reflects the use of the more toxic alpha-cypermethrin or of cypermethrin). Under conservative assumptions, a potential long-term consumer health risk cannot be excluded. However, the crops for which CXL proposals are higher than the EU MRLs (asparagus and tea) are not contributing significantly to the dietary intake. Before the proposed CXL for asparagus and tea are taken over in the EU legislation, the existing MRLs need to be reviewed under Article 12 of Regulation (EC) No 396/2005 in order to have the necessary detailed information which would allow to perform a more accurate consumer risk assessment reflecting the actual uses of cypermethrin and alpha-cypermethrin at EU level and in third countries.

Diflubenzuron (130):

At EU level certain metabolites and/or degradation products formed in processed products and in livestock or which were taken up via soil were considered as being of toxicological relevance (2,6-diflubenzoic acid (for mushrooms only), 4-chlorphenylurea, 4-chloraniline and 4-chloracetanilide) and were therefore included in the provisional residue definitions. (It is noted that metabolism studies were only available for fruit and mushrooms.) For the EU peer review the final toxicological evaluation of 4-chlorphenylurea (CPU) and 4-chloraniline (PCA) is still pending. PCA is currently considered as a genotoxic carcinogen. PCA has a legal classification as Carcinogen Cat 2 (R45 May cause cancer) according to Directive 67/548/EEC (Annex I, Adaptation to the Technical Progress 24). For the metabolite 4-chlorophenylurea, an assessment of its toxicological relevance was provided after the peer review (not peer reviewed), but insufficient data are available to derive reference values or to conclude that the reference values of the parent are also applicable.

In the framework of the pesticide and biocide evaluation, metabolism studies in pigs, goat and hens have been provided. From these studies it cannot be excluded that PCA is formed. Thus, the formation of PCA in humans cannot be excluded.

The JMPR residue definition was derived on studies on maize, soybean, cabbage, apple, cotton, organe, mushrooms, rice, wheat and beans (different modes of application of the radio labelled active substance). However, studies assessing the nature of residues in processed commodities were not assessed by JMPR. The degradation of parent into DFBA and CPU/PCA is expected and should therefore be taken into account in the risk assessment.

Peaches and plums: The CXL proposal for peaches and plums is based on 3 trials on plums and 5 trials on peaches. At EU level the merging of data from plums and peaches is not acceptable. The number of trials on plums and peaches is not robust enough to derive individual MRL proposals for these crops. Thus, 3 additional trials in peaches or apricots and 5 additional trials in plums would be required.

Peppers: The CXL proposal for peppers is based on 6 trials. The number of trials is not sufficient to derive a robust MRL.

For peanuts nine residue trials were provided. Using the OECD calculator a CXL proposal of 0.08 mg/kg is derived. The JMPR proposal of 0.15 mg/kg, reported in the CL refers to peanut meal, not to peanuts. The reason for using a processing factor of 2 for peanut meal needs to be further explained. It would be expected that diflubenzuron residues are lower in peanut meal as the active substance is fat soluble and would be expected to concentrate in the oil fraction rather than in the meal.

The proposed CXLs, if added to the existing EU MRLs, do not lead to an unacceptable exposure of the European population regarding parent diflubenzuron. However, the potential formation of metabolites/degradation products during processing should be assessed by JMPR. In particular formation of DFBA and CPU/PCA and consumer exposure to these substances need to be considered.

Profenofos (171):

Regarding the ADI and the ARfD only limited details are reported in the JMPR Report therefore final conclusion on the acceptability of the toxicological reference values cannot be made.

It is noted that in 2003 JMPR defined the residues as fat soluble whereas in the CL and in CX/PR 12/44/5 it is reported as not fat soluble. A correction should be made.

In the EU legislation the CXL proposal for chilli peppers would be applicable to sweet peppers (including sweet peppers). The CXL derived for chilli pepper extrapolated to sweet pepper is acceptable with regard to consumer safety only if the toxicological reference values derived by the

JMPR are used. Using the ADI and the ARfD derived by Germany in 2001, a potential consumer health risk would exist.

Hexythiazox (176):

At EU level the metabolite PT-1-3 was found to have a higher acute toxicity than the parent compound and therefore asked for additional toxicological information to elucidate the toxicological profile of the metabolite. Since this metabolite is included in the residue definition derived by JMPR, a hazard characterisation needs to be performed for this metabolite.

Hops: More details should be also reported regarding the formation of the metabolite/degradation product PT-1-3 during processing (i.e. production of beer).

Strawberry: The use of the proportionality approach for deriving a CXL proposal for strawberries is not acceptable.

Taking into account the exposure to the parent compound, the proposed CXLs are acceptable. However, the formation of the degradation product and its contribution to the exposure should be further assessed.

Etofenprox (184):

In all metabolism studies except in rice the metabolite α-CO was below 10% of the TRR. However, since this metabolite was found in residue trials in higher concentrations than expected from metabolism studies, it should be included in the residue definition for plant commodities.

For meat/fat a slightly lower CXL would be considered as sufficient.

The CXL proposal for grapes was derived by applying the proportionality approach. This approach is not acceptable for major crops.

Tebuconazole (189):

The conjugates of tebuconazole and hydroxy-tebuconazole should be included in the residue definition for animal commodities since they occur in significant concentrations and since the hydrolysis of these conjugates in the human intestinal tract cannot be excluded. It should be clarified whether these metabolites were considered in the livestock feeding studies considered by JMPR.

EFSA identified acute intake concerns for the draft CXLs on table grapes (1004%, VF 5), peaches (198%; includes nectarines at EU level), apples (163%), pears (152%), peppers (130%), cherries (126%) and apricots (103%).

For table grapes, peaches and cherries, the exceedance of the ARfD is mainly attributed to the lower ARfD established at EU level. For apples, pears, peppers and apricots, the exceedance of the ARfD is partially also attributed to the use of a higher variability factor at EU level.

By applying the lower VF of 5 an exceedance of the ARfD would still be calculated for apples (120%), pears (109%), peaches (145%). For table grapes and cherries no "refinement of the calculation" with alternative VF is possible. Thus, the identified concern still remains.

Spinosad (203):

Blackberrry, dewberries (including boysenberry and loganberry): The CXL proposal was extrapolated from raspberries. However, the database is not very robust (4 trials only). For extrapolations from raspberries to dewberries and blackberries at least 8 trials would be required.

Pyraclostrobin (210):

It is noted that pyraclostrobin was considered to be fat soluble when it was assessed by JMPR in 2004 whereas in document CX/PR 12/44/5 it is classified as not fat soluble. This needs to be corrected.

Citrus: The proposed group CXL is based on 8 trials on oranges reflecting the Spanish GAP for oranges which was extrapolated to the whole group. According to the EU guidance document this extrapolation would not be acceptable, because the GAP on oranges is not identical with the GAPs for the citrus crops and because the number of trials is not sufficient to support the extrapolation. Thus, for the Spanish GAP on oranges (*4 x 0.225 kg a.s./ha; PHI 7 days*) sufficient data would be available to derive the MRL value of 2 mg/kg for oranges. For other citrus, except oranges a CXL of 1.5 mg/kg would be derived from the combined dataset of oranges (13), grapefruit (6) and lemons (5) compliant with the cGAP for citrus fruits (*3 x 0.225 kg a.s./ha; PHI 0 days)*. This extrapolation would be in line with the extrapolation rules discussed last year in CCPR.

Oil seed except peanuts: The proposed group CXL is based on the results of residue trials on sunflowers which were extrapolated to the whole group (except peanuts). For cotton seeds, this extrapolation is not acceptable since the GAP is not comparable. Sufficient data would be available to derive a lower MRL value of 0.2 mg/kg for cotton seeds.

Papaya: The residue trials on papaya would justify a lower MRL of 0.07 mg/kg.

Tree nuts: It is noted that JMPR recommended to maintain the CXL of 1 mg/kg for pistachios (see JMPR report p. 220). Thus, an editorial change is required for the description of the commodity (tree nuts (except pistachios)).

Spirotetramat (234):

Brussels spouts: JMPR concluded that the trials are not sufficient to support the critical GAP because the trials were overdosed (3 applications were performed in the supervised field trials whereas the critical GAP allows only 2 applications). At EU level these trials were considered acceptable and a MRL of 0.3 mg/kg was derived.

Edible offal (mammalian): The highest residue resulting from the calculated maximum dietary burden is calculated to be 0.55 mg/kg (cattle kidney). Thus, 0.7 mg/kg would be a sufficient CXL for edible offal (mammalian)

Legume vegetables: The residue trials from beans with pods were extrapolated to all legume vegetables, although the data for beans and peas without pods would allow to set a lower CXL at a lower level (0.8 mg/kg calculated with OECD calculator).

Milks: Validated analytical methods are available for a LOQ of 0.005 mg/kg. Since in the feeding studies at the expected dietary burden is below the LOQ of 0.005 mg/kg, the CXL should be set at this level.

Clothianidin (238)

It is noted that the EU reservation expressed in the 43rd CCPR on the CXL proposal for root and tuber vegetables is maintained for the following reason (EU position paper 43rd CCPR):

"Root and tuber vegetables (including sugar beet roots): GAPs were reported for carrots, potatoes, radishes and sugar beet (in addition, GAPs for clothianidin were reported for carrots, chicory roots, tuberous and corm vegetable and sugar beet, but they were less critical than the use of thiamentoxam.) The GAPs were not comparable: seed treatment for sugar beets, foliar application for the other crops, different application rate for carrots and radishes compared with potatoes "

Dicamba (240):

Clarifications should be provided by JMPR whether the residue trials and the metabolism studies were performed on genetically modified soybeans (dicamba tolerant soybeans) or on conventional crops. The inclusion of the conjugates in the residue definitions for estimating the dietary intake and for enforcement (plants and animal commodities) should be considered.

The MRL for soybeans was derived by applying the proportionality approach. The EU does not accept this approach in the case of a herbicide use on a major crop.

Etoxazole (241):

A slightly lower MRL for pome fruit of 0.05 mg/kg would be sufficient.

Acetamiprid (246):

The residue definition for animal commodities reported in the circular letter and in CX/PR 12/44/5 is not correct and conflicting with the residue definition reported in the JMPR report.

The number of trials is not sufficient to derive a reliable CXL for spring onions, plums and beans (except broad bean and soya bean)

Using the EU methodology a potential acute consumer health risk is identified for **scarole and kale** (leafy vegetables except spinach). For kale the exposure would be below 100% if the calculation is performed with the less conservative variability factor of 5. (For scarole the EU calculation is based on VF of 5).

Emamectin benzoate (247):

It is noted that the residue definition reported in the CL and in CX/PR 12/44/5 is conflicting with the residue definition reported in the JMPR report (emamectin B1a benzoate). Regarding the EU residue definition for risk assessment (for plant commodities) discussions are still ongoing whether the avermectin-like metabolites need to be included.

Beans: The CXL proposal for beans (VP 0061) which is also applicable to beans without pods is based on trials on beans with pods. This extrapolation is not acceptable at EU level. For beans without pods the extrapolation from beans with pods would not be accepted at EU level.

For aubergines a lower CXL of 0.01 mg/kg would be sufficient (based on trials on normal sized tomatoes). JMPR extrapolated the results from peppers to aubergines. This extrapolation is normally not acceptable at EU level.

Flutriafol (248):

Grapes: The MRL proposal was derived from data applying the proportionality approach. For major crops this approach is not acceptable.

Isopyrazam (249):

The EU evaluation concluded on a lower ADI and ARfD compared to the JMPR assessment (EU ARfD is based on the maternal NOAEL of 20 mg/kg bw/day for reduced maternal body weight observed during the first days of dosing in the developmental toxicity study in rat; the EU ADI was derived from the same study, but the LOAEL was defined differently. Since no NOAEL was identified, a higher SF was applied.)

Regarding the residue definition for risk assessment derived by JMPR clarifications should be provided to explain if the CXCD459489 (hydroxyl-isopyrazam anti isomer) is included. (According to the CL and the conclusion reported in the JMPR Report p. 180/181 JMPR included metabolite 3-difluoromethyl-1-methyl-1H-pyrazole-4-carboxylic acid [9-(1-hydroxyl-1-methylethyl)-(1RS, 4RS, 9RS)-1,2,3,4-tetrahydro-1,4-methanonaphthalen-5-yl]amide (this name covers CSCD459488 and CSCD459489)**,** whereas on page 180, 11th paragraph of the JMPR report a different residue definition for dietary intake is mentioned ("For estimation of dietary intakes, the Meeting decided to include CSCD459488, the major metabolite in the residue definition for plant commodities").

Propylene oxide (250):

The JMPR database consists mainly of published papers, often with limited levels of detail and no statements of compliance with good laboratory practice. Pending the availability of the detailed evaluation including the confirmation of GLP compliance of the studies, the acceptability of the ADI and the ARfD cannot be concluded. EFSA shares the view of JMPR that for propylene chlorohydrin and propylene bromohydrin a full toxicological evaluation needs to be made. It is also noted that according to EU CLP Regulation (EC) No. 1272/2008 propylene oxide is classified for its mutagenic and carcinogenic properties:

- Muta. 1B H340: May cause genetic defects

- Carc. 1B H350: May cause cancer

The very brief summary presented in the JMPR report does not permit opinion regarding proposed residue definitions. The submitted metabolism data for plants and animals might be insufficient for a sound conclusion. Data in rats alone are usually not considered sufficient to conclude on livestock metabolism.

Sulfoxaflor (252):

CXL proposals were made as part of the CCPR Pilot project and are not based on official GAPs - (Pilot project in which JMPR conducted an independent and parallel review along with a joint review team from Australia, Canada and the USA and recommended MRLs before national governments or other regional registration authorities). It needs to be discussed whether the global dataset method is acceptable (to be discussed in response to the "General considerations", chapter 2 of the JMPR report).

JMPR decided on a ADI value of 0.05 mg/kg bw/day based on liver effects in the female rat at a dose of 750 ppm in the 2 year rat study when the same non-neoplastic liver effects were seen at a lower dose (500ppm) in the males, often with greater severity.
According to the EMS the ADI should be set at the level of 0.04 mg/kg bw, based on a NOAEL of 4.24 mg/kg bw/day (100 ppm) in male rats in a 2 year carcinogenicity study and application of a safety factor of 100.

