REASONED OPINION

Review of the existing maximum residue levels (MRLs) for 2,4-D according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

2,4-D was included in Annex I to Directive 91/414/EEC on 01 October 2002, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of afore mentioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Greece, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 19 November 2008 and, after having considered several comments made by EFSA, the RMS provided on 26 March 2010 a revised PROFile.

Based on the conclusions derived under the supervision of the European Commission in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 19 April 2011 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 24 June 2011 were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of 2,4-D was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.05 mg/kg bw/d which was established for 2,4-D acid. An ARfD was not required.

Primary crop metabolism of 2,4-D was investigated following foliar applications on wheat and potato and following soil treatment in apples, hereby covering 3 different crop groups. Metabolism of 2,4-D was also investigated for local treatments by injection in plants or cell cultures of soybean and maize. Metabolic patterns in the different studies were shown to be similar and the relevant residue for both enforcement and risk assessment in all plant commodities could be defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D. Validated analytical methods for enforcement of the residue definition in foods of plant origin are available with an LOQ of at least 0.05 mg/kg in high

[1] On request from EFSA, Question No EFSA-Q-2008-483, issued on 27 October 2011.
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[3] Acknowledgement: EFSA wishes to thank the rapporteur Member State Greece for the preparatory work on this scientific output.

Suggested citation: European Food Safety Authority; Review of the existing maximum residue levels (MRLs) for 2,4-D according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2011;9(11):2431. [52 pp.] doi:10.2903/j.efsa.2011.2431. Available online: www.efsa.europa.eu/efsajournal

water content, dry and acid commodities. An analytical method for the enforcement of 2,4-D, its salts, its esters and conjugates in high oil content commodities is also available but its ILV is still required.

Regarding the magnitude of residues, the available residues data are considered sufficient to derive adequate MRL proposals as well as risk assessment values for most of the commodities under assessment, except in almonds and hazelnuts where only a tentative MRL could be derived in the absence of an ILV of the analytical method; tentative MRLs were also derived for grass and cereal straws in view of the future need to set MRLs in feed items. For oranges, buckwheat, alfalfa and clover, the number of residues trials was too limited for deriving MRL proposals and risk assessment values.

As quantifiable residues of 2,4-D are not expected in edible part of crops and total chronic exposure represents less than 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

2,4-D was demonstrated to decline rapidly in soil. Further investigation of residues in rotational crops is therefore not required and relevant residues in these crops are not expected.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement and risk assessment was defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D. A validated analytical method for enforcement of the residue definition is also available with an LOQ of 0.01 mg/kg in milk and eggs, and an LOQ of 0.05 mg/kg in meat, liver, kidney and fat. Based on the available livestock feeding study in ruminants, significant residues in edible matrices of ruminants and pigs are not expected, except in ruminant fat and kidney as well as pig kidney. It is therefore concluded that MRLs for these commodities can be established at the LOQ, except for ruminant fat, ruminant kidney and pig kidney where higher MRLs are proposed. For poultry, no MRLs are proposed as a significant intake was not identified for this type of livestock.

Chronic consumer exposure resulting from the MRL proposed in the framework of this review was calculated using revision 2 of the EFSA PRIMo and no exceedance of the ADI was identified; the highest chronic exposure was calculated for German children, representing 8.8 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for 2,4-D. Additional calculations of the consumer exposure, including these CXLs, were therefore performed and no exceedance of the ADI was identified. In this case, the highest chronic exposure was calculated for Dutch children, representing 12.1 % of the ADI.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see table below for a summary). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain existing EU MRLs still need to be confirmed by the following data:

- an ILV for enforcement of residues in high oil content commodities;
- 4 residues trials complying with the northern GAP on buckwheat.

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

- 8 residues trials complying with the Spanish GAP on oranges and further clarification about this GAP;
- 6 residues trials complying with the southern GAP and 6 additional residues trials complying with the northern GAP on maize forage;
- 4 residue trials complying with the southern GAP and 4 residue trials complying with the northern GAP on alfalfa;
- 4 residue trials complying with the southern GAP and 4 residue trials complying with the northern GAP on clover.

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

A minor deficiency was also identified in the assessment but this deficiency is not expected to impact either on the validity of the 'Recommended' MRLs or on the national authorisations. A validation of the hydrolysis step for the analysis of esters and conjugates of 2,4-D in plant and animals (data gap resulting from the new guidance document) is therefore considered desirable but not essential.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: Sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D					
110010	Grapefruits	1	1(**)	1	Recommended [a]
110020	Oranges	1	1(**)	1	Recommended [b]
110030	Lemons	1	1(**)	1	Recommended [a]
110040	Limes	1	1(**)	1	Recommended [a]
110050	Mandarins	1	1(**)	1	Recommended [a]
120010	Almonds	0.05*	0.2	0.2	Further consideration needed [c]
120020	Brazil nuts	0.05*	0.2	0.2	Further consideration needed [d]
120030	Cashew nuts	0.05*	0.2	0.2	Further consideration needed [d]
120040	Chestnuts	0.05*	0.2	0.2	Recommended [a]
120050	Coconuts	0.05*	0.2	0.2	Further consideration needed [d]
120060	Hazelnuts	0.05*	0.2	0.2	Further consideration needed [c]
120070	Macadamia	0.05*	0.2	0.2	Further consideration needed [d]
120080	Pecans	0.05*	0.2	0.2	Further consideration needed [d]
120090	Pine nuts	0.05*	0.2	0.2	Further consideration needed [d]
120100	Pistachios	0.05*	0.2	0.2	Further consideration needed [d]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
120110	Walnuts	0.05*	0.2	0.2	Further consideration needed [(d)]
130000	Pome fruit	0.05*	0.01*	0.05*	Recommended [(e)]
140000	Stone fruit	0.05*	0.05*	0.05*	Recommended [(e)]
151000	Table and wine grapes	0.05*	0.1	0.1	Recommended [(a)]
152000	Strawberries	0.05*	0.1	0.1	Recommended [(f)]
153000	Cane fruit	0.05*	0.1	0.1	Recommended [(a)]
154000	Other small fruit & berries	0.05*	0.1	0.1	Recommended [(a)]
211000	Potatoes	0.05*	0.2	0.2	Recommended [(a)]
234000	Sweet corn	0.05*	0.05*	0.05*	Recommended [(a)]
270010	Asparagus	0.05*	-	0.05*	Recommended [(g)]
401070	Soya bean	0.1*	0.01*	0.01*	Further consideration needed [(d)]
500010	Barley grain	0.05*	-	0.05*	Recommended [(g)]
500020	Buckwheat grain	0.05*	-	0.05*	Further consideration needed [(h)]
500030	Maize grain	0.05*	0.05	0.05*	Recommended [(e)]
500040	Millet grain	0.05*	-	0.05*	Recommended [(g)]
500050	Oats Grain	0.05*	-	0.05*	Recommended [(g)]
500060	Rice grain	0.05*	0.1	0.1	Recommended [(a)]
500070	Rye grain	0.05*	2	2	Recommended [(f)]
500080	Sorghum grain	0.05*	0.01*	0.05*	Recommended [(e)]
500090	Wheat grain	0.05*	2	2	Recommended [(f)]
900020	Sugar cane	0.05*	0.05	0.05*	Recommended [(e)]
1011010	Swine meat	0.05*	0.2	0.2	Recommended [(f)]
1011020	Swine fat (free or lean meat)	0.05*	0.2	0.2	Recommended [(f)]
1011030	Swine liver	0.05*	5	5	Recommended [(f)]
1011040	Swine kidney	1	5	5	Recommended [(f)]
1012010	Bovine meat	0.05*	0.2	0.2	Recommended [(f)]
1012020	Bovine fat	0.05*	0.2	0.2	Recommended [(f)]
1012030	Bovine liver	0.05*	5	5	Recommended [(f)]
1012040	Bovine kidney	1	5	5	Recommended [(f)]
1013010	Sheep meat	0.05*	0.2	0.2	Recommended [(f)]
1013020	Sheep fat	0.05*	0.2	0.2	Recommended [(f)]
1013030	Sheep liver	0.05*	5	5	Recommended [(f)]
1013040	Sheep kidney	1	5	5	Recommended [(f)]
1014010	Goat meat	0.05*	0.2	0.2	Recommended [(f)]
1014020	Goat fat	0.05*	0.2	0.2	Recommended [(f)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1014030	Goat liver	0.05*	5	5	Recommended (f)
1014040	Goat kidney	1	5	5	Recommended (f)
1016010	Poultry meat	0.05*	0.05*	0.05*	Recommended (a)
1016020	Poultry fat	0.05*	0.05*	0.05*	Recommended (a)
1016030	Poultry liver	0.05*	0.05*	0.05*	Recommended (a)
1020010	Ruminant milk	0.01*	0.01	0.01*	Recommended (e)
1030010	Birds eggs	0.01*	0.01*	0.01*	Recommended (a)
-	Other products of plant and animal origin	See App. C.1	-	-	Further consideration needed (i)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(**): All citrus uses registered in Codex are post-harvest.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is not higher than the existing CXL (combination C-VII in Appendix D).
(c): MRL is derived from the existing CXL, which is not sufficiently supported by data (in the absence of a fully validated analytical method for high oil content commodities) but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(d): MRL is derived from the existing CXL, which is not sufficiently supported by data (in the absence of a fully validated analytical method for high oil content commodities) but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(e): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(g): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(h): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

KEY WORDS

2,4-D, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, phenoxy acetic, herbicide.