Regarding the dietary risk assessment, no acute intake concern was identified when the highest residue values for the crops for which a CXL is proposed were taken into consideration using the

EFSA PRIMo Model (max. IESTI: 84.5% ARfD, scarole broad-leaf). It is noted that using the ARfD proposed by the RMS (0.25 mg/kg bw) the exposure related to residues on scarole excees the ARfD (101.4% of the ARfD). Since the peer review is not yet finalised, the final agreed EU ARfD is not yet available.

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APPENDIX A: CALCULATIONS OF CONSUMER EXPOSURE WITH PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Methamidophos

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,018	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,001**	ARfD (mg/kg bw):	**0,003**
Source of ADI:	**Dir 2005/131**	Source of ARfD:	**Dir 2005/131**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Chronic risk assessment based on existing MRLs (MRLs for methamidophos + MRLs for acephate/30 (tox. equiv. factor). For rice a STMR of 0.057 was estimated (individual matching results are not reported in JMPR report).

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 18 - 125

No of diets exceeding ADI: 6

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)
124,9	NL child	52,8	Milk and cream,	11,4	Apples	10,6	Potatoes	116,8
123,8	UK Infant	69,7	Milk and cream,	18,1	Sugar beet (root)	5,9	Potatoes	119,5
123,7	FR toddler	71,3	Milk and cream,	9,1	Potatoes	4,7	Apples	119,1
114,5	UK Toddler	41,2	Sugar beet (root)	37,2	Milk and cream,	7,1	Wheat	110,6
110,4	WHO Cluster diet B	19,4	Soya bean	15,4	Wheat	5,7	Milk and cream,	76,9
100,3	DE child	25,7	Milk and cream,	21,7	Apples	7,4	Wheat	93,5
81,6	WHO cluster diet E	18,6	Soya bean	8,2	Peas (with pods)	7,1	Wheat	47,3
81,3	FR infant	46,3	Milk and cream,	7,4	Potatoes	4,8	Carrots	79,0
77,0	IE adult	6,4	Sweet potatoes	5,1	Peas (with pods)	5,0	Milk and cream,	64,3
72,2	WHO Cluster diet F	20,9	Soya bean	7,1	Milk and cream,	6,5	Wheat	41,6
67,5	ES child	22,5	Milk and cream,	8,0	Wheat	3,9	Oranges	60,8
66,4	DK child	22,7	Milk and cream,	9,9	Wheat	8,0	Rye	65,1
65,4	WHO regional European diet	11,9	Peas (with pods)	8,7	Milk and cream,	7,2	Potatoes	45,2
65,0	WHO cluster diet D	11,8	Soya bean	11,7	Wheat	9,1	Milk and cream,	47,5
64,4	SE general population 90th percentile	22,3	Milk and cream,	7,5	Potatoes	5,8	Wheat	56,7
50,2	PT General population	9,8	Soya bean	9,6	Potatoes	7,1	Wheat	33,8
44,8	NL general	11,8	Milk and cream,	4,9	Potatoes	3,7	Wheat	40,1
38,3	ES adult	8,9	Milk and cream,	4,2	Wheat	2,3	Oranges	34,4
35,1	FR all population	7,2	Wine grapes	5,9	Wheat	4,8	Milk and cream,	31,5
34,0	UK vegetarian	6,8	Sugar beet (root)	5,9	Milk and cream,	3,7	Wheat	30,6
32,0	IT kids/toddler	12,0	Wheat	2,7	Other cereal	2,6	Tomatoes	28,3
30,2	UK Adult	7,2	Sugar beet (root)	5,4	Milk and cream,	3,0	Wheat	27,3
29,8	LT adult	7,1	Milk and cream,	5,7	Potatoes	3,4	Apples	28,6
29,6	DK adult	9,7	Milk and cream,	3,6	Wheat	2,6	Potatoes	28,3
25,1	FI adult	10,2	Milk and cream,	2,2	Potatoes	1,8	Wheat	23,2
24,5	IT adult	7,4	Wheat	2,2	Peaches	2,1	Tomatoes	20,5
17,9	PL general population	6,2	Potatoes	3,7	Apples	1,6	Tomatoes	17,2

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 17,9 % to 125 % of the ADI.
For 6 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

	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)
	24,0	Rice	0,057 / -	24,0	Rice	0,057 / -	14,3	Rice	0,057 / -	14,3	Rice	0,057 / -
	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)			
	30,2	Peach juice	0,050666666666				3,6	Orange juice	0,010666666666			
	18,1	Apple juice	0,010666666666 66667 / -				3,4	Peach preserved with syrup	0,050666666666 66667 / -			
	17,6	Orange juice	0,010666666666				2,3	Apple juice	0,010666666666			
	15,3	Carrot, juice	0,010666666666				1,6	Bread/pizza	0,010666666666			
	11,7	Grape juice	0,010666666666				1,4	Wine	0,010666666666			
	*) 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 Methamidophos 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.											

Cypermethrin

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):	0,1	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,05	ARfD (mg/kg bw):	0,2
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2005	Year of evaluation:	2005

Chronic intake calculation without any refinement. EU MRLs were taken as input values for all crops except for asparagus and tea for which the CXL proposals are higher than the propsed EU MRLs and for which the STMR values were considered.

Chronic risk assessment - refined calculations

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	10 83
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)
82,9	UK Toddler	45,7	Sugar beet (root)	15,7	Wheat	7,9	Oranges	2,9
77,5	DE child	24,1	Apples	16,4	Wheat	15,2	Oranges	2,4
66,5	WHO Cluster diet B	34,1	Wheat	3,4	Oranges	3,1	Tomatoes	1,6
65,5	NL child	19,0	Wheat	12,7	Apples	12,5	Oranges	4,2
54,3	DK child	22,0	Wheat	17,7	Rye	4,6	Apples	1,9
52,2	UK Infant	20,2	Sugar beet (root)	10,5	Wheat	5,2	Oranges	4,8
45,6	IE adult	9,2	Wheat	5,0	Barley	4,2	Oranges	1,7
42,8	WHO cluster diet D	26,0	Wheat	2,2	Rice	1,6	Rye	1,2
40,9	IT kids/toddler	26,6	Wheat	1,9	Oranges	1,8	Apples	0,3
39,9	ES child	17,7	Wheat	8,7	Oranges	2,3	Apples	1,9
39,1	FR toddler	10,5	Wheat	8,0	Oranges	5,2	Apples	5,1
38,1	WHO cluster diet E	15,8	Wheat	3,2	Barley	1,8	Oranges	1,3
33,9	WHO Cluster diet F	14,4	Wheat	3,5	Oranges	3,1	Rye	1,2
33,0	PT General population	15,7	Wheat	3,1	Rice	2,5	Wine grapes	0,8
31,6	SE general population 90th percentile	12,8	Wheat	3,0	Oranges	2,1	Apples	2,2
30,0	IT adult	16,5	Wheat	1,6	Apples	1,5	Lettuce	0,2
28,8	WHO regional European diet	11,9	Wheat	2,0	Oranges	1,5	Lettuce	1,3
28,1	UK vegetarian	8,2	Wheat	7,6	Sugar beet (root)	3,5	Oranges	0,7
27,8	NL general	8,3	Wheat	5,9	Oranges	2,4	Apples	1,2
27,4	ES adult	9,4	Wheat	5,2	Oranges	2,1	Lettuce	0,9
26,2	FR all population	13,2	Wheat	4,0	Wine grapes	1,2	Oranges	0,6
24,7	UK Adult	8,0	Sugar beet (root)	6,7	Wheat	2,2	Oranges	0,6
21,4	FR infant	5,0	Apples	3,6	Oranges	3,4	Wheat	3,5
18,7	DK adult	8,1	Wheat	2,7	Rye	1,6	Apples	0,9
17,6	LT adult	4,3	Rye	4,2	Wheat	3,7	Apples	0,8
15,6	FI adult	3,9	Wheat	3,9	Oranges	2,7	Rye	0,9
9,5	PL general population	4,1	Apples	0,9	Tomatoes	0,7	Head cabbage	0,5

Acute risk assessment /children - refined calculations

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

Acute risk assessment / adults / general population - refined calculations

	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)
	1,7	Tea	3,75 / -	1,7	Tea	3,75 / -	0,6	Asparagus	0,2 / -	0,6	Asparagus	0,2 / -
	0,5	Asparagus	0,2 / -	0,5	Asparagus	0,2 / -	0,6	Tea	3,75 / -	0,6	Tea	3,75 / -
	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)			
	49,5	Orange juice	2 / -				10,1	Orange juice	2 / -			
	25,5	Apple juice	1 / -				4,4	Bread/pizza	2 / -			
	17,9	Peach juice	2 / -				3,3	Apple juice	1 / -			
	13,9	Plums juice	2 / -				2,0	Peach preserved with	2 / -			
	*) 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 Cypermethrin 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.											

Alpha-cypermethrin

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	included	Code no.	
LOQ (mg/kg bw):	0,1	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,015	ARfD (mg/kg bw):	0,04
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2005	Year of evaluation:	2005

Chronic intake calculation without any refinement. EU MRLs were taken as input values for all crops except for asparagus and tea for which the CXL proposals are higher than the propsed EU MRLs and for which the STMR values were considered.

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	32 - 276
No of diets exceeding ADI:	16

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)
275,8	UK Toddler	152,5	Sugar beet (root)	52,2	Wheat	26,4	Oranges	9,6
260,2	DE child	80,5	Apples	54,8	Wheat	50,8	Oranges	8,0
228,6	WHO Cluster diet B	113,8	Wheat	11,4	Oranges	10,3	Tomatoes	5,5
226,8	NL child	63,2	Wheat	42,2	Apples	41,6	Oranges	13,9
181,0	DK child	73,4	Wheat	58,9	Rye	15,5	Apples	6,5
173,0	UK Infant	67,2	Sugar beet (root)	34,9	Wheat	17,3	Oranges	16,0
152,6	IE adult	30,6	Wheat	16,5	Barley	13,9	Oranges	5,7
145,9	WHO cluster diet D	86,7	Wheat	7,4	Rice	5,4	Rye	4,2
142,0	ES child	59,1	Wheat	28,9	Oranges	7,6	Apples	6,6
136,2	IT kids/toddler	88,6	Wheat	6,4	Oranges	5,9	Apples	0,9
135,1	FR toddler	35,0	Wheat	26,7	Oranges	17,5	Apples	17,3
132,9	WHO cluster diet E	52,6	Wheat	10,8	Barley	5,9	Oranges	4,4
119,4	WHO Cluster diet F	48,0	Wheat	11,6	Oranges	10,2	Rye	4,2
110,0	PT General population	52,2	Wheat	10,5	Rice	8,3	Wine grapes	2,8
105,3	SE general population 90th percentile	42,7	Wheat	10,0	Oranges	7,0	Apples	7,5
103,9	WHO regional European diet	39,6	Wheat	6,6	Oranges	5,0	Lettuce	4,6
100,0	IT adult	55,1	Wheat	5,3	Apples	5,0	Lettuce	0,6
97,5	NL general	27,6	Wheat	19,8	Oranges	7,9	Apples	4,2
96,7	ES adult	31,3	Wheat	17,2	Oranges	7,1	Lettuce	3,0
92,5	UK vegetarian	27,3	Wheat	25,2	Sugar beet (root)	11,6	Oranges	2,4
89,4	FR all population	43,8	Wheat	13,3	Wine grapes	3,8	Oranges	2,1
81,0	UK Adult	26,6	Sugar beet (root)	22,4	Wheat	7,5	Oranges	2,1
73,2	FR infant	16,7	Apples	12,1	Oranges	11,2	Wheat	11,8
63,7	LT adult	14,4	Rye	14,0	Wheat	12,4	Apples	2,7
63,6	DK adult	26,8	Wheat	9,1	Rye	5,2	Apples	2,9
51,6	FI adult	13,1	Wheat	12,9	Oranges	9,1	Rye	2,9
31,5	PL general population	13,6	Apples	2,9	Tomatoes	2,4	Head cabbage	1,7

Acute risk assessment /children - refined calculations

Acute risk assessment / adults / general population - refined calculations

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 31,5 % to 276 % of the ADI.
For 16 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

Alpha-cypermethrin

Status of the active substance:	**inlcuded**	Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,015**	ARfD (mg/kg bw):	**0,04**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Prepare workbook for refined calculations

Undo refined calculations

refined chronic risk assessment: deletion of sugar beet (assuming that there is not transfer into sugar); PF for wheat flour (PF=0.43, JMPR); PF for wheat was extrapolated to rye; PF (grapes to wine): 0.08 (JMPR); deletion of all crops for which only cpermethrin uses were notified (blackberries, horse radish, parsnip, etc), deletion of asparagus (post-harvest use), use of STMR for alpha-cypermethrin where available (table and wine grapes, strawberries, animal commodities). cypermethrin STMR for apple, pears, peaches, potatoes, carrots, tomatoes, water melons, lettuce.

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
16	83

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)
83,0	DE child	26,5	Apples	7,9	Wheat	5,1	Oranges	3,1
74,0	WHO Cluster diet B	16,3	Wheat	7,0	Rice	6,4	Tomatoes	3,6
70,8	NL child	13,9	Apples	9,1	Wheat	4,7	Rice	4,4
62,2	IE adult	7,6	Peaches	4,6	Maize	4,4	Wheat	4,3
61,1	DK child	25,3	Rye	10,5	Wheat	5,3	Oats	1,8
46,3	WHO cluster diet D	12,4	Wheat	7,4	Rice	2,3	Rye	1,4
45,3	FR toddler	5,8	Apples	5,2	Beans (with pods)	5,0	Wheat	4,5
43,7	WHO cluster diet E	7,5	Wheat	2,8	Rice	2,5	Rye	2,1
41,1	IT kids/toddler	12,7	Wheat	4,6	Peaches	3,0	Other cereal	0,4
40,5	UK Infant	8,4	Rice	5,0	Wheat	3,4	Apples	4,0
39,1	ES child	8,5	Wheat	6,4	Rice	2,9	Oranges	2,8
37,7	SE general population 90th percentile	6,1	Wheat	5,4	Rice	4,2	Head cabbage	2,1
36,5	WHO regional European diet	5,7	Wheat	2,8	Peaches	2,6	Rice	2,1
36,2	PT General population	10,5	Rice	7,5	Wheat	4,8	Peaches	0,7
35,9	IT adult	7,9	Wheat	5,0	Peaches	2,4	Tomatoes	0,3
34,2	UK Toddler	7,7	Rice	7,5	Wheat	3,8	Apples	2,6
33,6	WHO Cluster diet F	6,9	Wheat	4,4	Rye	2,8	Rice	2,0
28,7	NL general	4,0	Wheat	2,6	Apples	2,1	Rice	1,5
27,8	ES adult	4,5	Wheat	3,2	Rice	2,8	Peaches	1,5
27,4	FR infant	5,5	Apples	3,9	Beans (with pods)	2,1	Spinach	2,8
24,3	LT adult	6,2	Rye	4,1	Apples	2,9	Rice	0,8
22,8	FR all population	6,3	Wheat	2,5	Other lettuce and other salad plants	1,9	Peaches	1,0
22,7	UK vegetarian	5,1	Rice	3,9	Wheat	1,3	Apples	0,8
19,5	DK adult	3,9	Rye	3,8	Wheat	1,7	Apples	0,9
19,0	UK Adult	4,9	Rice	3,2	Wheat	1,3	Tea (dried leaves and stalks,	0,7
16,4	PL general population	4,5	Apples	2,4	Head cabbage	2,3	Plums	0,4
15,5	FI adult	3,9	Rye	1,9	Wheat	1,5	Rice	0,7

Conclusion:

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

Diflubenzuron

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,02**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**JMPR**	Source of ARfD:	
Year of evaluation:	**2001**	Year of evaluation:	

Explain choice of toxicological reference values.

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

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
14	94
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)
93,5	DE child	36,2	Apples	19,0	Oranges	6,3	Table grapes	
93,5	DE child	36,2	Apples	19,0	Oranges	6,3	Table grapes	
77,5	NL child	19,0	Apples	15,6	Oranges	7,3	Milk and cream,	
54,4	IE adult	6,3	Wine grapes	5,2	Oranges	3,5	Grapefruit	
49,3	FR toddler	10,0	Oranges	9,9	Milk and cream,	7,9	Apples	
47,2	WHO Cluster diet B	9,0	Wine grapes	4,3	Wheat	4,3	Oranges	
41,5	UK Toddler	9,9	Oranges	5,7	Sugar beet (root)	5,2	Milk and cream,	
36,2	UK Infant	9,7	Milk and cream,	6,5	Oranges	4,7	Apples	
33,1	FR all population	20,0	Wine grapes	1,6	Wheat	1,4	Oranges	
32,2	FR infant	7,5	Apples	6,4	Milk and cream,	4,9	Strawberries	
31,9	WHO cluster diet E	8,0	Wine grapes	2,5	Apples	2,2	Oranges	
30,2	ES child	10,8	Oranges	3,4	Apples	3,1	Milk and cream,	
30,1	NL general	7,4	Oranges	3,5	Apples	3,1	Wine grapes	
30,0	PT General population	12,4	Wine grapes	3,2	Apples	3,1	Oranges	
29,6	SE general population 90th percentile	3,7	Oranges	3,2	Apples	3,1	Head cabbage	
28,3	DK child	7,0	Apples	3,2	Milk and cream,	2,8	Wheat	
24,5	WHO Cluster diet F	4,4	Oranges	3,0	Wine grapes	2,0	Apples	
24,0	WHO regional European diet	2,5	Oranges	2,0	Apples	1,8	Head cabbage	
23,3	WHO cluster diet D	3,3	Wheat	2,0	Apples	1,8	Wine grapes	
22,5	ES adult	6,5	Oranges	2,3	Apples	2,1	Wine grapes	
20,8	UK vegetarian	4,3	Oranges	4,1	Wine grapes	1,8	Apples	
19,0	DK adult	7,0	Wine grapes	2,4	Apples	1,3	Milk and cream,	
18,4	IT kids/toddler	3,3	Wheat	2,7	Apples	2,4	Oranges	
17,6	UK Adult	5,4	Wine grapes	2,8	Oranges	1,2	Apples	
16,9	PL general population	6,1	Apples	1,8	Head cabbage	1,6	Table grapes	
15,9	FI adult	4,8	Oranges	1,5	Wine grapes	1,4	Milk and cream,	
15,5	IT adult	2,4	Apples	2,1	Wheat	1,9	Peaches	

Conclusion:

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

Glyphosate

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,3**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2002**	Year of evaluation:	**2002**

Glyphosate, N-acteyl-gyphosate, N-acetyl-AMPA and AMPA, expressed glyphosate

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 47
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)
47,2	WHO Cluster diet B	28,5	Wheat	5,7	Soya bean	4,9	Sunflower seed	0,1
41,7	UK Toddler	25,9	Sugar beet (root)	13,1	Wheat	0,6	Potatoes	0,4
36,8	DK child	18,3	Wheat	14,7	Rye	2,6	Oats	0,2
33,9	WHO cluster diet D	21,7	Wheat	3,5	Soya bean	3,3	Sunflower seed	0,1
33,0	WHO cluster diet E	13,1	Wheat	5,5	Soya bean	5,4	Barley	0,1
29,0	WHO Cluster diet F	12,0	Wheat	6,2	Soya bean	4,0	Barley	0,1
24,8	UK Infant	11,4	Sugar beet (root)	8,7	Wheat	1,7	Oats	0,7
24,3	IE adult	8,3	Barley	7,7	Wheat	2,0	Maize	0,1
23,2	IT kids/toddler	22,2	Wheat	0,1	Potatoes	0,1	Wild fungi	
21,6	DE child	13,7	Wheat	2,6	Rye	1,4	Oats	0,3
21,1	NL child	15,8	Wheat	1,0	Potatoes	0,7	Oats	0,6
21,0	PT General population	13,1	Wheat	2,9	Soya bean	1,9	Sunflower seed	
18,0	ES child	14,8	Wheat	0,8	Sunflower seed	0,4	Peas	0,3
16,2	WHO regional European diet	9,9	Wheat	2,2	Barley	0,9	Sunflower seed	0,2
14,6	IT adult	13,8	Wheat	0,2	Wild fungi	0,1	Potatoes	
14,5	FR all population	11,0	Wheat	2,2	Sunflower seed	0,7	Wine grapes	0,1
13,1	SE general population 90th percentile	10,7	Wheat	1,0	Rye	0,7	Potatoes	0,2
13,1	ES adult	7,8	Wheat	3,3	Barley	0,7	Sunflower seed	0,1
12,8	UK vegetarian	6,8	Wheat	4,3	Sugar beet (root)	0,3	Oats	0,1
12,2	FR toddler	8,7	Wheat	1,1	Sunflower seed	0,8	Potatoes	0,7
11,5	NL general	6,9	Wheat	2,5	Barley	0,5	Potatoes	0,1
11,4	UK Adult	5,6	Wheat	4,5	Sugar beet (root)	0,2	Potatoes	0,1
10,5	DK adult	6,7	Wheat	2,3	Rye	0,8	Oats	0,1
9,2	LT adult	3,6	Rye	3,5	Wheat	0,6	Oats	0,1
7,1	FI adult	3,3	Wheat	2,3	Rye	0,6	Oats	0,1
4,7	FR infant	2,8	Wheat	0,7	Potatoes	0,4	Milk and cream,	0,5
1,0	PL general population	0,6	Potatoes	0,1	Peas	0,1	Apples	

Conclusion:

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

Profenofos

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	not included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,03	ARfD (mg/kg bw):	1
Source of ADI:	JMPR	Source of ARfD:	JMPR
Year of evaluation:	2007	Year of evaluation:	2007

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	4 - 23
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)
22,8	WHO Cluster diet B	13,4	Tomatoes	2,4	Peppers	1,4	Wheat	
14,5	FR toddler	6,6	Milk and cream,	3,4	Tomatoes	0,8	Potatoes	
14,3	DE child	4,2	Tomatoes	2,4	Milk and cream,	2,0	Apples	
14,1	NL child	4,9	Milk and cream,	2,7	Tomatoes	1,1	Apples	
13,0	UK Toddler	3,8	Sugar beet (root)	3,4	Milk and cream,	2,6	Tomatoes	
12,8	UK Infant	6,5	Milk and cream,	1,7	Sugar beet (root)	1,6	Tomatoes	
10,6	ES child	4,3	Tomatoes	2,1	Milk and cream,	0,7	Wheat	
10,0	DK child	2,3	Tomatoes	2,1	Milk and cream,	1,1	Peppers	
9,9	WHO regional European diet	4,8	Tomatoes	0,8	Peppers	0,8	Milk and cream,	
9,5	SE general population 90th percentile	3,3	Tomatoes	2,1	Milk and cream,	0,9	Peppers	
9,4	WHO cluster diet D	4,4	Tomatoes	1,1	Wheat	0,8	Milk and cream,	
9,0	IT kids/toddler	6,2	Tomatoes	1,1	Wheat	0,3	Peppers	
8,6	IE adult	1,7	Tomatoes	0,6	Peppers	0,6	Sweet potatoes	
8,1	FR infant	4,3	Milk and cream,	0,7	Potatoes	0,6	Tomatoes	
8,1	PT General population	3,9	Tomatoes	0,9	Peppers	0,9	Potatoes	
7,6	WHO cluster diet E	2,3	Tomatoes	0,7	Wheat	0,6	Potatoes	
7,4	WHO Cluster diet F	3,0	Tomatoes	0,7	Milk and cream,	0,6	Wheat	
7,3	ES adult	3,4	Tomatoes	0,8	Milk and cream,	0,7	Peppers	
7,2	IT adult	5,0	Tomatoes	0,7	Wheat	0,3	Peppers	
5,9	UK vegetarian	2,7	Tomatoes	0,6	Sugar beet (root)	0,5	Milk and cream,	
5,9	NL general	1,9	Tomatoes	1,1	Milk and cream,	0,5	Potatoes	
5,7	PL general population	3,8	Tomatoes	0,6	Potatoes	0,4	Peppers	
5,4	LT adult	2,7	Tomatoes	0,7	Milk and cream,	0,5	Potatoes	
5,1	DK adult	1,8	Tomatoes	0,9	Milk and cream,	0,5	Peppers	
5,0	FR all population	1,9	Tomatoes	0,7	Wine grapes	0,5	Wheat	
4,7	UK Adult	1,9	Tomatoes	0,7	Sugar beet (root)	0,5	Milk and cream,	
4,4	FI adult	1,9	Tomatoes	0,9	Milk and cream,	0,2	Peppers	

Conclusion:

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

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)
4,9	Peppers	0,78 / -	3,5	Peppers	0,78 / -	1,3	Peppers	0,78 / -	0,9	Peppers	0,78 / -

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)

*) 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 Profenofos 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.

Profenofos

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	not included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0,005	ARfD (mg/kg bw):	0,01
Source of ADI:	DE	Source of ARfD:	DE
Year of evaluation:	2001	Year of evaluation:	2001

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	27 - 137
No of diets exceeding ADI:	1

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)
137,1	WHO Cluster diet B	80,2	Tomatoes	14,2	Peppers	8,5	Wheat	
86,8	FR toddler	39,6	Milk and cream,	20,1	Tomatoes	5,1	Potatoes	
85,6	DE child	25,1	Tomatoes	14,3	Milk and cream,	12,1	Apples	
84,4	NL child	29,3	Milk and cream,	16,2	Tomatoes	6,3	Apples	
78,1	UK Toddler	22,9	Sugar beet (root)	20,7	Milk and cream,	15,3	Tomatoes	
77,1	UK Infant	38,7	Milk and cream,	10,1	Sugar beet (root)	9,6	Tomatoes	
63,5	ES child	25,5	Tomatoes	12,5	Milk and cream,	4,4	Wheat	
59,9	DK child	13,8	Tomatoes	12,6	Milk and cream,	6,3	Peppers	
59,3	WHO regional European diet	28,6	Tomatoes	4,9	Peppers	4,8	Milk and cream,	
56,7	SE general population 90th percentile	19,9	Tomatoes	12,4	Milk and cream,	5,3	Peppers	
56,3	WHO cluster diet D	26,3	Tomatoes	6,5	Wheat	5,0	Milk and cream,	
53,7	IT kids/toddler	37,1	Tomatoes	6,6	Wheat	1,7	Peppers	
51,7	IE adult	10,4	Tomatoes	3,9	Peppers	3,5	Sweet potatoes	
48,5	FR infant	25,7	Milk and cream,	4,1	Potatoes	3,8	Tomatoes	
48,3	PT General population	23,3	Tomatoes	5,5	Peppers	5,3	Potatoes	
45,4	WHO cluster diet E	13,7	Tomatoes	3,9	Wheat	3,8	Potatoes	
44,6	WHO Cluster diet F	17,7	Tomatoes	4,0	Milk and cream,	3,6	Wheat	
43,9	ES adult	20,4	Tomatoes	5,0	Milk and cream,	4,4	Peppers	
43,1	IT adult	30,3	Tomatoes	4,1	Wheat	2,0	Peppers	
35,5	UK vegetarian	16,2	Tomatoes	3,8	Sugar beet (root)	3,3	Milk and cream,	
35,5	NL general	11,1	Tomatoes	6,6	Milk and cream,	2,7	Potatoes	
33,9	PL general population	23,0	Tomatoes	3,4	Potatoes	2,2	Peppers	
32,2	LT adult	16,1	Tomatoes	4,0	Milk and cream,	3,2	Potatoes	
30,5	DK adult	10,8	Tomatoes	5,4	Milk and cream,	3,0	Peppers	
30,2	FR all population	11,3	Tomatoes	4,0	Wine grapes	3,3	Wheat	
28,4	UK Adult	11,3	Tomatoes	4,0	Sugar beet (root)	3,0	Milk and cream,	
26,5	FI adult	11,1	Tomatoes	5,7	Milk and cream,	1,4	Peppers	

Conclusion:

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 26,5 % to 137 % of the ADI.
For 1 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

	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):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**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)
	491,2	Peppers	0,78 / 0,15	350,9	Peppers	0,78 / 0,22	127,5	Peppers	0,78 / 0,61	91,0	Peppers	0,78 / -
	No of critical MRLs (IESTI 1)		1				**No of critical MRLs (IESTI 2)**		1			
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)			
	*) 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 Profenofos IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.											
	The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.											
	Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.											
	For processed commodities, no exceedance of the ARfD/ADI was identified.											