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting as well as the review of pesticide MRLs at European level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As 2,4-D was included in Annex I to the above mentioned directive on 01 October 2002, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-483 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated while MRLs set out in Regulation (EC) No 396/2005 should accommodate for all uses authorised within the EU as well as uses authorised in third countries having a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

Greece, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for 2,4-D. The requested information was submitted to EFSA on 19 November 2008 and subsequently checked for completeness. On 26 March 2010, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 19 April 2011 and submitted to Member States (MS) for commenting. All MS comments received by 24 June 2011 were considered by EFSA for finalization of the reasoned opinion.

[4]Commission Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[5]Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

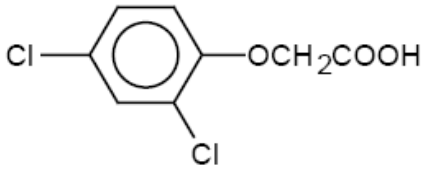
TERMS OF REFERENCE

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

2,4-D is the ISO common name for (2,4-dichlorophenoxy) acetic acid (IUPAC). 2,4-D may be manufactured as different variants such as salts (e.g. dimethylamine salt) and esters (e.g. 2-ethylexyl ester), but 2,4-D (acid compound) is considered as the active component.



2,4-D, its salts and its esters belong to the group of phenoxy acetic compounds. 2,4-D acid is a selective, systemic herbicide readily absorbed by leaves and roots, with a growth regulating activity at lower application rates. 2,4-D is used for post-emergence control of broad leaved weeds in agriculture and horticulture. It induces uncontrolled cell division in the plant tissues which causes such a disproportion between assimilation performed and water balance on the one hand, and the normal vegetative growth process on the other hand, that eventually the plant dies. Esters and salts of 2,4-D are rapidly converted in its acid form resulting in the same activity as 2,4-D.

2,4-D was evaluated in the framework of Directive 91/414/EEC with Greece being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were outdoor treatments of winter cereals (wheat, barley and rye) at a rate of 0.9 kg a.s./ha, spring cereals (wheat and barley) at a rate of 0.42 kg a.s./ha, pasture and seed grasses at a rate of 1.5 kg a.s./ha and fallow lands at a rate of 3 kg a.s./ha. These uses were supported both in northern and southern Europe. Following the peer review, which was carried out under the supervision of the European Commission, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2001/103/EC[6], entering into force on 01 October 2002. According to Regulation (EU) No 540/2011[7], 2,4-D is deemed to have been approved under regulation (EC) No 1107/2009[8] as well. This approval is restricted to uses as a herbicide only.

EU MRLs for 2,4-D in products of plant and animal origin have been set for the first time in 2002 by means of Directive 2002/97/EC[9]. These MRLs were based on the uses authorised within the EC at that time and have been transferred to Annex II of Regulation (EC) No 396/2005 without further

[6]Commission Directive 2001/103/EC of 28 November 2001, OJ L 313, 30/11/2001, p. 37-39.
[7] Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.06.2011, p. 1-186
[8] Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p.1-50
[9]Commission Directive 2002/97/EC of 16 December 2002, OJ L343, 18/12/2002, p. 23-30.

amendments. Additional MRLs for commodities that were not covered by the former European MRL legislation are established in Annex III B of the Regulation. These temporary MRLs were derived from the MRLs that have been set at national level before the Regulation entered into force. All existing EU MRLs, which are established for the sum of 2,4-D and its esters expressed as 2,4-D, are summarized in Appendix C.1 to this document. CXLs for 2,4-D were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to parent compound only.

For the purpose of this MRL review, the critical uses of 2,4-D currently authorized within the EU have been collected by the RMS and reported in the PROFile (see Appendix A). They include soil and foliar applications on a wide range of crops in outdoor conditions. Local treatment on citrus fruits is also reported but it is not clear to EFSA what kind of application it refers to. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by Greece, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Greece, 1996, 1997, 2000, 2001), the Review Report on 2,4-D (EC, 2001), the JMPR Evaluation reports (FAO, 1998, 2001) and the French evaluation report submitted during the Member State consultation (France, 2011a, 2011b). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[10] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2004, 2010a, 2010b, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD and its ILV were evaluated and validated in plant matrices for the determination of 2,4-D and its salts, with an LOQ of 0.05 mg/kg for the sum of the compounds in dry commodities (wheat). However, as this method is using diazomethane in its derivatization step, it cannot be reported as enforcement method.

In addition, an analytical method using GC-ECD was evaluated and validated in plant matrices for the determination of 2,4-D and its salts, with an LOQ of 0.01 mg/kg for the sum of the compounds in dry (wheat, rice, sorghum, corn) and high water content (sugar cane, grass rangeland) and high oil (soybean) commodities (Greece, 1996). Nevertheless, no ILV was available for this method.

During the Member State Consultation, France provided an additional analytical method using GC-MS which does not require diazomethane for the derivatization step. This method was evaluated and validated in plant matrices for the determination of 2,4-D and its salts, with an LOQ of 0.05 mg/kg for the sum of the compounds in dry (wheat), high water commodities (grass) and straw. An ILV was also available (France, 2011b).

Moreover, it must be mentioned that a validated method using GC-MS is also available in the JMPR report for the determination of 2,4-D and its salts in acidic commodities (raw citrus fruit) with an LOQ of 0.05 mg/kg (FAO, 2001).

[10] Regulation (EU) No546/2011 of 10 June 2011, OJ L 155, 11.06.2011, p.127-175

All the methods cited above include a hydrolysis step and has therefore always been considered adequate for the analysis of esters and conjugates as well. Nevertheless, the hydrolysis step was never formally validated. In order to be in compliance with the current guidance documents (EC, 2010b) and considering that all available methods were assessed before this new guidance document came into force, further validation of this hydrolysis step is considered desirable.

For information, the multi-residue QuEChERS method in combination with HPLC-MS/MS is also available to dose parent 2,4-D with an LOQ of 0.01 mg/kg for high water content, acidic and dry commodities (EURL, 2011). A detailed description of the QuEChERS method is reported by CEN (2008) but this method does not include hydrolysis step of esters and conjugates; it is therefore not suitable for enforcement of this substance according to its complete residue definition.

Table 1-1: Recovery data for the analysis o.f 2,4-D in different crop groups using the QuEChERS method in combination with LC-MS/MS (EURL, 2011)

Commodity group	Spiking levels (mg/kg)		Recoveries			No of labs
	Min.	Max.	Mean (%)	RSD (%)	n	
Acidic	0.01	0.25	90	23	215	8
Watery	0.005	0.25	91	23	328	8
Dry (cereals, pulses)	0.01	0.1	89	18	106	8

Hence it is concluded, according to overall availability of methods, that the sum of 2,4-D, its salts, its esters and conjugates (only the conjugates obtained by alkaline hydrolysis step), expressed as 2, 4-D can be enforced in food of plant origin with an LOQ of at least 0.05 mg/kg in high water, dry and acidic commodities. However, independent laboratory validation of this LOQ in high oil content commodities is still required and a validation of the hydrolysis step for the analysis of esters and conjugates of 2,4-D is also desirable.

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

During the peer review under Directive 91/414/EEC, two analytical methods using GC-ECD confirmed by GC-MS were evaluated and validated in food of animal origin for the determination of 2,4-D and its salts, with an LOQ of 0.05 mg/kg for poultry and beef muscle, fat, liver and kidney and an LOQ of 0.01 mg/kg for milk and eggs. No ILV for both methods have been submitted and should therefore be provided (Greece, 2000). The method includes a hydrolysis step and has therefore always been considered adequate for the analysis of esters and conjugates as well. Nevertheless, the hydrolysis step was never formally validated. In order to be in compliance with the current guidance documents (EC, 2010b) and considering that this method was assessed before this new guidance document came into force, further validation of this hydrolysis step is considered desirable.

Hence it is concluded that the sum of 2,4-D, its salts, its esters and conjugates, expressed as 2,4-D can be enforced in food of animal origin with an LOQ of 0.05 mg/kg for poultry and beef muscle, fat, liver and kidney and an LOQ of 0.01 mg/kg for milk and eggs. Nevertheless, a validation of the hydrolysis step for the analysis of esters and conjugates of 2,4-D is still desirable.