Hexythiazox

Status of the active substance:	**included**	Code no.	
LOQ (mg/kg bw):	0,05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	15 - 94
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)
93,9	DE child	40,2	Apples	12,7	Oranges	6,9	Wheat	3,2
77,3	NL child	21,1	Apples	10,4	Oranges	7,9	Wheat	6,6
70,0	WHO Cluster diet B	14,2	Wheat	6,0	Wine grapes	5,1	Tomatoes	2,0
68,1	IE adult	5,9	Sweet potatoes	4,2	Wine grapes	3,8	Maize	1,4
51,6	FR toddler	8,7	Apples	6,7	Oranges	6,6	Milk and cream,	8,0
44,0	DK child	9,2	Wheat	7,7	Apples	7,4	Rye	3,3
43,1	UK Infant	6,5	Milk and cream,	5,2	Apples	4,4	Wheat	8,8
41,7	UK Toddler	6,6	Oranges	6,5	Wheat	5,7	Apples	8,0
40,2	WHO cluster diet E	6,6	Wheat	5,4	Wine grapes	2,8	Apples	1,8
37,3	SE general population 90th percentile	5,3	Wheat	4,2	Head cabbage	3,5	Apples	2,8
36,5	WHO cluster diet D	10,8	Wheat	2,2	Apples	1,7	Tomatoes	1,8
36,0	ES child	7,4	Wheat	7,2	Oranges	3,8	Apples	3,3
35,2	PT General population	8,3	Wine grapes	6,5	Wheat	3,5	Apples	0,9
34,4	FR infant	8,3	Apples	4,4	Carrots	4,3	Milk and cream,	5,2
32,6	FR all population	13,3	Wine grapes	5,5	Wheat	1,6	Apples	0,9
31,8	WHO regional European diet	4,9	Wheat	2,4	Head cabbage	2,2	Apples	2,2
31,3	WHO Cluster diet F	6,0	Wheat	2,9	Oranges	2,2	Apples	1,8
30,9	NL general	5,0	Oranges	3,9	Apples	3,5	Wheat	1,9
28,4	IT kids/toddler	11,1	Wheat	3,0	Apples	2,4	Tomatoes	0,4
25,3	ES adult	4,3	Oranges	3,9	Wheat	2,6	Apples	1,4
23,0	UK vegetarian	3,4	Wheat	2,9	Oranges	2,7	Wine grapes	1,4
22,5	IT adult	6,9	Wheat	2,6	Apples	1,9	Tomatoes	0,2
20,7	DK adult	4,6	Wine grapes	3,4	Wheat	2,6	Apples	1,5
19,3	UK Adult	3,6	Wine grapes	2,8	Wheat	1,9	Oranges	1,5
18,7	LT adult	6,2	Apples	2,7	Head cabbage	1,8	Rye	1,5
18,2	PL general population	6,8	Apples	2,4	Head cabbage	1,5	Tomatoes	0,6
15,1	FI adult	3,2	Oranges	1,6	Wheat	1,3	Apples	1,4

Conclusion:

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

Etofenprox

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 16 - 79

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)
79,4	DE child	21,2	Table grapes	12,7	Oranges	8,0	Apples	0,2
78,2	NL child	12,7	Table grapes	10,4	Oranges	9,8	Potatoes	0,2
74,7	UK Toddler	38,1	Sugar beet (root)	6,6	Oranges	6,5	Wheat	0,1
73,1	WHO Cluster diet B	14,2	Wheat	10,3	Tomatoes	5,8	Table grapes	0,4
52,3	FR toddler	8,4	Potatoes	7,1	Spinach	6,7	Oranges	0,3
51,0	IE adult	4,3	Table grapes	3,8	Maize	3,8	Maize	0,4
48,6	UK Infant	16,8	Sugar beet (root)	6,5	Milk and cream,	5,4	Potatoes	0,2
44,1	DK child	9,2	Wheat	7,4	Rye	4,1	Potatoes	0,1
41,8	ES child	7,4	Wheat	7,2	Oranges	4,2	Lettuce	0,2
41,2	WHO cluster diet D	10,8	Wheat	6,8	Potatoes	3,4	Tomatoes	0,1
40,7	WHO regional European diet	6,7	Potatoes	4,9	Wheat	3,8	Lettuce	0,2
38,9	WHO cluster diet E	6,6	Wheat	6,4	Potatoes	2,6	Table grapes	0,2
36,1	WHO Cluster diet F	6,0	Wheat	5,7	Potatoes	3,0	Lettuce	0,1
35,1	PT General population	8,9	Potatoes	6,5	Wheat	4,6	Table grapes	0,1
34,2	SE general population 90th percentile	6,9	Potatoes	5,3	Wheat	4,2	Head cabbage	0,2
33,7	NL general	5,0	Oranges	4,6	Potatoes	3,8	Table grapes	0,1
32,9	IT kids/toddler	11,1	Wheat	4,8	Tomatoes	2,9	Lettuce	0,1
31,0	ES adult	5,4	Lettuce	4,3	Oranges	3,9	Wheat	0,1
29,7	FR infant	6,9	Potatoes	4,4	Spinach	4,3	Milk and cream,	0,2
27,3	IT adult	6,9	Wheat	3,9	Tomatoes	3,8	Lettuce	0,0
26,4	UK vegetarian	6,3	Sugar beet (root)	3,4	Wheat	2,9	Oranges	0,1
23,2	FR all population	5,5	Wheat	3,7	Wine grapes	1,9	Potatoes	0,1
22,5	UK Adult	6,7	Sugar beet (root)	2,8	Wheat	2,3	Potatoes	0,1
21,3	PL general population	5,7	Potatoes	5,3	Table grapes	2,9	Tomatoes	0,0
21,0	LT adult	5,3	Potatoes	2,7	Head cabbage	2,1	Tomatoes	0,0
18,7	DK adult	3,4	Wheat	2,4	Potatoes	1,6	Swine	0,1
16,3	FI adult	3,2	Oranges	2,0	Potatoes	1,6	Wheat	0,0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Etofenprox 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)
	2,2	Peaches	0,37 / -	1,6	Peaches	0,37 / -	0,6	Peaches	0,37 / -	0,5	Peaches	0,37 / -
	0,1	Beans	0,05 / -	0,1	Beans	0,05 / -	0,0	Beans	0,05 / -	0,0	Beans	0,05 / -
	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)			
	*) 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 Etofenprox 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.											

Tebuconazole			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**0,03**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
3 24

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)
23,8	DE child	11,1	Apples	3,0	Table grapes	1,0	Cherries	1,1
20,7	WHO Cluster diet B	4,3	Wine grapes	2,4	Tomatoes	2,2	Beans (with pods)	0,3
20,0	NL child	5,8	Apples	3,4	Beans (with pods)	2,0	Milk and milk products: Cattle	2,1
16,5	IE adult	3,0	Wine grapes	2,8	Barley	1,2	Beans (without pods)	0,3
15,9	FR toddler	7,4	Beans (with pods)	2,4	Apples	1,2	Carrots	0,1
15,2	WHO cluster diet E	3,9	Wine grapes	1,9	Beans (with pods)	1,8	Barley	0,3
14,3	FR all population	9,6	Wine grapes	0,9	Beans (with pods)	0,5	Wheat	0,2
13,4	FR infant	5,6	Beans (with pods)	2,3	Apples	1,7	Milk and milk products: Cattle	1,8
13,4	PT General population	6,0	Wine grapes	1,7	Beans (without pods)	1,0	Apples	0,1
10,2	UK Toddler	3,8	Sugar beet (root)	1,6	Apples	0,7	Wheat	0,1
9,5	NL general	1,7	Beans (with pods)	1,5	Wine grapes	1,1	Apples	0,5
9,3	ES child	1,6	Beans (with pods)	1,0	Apples	0,8	Milk and milk products: Cattle	0,9
9,1	WHO regional European diet	1,3	Beans (with pods)	0,8	Tomatoes	0,7	Barley	0,4
8,8	ES adult	1,6	Beans (with pods)	1,1	Barley	1,0	Wine grapes	0,4
8,4	DK child	2,1	Apples	0,9	Wheat	0,9	Oats	0,1
8,4	WHO Cluster diet F	1,4	Wine grapes	1,4	Barley	0,6	Apples	0,3
7,9	UK Infant	1,7	Sugar beet (root)	1,4	Apples	0,7	Carrots	0,1
7,9	WHO cluster diet D	1,1	Wheat	0,9	Wine grapes	0,8	Tomatoes	0,4
7,1	SE general population 90th percentile	1,0	Apples	0,8	Milk and milk products: Cattle	0,6	Tomatoes	0,9
6,7	DK adult	3,3	Wine grapes	0,7	Apples	0,3	Wheat	0,0
6,2	UK vegetarian	2,0	Wine grapes	0,6	Sugar beet (root)	0,5	Apples	0,0
6,1	UK Adult	2,6	Wine grapes	0,7	Sugar beet (root)	0,4	Apples	0,0
6,0	IT kids/toddler	1,1	Wheat	1,1	Tomatoes	0,8	Apples	0,0
5,5	IT adult	1,0	Beans (with pods)	0,9	Tomatoes	0,7	Apples	0,0
4,9	PL general population	1,9	Apples	0,8	Table grapes	0,7	Tomatoes	0,0
4,8	LT adult	1,7	Apples	0,5	Tomatoes	0,3	Swine: Meat	0,3
3,2	FI adult	0,7	Wine grapes	0,4	Apples	0,3	Tomatoes	0,0

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Tebuconazole 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):		**7**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**5**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**
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)
1004,0	Table grapes	4,6 / 0,45	1004,0	Table grapes	4,6 / 0,45	486,8	Table grapes	4,6 / 0,94	486,8	Table grapes	4,6 / 0,94
197,8	Peaches	1 / 0,5	145,1	Peaches	1 / 0,68	70,7	Wine grapes	0,89444444444	70,7	Wine grapes	0,89444444444
163,3	Apples	0,5 / 0,3	126,3	Cherries	3,1 / 2,45	59,3	Head cabbage	0,56 / -	45,2	Peaches	1 / -
151,8	Pears	0,5 / 0,32	120,4	Apples	0,5 / 0,41	58,3	Peaches	1 / -	43,8	Cherries	3,1 / -
130,2	Peppers	0,62 / 0,47	109,2	Pears	0,5 / 0,45	43,8	Cherries	3,1 / -	35,6	Head cabbage	0,56 / -
126,3	Cherries	3,1 / 2,45	93,0	Peppers	0,62 / -						
103,2	Apricots	1 / 0,96									
98,2	Head cabbage	0,56 / -									
No of critical MRLs (IESTI 1)		7				**No of critical MRLs (IESTI 2)**		5			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**1**				**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)			
504,4	Grape juice	4,6 / 0,91				59,2	Wine	4,6 / -			
84,9	Apple juice	0,5 / -				10,9	Apple juice	0,5 / -			
59,7	Peach juice	1 / -				6,7	Peach preserved with	1 / -			
40,4	Cuurant juice	1,2 / -				6,2	Raisins	4,6 / -			
37,4	Elderberry juice	0,7 / -				2,9	Tomato (preserved-	0,46 / -			

*) 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 Tebuconazole IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 7 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 5 commodities.
For processed commodities, the ARfD/ADI was exceeded in one or several cases.

Spinosad

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,024**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**COM**	Source of ARfD:	**COM**
Year of evaluation:	**2006**	Year of evaluation:	**2006**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 11 - 86

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)
86,0	WHO Cluster diet B	24,9	Wheat	12,8	Tomatoes	7,2	Maize	
56,5	IE adult	6,7	Maize	6,7	Maize	3,6	Barley	
54,1	DE child	12,0	Wheat	4,0	Tomatoes	4,0	Bananas	
51,6	DK child	16,1	Wheat	12,9	Rye	6,8	Cucumbers	
50,8	NL child	13,8	Wheat	4,4	Bananas	2,9	Spinach	
47,0	WHO cluster diet D	19,0	Wheat	4,2	Tomatoes	1,8	Watermelons	
44,0	IT kids/toddler	19,4	Wheat	5,9	Tomatoes	4,4	Other cereal	
41,9	WHO cluster diet E	11,5	Wheat	3,3	Wine grapes	2,4	Barley	
38,4	FR toddler	7,6	Wheat	5,6	Spinach	3,3	Bananas	
38,2	ES child	12,9	Wheat	4,1	Tomatoes	3,3	Lettuce	
37,2	WHO regional European diet	8,7	Wheat	4,6	Tomatoes	3,0	Lettuce	
34,6	IT adult	12,1	Wheat	4,8	Tomatoes	3,0	Lettuce	
32,8	WHO Cluster diet F	10,5	Wheat	2,8	Tomatoes	2,4	Lettuce	
31,7	PT General population	11,4	Wheat	5,2	Wine grapes	3,7	Tomatoes	
31,6	FR all population	9,6	Wheat	8,3	Wine grapes	1,8	Tomatoes	
31,0	UK Toddler	11,4	Wheat	4,8	Sugar beet (root)	2,8	Bananas	
30,4	SE general population 90th percentile	9,3	Wheat	4,6	Bananas	3,2	Tomatoes	
29,4	UK Infant	7,6	Wheat	3,7	Bananas	3,2	Milk and cream,	
29,2	ES adult	6,8	Wheat	4,2	Lettuce	3,3	Tomatoes	
25,1	NL general	6,0	Wheat	1,8	Tomatoes	1,3	Wine grapes	
20,4	FR infant	3,5	Spinach	2,5	Wheat	2,1	Milk and cream,	
20,2	UK vegetarian	6,0	Wheat	2,6	Tomatoes	1,7	Wine grapes	
19,8	DK adult	5,9	Wheat	2,9	Wine grapes	2,0	Rye	
17,0	LT adult	3,1	Rye	3,1	Wheat	2,6	Tomatoes	
16,9	UK Adult	4,9	Wheat	2,3	Wine grapes	1,8	Tomatoes	
12,4	FI adult	2,9	Wheat	2,0	Rye	1,8	Tomatoes	
10,9	PL general population	3,7	Tomatoes	1,3	Walnuts	0,7	Plums	

Conclusion:

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

CXL assessment

Pyraclostrobin			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**0,03**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum
2 14

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)
14,3	DE child	5,6	Apples	1,5	Table grapes	0,9	Oranges	1,1
10,6	NL child	3,0	Apples	1,0	Milk and milk products: Cattle	0,9	Table grapes	1,9
8,0	WHO Cluster diet B	1,0	Tomatoes	0,6	Gooseberries	0,6	Wheat	1,2
7,8	IE adult	1,4	Barley	0,4	Plums	0,4	Apples	0,8
7,0	UK Toddler	2,7	Sugar beet (root)	0,8	Apples	0,5	Oranges	0,6
6,4	FR toddler	1,2	Apples	1,0	Carrots	0,6	Strawberries	0,7
5,7	FR infant	1,2	Apples	1,1	Carrots	0,9	Milk and milk products: Cattle	1,3
5,3	WHO cluster diet E	0,9	Barley	0,4	Apples	0,3	Wheat	0,9
5,2	UK Infant	1,2	Sugar beet (root)	0,7	Apples	0,5	Carrots	0,6
5,0	DK child	1,1	Apples	0,5	Carrots	0,5	Oats	0,9
4,7	ES child	0,5	Apples	0,5	Oranges	0,4	Milk and milk products: Cattle	0,9
4,6	WHO regional European diet	0,4	Barley	0,4	Tomatoes	0,3	Lettuce	0,8
4,5	WHO Cluster diet F	0,7	Barley	0,3	Apples	0,3	Lettuce	0,8
4,4	WHO cluster diet D	0,4	Wheat	0,3	Tomatoes	0,3	Apples	1,0
4,0	NL general	0,6	Apples	0,4	Barley	0,3	Oranges	0,7
4,0	SE general population 90th percentile	0,5	Apples	0,4	Milk and milk products: Cattle	0,3	Carrots	1,1
3,8	ES adult	0,6	Barley	0,5	Lettuce	0,4	Apples	0,5
3,1	IT kids/toddler	0,5	Tomatoes	0,4	Wheat	0,4	Apples	0,6
3,1	PT General population	0,5	Apples	0,4	Potatoes	0,3	Table grapes	0,8
3,0	PL general population	1,0	Apples	0,4	Table grapes	0,3	Tomatoes	0,3
2,8	IT adult	0,4	Tomatoes	0,4	Apples	0,3	Lettuce	0,3
2,7	LT adult	0,9	Apples	0,2	Potatoes	0,2	Tomatoes	0,5
2,6	FR all population	0,2	Apples	0,2	Wheat	0,2	Wine grapes	0,6
2,6	UK vegetarian	0,4	Sugar beet (root)	0,3	Apples	0,2	Tomatoes	0,3
2,1	UK Adult	0,5	Sugar beet (root)	0,2	Apples	0,1	Tomatoes	0,3
1,9	DK adult	0,4	Apples	0,2	Carrots	0,1	Tomatoes	0,4
1,8	FI adult	0,2	Currants (red, black and white)	0,2	Oranges	0,2	Apples	0,2

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Pyraclostrobin 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)
82,3	Onions	0,62 / -	64,0	Cherries	1,57 / -	30,7	Onions	0,62 / -	22,2	Cherries	1,57 / -
69,9	Oranges	0,1582 / -	59,1	Onions	0,62 / -	22,2	Cherries	1,57 / -	22,0	Blueberries	2,08 / -
64,0	Cherries	1,57 / -	50,5	Oranges	0,1582 / -	22,0	Blueberries	2,08 / -	21,9	Onions	0,62 / -
47,2	Blackberries	1,32 / -	47,2	Blackberries	1,32 / -	17,5	Raspberries	1,32 / -	17,5	Raspberries	1,32 / -
47,0	Grapefruit	0,1582 / -	47,0	Grapefruit	0,1582 / -	15,0	Barley	0,62 / -	15,0	Barley	0,62 / -
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)	

*) 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 Pyraclostrobin 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.

Azoxystrobin

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,2**	ARfD (mg/kg bw):	**n.n.**
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: 6 – 52

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)
52,4	DE child	28,6	Oranges	3,1	Mandarins	2,4	Strawberries	
50,5	NL child	23,4	Oranges	5,6	Mandarins	2,9	Potatoes	
41,4	IE adult	7,8	Oranges	5,2	Grapefruit	4,3	Mandarins	
39,9	UK Toddler	14,8	Oranges	11,4	Sugar beet (root)	2,1	Mandarins	
38,9	WHO Cluster diet B	6,4	Oranges	4,6	Tomatoes	3,9	Onions	
38,3	FR toddler	15,0	Oranges	3,6	Leek	3,1	Strawberries	
27,1	ES child	16,3	Oranges	1,5	Tomatoes	1,3	Mandarins	
26,8	UK Infant	9,7	Oranges	5,0	Sugar beet (root)	1,6	Potatoes	
26,0	SE general population 90th percentile	5,6	Oranges	3,3	Mandarins	2,3	Onions	
24,4	NL general	11,2	Oranges	1,6	Mandarins	1,4	Potatoes	
23,0	WHO cluster diet E	3,3	Oranges	1,9	Potatoes	1,9	Onions	
21,3	FR infant	6,8	Oranges	2,4	Strawberries	2,1	Leek	
20,8	WHO regional European diet	3,7	Oranges	2,2	Onions	2,0	Potatoes	
20,3	WHO cluster diet D	2,5	Onions	2,0	Potatoes	1,8	Oranges	
19,6	PT General population	4,6	Oranges	2,7	Potatoes	2,5	Wine grapes	
19,4	WHO Cluster diet F	6,5	Oranges	1,7	Potatoes	1,5	Mandarins	
18,7	ES adult	9,7	Oranges	1,2	Tomatoes	1,1	Mandarins	
18,0	UK vegetarian	6,5	Oranges	1,9	Sugar beet (root)	1,1	Onions	
15,3	FR all population	4,0	Wine grapes	2,2	Oranges	1,4	Mandarins	
15,2	IT kids/toddler	3,6	Oranges	2,1	Tomatoes	1,6	Mandarins	
14,1	UK Adult	4,2	Oranges	2,0	Sugar beet (root)	1,1	Wine grapes	
13,4	FI adult	7,3	Oranges	0,8	Mandarins	0,7	Onions	
13,0	IT adult	2,8	Oranges	1,7	Tomatoes	1,2	Mandarins	
12,6	DK child	1,4	Onions	1,3	Oranges	1,2	Potatoes	
9,2	PL general population	1,7	Potatoes	1,6	Onions	1,3	Tomatoes	
8,4	DK adult	1,4	Wine grapes	1,0	Oranges	0,8	Onions	
6,3	LT adult	1,6	Potatoes	1,0	Head cabbage	0,9	Tomatoes	

Conclusion:

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

Spirotetramat

Status of the active substance:	**pending**	Code no.	
LOQ (mg/kg bw):	0,1	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,05**	ARfD (mg/kg bw):	**1**
Source of ADI:	**DAR**	Source of ARfD:	**DAR**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Prepare workbook for refined calculations

Undo refined calculations

Chronic exposure assessment performed in the framework of the most recent reasoned opinion in the context of a MRL application is updated by replacing the EU risk assessment input values with the STMR/HR values derived by JMPR for crops where the CXL proposal exceeds the EU MRL (unless EU STMR is higher).
Acute exposure assessment is presented only for the crops under consideration for which the CXL proposal exceeds the EU MRL (unless the EU STMR/HR is higher).

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	5 – 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)
32,9	WHO Cluster diet B	12,3	Tomatoes	2,7	Lettuce	2,0	Peppers	4,5
23,4	NL child	2,8	Spinach	2,5	Tomatoes	2,3	Apples	2,8
22,5	DE child	4,3	Apples	3,9	Tomatoes	2,5	Oranges	2,3
19,6	IE adult	1,6	Tomatoes	1,5	Other leafy brassica	1,1	Wine grapes	3,7
19,0	FR toddler	5,2	Spinach	3,1	Tomatoes	1,4	Beans (with pods)	2,5
15,8	IT kids/toddler	5,7	Tomatoes	2,2	Lettuce	1,3	Wheat	1,9
15,6	WHO regional European diet	4,4	Tomatoes	2,8	Lettuce	1,0	Potatoes	1,7
15,6	IT adult	4,7	Tomatoes	2,8	Lettuce	1,2	Other lettuce and other salad	1,2
15,4	WHO cluster diet D	4,0	Tomatoes	1,4	Chinese cabbage	1,3	Wheat	2,2
15,1	ES child	3,9	Tomatoes	3,1	Lettuce	1,4	Oranges	2,2
14,7	WHO cluster diet E	2,1	Tomatoes	1,4	Wine grapes	0,9	Potatoes	2,4
14,1	UK Toddler	4,6	Sugar beet (root)	2,4	Tomatoes	1,3	Oranges	6,2
13,7	ES adult	4,0	Lettuce	3,1	Tomatoes	0,9	Oranges	1,3
12,9	SE general population 90th percentile	3,1	Tomatoes	1,5	Chinese cabbage	1,0	Potatoes	1,7
12,7	WHO Cluster diet F	2,7	Tomatoes	2,2	Lettuce	0,8	Potatoes	2,1
12,2	PT General population	3,6	Tomatoes	2,2	Wine grapes	1,3	Potatoes	1,5
12,1	NL general	1,7	Tomatoes	1,1	Spinach	1,0	Oranges	1,3
11,5	FR all population	3,6	Wine grapes	1,7	Tomatoes	1,4	Other lettuce and other salad	1,2
10,9	FR infant	3,3	Spinach	1,1	Beans (with pods)	1,0	Potatoes	1,5
10,4	DK child	2,1	Tomatoes	1,1	Wheat	1,0	Lettuce	2,8
10,1	UK Infant	2,0	Sugar beet (root)	1,5	Tomatoes	0,9	Oranges	4,0
9,5	UK vegetarian	2,5	Tomatoes	1,0	Lettuce	0,8	Sugar beet (root)	1,6
7,5	UK Adult	1,7	Tomatoes	1,0	Wine grapes	0,9	Lettuce	1,4
7,4	PL general population	3,5	Tomatoes	0,8	Potatoes	0,7	Apples	0,2
6,1	DK adult	1,7	Tomatoes	1,3	Wine grapes	0,4	Peppers	0,9
6,0	LT adult	2,5	Tomatoes	0,8	Potatoes	0,7	Apples	0,9
5,3	FI adult	1,7	Tomatoes	0,6	Oranges	0,6	Lettuce	0,7

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Spirotetramat 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)
	2,0	Mangoes	0,25 / -	1,4	Mangoes	0,25 / -	0,7	Mangoes	0,25 / -	0,7	Mangoes	0,25 / -
	1,1	Onions	0,27 / -	1,0	Beans (with pods)	0,84 / -	0,4	Beans (with pods)	0,84 / -	0,4	Beans (with pods)	0,84 / -
	1,0	Beans (with pods)	0,84 / -	0,8	Onions	0,27 / -	0,4	Beans (without pods)	0,84 / -	0,4	Beans (without pods)	0,84 / -
	0,7	Peas (without pods)	0,84 / -	0,7	Peas (without	0,84 / -	0,4	Onions	0,27 / -	0,3	Peas (without pods)	0,84 / -
	0,6	Beans (without pods)	0,84 / -	0,6	Beans (without	0,84 / -	0,3	Peas (without pods)	0,84 / -	0,3	Onions	0,27 / -
	0,4	Bovine: Liver	0,55 / -	0,4	Bovine: Liver	0,55 / -	0,3	Peas (with pods)	0,84 / -	0,3	Peas (with pods)	0,84 / -
	0,4	Bovine: Edible offal	0,55 / -	0,4	Bovine: Edible	0,55 / -	0,2	Bovine: Edible offal	0,55 / -	0,2	Bovine: Edible offal	0,55 / -
	0,4	Beans	0,21 / -	0,4	Beans	0,21 / -	0,1	Bovine: Liver	0,55 / -	0,1	Bovine: Liver	0,55 / -
	0,3	Peas (with pods)	0,84 / -	0,3	Peas (with pods)	0,84 / -	0,1	Beans	0,21 / -	0,1	Beans	0,21 / -
	0,2	Bovine: Kidney	0,55 / -	0,2	Bovine: Kidney	0,55 / -	0,1	Bovine: Kidney	0,55 / -	0,1	Bovine: Kidney	0,55 / -
	0,1	Lentils	0,21 / -	0,1	Lentils	0,21 / -	0,1	Goat: Meat	0,55 / -	0,1	Goat: Meat	0,55 / -
	0,1	Soya bean	0,45 / -	0,1	Soya bean	0,45 / -	0,1	Swine: Kidney	0,55 / -	0,1	Swine: Kidney	0,55 / -
	0,1	Peas	0,21 / -	0,1	Peas	0,21 / -	0,1	Peas	0,21 / -	0,1	Peas	0,21 / -
	0,1	Swine: Kidney	0,55 / -	0,1	Swine: Kidney	0,55 / -	0,1	Lentils	0,21 / -	0,1	Lentils	0,21 / -
	0,1	Milk and milk	0,005 / -	0,1	Milk and milk	0,005 / -	0,0	Sheep: Edible offal	0,55 / -	0,0	Sheep: Edible offal	0,55 / -
	0,1	Swine: Liver	0,55 / -	0,1	Swine: Liver	0,55 / -	0,0	Sheep: Liver	0,55 / -	0,0	Sheep: Liver	0,55 / -
	0,0	Bovine: Meat	0,032 / -	0,0	Bovine: Meat	0,032 / -	0,0	Swine: Liver	0,55 / -	0,0	Swine: Liver	0,55 / -
	0,0	Sheep: Meat	0,032 / -	0,0	Sheep: Meat	0,032 / -	0,0	Soya bean	0,45 / -	0,0	Soya bean	0,45 / -
	0,0	Swine: Meat	0,032 / -	0,0	Swine: Meat	0,032 / -	0,0	Bovine: Meat	0,032 / -	0,0	Bovine: Meat	0,032 / -
	0,0	Horse: Meat	0,032 / -	0,0	Horse: Meat	0,032 / -	0,0	Swine: Meat	0,032 / -	0,0	Swine: Meat	0,032 / -
	0,0	Milk and milk	0,005 / -	0,0	Milk and milk	0,005 / -	0,0	Sheep: Meat	0,032 / -	0,0	Sheep: Meat	0,032 / -
	0,0	Milk and milk	0,005 / -	0,0	Milk and milk	0,005 / -	0,0	Milk and milk	0,005 / -	0,0	Milk and milk products: Cattle	0,005 / -
							0,0	Horse: Meat	0,032 / -	0,0	Horse: Meat	0,032 / -
							0,0	Milk and milk	0,005 / -	0,0	Milk and milk products: Goat	0,005 / -
							0,0	Milk and milk	0,005 / -	0,0	Milk and milk products: Sheep	0,005 / -
	No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
	*) 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 Spirotetramat 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.											