2. Mammalian toxicology

The toxicological assessment of 2,4-D was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission from studies carried out with 2,4-D ester and 2,4-D acid (2001). These toxicological reference values, expressed as 2,4-D acid, are summarized in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
2,4-D (acid)					
ADI	EC	2001	0.05 mg/kg bw/d	Long term studies on rats and mice	100
ARfD	EC	2001	Not required.		

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of 2,4-D was investigated for foliar applications on cereals (wheat) and root and tuber vegetables (potato) and for soil treatment in fruits and fruiting vegetables (apple). Metabolism of 2,4-D was also investigated for local treatments by injection in plants or cell cultures of pulses and oilseeds (soybean), and cereals (maize) (Greece, 1996). Data are summarized in table 3-1.

In apples and potatoes, residues were too low for identification (0.009 mg 2,4 D eq./kg and 0.005 mg 2,4 D eq./kg respectively). In wheat grain, almost half of the TRR was associated with natural products (protein, starch and cellulose fractions). The remaining residue consisted primarily of polar unknowns and unextractable compounds. Parent 2,4-D accounted for 6 % of the TRR and was the only identified component. In wheat forage and straw, parent 2,4-D was the major component of the total residue, since 72 to 77% of the TRR are identified as free or conjugated parent compound. The remaining residue comprised a large number of distinct metabolites, out of which 4-OH-2,5-D[11] was the major metabolite of 2,4-D. This metabolite results from the shift of one chlorine atom of the phenyl ring of 2,4-D and its replacement by a hydroxy group; it accounted for 8 % of the TRR. Other metabolites were defined as hydroxylated derivatives of 2,4-D and unknowns, none of them exceeding 2.5 % of the TRR. Following injection of 2,4-D into the stem or into the callus, it was shown that metabolic pathways in soybean and maize plants were quite similar to the one observed in wheat straw and forage, i.e. conjugation of 2,4-D, and, to a lesser extent, hydroxylation of the phenyl ring. Based on these studies, it is concluded that metabolic pathway is similar in all categories of crop.

Consequently, as 2,4-D is commercialised under a wide variety of salts and esters and metabolism studies demonstrated that the final residue in plants comprises both esters and 2,4-D in its acid form,

[11] 4-OH-2,5-D: 4-hydroxy-2,5-dichlorophenoxyacetic acid. See Appendix E.

the residue for both enforcement and risk assessment in all plant commodities is defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D. According to the RMS, validated analytical methods for enforcement of the proposed residue definition are available, except in high oil content commodities where an ILV is still missing (see also section 1.1). Considering that the use of 2,4-D is also supported in almonds and hazelnuts, this ILV is required.

It is noted that the JMPR proposed to define the residue for both enforcement and risk assessment as 2,4-D (parent compound) only. Nevertheless, the difference in residue definitions proposed by JMPR and EFSA is not expected to impact the outcome of the risk assessment because, although not explicitly mentioned in the residue definitions of the JMPR, CXLs for 2,4-D also include all salts, esters and conjugates. Indeed, analytical methods reported by JMPR hydrolyse esters, conjugates and salts of 2,4-D into the acid form.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetables	Apple	U-^{14}C-phenyl labelled	Application around the trunk	2.13 kg /ha	2	56	-
Root and tuber vegetables	Potato	U-^{14}C-phenyl labelled	Foliar	0.07 kg/ha	2	82	-
	Potato	U-^{14}C-phenyl labelled	Foliar	0.14 kg/ha 0.28 kg/ha	2	29	-
Pulses and oilseeds	Soybean	1-^{14}C-2,4-D	Injection, G	21 µg/plant or callus	1	Plants: 14 Callus: 7	-
Cereals	Wheat	U-^{14}C-phenyl labelled	Foliar	1.68 kg/ha	1	0, 10, 28, 49	-
	Wheat	Unlabelled	Foliar, F	0.50 kg/ha	1	1, 2, 3, 5, 9, 19, 35	-
	Maize	1-^{14}C-2,4-D	Injection, G	21 µg/plant or callus	1	Plants: 14 Callus: 7	-

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

3.1.1.2. Magnitude of residues

According to the RMS, the active substance 2,4-D is authorised for soil and foliar applications in a large number of crops (see Appendix A). 2,4-D is also authorised for local treatment in oranges. To assess the magnitude of 2,4-D residues resulting from these GAPs, EFSA considered all residues trials reported in the PROFile by the RMS, including residues trials evaluated in the framework of the peer review (Greece, 1997, 2000, 2001), and additional data submitted during the Member State consultation (France, 2011a). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarized in Table 3-2.

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

Commodity	Region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)	Risk assessment (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)					
Oranges	SEU	Outdoor	-	-	-	-	-	-	-
Almonds Hazelnuts	NEU	Outdoor	3 x <0.01	3 x <0.01	0.01	0.01	0.05* (tentative)	1.00	Extrapolation from combined data sets on pome fruits and stone fruits (see below; France, 2011a). In the absence of validated analytical method for enforcement in high oil content commodities, only a tentative MRL can be derived (see also body text and section 1.1).
	SEU	Outdoor	3 x <0.01	3 x <0.01	0.01	0.01	0.05* (tentative)	1.00	
Pome fruit Stone fruit	NEU	Outdoor	3 x <0.01	3 x <0.01	0.01	0.01	0.05*	1.00	Trials carried out with an application rate of 0.96 kg as/ha. Combined data set on apple, pears and plums (France, 2011a).
	SEU	Outdoor	3 x <0.01	3 x <0.01	0.01	0.01	0.05*	1.00	Trials carried out with an application rate of 0.96 kg as/ha. Combined data set on apples, peaches, and plums (France, 2011a). Not authorised on quinces, medlar and loquat in SEU.

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)	Risk assessment (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)					
Strawberries	NEU	Outdoor	-	-	0.05	0.05	0.05*	1.00	Considering that the application is made on plants after the fruits were harvested and that no residues are expected in rotational crops, residues exceeding the enforcement LOQ are not expected.
Asparagus	SEU/ NEU	Outdoor	-	-	0.05	0.05	0.05*	1.00	Considering that the application is made after harvest and that no residues are expected in rotational crops, residues exceeding the enforcement LOQ are not expected.
Barley grain Oats grain Rye grain Wheat grain	SEU	Outdoor	8 x <0.05	8 x <0.05	0.05	0.05	0.05*	1.00	Trials on barley (3) and wheat (5) compliant with GAP (France, 2011a).
	NEU	Outdoor	11 x <0.05	11 x <0.05	0.05	0.05	0.05*	1.00	Trials on barley (7) and wheat (4) compliant with the GAP (France, 2011a).
Buckwheat grain	NEU	Outdoor	-	-	-	-	-	-	-

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)	Risk assessment (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)					
Maize grain Millet grain Sorghum grain	SEU	Outdoor	2 x <0.05	2 x <0.05	0.05	0.05	0.05*	1.00	Residue trials on maize performed with an application rate of 1.2 kg a.s./ha (compliant with GAP on maize and sorghum). Considering that residues are below the LOQ, extrapolation to less critical GAP on millet is also acceptable (France, 2011a).
	NEU	Outdoor	2 x <0.05	2 x <0.05	0.05	0.05	0.05*	1.00	
Sugar cane	SEU	Outdoor	9 x <0.01; 0.015	9 x <0.01; 0.015	0.01	0.015	0.05*	1.00	Trials compliant with GAP (France, 2011a). R_{max}= 0.02 R_{ber}= 0.02
Alfalfa	SEU/ NEU	Outdoor	-	-	-	-	-	-	-
Clover	SEU/ NEU	Outdoor	-	-	-	-	-	-	-

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)	Risk assessment (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)					
Grass	SEU	Outdoor	1; 3; 3.8; 7.2; 18; 19.8; 22; 26	1; 3; 3.8; 7.2; 18; 19.8; 22; 26	**12.6**	**26**	**50 (tentative)**	**1.00**	Trials compliant with the GAP. Results on dry weight basis were recalculated to fresh weight assuming a dry matter content of 20% for grass. R_{max}=44.07 R_{ber}=42.90
	NEU	Outdoor	2.4; 4.8; 7.2; 9.4; 9.4; 11.4; 16.4; 17.2	2.4; 4.8; 7.2; 9.4; 9.4; 11.4; 16.4; 17.2	9.4	17.2	30 (tentative)	1.00	Trials compliant with the GAP. Results on dry weight basis were recalculated to fresh weight assuming a dry matter content of 20% for grass. R_{max}=26.28 R_{ber}=30.30
Barley straw Oats straw Rye straw Wheat straw	SEU	Outdoor	2 x <0.05; 0.06; 2 x 0.08; 0.44; 0.96; 1.23	2 x <0.05; 0.06; 2 x 0.08; 0.44; 0.96; 1.23	**0.08**	1.23	**2 (tentative)**	1.00	Trials on barley (3) and wheat (5) compliant with the GAP (France, 2011a). Rber: 1.66 Rmax: 1.87
	NEU	Outdoor	7 x <0.05; 0.06; 0.69; 0.83; 1.88	7 x <0.05; 0.06; 0.69; 0.83; 1.88	0.05	**1.88**	**2 (tentative)**	1.00	Trials on barley (7) and wheat (4) compliant with the GAP (France, 2011a). Rber: 1.38 Rmax: 1.99

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)	Risk assessment (sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D)					
Maize forage	SEU	Outdoor	<0.05; 0.06	<0.05; 0.06	**0.055**	**0.06**	**0.3 (tentative)**	**1.00**	Trials on immature maize compliant with the GAP (France, 2011a). Rber: 0.09 Rmax: 0.24
	NEU	Outdoor	2 x <0.05	2 x <0.05	0.05	0.05	0.05* (tentative)	1.00	Trials on immature maize compliant with the GAP (France, 2011a).