Dicamba

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,3**	ARfD (mg/kg bw):	**0,3**
Source of ADI:	**EFSA/JMPR**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010/2011**	Year of evaluation:	**2011**

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum: 0 – 9

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)
9,0	WHO Cluster diet B	5,7	Wheat	1,0	Soya bean	0,7	Barley	
6,4	WHO cluster diet E	2,6	Wheat	1,9	Barley	1,0	Soya bean	
6,4	WHO cluster diet D	4,3	Wheat	0,6	Soya bean	0,5	Barley	
6,2	NL child	3,2	Wheat	2,0	Milk and cream,	0,2	Pome fruit	
6,0	IE adult	2,9	Barley	1,5	Wheat	0,4	Maize	
5,8	DK child	3,7	Wheat	0,8	Milk and cream,	0,7	Rye	
5,8	WHO Cluster diet F	2,4	Wheat	1,4	Barley	1,1	Soya bean	
5,1	FR toddler	2,6	Milk and cream,	1,7	Wheat	0,2	Bovine	
5,0	UK Infant	2,6	Milk and cream,	1,7	Wheat	0,2	Maize	
4,9	DE child	2,7	Wheat	1,0	Milk and cream,	0,4	Pome fruit	
4,8	IT kids/toddler	4,4	Wheat	0,2	Other cereal	0,0	Pome fruit	
4,7	UK Toddler	2,6	Wheat	1,4	Milk and cream,	0,4	Sugar beet (root)	
4,4	ES child	3,0	Wheat	0,8	Milk and cream,	0,2	Bovine	
3,8	WHO regional European diet	2,0	Wheat	0,8	Barley	0,3	Milk and cream,	
3,6	PT General population	2,6	Wheat	0,5	Soya bean	0,1	Maize	
3,5	ES adult	1,6	Wheat	1,1	Barley	0,3	Milk and cream,	
3,4	SE general population 90th percentile	2,1	Wheat	0,8	Milk and cream,	0,1	Root and tuber vegetables	
3,0	IT adult	2,8	Wheat	0,1	Other cereal	0,0	Pome fruit	
3,0	NL general	1,4	Wheat	0,9	Barley	0,4	Milk and cream,	
2,7	FR all population	2,2	Wheat	0,2	Milk and cream,	0,1	Bovine	
2,7	FR infant	1,7	Milk and cream,	0,6	Wheat	0,1	Root and tuber vegetables	
2,1	DK adult	1,3	Wheat	0,4	Milk and cream,	0,1	Rye	
1,9	UK vegetarian	1,4	Wheat	0,2	Milk and cream,	0,1	Sugar beet (root)	
1,6	UK Adult	1,1	Wheat	0,2	Milk and cream,	0,1	Sugar beet (root)	
1,6	LT adult	0,7	Wheat	0,3	Milk and cream,	0,2	Rye	
1,4	FI adult	0,7	Wheat	0,4	Milk and cream,	0,1	Rye	
0,2	PL general population	0,1	Pome fruit	0,1	Root and tuber vegetables	0,0	Fruiting vegetables	

Conclusion:

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

Acute risk assessment /children						Acute risk assessment / adults / general population					
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)
	9,6	Wheat	2 / -	9,6	Wheat	2 / -	16,9	Barley	7 / -	16,9	Barley	7 / -
	8,3	Milk and milk	0,2 / -	8,3	Milk and milk	0,2 / -	10,6	Asparagus	5 / -	10,6	Asparagus	5 / -
	7,6	Asparagus	5 / -	7,6	Asparagus	5 / -	5,2	Wheat	2 / -	5,2	Wheat	2 / -
	4,5	Sorghum	4 / -	4,5	Sorghum	4 / -	1,3	Sugar cane	1 / -	1,3	Sugar cane	1 / -
	4,1	Barley	7 / -	4,1	Barley	7 / -	1,1	Milk and milk	0,2 / -	1,1	Milk and milk products: Cattle	0,2 / -
	3,8	Soya bean	5 / -	3,8	Soya bean	5 / -	1,0	Soya bean	5 / -	1,0	Soya bean	5 / -
	3,3	Apples	0,1 / -	2,7	Sugar cane	1 / -	1,0	Bovine: Meat	0,5 / -	1,0	Bovine: Meat	0,5 / -
	3,0	Pears	0,1 / -	2,5	Melons	0,05 / -	0,9	Pumpkins	0,05 / -	0,9	Pumpkins	0,05 / -
	2,7	Sugar cane	1 / -	2,4	Apples	0,1 / -	0,8	Rye	0,5 / -	0,8	Rye	0,5 / -
	2,6	Potatoes	0,05 / -	2,2	Pears	0,1 / -	0,8	Rice	0,3 / -	0,8	Rice	0,3 / -
	2,5	Melons	0,05 / -	2,1	Bovine: Meat	0,5 / -	0,7	Apples	0,1 / -	0,7	Watermelons	0,05 / -
	2,2	Oranges	0,05 / -	2,0	Watermelons	0,05 / -	0,7	Pears	0,1 / -	0,7	Melons	0,05 / -
	2,1	Bovine: Meat	0,5 / -	1,8	Potatoes	0,05 / -	0,7	Watermelons	0,05 / -	0,6	Apples	0,1 / -
	2,0	Watermelons	0,05 / -	1,7	Pineapples	0,05 / -	0,7	Melons	0,05 / -	0,6	Chinese cabbage	0,05 / -
	1,7	Sweet corn	0,07 / -	1,6	Milk and milk	0,2 / -	0,6	Chinese cabbage	0,05 / -	0,5	Pears	0,1 / -
	1,7	Pineapples	0,05 / -	1,6	Oranges	0,05 / -	0,5	Cauliflower	0,05 / -	0,5	Cauliflower	0,05 / -
	1,6	Milk and milk	0,2 / -	1,5	Grapefruit	0,05 / -	0,5	Table grapes	0,05 / -	0,5	Table grapes	0,05 / -
	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)			
	7,9	Wheat flour	2 / -				2,9	Bread/pizza	2 / -			
	1,7	Apple juice	0,1 / -				0,2	Apple juice	0,1 / -			
	0,8	Orange juice	0,05 / -				0,2	Orange juice	0,05 / -			
	0,7	Maize flour	0,5 / -				0,1	Wine	0,05 / -			
	0,7	Carrot, juice	0,05 / -				0,1	Maize flour	0,5 / -			
*) 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 Dicamba 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.												

Etoxazole

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**included**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
1	6
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)
6,1	FR all population	5,0	Wine grapes	0,2	Wheat	0,1	Table grapes	0,1
6,0	WHO Cluster diet B	2,2	Wine grapes	0,8	Tomatoes	0,4	Table grapes	0,2
5,0	DE child	1,6	Table grapes	1,0	Oranges	0,4	Milk and cream,	0,7
4,8	PT General population	3,1	Wine grapes	0,3	Table grapes	0,3	Potatoes	0,0
4,6	NL child	0,9	Table grapes	0,8	Oranges	0,7	Milk and cream,	1,0
4,5	IE adult	1,6	Wine grapes	0,3	Table grapes	0,3	Oranges	0,2
4,1	WHO cluster diet E	2,0	Wine grapes	0,2	Wheat	0,2	Table grapes	0,2
3,6	UK Toddler	1,1	Sugar beet (root)	0,5	Milk and cream,	0,5	Oranges	0,6
3,4	FR toddler	1,0	Milk and cream,	0,5	Oranges	0,3	Strawberries	1,2
2,9	UK Infant	1,0	Milk and cream,	0,5	Sugar beet (root)	0,3	Oranges	1,1
2,6	DK adult	1,7	Wine grapes	0,1	Milk and cream,	0,1	Tomatoes	0,2
2,6	UK Adult	1,4	Wine grapes	0,2	HOPS (dried),	0,2	Sugar beet (root)	0,1
2,5	NL general	0,8	Wine grapes	0,4	Oranges	0,3	Table grapes	0,2
2,5	WHO Cluster diet F	0,7	Wine grapes	0,2	Oranges	0,2	Wheat	0,2
2,4	WHO cluster diet D	0,5	Wine grapes	0,3	Wheat	0,3	Tomatoes	0,2
2,4	UK vegetarian	1,0	Wine grapes	0,2	Oranges	0,2	Sugar beet (root)	0,1
2,2	WHO regional European diet	0,3	Wine grapes	0,3	Tomatoes	0,2	Potatoes	0,3
2,1	ES child	0,5	Oranges	0,3	Milk and cream,	0,2	Tomatoes	0,5
2,0	FR infant	0,6	Milk and cream,	0,2	Strawberries	0,2	Oranges	0,8
2,0	DK child	0,3	Milk and cream,	0,3	Wheat	0,2	Table grapes	0,5
1,9	ES adult	0,5	Wine grapes	0,3	Oranges	0,2	Tomatoes	0,2
1,8	SE general population 90th percentile	0,3	Milk and cream,	0,2	Potatoes	0,2	Tomatoes	0,4
1,5	IT kids/toddler	0,4	Tomatoes	0,3	Wheat	0,1	Table grapes	0,0
1,3	FI adult	0,4	Wine grapes	0,2	Oranges	0,1	Milk and cream,	0,2
1,3	IT adult	0,3	Tomatoes	0,2	Wheat	0,2	Table grapes	0,0
1,0	PL general population	0,4	Table grapes	0,2	Tomatoes	0,2	Potatoes	0,1
0,8	LT adult	0,2	Potatoes	0,2	Tomatoes	0,1	Milk and cream,	0,2

Conclusion:

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

ACETAMIPRID			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,07**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 6
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)
6,1	DE child	3,9	Apples	0,4	Milk and milk products: Cattle	0,2	Spinach	
5,0	NL child	2,0	Apples	0,8	Milk and milk products: Cattle	0,4	Spinach	
2,7	WHO Cluster diet B	0,4	Lettuce	0,3	Apples	0,2	Wine grapes	
2,5	FR infant	0,8	Apples	0,7	Milk and milk products: Cattle	0,5	Spinach	
2,4	FR toddler	0,8	Apples	0,8	Spinach	0,1	Strawberries	
2,1	ES child	0,5	Lettuce	0,4	Apples	0,4	Milk and milk products: Cattle	
2,0	IE adult	0,3	Apples	0,2	Pears	0,2	Peaches	
1,7	ES adult	0,6	Lettuce	0,2	Apples	0,1	Milk and milk products: Cattle	
1,7	SE general population 90th percentile	0,4	Milk and milk products: Cattle	0,3	Apples	0,2	Chinese cabbage	
1,7	WHO regional European diet	0,4	Lettuce	0,2	Apples	0,1	Milk and milk products: Cattle	
1,7	NL general	0,4	Apples	0,2	Milk and milk products: Cattle	0,2	Spinach	
1,6	DK child	0,7	Apples	0,2	Pears	0,2	Lettuce	
1,5	WHO cluster diet E	0,3	Apples	0,2	Wine grapes	0,1	Lettuce	
1,5	WHO cluster diet D	0,2	Apples	0,2	Chinese cabbage	0,1	Milk and milk products: Cattle	
1,4	IT adult	0,4	Lettuce	0,3	Apples	0,1	Spinach	
1,4	IT kids/toddler	0,3	Lettuce	0,3	Apples	0,1	Pears	
1,3	WHO Cluster diet F	0,4	Lettuce	0,2	Apples	0,1	Milk and milk products: Cattle	
1,3	UK Toddler	0,5	Apples	0,1	Currants (red, black and white)	0,1	Raspberries	
1,2	FR all population	0,5	Wine grapes	0,2	Apples	0,1	Lettuce	
1,2	PT General population	0,3	Apples	0,3	Wine grapes	0,1	Pears	
1,2	PL general population	0,7	Apples	0,1	Pears	0,1	Cherries	
1,1	LT adult	0,6	Apples	0,1	Milk and milk products: Cattle	0,1	Lettuce	
1,0	UK Infant	0,5	Apples	0,1	Pears	0,1	Currants (red, black and white)	
0,8	UK vegetarian	0,2	Apples	0,2	Lettuce	0,1	Wine grapes	
0,7	DK adult	0,3	Apples	0,2	Wine grapes	0,1	Pears	
0,6	UK Adult	0,1	Lettuce	0,1	Apples	0,1	Wine grapes	
0,5	FI adult	0,1	Apples	0,1	Lettuce	0,1	Currants (red, black and white)	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of ACETAMIPRID 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):		**2**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**	**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)
166,1	Scarole (broad-leaf	1,9 / 1,14	166,1	Scarole (broad-leaf	1,9 / 1,14	67,9	Chinese cabbage	1,9 / -	67,9	Chinese cabbage	1,9 / -
128,4	Kale	1,9 / 1,47	91,8	Kale	1,9 / -	38,7	Kale	1,9 / -	28,8	Kale	1,9 / -
70,6	Chinese cabbage	1,9 / -	70,6	Chinese cabbage	1,9 / -	23,1	Spinach	2,58 / -	23,1	Spinach	2,58 / -
58,3	Spinach	2,58 / -	58,3	Spinach	2,58 / -	20,9	Lettuce	1,9 / -	17,9	Purslane	1,9 / -
57,8	Apples	0,59 / -	42,6	Apples	0,59 / -	19,6	Purslane	1,9 / -	16,9	Scarole (broad-leaf endive)	1,9 / -
No of critical MRLs (IESTI 1)		2				**No of critical MRLs (IESTI 2)**		1			

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)			
30,1	Apple juice	0,59 / -				3,9	Apple juice	0,59 / -			
16,0	Elderberry juice	1 / -				1,0	Wine	0,25 / -			
12,0	Raspberries juice	1 / -				0,9	Peach preserved with	0,44 / -			
10,3	Pear juice	0,59 / -				0,7	Quince jelly	0,59 / -			
10,1	Cuurant juice	1 / -				0,3	Tomato (preserved-	0,14 / -			

*) 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 ACETAMIPRID IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 2 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Emamectin

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**pending**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,0005**	ARfD (mg/kg bw):	**0,03**
Source of ADI:	**JMPR**	Source of ARfD:	**JMPR**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

The toxicological reference value is expressed as emamectin. Provisional residue definition for risk assessment: emamectin B1a benzoate, expressed as emamectin (free base).