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

The number of residues trials and extrapolations were evaluated in view of the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). The following considerations were made by EFSA:

- Oranges: no residue trials are available to support the Spanish GAP. Therefore 8 residue trials complying with the southern GAP are required. Furthermore, further clarifications are needed for this GAP (application rate, PHI, intended use as herbicide or growth regulator). No MRL or risk assessment values are derived.

- Orchard trees (including tree nuts, pome fruits and stone fruits): Only 3 northern and 3 southern outdoor residues trials have been provided. Considering that the residue levels of the trials remain below the LOQ and the very low level of residues in the metabolism studies, no additional data are required. Appropriate risk assessment values can be derived for all these commodities and an MRL of 0.05* mg/kg can be derived on pome fruits and stone fruits. However, in the absence of validated analytical method for high oil content commodities (see also section 1.1), only a tentative MRL can be derived on almonds and hazelnuts.

- Strawberries: no residue trials are available to support the northern GAP. Nevertheless, considering that the application is made on plants after the fruits were harvested and that no residues are expected in rotational crops, residues exceeding the enforcement LOQ of 0.05 mg/kg are not expected. Consequently, a waiver for residue trials can be accepted.

- Asparagus: no residue trials are available to support the northern and southern GAPs. Nevertheless, considering that the application is made on plants after the asparagi are harvested and that no residues are expected in rotational crops, residues exceeding the enforcement LOQ of 0.01 mg/kg are not expected. Consequently, a waiver for residue trials can be accepted.

- Buckwheat: no residue trials are available to support the northern outdoor GAP. 4 residue trials are required. No MRL or risk assessment values are derived.

- Maize, millet and sorghum grain: only 2 northern and 2 southern outdoor residues trials are available. However, as they remain below the LOQ, no additional trial is considered necessary.

- Maize forage: only 2 northern and 2 southern outdoor residues trials are available. Considering that residues above the LOQ were quantified and that maize is a major crop in both northern and southern zones, 6 northern and 6 southern additional residues trials complying GAP are requested. In the absence of these trials, only tentative MRLs and risk assessment can be derived.

- Sugar cane: 10 US residue trials were provided. They were considered acceptable by the French authorities as they were performed under climatic conditions comparable to those of the French regions where sugar cane is grown (oversea departments). Application rates were significantly higher than the critical GAP: 2 applications instead of 1 and dose rates of 2240 g/ha or 4480 g/ha instead of 1140 g/ha. Residue levels in the sugarcane were <0.01 mg/kg in all trials except in one (0.015 mg/kg). It can therefore be concluded that all residue levels are below the enforcement LOQ of 0.05 mg/kg.

- Alfalfa: no residue trials are available to support the northern and the southern GAP. 4 residue trials complying with the GAPs are required for each area. No MRL or risk assessment values are derived.

- Clover: no residue trials are available to support the northern and the southern GAPs. 4 residue trials complying with the GAPs are required for each area. No MRL or risk assessment values are derived.

The number of supervised residues trials requested above may be reduced if residue levels are demonstrated to be below the LOQ.

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of 2,4-D was demonstrated for a period of 12 months under frozen conditions in high water content (sugar cane, wheat and maize forage), dry (wheat, sorghum and maize grain) and high oil content commodities (soybean seeds) (Greece, 2000). According to the RMS, all residue trials samples reported in the PROFile were stored in compliance with the above reported storage conditions, except for grass. It is highlighted however that, if residues trials on citrus fruits are provided in the future, a study investigating storage stability of 2,4-D in high acid content commodities might be required depending on the storage conditions of the residues trials samples.

Consequently, the available residues data are considered sufficient to derive adequate MRL proposals as well as risk assessment values for most of the commodities under assessment, except in almonds and hazelnuts where only a tentative MRL could be derived in the absence of an ILV of the analytical method; tentative MRLs were also derived for grass and cereal straws in view of the future need to set MRLs in feed items. For oranges, buckwheat, alfalfa and clover, the number of residues trials was too limited for deriving MRL proposals and risk assessment values.

3.1.1.3. Effect of industrial processing and/or household preparation

As quantifiable residues of 2,4-D are not expected in edible part of crops based on available residue data and total chronic exposure was found to represent less than 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing.

3.1.2. Rotational crops

All crops under consideration, except permanent crops (orchard trees and grass), may be grown in rotation but, according to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value calculated of 2,4-D, was 67.7 days which is below the trigger value of 100 days. Relevant soil metabolites were also not identified (Greece, 1997). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is not required and relevant residues in these crops are not expected.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

2,4-D is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-3. For grass hay and cereal bran, default processing factors of 4 and 8 respectively have been included in the calculation in order to consider potential concentration of residues in these commodities. For grass and maize silage, the default processing factor is in any case 1 while for apple pomace, no default processing factor was applied because esfenvalerate is applied early in the growing season (soil treatment) and residues are expected to be below the LOQ. For oranges, alfalfa, clover and all processed commodities thereof, no

values have been selected because no residue trials data are available for these crops. Nevertheless, it should be noted that the lack of residues trials in these crops are not expected to impact significantly the livestock dietary burden which is already driven by grass consumption mainly.

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

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D				
Grass (fresh & silage)	12.60	Median residue	26.00	Highest residue
Maize silage	0.055	Median residue	0.06	Highest residue
Apple pomace	0.01	Median residue	0.01	Highest residue
Grass (hay)	50.40	Median residue x 4	104.00	Highest residue x 4
Cereal grain	0.05	Median residue	0.05	Median residue
Maize grain	0.05	Median residue	0.05	Median residue
Cereal bran	0.40	Median residue x 8	0.40	Median residue x 8
Cereal straw	0.05	Median residue	1.88	Highest residue

The results of the calculations are reported in Table 3-4. The calculated dietary burdens for dairy ruminants, meat ruminants and pigs were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore only required in these groups of livestock.

Table 3-4: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D					
Dairy ruminants	4.727	2.290	Grass (fresh)	131.31	Yes
Meat ruminants	5.571	2.700	Grass (fresh)	129.57	Yes
Poultry	0.004	0.004	Wheat (bran)	0.07	No
Pigs	0.783	0.381	Grass silage	19.59	Yes

3.2.2. Nature of residues

The nature of 2,4-D residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC. Reported metabolism studies include one study in lactating goats and one in laying hens using ^{14}C-phenyl ring labelled 2,4-D (Greece, 1997).

Table 3-5: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	U-^{14}C-phenyl labelled	1	24	3	Milk	Daily
						Urine and faeces	Daily
						Tissues	After sacrifice
Laying poultry	Hens	U-^{14}C-phenyl labelled	15	1.4	7	Eggs	Daily
						Excreta	Daily
						Tissues	After sacrifice

A single lactating goat was dosed at 24 mg/kg bw/d for 3 consecutive days, corresponding to the 4N exposure of meat ruminants. For poultry there is in principle no necessity to establish a residue definition because the calculated dietary burden of poultry to 2,4-D residues amounted to less than 0.1 mg/kg DM based on the available residue data. Nevertheless, a metabolism study with laying hens is reported in the DAR. 15 laying hens were dosed at 1.4 mg/kg bw/d for 7 days (Greece, 1997).

When fed to livestock, 2,4-D is extensively excreted in urine (90 % or more of the TRR). Degradation into dichlorophenol and into dichloroanisole is observed but it affects a relatively small portion of the administered compound, which is primarily recovered as unchanged or conjugated forms of 2,4-D.