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	4 35
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)
35	IT adult	20,4	Lettuce	8,5	Other lettuce and other salad plants	1,4	Tomatoes	4,5
35	ES adult	28,9	Lettuce	1,1	Pome fruit	0,9	Tomatoes	5,4
35	WHO Cluster diet B	19,4	Lettuce	3,7	Tomatoes	2,5	Herbs	11,2
33	ES child	22,5	Lettuce	2,1	Cocoa (fermented beans)	1,6	Pome fruit	7,8
29	WHO regional European diet	20,3	Lettuce	1,9	Herbs	1,3	Tomatoes	5,7
29	DE child	12,7	Pome fruit	3,3	Lettuce	2,8	Citrus fruit	21,2
28	IT kids/toddler	15,7	Lettuce	6,0	Other lettuce and other salad plants	1,7	Tomatoes	4,9
24	NL child	6,8	Pome fruit	5,3	Lettuce	2,9	Milk and cream,	16,5
22	WHO Cluster diet F	16,2	Lettuce	0,8	Tomatoes	0,8	Pome fruit	4,5
21	FR all population	10,3	Other lettuce and other salad	5,0	Lettuce	1,6	Wine grapes	4,5
16	IE adult	4,6	Lettuce	2,4	Herbs	1,6	Citrus fruit	8,8
15	WHO cluster diet E	5,0	Lettuce	2,7	Herbs	1,4	Other lettuce and other salad	5,0
14	DK child	7,6	Lettuce	3,0	Pome fruit	1,3	Milk and cream,	6,2
13	NL general	6,5	Lettuce	1,4	Pome fruit	1,1	Citrus fruit	5,5
13	FR toddler	4,0	Milk and cream,	2,9	Pome fruit	1,4	Spinach	12,3
11	UK vegetarian	7,6	Lettuce	0,7	Tomatoes	0,7	Pome fruit	3,1
9	UK Adult	6,3	Lettuce	0,5	Tomatoes	0,5	Pome fruit	2,5
9	WHO cluster diet D	3,6	Herbs	1,2	Tomatoes	0,8	Pome fruit	4,8
8	FR infant	2,8	Pome fruit	2,6	Milk and cream,	0,9	Spinach	8,1
8	UK Toddler	2,1	Milk and cream,	1,9	Pome fruit	1,4	Citrus fruit	6,6
8	UK Infant	3,9	Milk and cream,	1,8	Pome fruit	0,8	Citrus fruit	7,6
7	LT adult	3,4	Lettuce	2,0	Pome fruit	0,7	Tomatoes	4,0
7	SE general population 90th percentile	1,4	Pome fruit	1,2	Milk and cream,	0,9	Tomatoes	5,9
7	FI adult	4,2	Lettuce	0,7	Citrus fruit	0,6	Milk and cream,	2,6
5	PL general population	2,3	Pome fruit	1,1	Tomatoes	0,7	Lettuce	4,0
5	PT General population	1,4	Pome fruit	1,1	Tomatoes	1,0	Wine grapes	4,9
4	DK adult	1,0	Pome fruit	0,6	Wine grapes	0,5	Milk and cream,	3,5

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Emamectin 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)
	56	Lettuce	0,62 / -	33	Lettuce	0,62 / -	22,7	Lettuce	0,62 / -	13,6	Lettuce	0,62 / -
	32	Scarole (broad-leaf	0,11 / -	32	Scarole (broad-leaf	0,11 / -	3,9	Lamb's lettuce	0,62 / -	3,9	Lamb's lettuce	0,62 / -
	11	Celery leaves	0,6 / -	11	Celery leaves	0,6 / -	3,3	Scarole (broad-leaf	0,11 / -	3,3	Scarole (broad-leaf endive)	0,11 / -
	6	Rocket, Rucola	0,62 / -	6	Rocket, Rucola	0,62 / -	2,4	Parsley	0,6 / -	2,4	Parsley	0,6 / -
	6	Lamb's lettuce	0,62 / -	6	Lamb's lettuce	0,62 / -	2,2	Table grapes	0,021 / -	2,2	Table grapes	0,021 / -
	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)			
	0,5	Orange juice	0,003 / -				0,1	Orange juice	0,003 / -			
	0,1	Plums juice	0,003 / -									
	*) 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 Emamectin 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.											

Flutriafol

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	pending	Code no.	85
LOQ (mg/kg bw):	0,05	proposed LOQ:	

Toxicological end points

ADI (mg/kg bw/day):	0,01	ARfD (mg/kg bw):	0,05
Source of ADI:	DAR- UK	Source of ARfD:	DAR- UK
Year of evaluation:	2010	Year of evaluation:	2010

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	14 98
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)
98,0	WHO Cluster diet B	42,7	Wheat	12,4	Maize	9,3	Tomatoes	7,1
69,5	DK child	27,5	Wheat	22,1	Rye	4,9	Potatoes	3,9
67,6	UK Toddler	22,9	Sugar beet (root)	19,6	Wheat	7,0	Potatoes	4,0
67,4	DE child	20,6	Wheat	8,4	Apples	7,6	Oranges	5,0
66,8	NL child	23,7	Wheat	11,8	Potatoes	6,2	Oranges	7,2
62,4	IE adult	11,5	Maize	11,5	Maize	6,2	Barley	8,1
61,5	WHO cluster diet D	32,5	Wheat	8,1	Potatoes	3,0	Tomatoes	2,9
56,0	PT General population	19,6	Wheat	10,7	Potatoes	8,5	Wine grapes	1,2
55,7	WHO cluster diet E	19,7	Wheat	7,7	Potatoes	5,5	Wine grapes	3,6
54,7	UK Infant	13,1	Wheat	10,1	Sugar beet (root)	6,5	Potatoes	5,9
53,7	IT kids/toddler	33,2	Wheat	7,5	Other cereal	4,3	Tomatoes	1,5
50,7	FR toddler	13,1	Wheat	10,1	Potatoes	4,9	Carrots	7,5
46,7	WHO Cluster diet F	18,0	Wheat	6,8	Potatoes	3,8	Rye	2,7
44,2	ES child	22,2	Wheat	4,3	Oranges	3,7	Potatoes	4,2
41,6	SE general population 90th percentile	16,0	Wheat	8,3	Potatoes	2,3	Tomatoes	4,4
40,2	FR all population	16,4	Wheat	13,6	Wine grapes	2,2	Potatoes	1,8
39,3	WHO regional European diet	14,8	Wheat	8,0	Potatoes	3,3	Tomatoes	3,6
34,9	IT adult	20,7	Wheat	3,5	Other cereal	3,5	Tomatoes	1,5
32,0	NL general	10,4	Wheat	5,5	Potatoes	3,0	Oranges	2,7
30,7	FR infant	8,3	Potatoes	5,3	Carrots	4,2	Wheat	5,0
29,5	UK vegetarian	10,2	Wheat	3,8	Sugar beet (root)	2,8	Wine grapes	1,7
29,2	ES adult	11,7	Wheat	2,6	Oranges	2,5	Barley	2,6
27,8	DK adult	10,1	Wheat	4,7	Wine grapes	3,4	Rye	1,5
26,3	UK Adult	8,4	Wheat	4,0	Sugar beet (root)	3,7	Wine grapes	1,3
25,4	LT adult	6,3	Potatoes	5,4	Rye	5,3	Wheat	1,2
19,3	FI adult	4,9	Wheat	3,4	Rye	2,5	Potatoes	1,5
14,2	PL general population	6,9	Potatoes	2,6	Tomatoes	1,4	Apples	1,1

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)
80	Table grapes	0,61 / -	79,9	Table grapes	0,61 / -	42,2	Wine grapes	0,89 / -	42,2	Wine grapes	0,89 / -
52	Peppers	0,41 / -	36,9	Peppers	0,41 / -	38,7	Table grapes	0,61 / -	38,7	Table grapes	0,61 / -
31	Apples	0,16 / -	23,1	Apples	0,16 / -	13,4	Peppers	0,41 / -	9,6	Peppers	0,41 / -
29	Pears	0,16 / -	21,0	Pears	0,16 / -	7,8	Wheat	0,5 / -	7,8	Wheat	0,5 / -
15	Bananas	0,09 / -	14,4	Wheat	0,5 / -	7,2	Apples	0,16 / -	6,0	Apples	0,16 / -
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)			

*) 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.

Isopyrazam

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	

Toxicological end points

ADI (mg/kg bw/day):	**0,03**	ARfD (mg/kg bw):	**0,2**
Source of ADI:	**EU**	Source of ARfD:	**EU**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Explain choice of toxicological reference values.

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

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum: 0 – 8

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)
8,5	DK child	3,7	Wheat	2,9	Rye	0,8	Oats	0,9
7,6	WHO Cluster diet B	5,7	Wheat	0,6	Barley	0,5	VEGETABLES	1,2
5,9	WHO cluster diet D	4,3	Wheat	0,4	Barley	0,3	VEGETABLES	0,7
5,9	NL child	3,2	Wheat	1,0	Milk and cream,	0,4	VEGETABLES	2,0
5,6	WHO cluster diet E	2,6	Wheat	1,6	Barley	0,3	VEGETABLES	0,8
5,6	IE adult	2,5	Barley	1,5	Wheat	0,4	Oats	1,0
5,6	DE child	2,7	Wheat	0,5	Rye	0,5	Milk and cream,	1,5
5,2	WHO Cluster diet F	2,4	Wheat	1,2	Barley	0,5	Rye	0,7
5,0	UK Toddler	2,6	Wheat	0,8	SUGAR PLANTS	0,7	Milk and cream,	2,0
4,9	IT kids/toddler	4,4	Wheat	0,1	VEGETABLES	0,1	Bananas	0,3
4,7	UK Infant	1,7	Wheat	1,3	Milk and cream,	0,5	Oats	2,2
4,3	FR toddler	1,7	Wheat	1,3	Milk and cream,	0,6	VEGETABLES	2,3
4,2	ES child	3,0	Wheat	0,4	Milk and cream,	0,2	Bananas	1,0
3,6	SE general population 90th percentile	2,1	Wheat	0,4	Milk and cream,	0,4	Bananas	0,9
3,6	WHO regional European diet	2,0	Wheat	0,7	Barley	0,3	VEGETABLES	0,8
3,3	PT General population	2,6	Wheat	0,2	VEGETABLES	0,1	Berries & small fruit	0,5
3,2	ES adult	1,6	Wheat	1,0	Barley	0,2	Milk and cream,	0,6
3,1	IT adult	2,8	Wheat	0,1	VEGETABLES	0,0	Bananas	0,3
3,0	NL general	1,4	Wheat	0,7	Barley	0,2	Milk and cream,	0,7
2,8	FR all population	2,2	Wheat	0,1	Berries & small fruit	0,1	VEGETABLES	0,5
2,5	DK adult	1,3	Wheat	0,5	Rye	0,2	Oats	0,4
2,5	FR infant	0,9	Milk and cream,	0,7	VEGETABLES	0,6	Wheat	1,8
2,2	LT adult	0,7	Rye	0,7	Wheat	0,2	Oats	0,5
2,1	UK vegetarian	1,4	Wheat	0,1	SUGAR PLANTS	0,1	VEGETABLES	0,6
1,8	UK Adult	1,1	Wheat	0,1	SUGAR PLANTS	0,1	VEGETABLES	0,5
1,8	FI adult	0,7	Wheat	0,5	Rye	0,2	Milk and cream,	0,4
0,4	PL general population	0,2	VEGETABLES	0,1	Pome fruit	0,0	Bananas	0,3

Conclusion:

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

Acute risk assessment /children						Acute risk assessment / adults / general population					
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)
	2,5	Bananas	0,06 / -	1,8	Bananas	0,06 / -	2,2	Barley	0,6 / -	2,2	Barley	0,6 / -
	1,4	Wheat	0,2 / -	1,4	Wheat	0,2 / -	0,8	Wheat	0,2 / -	0,8	Wheat	0,2 / -
	1,2	Oats	0,6 / -	1,2	Oats	0,6 / -	0,5	Rye	0,2 / -	0,5	Rye	0,2 / -
	0,8	Potatoes	0,01 / -	0,8	Melons	0,01 / -	0,4	Oats	0,6 / -	0,4	Oats	0,6 / -
	0,8	Melons	0,01 / -	0,6	Rye	0,2 / -	0,4	Bananas	0,06 / -	0,3	Bananas	0,06 / -
	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)			
	1,2	Wheat flour	0,2 / -				0,4	Bread/pizza	0,2 / -			
	0,3	Apple juice	0,01 / -				0,1	Orange juice	0,01 / -			
	0,2	Orange juice	0,01 / -				0,0	Apple juice	0,01 / -			
	0,2	Carrot, juice	0,01 / -				0,0	Wine	0,01 / -			
	0,2	Grape juice	0,01 / -				0,0	Pineapples preserved	0,01 / -			
*) 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 Isopyrazam 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.												

Sulfoxaflor

Status of the active substance:	**Not approved**	Code no.	
LOQ (mg/kg bw):	0,01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**0,25**
Source of ADI:	**IE proposal**	Source of ARfD:	**IE proposal**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum: 2 – 13

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)
13,3	NL child	3,7	Milk and cream,	2,4	Oranges	1,2	Pome fruit	0,4
12,9	DE child	3,0	Oranges	2,2	Pome fruit	1,8	Milk and cream,	0,2
11,0	FR toddler	5,0	Milk and cream,	2,2	Spinach	1,6	Oranges	0,3
8,4	WHO Cluster diet B	1,1	Lettuce	1,0	Peaches	0,8	Tomatoes	0,4
7,8	IE adult	1,3	Peaches	0,8	Oranges	0,7	Plums	0,5
7,8	UK Infant	4,8	Milk and cream,	1,0	Oranges	0,3	Pome fruit	0,5
7,2	ES child	1,7	Oranges	1,6	Milk and cream,	1,3	Lettuce	0,2
7,0	FR infant	3,2	Milk and cream,	1,4	Spinach	0,7	Oranges	0,2
6,6	UK Toddler	2,6	Milk and cream,	1,5	Oranges	0,6	Sugar beet (root)	0,8
5,7	ES adult	1,7	Lettuce	1,0	Oranges	0,6	Milk and cream,	0,1
5,5	IT adult	1,2	Lettuce	0,9	Peaches	0,5	Other lettuce and other salad	0,0
5,5	NL general	1,2	Oranges	0,8	Milk and cream,	0,5	Witloof	0,2
5,2	IT kids/toddler	0,9	Lettuce	0,8	Peaches	0,4	Wheat	0,1
5,0	FR all population	1,4	Wine grapes	0,6	Other lettuce and other salad plants	0,4	Witloof	0,1
4,9	WHO regional European diet	1,2	Lettuce	0,6	Milk and cream,	0,5	Peaches	0,2
4,9	WHO cluster diet E	0,6	Wine grapes	0,4	Milk and cream,	0,3	Oranges	0,3
4,9	SE general population 90th percentile	1,5	Milk and cream,	0,6	Oranges	0,3	Mandarins	0,2
4,4	DK child	1,6	Milk and cream,	0,5	Pome fruit	0,4	Lettuce	0,3
4,1	WHO Cluster diet F	0,9	Lettuce	0,7	Oranges	0,5	Milk and cream,	0,3
4,0	WHO cluster diet D	0,6	Milk and cream,	0,4	Wheat	0,3	Tomatoes	0,2
3,6	PT General population	0,9	Wine grapes	0,8	Peaches	0,5	Oranges	0,3
3,1	UK vegetarian	0,7	Oranges	0,4	Lettuce	0,4	Milk and cream,	0,2
2,5	UK Adult	0,4	Oranges	0,4	Wine grapes	0,4	Milk and cream,	0,2
2,5	FI adult	0,8	Oranges	0,7	Milk and cream,	0,2	Lettuce	0,1
2,3	DK adult	0,7	Milk and cream,	0,5	Wine grapes	0,2	Peaches	0,1
2,0	PL general population	0,4	Pome fruit	0,4	Plums	0,2	Tomatoes	0,1
1,8	LT adult	0,5	Milk and cream,	0,4	Pome fruit	0,2	Lettuce	0,2

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Sulfoxaflor 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):**		1	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		1	**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)
	101,4	Scarole (broad-leaf	2,9 / 2,85	101,4	Scarole (broad-leaf	2,9 / 2,85	20,3	Table grapes	1,6 / -	20,3	Table grapes	1,6 / -
	53,8	Witloof	2,9 / -	41,9	Table grapes	1,6 / -	19,2	Witloof	2,9 / -	15,7	Witloof	2,9 / -
	41,9	Table grapes	1,6 / -	41,0	Witloof	2,9 / -	15,2	Wine grapes	1,6 / -	15,2	Wine grapes	1,6 / -
	37,3	Broccoli	1,6 / -	26,6	Broccoli	1,6 / -	13,6	Broccoli	1,6 / -	13,6	Broccoli	1,6 / -
	31,2	Lettuce	2,9 / -	26,2	Spinach	2,9 / -	12,7	Lettuce	2,9 / -	10,9	Purslane	2,9 / -
	28,5	Peaches	1,2 / -	20,9	Peaches	1,2 / -	12,0	Purslane	2,9 / -	10,4	Spinach	2,9 / -
	26,2	Spinach	2,9 / -	18,7	Lettuce	2,9 / -	10,4	Spinach	2,9 / -	10,3	Scarole (broad-leaf endive)	2,9 / -
	23,3	Oranges	0,44 / -	16,9	Oranges	0,44 / -	10,3	Scarole (broad-leaf endive)	2,9 / -	7,6	Lettuce	2,9 / -
	20,4	Beet leaves (chard)	2,9 / -	16,4	Melons	0,27 / -	8,6	Beet leaves (chard)	2,9 / -	7,3	Beet leaves (chard)	2,9 / -
	17,5	Purslane	2,9 / -	15,7	Grapefruit	0,44 / -	8,4	Peaches	1,2 / -	6,5	Peaches	1,2 / -
	16,4	Melons	0,27 / -	15,5	Beet leaves (chard)	2,9 / -	7,1	Celery	0,77 / -	6,0	Aubergines (egg plants)	0,6 / -
	15,8	Plums	1,2 / -	14,1	Celery	0,77 / -	6,0	Aubergines (egg	0,6 / -	5,7	Pumpkins	0,27 / -
	15,7	Grapefruit	0,44 / -	13,3	Purslane	2,9 / -	5,7	Pumpkins	0,27 / -	5,2	Celery	0,77 / -
	15,1	Peppers	0,6 / -	13,2	Watermelons	0,27 / -	4,5	Plums	1,2 / -	4,4	Watermelons	0,27 / -
	14,9	Apricots	1,2 / -	12,8	Plums	1,2 / -	4,5	Oranges	0,44 / -	4,3	Melons	0,27 / -
	14,1	Celery	0,77 / -	11,9	Apricots	1,2 / -	4,4	Watermelons	0,27 / -	3,7	Plums	1,2 / -
	14,0	Tomatoes	0,6 / -	10,8	Peppers	0,6 / -	4,3	Melons	0,27 / -	3,7	Oranges	0,44 / -
	No of critical MRLs (IESTI 1)		1				**No of critical MRLs (IESTI 2)**		1			
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)			
	6,5	Peach juice	0,91 / -				1,2	Orange juice	0,31 / -			
	6,1	Orange juice	0,31 / -				0,7	Peach preserved with syrup	0,91 / -			
	5,1	Plums juice	0,91 / -				0,2	Wine	0,14 / -			
	1,8	Grape juice	0,14 / -				0,1	Tomato (preserved-	0,11 / -			
	0,8	Tomato juice	0,11 / -				0,0	Bread/pizza	0,025 / -			
	*) 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 Sulfoxaflor IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.											
	The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.											
	Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.											
	For processed commodities, no exceedance of the ARfD/ADI was identified.											

Saflufenacil

Prepare workbook for refined calculations

Undo refined calculations

Status of the active substance:	**Not included**	Code no.	
LOQ (mg/kg bw):	0,03	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,046**	ARfD (mg/kg bw):	**0,05**
Source of ADI:	**UK, EFSA**	Source of ARfD:	**UK, EFSA**
Year of evaluation:	**2011**	Year of evaluation:	**2011**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 - 2
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
2,4	NL child	0,6	Milk and cream,	0,4	Apples	0,3	Wheat	2,3
2,3	DE child	0,8	Apples	0,3	Milk and cream,	0,3	Wheat	2,3
2,3	WHO Cluster diet B	0,6	Wheat	0,4	Sunflower seed	0,2	Maize	1,8
2,0	UK Infant	0,8	Milk and cream,	0,2	Sugar beet (root)	0,2	Wheat	1,9
2,0	FR toddler	0,9	Milk and cream,	0,2	Apples	0,2	Apples	1,9
1,9	UK Toddler	0,5	Sugar beet (root)	0,4	Milk and cream,	0,3	Wheat	1,9
1,8	IE adult	0,2	Sheep: Liver	0,1	Maize	0,1	Maize	1,4
1,6	DK child	0,4	Wheat	0,3	Rye	0,3	Milk and cream,	1,5
1,4	WHO cluster diet E	0,3	Wheat	0,2	Sunflower seed	0,1	Wine grapes	1,1
1,3	WHO cluster diet D	0,4	Wheat	0,2	Sunflower seed	0,1	Milk and cream,	1,1
1,3	ES child	0,3	Wheat	0,3	Milk and cream,	0,1	Oranges	1,2
1,3	FR infant	0,6	Milk and cream,	0,2	Apples	0,1	Potatoes	1,3
1,1	PT General population	0,3	Wheat	0,2	Wine grapes	0,1	Sunflower seed	1,0
1,1	SE general population 90th percentile	0,3	Milk and cream,	0,2	Wheat	0,1	Bananas	1,1
1,0	WHO Cluster diet F	0,2	Wheat	0,1	Milk and cream,	0,1	Potatoes	1,0
1,0	WHO regional European diet	0,2	Wheat	0,1	Milk and cream,	0,1	Potatoes	0,9
1,0	FR all population	0,3	Wine grapes	0,2	Wheat	0,2	Sunflower seed	0,8
0,9	NL general	0,1	Milk and cream,	0,1	Wheat	0,1	Oranges	0,8
0,8	ES adult	0,2	Wheat	0,1	Milk and cream,	0,1	Oranges	0,7
0,8	IT kids/toddler	0,4	Wheat	0,1	Apples	0,0	Bananas	0,8
0,7	DK adult	0,1	Wheat	0,1	Milk and cream,	0,1	Wine grapes	0,6
0,7	UK vegetarian	0,1	Wheat	0,1	Sugar beet (root)	0,1	Milk and cream,	0,7
0,6	LT adult	0,1	Apples	0,1	Milk and cream,	0,1	Rye	0,6
0,6	UK Adult	0,1	Wheat	0,1	Sugar beet (root)	0,1	Wine grapes	0,6
0,6	IT adult	0,3	Wheat	0,1	Apples	0,0	Solanacea	0,6
0,5	FI adult	0,1	Milk and cream,	0,1	Wheat	0,1	Oranges	0,5
0,4	PL general population	0,1	Apples	0,1	Potatoes	0,0	Solanacea	0,4

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Saflufenacil 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)
	2,0	Bovine: Kidney	0,26 / -	2,0	Bovine: Kidney	0,26 / -	0,9	Bovine: Kidney	0,26 / -	0,9	Bovine: Kidney	0,26 / -
	1,1	Mandarins	0,01 / -	0,8	Mandarins	0,01 / -	0,7	Swine: Kidney	0,26 / -	0,7	Swine: Kidney	0,26 / -
	0,7	Swine: Kidney	0,26 / -	0,7	Swine: Kidney	0,26 / -	0,3	Mandarins	0,01 / -	0,2	Mandarins	0,01 / -
	0,6	Apricots	0,01 / -	0,5	Apricots	0,01 / -	0,2	Quinces	0,01 / -	0,1	Apricots	0,01 / -
	0,4	Limes	0,01 / -	0,3	Limes	0,01 / -	0,2	Apricots	0,01 / -	0,1	Quinces	0,01 / -
	0,3	Quinces	0,01 / -	0,2	Quinces	0,01 / -	0,1	Limes	0,01 / -	0,1	Limes	0,01 / -
	0,2	Medlar	0,01 / -	0,2	Medlar	0,01 / -	0,1	Medlar	0,01 / -	0,1	Medlar	0,01 / -
	0,1	Rape seed	0,054 / -	0,1	Rape seed	0,054 / -	0,1	Pistachios	0,01 / -	0,1	Pistachios	0,01 / -
	0,1	Chestnuts	0,01 / -	0,1	Chestnuts	0,01 / -	0,0	Chestnuts	0,01 / -	0,0	Chestnuts	0,01 / -
	0,1	Walnuts	0,01 / -	0,1	Walnuts	0,01 / -	0,0	Coconuts	0,01 / -	0,0	Coconuts	0,01 / -
	0,0	Pistachios	0,01 / -	0,0	Pistachios	0,01 / -	0,0	Walnuts	0,01 / -	0,0	Walnuts	0,01 / -
	0,0	Cashew nuts	0,01 / -	0,0	Cashew nuts	0,01 / -	0,0	Cashew nuts	0,01 / -	0,0	Cashew nuts	0,01 / -
	0,0	Coconuts	0,01 / -	0,0	Coconuts	0,01 / -	0,0	Coffee beans	0,01 / -	0,0	Coffee beans	0,01 / -
	0,0	Hazelnuts	0,01 / -	0,0	Hazelnuts	0,01 / -	0,0	Brazil nuts	0,01 / -	0,0	Brazil nuts	0,01 / -
	0,0	Brazil nuts	0,01 / -	0,0	Brazil nuts	0,01 / -	0,0	Hazelnuts	0,01 / -	0,0	Hazelnuts	0,01 / -
	0,0	Coffee beans	0,01 / -	0,0	Coffee beans	0,01 / -	0,0	Pine nuts	0,01 / -	0,0	Pine nuts	0,01 / -
	0,0	Pine nuts	0,01 / -	0,0	Pine nuts	0,01 / -						
	0,0	Macadamia	0,01 / -	0,0	Macadamia	0,01 / -						
	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)			
	*) 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 Saflufenacil 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: ABBREVIATIONS

ADI	acceptable daily intake
AIR	Annex I (of Council Directive 91/414/EEC) Renewal
AR	applied radioactivity
ARfD	acute reference dose
a.s.	active substance
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
ca.	circa, approximately
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CEN	European Committee for Standardization (Comité Européen de Normalisation, *French*)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CV	coefficient of variation
CXL	Codex Maximum Residue Limit (Codex MRL)
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
dw	dry weight
EFSA	European Food Safety Authority
EMA	European Medicines Agency (former EMEA)
EMS	evaluating Member State
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	Good Agricultural Practice
GD	Guidance document
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
i.e.	that is (id est, *Latin*)
ILV	independent laboratory validation
IPCS	International Programme of Chemical Science

ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
kg	kilogram
K_{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification (determination)
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
NOAEL	no observed adverse effect level
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
P_{ow}	partition coefficient between n-octanol and water
ppm	parts per million (10^{-6})
PRIMo	(EFSA) Pesticide Residues Intake Model
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
RAC	raw agricultural commodity
RD-RA	residue definition for risk assessment
RD-ENF	residue definition for enforcement practice
RMS	rapporteur Member State
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
WHO	World Health Organisation
wk	week
yr	year