Less than 0.1 % of the administrated radioactivity was recovered in milk, eggs and tissues. Parent 2,4-D was the major compound (38 % of the TRR in milk, 23 % of the TRR in eggs, 25 % of the TRR in chicken fat, 18 % of the TRR in chicken liver and 76 % of the TRR in chicken kidney). The low concentration of residues in most edible fractions impeded their identification. However, in others fractions some metabolites were identified, among them 4-chlorophenoxyacetic acid[12] (6.9 % of the TRR in milk) and 2,4-dichlorophenol[13] (5 % of the TRR in milk; 7.3 % of the TRR in eggs and 4 % of the TRR in chicken liver). Residues levels in kidney were higher than in other tissues with concentrations of 1.44 and 0.71 mg 2,4-D eq./kg in goat and hen respectively.

The metabolic patterns identified for goats and hens were consistent with the rat metabolism and therefore considered applicable to pigs as well. However, metabolism studies in livestock were performed with 2,4-D under its acid form and it is therefore not clear whether esters will be completely hydrolysed in livestock commodities. Considering that livestock will be exposed to different salts and esters of 2,4-D, it is therefore desirable, according to EFSA, to use the same residue definition as for plant commodities for both enforcement and risk assessment: sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D. Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.2). There is some evidence that salts and esters of 2,4-D might be extensively hydrolysed through the livestock metabolism. However, this was not properly demonstrated in the available studies. Besides, the available analytical methods will anyhow determine 2,4-D, its salts and esters all together. Therefore, a modification of the residue definition is not relevant.

[12] 4-CPA : 4-chlorophenoxyacetic acid. See Appendix E.
[13] 2,4-DCP : 2,4-dichlorophenol. See Appendix E.

It is also noted that the JMPR proposed to define the residue for both enforcement and risk assessment as 2,4-D (parent compound) only. Nevertheless, the differences in residue definitions proposed by JMPR and EFSA is not expected to impact the outcome of the risk assessment because, although not explicitly mentioned in the residue definitions of the JMPR, CXLs for 2,4-D also include all salts, esters and conjugates. Indeed, analytical methods reported by JMPR hydrolyse esters, conjugates and salts of 2,4-D into the acid form.

3.2.3. Magnitude of residues

During the peer review of Directive 91/414/EEC the magnitude of 2,4-D residues in livestock was investigated in a feeding study on lactating cows (Greece, 2000). Four groups of lactating cows, each consisting of three animals, were dosed for 28 days with 2,4-D at levels of 52, 105, 210 and 312 mg a.s./kg bw/d. Results of the livestock feeding study for the three lowest doses are summarized in Table 3-6.

Residues of 2,4-D were detected in most milk and tissues samples analysed. The highest relative residue level of the various cattle matrices analysed was found in kidney, followed by liver, fat muscle and milk. The magnitude of residues was generally found to be dose-dependant.

The storage stability of 2,4-D in animal products was evaluated under the peer review of Directive 91/414/EEC (Greece, 2000). Studies demonstrated storage stability of 2,4-D in milk and beef tissues for up to 4 months when stored deep frozen. Samples of the livestock feeding study were stored less than 1 month according to the RMS; degradation of residues during storage of the samples is therefore not expected.

Based on the available livestock feeding study, MRLs and risk assessment values in ruminant and pig products were calculated in compliance with the latest international recommendations on this matter (FAO, 2009). The feeding doses were exaggerated, and it can be concluded that significant residues in edible matrices of ruminants and pigs are not expected except in ruminant fat and kidney as well as pig kidney. It is therefore concluded that MRLs for these commodities can be established at the LOQ, except for ruminant fat, ruminant kidney and pig kidney where higher MRLs are proposed. For poultry, no MRLs are proposed as a significant intake was not identified for this type of livestock.

Table 3-6: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition 1: Sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D												
Pig meat[(a)]	0.381	0.783	52.58	3	0.21	0.24	See results for enforcement residue definition		0.050	0.050	0.05*	1
			105.10	3	0.41	0.51						
			210.10	3	0.76	1.10						
Pig fat[(a)]			52.58	3	0.42	0.51			0.050	0.050	0.05*	1
			105.10	3	0.59	0.75						
			210.10	3	2.50	3.60						
Pig liver[(a)]			52.58	3	0.12	0.20			0.050	0.050	0.05*	1
			105.10	3	1.90	2.40						
			210.10	3	3.00	3.50						
Pig kidney[(a)]			52.58	3	3.80	6.50			0.050	0.097	0.1	1
			105.10	3	14	18						
			210.10	3	17	29						
Ruminant meat	2.700	5.571	52.58	3	0.21	0.24			0.050	0.050	0.05*	1
			105.10	3	0.41	0.51						
			210.10	3	0.76	1.10						

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ruminant fat	2.700	5.571	52.58	3	0.42	0.51	See results for enforcement residue definition		0.050	0.054	0.1	1
			105.10	3	0.59	0.75						
			210.10	3	2.50	3.60						
Ruminant liver			52.58	3	0.12	0.20			0.050	0.050	0.05*	1
			105.10	3	1.90	2.40						
			210.10	3	3.00	3.50						
Ruminant kidney			52.58	3	3.80	6.50			0.195	0.689	1	1
			105.10	3	14	18						
			210.10	3	17	29						
Milk	2.290	4.727	52.58	21	0.04 (b)	0.07 (b)			0.01	0.01	0.01*	1
			105.10	27	0.12 (c)	0.18 (c)						
			210.10	27	0.29 (c)	0.59 (c)						

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): The feeding studies were carried out with ruminants, according to the metabolism pathway, an extrapolation between ruminant and pig is acceptable
(b): mean residue level from day 7 until day 28 (3 cows, 7 sampling days)
(c): mean residue level from day 1 until day 28 (3 cows, 9 sampling days)

4. Consumer risk assessment

In the framework of this review, only the uses of 2,4-D reported by the RMS in Appendix A were considered but the use of 2,4D was previously also assessed by the JMPR (FAO,1998, 2001). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarized in Table 4-1. The (tentative) median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3.The contributions of other commodities, where the use of 2,4-D is not authorised, were not included in the calculation.

Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Oranges	1	EU MRL [(b)]
Almonds	0.01	Median residue (<LOQ) (tentative) [(c)]
Hazelnuts	0.01	Median residue (<LOQ) (tentative) [(c)]
Pome fruit	0.01	Median residue (<LOQ) [(a)]
Stone fruit	0.01	Median residue (<LOQ) [(a)]
Strawberries	0.05	Median residue (=LOQ) [(a)]
Asparagus	0.05	Median residue (=LOQ) [(a)]
Barley, oats, rye, wheat grain	0.05	Median residue (=LOQ) [(a)]
Buckwheat	0.05	EU MRL (=LOQ) [(b)]
Maize, millet, sorghum grain	0.05	Median residue (=LOQ) [(a)]
Sugar cane	0.01	Median residue (<LOQ) [(a)]
Swine meat	0.05	Median residue (=LOQ) [(a)]
Swine fat	0.05	Median residue (=LOQ) [(a)]
Swine liver	0.05	Median residue (=LOQ) [(a)]
Swine kidney	0.05	Median residue [(a)]
Ruminant meat	0.05	Median residue (=LOQ) [(a)]
Ruminant fat	0.05	Median residue (=LOQ) [(a)]
Ruminant liver	0.05	Median residue (=LOQ) [(a)]
Ruminant kidney	0.20	Median residue [(a)]

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Ruminant milk	0.01	Median residue (=LOQ) [a]

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data; the existing EU MRL is used for indicative exposure calculations (also assuming the existing residue definition).
(c): Use reported by the RMS is not fully supported by data (an ILV for the analytical method for enforcement in high oil content commodities is required) but the risk assessment value derived in section 3 is used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for 2,4-D (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for German children, representing 8.8 % of the ADI.

Based on the above calculations, EFSA concludes that the uses of 2,4-D on crops fully supported by data (footnote a in Table 4-1), are acceptable with regard to consumer exposure. For all remaining crops, major uncertainties remain due to the data gaps identified in section 3, but considering tentative MRLs or the existing EU MRLs in the exposure, calculation did not indicate a risk to consumers.

4.2. Consumer risk assessment with consideration of the existing CXLs

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

CXLs for 2,4-D have been established for 2,4-D only, whereas MRLs have been established for the sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D. Nevertheless, according to EFSA, the difference in residues definition proposed by JMPR and EFSA is not expected to impact on the outcome of the risk assessment. Indeed, although not explicitly mentioned in the residue definitions, CXLs for 2,4-D also include all salts, esters and conjugates and analytical methods reported by JMPR hydrolyse esters, conjugates and salts of 2,4-D into the acid form.

At European level there are also no agreed extrapolations for commodities of animal origin between animals (from ruminants to horses and other farm animals) and between commodities (from a single offal to all edible offals). Therefore there is no need to consider the CXLs that have been established in horses and other farm animals and in edible offals (other than liver and kidney). Considering that the CAC did not establish specific MRLs for fat, EFSA assumed that the CXL for meat applies to fat as well.

Chronic exposure calculation was performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference value derived for 2,4-D (see Table 2-1); detailed results of the calculations are presented as EU/Codex scenario in Appendix B.2. The highest chronic exposure was calculated for Dutch children, representing 12.1 % of the ADI.

Based on the above calculations, EFSA concludes that the CXLs fully supported by data (footnote c in Table 4-2) are not expected to be of concern for European consumers. For the remaining CXLs, uncertainties remain as they are not well supported by data. Nevertheless, inclusion of these CXLs in the exposure calculation did not indicate any risk to European consumers.

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Citrus fruit	0.31	Median residue (CXL) [(c)]
Tree nuts, except chestnuts	0.05	Median residue (CXL) (tentative) [(d)]
Chestnuts	0.05	Median residue (CXL) [(c)]
Pome fruit	0.01	Median residue (<LOQ) [(a)]
Stone fruit	0.01	Median residue (<LOQ) [(a)]
Berries and small fruit	0.05	Median residue (CXL) [(c)]
Potatoes	0.05	Median residue (CXL) [(c)]
Sweet corn	0.05	Median residue (CXL) [(c)]
Asparagus	0.05	Median residue (=LOQ) [(a)]
Soya bean	0.01	Median residue (CXL) (tentative) [(d)]
Barley and oats grain	0.05	Median residue (=LOQ) [(a)]
Buckwheat grain	0.05	EU MRL (=LOQ) [(b)]
Maize, millet, sorghum grain	0.05	Median residue (=LOQ) [(a)]
Rice grain	0.01	Median residue (CXL) [(c)]
Wheat and rye grain	0.22	Median residue (CXL) [(c)]
Sugar cane	0.01	Median residue (<LOQ) [(a)]
Swine meat	0.13	Median residue (CXL) [(c)]
Swine fat	0.13	Median residue (CXL) [(c)]
Swine liver	2.75	Median residue (CXL) [(c)]
Swine kidney	2.75	Median residue (CXL) [(c)]
Ruminant meat	0.13	Median residue (CXL) [(c)]
Ruminant fat	0.13	Median residue (CXL) [(c)]
Ruminant liver	2.75	Median residue (CXL) [(c)]
Ruminant kidney	2.75	Median residue (CXL) [(c)]
Poultry meat	0.05	Median residue (CXL) [(c)]
Poultry fat	0.05	Median residue (CXL) [(c)]
Poultry liver	0.05	Median residue (CXL) [(c)]
Ruminant milk	0.01	Median residue (=LOQ) [(a)]
Birds eggs	0.01	Median residue (CXL) [(c)]

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data; the existing EU MRL is used for indicative exposure calculations (also assuming the existing residue definition).
(c): CXL is supported by data; the corresponding risk assessment values are used for the exposure calculations.
(d): CXL is supported by data but is considered tentative in the absence of fully validated analytical method for high oil content commodities; the corresponding risk assessment value is used for indicative exposure calculations.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of 2,4-D was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.05 mg/kg bw/d which was established for 2,4-D acid. An ARfD was not required.

Primary crop metabolism of 2,4-D was investigated following foliar applications on wheat and potato and following soil treatment in apples, hereby covering 3 different crop groups. Metabolism of 2,4-D was also investigated for local treatments by injection in plants or cell cultures of soybean and maize. Metabolic patterns in the different studies were shown to be similar and the relevant residue for both enforcement and risk assessment in all plant commodities could be defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D. Validated analytical methods for enforcement of the residue definition in foods of plant origin are available with an LOQ of at least 0.05 mg/kg in high water content, dry and acid commodities. An analytical method for the enforcement of 2,4-D, its salts, its esters and conjugates in high oil content commodities is also available but its ILV is still required.

Regarding the magnitude of residues, the available residues data are considered sufficient to derive adequate MRL proposals as well as risk assessment values for most of the commodities under assessment, except in almonds and hazelnuts where only a tentative MRL could be derived in the absence of an ILV of the analytical method; tentative MRLs were also derived for grass and cereal straws in view of the future need to set MRLs in feed items. For oranges, buckwheat, alfalfa and clover, the number of residues trials was too limited for deriving MRL proposals and risk assessment values.

As quantifiable residues of 2,4-D are not expected in edible part of crops and total chronic exposure represents less than 10% of the ADI, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

2,4-D was demonstrated to decline rapidly in soil. Further investigation of residues in rotational crops is therefore not required and relevant residues in these crops are not expected.

Based on the uses reported by the RMS, significant intakes were calculated for dairy ruminant, meat ruminants and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement and risk assessment was defined as the sum of 2,4-D, its salts, esters and conjugates, expressed as 2,4-D. A validated analytical method for enforcement of the residue definition is also available with an LOQ of 0.01 mg/kg in milk and eggs, and an LOQ of 0.05 mg/kg in meat, liver, kidney and fat. Based on the available livestock feeding study in ruminants, significant residues in edible matrices of ruminants and pigs are not expected, except in ruminant fat and kidney as well as pig kidney. It is therefore concluded that MRLs for these commodities can be established at the LOQ, except for ruminant fat, ruminant kidney and pig kidney where higher MRLs are proposed. For poultry, no MRLs are proposed as a significant intake was not identified for this type of livestock.

Chronic consumer exposure resulting from the MRL proposed in the framework of this review was calculated using revision 2 of the EFSA PRIMo and no exceedance of the ADI was identified; the highest chronic exposure was calculated for German children, representing 8.8 % of the ADI. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for 2,4-D. Additional calculations of the consumer exposure, including

these CXLs, were therefore performed and no exceedance of the ADI was identified. In this case, the highest chronic exposure was calculated for Dutch children, representing 12.1 % of the ADI.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see table below for a summary). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain existing EU MRLs still need to be confirmed by the following data:

- an ILV for enforcement of residues in high oil content commodities;
- 4 residues trials complying with the northern GAP on buckwheat.

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

- 8 residues trials complying with the Spanish GAP on oranges and further clarification about this GAP;
- 6 residues trials complying with the southern GAP and 6 additional residues trials complying with the northern GAP on maize forage;
- 4 residue trials complying with the southern GAP and 4 residue trials complying with the northern GAP on alfalfa;
- 4 residue trials complying with the southern GAP and 4 residue trials complying with the northern GAP on clover.

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

A minor deficiency was also identified in the assessment but this deficiency is not expected to impact either on the validity of the 'Recommended' MRLs or on the national authorisations. A validation of the hydrolysis step for the analysis of esters and conjugates of 2,4-D in plant and animals (data gap resulting from the new guidance document) is therefore considered desirable but not essential.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: Sum of 2,4-D, its salts, esters and conjugates expressed as 2,4-D					
110010	Grapefruits	1	1(**)	1	Recommended [a]
110020	Oranges	1	1(**)	1	Recommended [b]
110030	Lemons	1	1(**)	1	Recommended [a]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
110040	Limes	1	1(**)	1	Recommended (a)
110050	Mandarins	1	1(**)	1	Recommended (a)
120010	Almonds	0.05*	0.2	0.2	Further consideration needed (c)
120020	Brazil nuts	0.05*	0.2	0.2	Further consideration needed (d)
120030	Cashew nuts	0.05*	0.2	0.2	Further consideration needed (d)
120040	Chestnuts	0.05*	0.2	0.2	Recommended (a)
120050	Coconuts	0.05*	0.2	0.2	Further consideration needed (d)
120060	Hazelnuts	0.05*	0.2	0.2	Further consideration needed (c)
120070	Macadamia	0.05*	0.2	0.2	Further consideration needed (d)
120080	Pecans	0.05*	0.2	0.2	Further consideration needed (d)
120090	Pine nuts	0.05*	0.2	0.2	Further consideration needed (d)
120100	Pistachios	0.05*	0.2	0.2	Further consideration needed (d)
120110	Walnuts	0.05*	0.2	0.2	Further consideration needed (d)
130000	Pome fruit	0.05*	0.01*	0.05*	Recommended (e)
140000	Stone fruit	0.05*	0.05*	0.05*	Recommended (e)
151000	Table and wine grapes	0.05*	0.1	0.1	Recommended (a)
152000	Strawberries	0.05*	0.1	0.1	Recommended (f)
153000	Cane fruit	0.05*	0.1	0.1	Recommended (a)
154000	Other small fruit & berries	0.05*	0.1	0.1	Recommended (a)
211000	Potatoes	0.05*	0.2	0.2	Recommended (a)
234000	Sweet corn	0.05*	0.05*	0.05*	Recommended (a)
270010	Asparagus	0.05*	-	0.05*	Recommended (g)
401070	Soya bean	0.1*	0.01*	0.01*	Further consideration needed (d)
500010	Barley grain	0.05*	-	0.05*	Recommended (g)
500020	Buckwheat grain	0.05*	-	0.05*	Further consideration needed (h)
500030	Maize grain	0.05*	0.05	0.05*	Recommended (e)
500040	Millet grain	0.05*	-	0.05*	Recommended (g)
500050	Oats Grain	0.05*	-	0.05*	Recommended (g)
500060	Rice grain	0.05*	0.1	0.1	Recommended (a)
500070	Rye grain	0.05*	2	2	Recommended (f)
500080	Sorghum grain	0.05*	0.01*	0.05*	Recommended (e)
500090	Wheat grain	0.05*	2	2	Recommended (f)
900020	Sugar cane	0.05*	0.05	0.05*	Recommended (e)
1011010	Swine meat	0.05*	0.2	0.2	Recommended (f)
1011020	Swine fat (free or lean meat)	0.05*	0.2	0.2	Recommended (f)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1011030	Swine liver	0.05*	5	5	Recommended (f)
1011040	Swine kidney	1	5	5	Recommended (f)
1012010	Bovine meat	0.05*	0.2	0.2	Recommended (f)
1012020	Bovine fat	0.05*	0.2	0.2	Recommended (f)
1012030	Bovine liver	0.05*	5	5	Recommended (f)
1012040	Bovine kidney	1	5	5	Recommended (f)
1013010	Sheep meat	0.05*	0.2	0.2	Recommended (f)
1013020	Sheep fat	0.05*	0.2	0.2	Recommended (f)
1013030	Sheep liver	0.05*	5	5	Recommended (f)
1013040	Sheep kidney	1	5	5	Recommended (f)
1014010	Goat meat	0.05*	0.2	0.2	Recommended (f)
1014020	Goat fat	0.05*	0.2	0.2	Recommended (f)
1014030	Goat liver	0.05*	5	5	Recommended (f)
1014040	Goat kidney	1	5	5	Recommended (f)
1016010	Poultry meat	0.05*	0.05*	0.05*	Recommended (a)
1016020	Poultry fat	0.05*	0.05*	0.05*	Recommended (a)
1016030	Poultry liver	0.05*	0.05*	0.05*	Recommended (a)
1020010	Ruminant milk	0.01*	0.01	0.01*	Recommended (e)
1030010	Birds eggs	0.01*	0.01*	0.01*	Recommended (a)
-	Other products of plant and animal origin	See App. C.1	-	-	Further consideration needed (i)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(**): All citrus uses registered in Codex are post-harvest.
(a): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(b): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is not higher than the existing CXL (combination C-VII in Appendix D).
(c): MRL is derived from the existing CXL, which is not sufficiently supported by data (in the absence of a fully validated analytical method for high oil content commodities) but for which no risk to consumers is identified; GAP evaluated at EU level, which is also not fully supported by data, would lead to a lower tentative MRL (combination E-V in Appendix D).
(d): MRL is derived from the existing CXL, which is not sufficiently supported by data (in the absence of a fully validated analytical method for high oil content commodities) but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(e): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(g): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(h): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(i): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on 2,4-D prepared by the rapporteur Member State Greece in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 19 November 2008. Last updated on 26 March 2010.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Almonds	*Prunus dulcis*	NEU	Outdoor	FR					Soil treatment - spraying				1				0,96	kg a.i./ha	n.a.	Application in automn or spring.
Hazelnuts	*Corylus avellana*	NEU	Outdoor	FR					Soil treatment - spraying				1				0,96	kg a.i./ha	n.a.	Application in automn or spring.
Apples	*Malus domesticus*	NEU	Outdoor	NL	ANNUAL AND PERENNIAL DICOTYL WEEDS	SL	500,0	g/L	Soil treatment - spraying				1			1,00	2,00	kg a.i./ha	n.a.	Application in automn or spring.
Pears	*Pyrus communis*	NEU	Outdoor	NL	ANNUAL AND PERENNIAL DICOTYL WEEDS	SL	500,0	g/L	Soil treatment - spraying				1			1,00	2,00	kg a.i./ha	n.a.	Application in automn or spring.
Quinces	*Cydonia oblonga*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Medlar	*Mespilus germanica*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Loquat	*Eriobotrya japonica*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Apricots	*Prunus armeniaca*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Cherries	*Prunus cerasus, Prunus avium*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Peaches	*Prunus persica*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Plums	*Prunus domestica*	NEU	Outdoor	IE	WEEDS		500,0	g/L	Soil treatment - spraying				1				1,40	kg a.i./ha	n.a.	Application in automn or spring.
Strawberries	*Fragaria x ananassa*	NEU	Outdoor	NL	ANNUAL AND PERENNIAL DICOTYL WEEDS	SL	103,0	g/L	Foliar treatment - spraying	91	0		1				1,44	kg a.i./ha	n.a.	Application after last harvest and before clearing up of spent strawberry crops
Asparagus	*Asparagus officinalis*	NEU	Outdoor	FR					Soil treatment - general (see also comment field)		0		1				0,80	kg a.i./ha	n.a.	Application is made after harvest of the asparagi, during the year preceeding the next harvest season.
Barley	*Hordeum spp.*	NEU	Outdoor	IE			500,0	g/L	Foliar treatment - spraying	30	31		1				1,00	kg a.i./ha	n.a.	
Buckwheat	*Fagopyrum esculentum*	NEU	Outdoor	LV	DICOTYL WEEDS	SC	160,8	g/L	Foliar treatment - spraying	0	9		1				0,72	kg a.i./ha	n.a.	
Maize	*Zea mays*	NEU	Outdoor	FR			600,0	g/L	Foliar treatment - spraying	21	26		1				1,20	kg a.i./ha	n.a.	
Millet	*Panicum spp.*	NEU	Outdoor	FR					Foliar treatment - spraying	21	26		1				0,72	kg a.i./ha	n.a.	
Oats	*Avena fatua*	NEU	Outdoor	IE			500,0	g/L	Foliar treatment - spraying	30	31		1				1,00	kg a.i./ha	n.a.	
Rye	*Secale cereale*	NEU	Outdoor	IE			500,0	g/L	Foliar treatment - spraying	30	31		1				1,25	kg a.i./ha	n.a.	
Sorghum	*Sorghum bicolor*	NEU	Outdoor	FR					Foliar treatment - spraying	21	26		1				1,20	kg a.i./ha	n.a.	
Wheat	*Triticum aestivum*	NEU	Outdoor	IE			500,0	g/L	Foliar treatment - spraying	30	31		1				1,25	kg a.i./ha	n.a.	
Alfalfa	*Medicago Sativa*	NEU	Outdoor	DE	DICOTYL WEEDS	SL	500,0	g/L	Foliar treatment - spraying				1				1,00	kg a.i./ha	28	
Clover	*Trifolium spp.*	NEU	Outdoor	DE	DICOTYL WEEDS	SL	500,0	g/L	Foliar treatment - spraying				1				1,00	kg a.i./ha	28	
Grass	*not specified*	NEU	Outdoor	FR					Foliar treatment - spraying				1				1,50	kg a.i./ha	15	15 DAYS FOR LIVESTOCK INTRODUCTION
Maize (for forage)	*Zea mays*	NEU	Outdoor	FR			600,0	g/L	Foliar treatment - spraying	21	26		1				1,20	kg a.i./ha	n.a.	

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Oranges	*Citrus sinensis*	SEU	Outdoor	ES		EC	100,0	g/L	Local treatment - dipping											Spanish use as growth regulator but a detailed GAP is not available.
Almonds	*Prunus dulcis*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,96	kg a.i./ha	n.a.	Application in automn or spring.
Hazelnuts	*Corylus avellana*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,96	kg a.i./ha	n.a.	Application in automn or spring.
Apples	*Malus domesticus*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,94	kg a.i./ha	30	Application in automn or spring.
Pears	*Pyrus communis*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,94	kg a.i./ha	30	Application in automn or spring.
Apricots	*Prunus armeniaca*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,94	kg a.i./ha	15	Application in automn or spring.
Cherries	*Prunus cerasus, Prunus avium*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,94	kg a.i./ha	15	Application in automn or spring.
Peaches	*Prunus persica*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,94	kg a.i./ha	15	Application in automn or spring.
Plums	*Prunus domestica*	SEU	Outdoor	FR					Soil treatment - spraying				1				0,94	kg a.i./ha	15	Application in automn or spring.
Asparagus	*Asparagus officinalis*	SEU	Outdoor	FR					Soil treatment - general (see also comment field)		0		1				0,80	kg a.i./ha	n.a.	Application is made after harvest of the asparagi, during the year preceeding the next harvest season.
Barley	*Hordeum spp.*	SEU	Outdoor	FR					Foliar treatment - spraying	29	38		1				0,84	kg a.i./ha	90	
Maize	*Zea mays*	SEU	Outdoor	FR					Foliar treatment - spraying	21	26		1				1,20	kg a.i./ha	n.a.	
Millet	*Panicum spp.*	SEU	Outdoor	FR					Foliar treatment - spraying	21	26		1				0,72	kg a.i./ha	n.a.	
Oats	*Avena fatua*	SEU	Outdoor	FR					Foliar treatment - spraying	29	38		1				0,84	kg a.i./ha	60	
Rye	*Secale cereale*	SEU	Outdoor	FR					Foliar treatment - spraying	29	38		1				0,90	kg a.i./ha	90	
Sorghum	*Sorghum bicolor*	SEU	Outdoor	FR					Foliar treatment - spraying	21	26		1				1,20	kg a.i./ha	90	
Wheat	*Triticum aestivum*	SEU	Outdoor	FR					Foliar treatment - spraying	29	38		1				0,84	kg a.i./ha	90	
Sugar cane	*Saccharum officinarum*	SEU	Outdoor	FR					Foliar treatment - spraying	29	32		1				1,44	kg a.i./ha	n.a.	
Alfalfa	*Medicago Sativa*	SEU	Outdoor	SI	Broad Leaves Weeds	SE	460,0	g/L	Foliar treatment - spraying				1				1,01	kg a.i./ha	n.a.	
Clover	*Trifolium spp.*	SEU	Outdoor	SI	Broad Leaves Weeds	SE	460,0	g/L	Foliar treatment - spraying				1				1,01	kg a.i./ha	n.a.	
Grass	*not specified*	SEU	Outdoor	FR					Foliar treatment - spraying				1				1,50	kg a.i./ha	15	15 DAYS FOR THE LIVESTOCK INTRODUCTION
Maize (for forage)	*Zea mays*	SEU	Outdoor	FR					Foliar treatment - spraying	21	26		1				1,20	kg a.i./ha	n.a.	

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

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

Appendix B.2 – EU/Codex scenario 1 including demonstrated safe EU MRL proposals and all CXLs

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

2,4-D			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,05**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2001**	Year of evaluation:	**2001**

Chronic risk assessment - refined calculations

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)
8,8	DE child	7,6	Oranges	0,4	Wheat	0,3	Milk and milk products: Cattle	0,6
7,8	NL child	6,2	Oranges	0,6	Milk and milk products: Cattle	0,5	Wheat	0,7
5,4	ES child	4,3	Oranges	0,4	Wheat	0,2	Milk and milk products: Cattle	0,3
4,6	FR toddler	4,0	Oranges	0,3	Wheat	0,1	Bovine: Meat	0,1
4,4	UK Toddler	4,0	Oranges	0,4	Wheat	0,0	Apples	0,0
3,6	NL general	3,0	Oranges	0,2	Wheat	0,1	Milk and milk products: Cattle	0,2
3,2	WHO Cluster diet B	1,7	Oranges	0,9	Wheat	0,2	Maize	0,1
3,2	ES adult	2,6	Oranges	0,2	Wheat	0,1	Milk and milk products: Cattle	0,1
3,1	UK Infant	2,6	Oranges	0,3	Wheat	0,1	Maize	0,0
3,0	IE adult	2,1	Oranges	0,2	Maize	0,2	Maize	0,1
2,6	WHO Cluster diet F	1,7	Oranges	0,4	Wheat	0,1	Swine: Meat	0,1
2,6	FR infant	1,8	Oranges	0,5	Milk and milk products: Cattle	0,1	Wheat	0,6
2,1	SE general population 90th percentile	1,5	Oranges	0,3	Wheat	0,2	Milk and milk products: Cattle	0,3
2,1	FI adult	1,9	Oranges	0,1	Wheat	0,1	Rye	0,0
2,0	UK vegetarian	1,7	Oranges	0,2	Wheat	0,0	Apples	0,0
1,7	WHO regional European diet	1,0	Oranges	0,3	Wheat	0,1	Swine: Meat	0,1
1,7	WHO cluster diet E	0,9	Oranges	0,4	Wheat	0,1	Barley	0,1
1,7	PT General population	1,2	Oranges	0,4	Wheat	0,0	Maize	0,0
1,7	IT kids/toddler	1,0	Oranges	0,7	Wheat	0,0	Apples	0,0
1,5	WHO cluster diet D	0,7	Wheat	0,5	Oranges	0,1	Milk and milk products: Cattle	0,1
1,5	DK child	0,6	Wheat	0,4	Rye	0,3	Oranges	0,1
1,3	UK Adult	1,1	Oranges	0,2	Wheat	0,0	Apples	0,0
1,2	IT adult	0,7	Oranges	0,4	Wheat	0,0	Apples	0,0
1,1	FR all population	0,6	Oranges	0,3	Wheat	0,1	Milk and milk products: Cattle	0,1
0,7	LT adult	0,1	Oranges	0,1	Rye	0,1	Wheat	0,1
0,6	DK adult	0,3	Oranges	0,2	Wheat	0,1	Rye	0,0
0,1	PL general population	0,0	Apples	0,0	Oranges	0,0	Pears	0,1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of 2,4-D is unlikely to present a public health concern.

APPENDIX B.2 – EU/CODEX SCENARIO 1 INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

2,4-D			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,05**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2001**	Year of evaluation:	**2001**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	1 12
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)
12,1	NL child	6,2	Oranges	2,1	Wheat	0,6	Potatoes	0,7
11,5	DE child	7,6	Oranges	1,8	Wheat	0,3	Rye	0,6
8,2	WHO Cluster diet B	3,8	Wheat	1,7	Oranges	0,4	Bovine: Liver	0,1
8,1	ES child	4,3	Oranges	2,0	Wheat	0,4	Bovine: Meat	0,3
6,7	IE adult	2,1	Oranges	1,2	Sheep: Liver	1,0	Wheat	0,1
6,5	UK Toddler	4,0	Oranges	1,7	Wheat	0,3	Potatoes	0,1
6,5	FR toddler	4,0	Oranges	1,2	Wheat	0,5	Potatoes	0,1
5,9	DK child	2,4	Wheat	1,9	Rye	0,7	Bovine: Liver	0,1
5,4	NL general	3,0	Oranges	0,9	Wheat	0,3	Potatoes	0,2
5,1	WHO Cluster diet F	1,7	Oranges	1,6	Wheat	0,3	Potatoes	0,1
5,0	UK Infant	2,6	Oranges	1,2	Wheat	0,5	Bovine: Liver	0,1
4,8	WHO cluster diet D	2,9	Wheat	0,5	Oranges	0,4	Potatoes	0,1
4,6	ES adult	2,6	Oranges	1,0	Wheat	0,2	Bovine: Meat	0,1
4,4	WHO cluster diet E	1,7	Wheat	0,9	Oranges	0,4	Potatoes	0,1
4,2	IT kids/toddler	2,9	Wheat	1,0	Oranges	0,1	Mandarins	0,0
4,2	SE general population 90th percentile	1,5	Oranges	1,4	Wheat	0,4	Potatoes	0,3
4,0	PT General population	1,7	Wheat	1,2	Oranges	0,5	Potatoes	0,1
3,8	WHO regional European diet	1,3	Wheat	1,0	Oranges	0,4	Potatoes	0,1
3,5	FR infant	1,8	Oranges	0,5	Milk and milk products: Cattle	0,4	Potatoes	0,6
3,1	FR all population	1,4	Wheat	0,6	Oranges	0,4	Wine grapes	0,1
3,0	UK vegetarian	1,7	Oranges	0,9	Wheat	0,1	Potatoes	0,0
3,0	FI adult	1,9	Oranges	0,4	Wheat	0,3	Rye	0,0
2,8	IT adult	1,8	Wheat	0,7	Oranges	0,1	Mandarins	0,0
2,3	UK Adult	1,1	Oranges	0,7	Wheat	0,1	Potatoes	0,0
2,3	DK adult	0,9	Wheat	0,3	Rye	0,3	Bovine: Liver	0,0
2,1	LT adult	0,5	Rye	0,5	Wheat	0,3	Potatoes	0,1
0,5	PL general population	0,3	Potatoes	0,0	Apples	0,0	Lemons	0,1

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of 2,4-D is unlikely to present a public health concern.

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

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs (File created on 11/02/2011 11:15)

Code number	Groups and examples of individual products to which the MRLs apply (a)	2,4-D (sum of 2,4-D and its esters expressed as 2,4-D)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	**1**
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	**1**
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	**1**
110030	Lemons (Citron, lemon)	**1**
110040	Limes	**1**
110050	Mandarins (Clementine, tangerine and other hybrids)	**1**
110990	Others	**1**
120000	(ii) Tree nuts (shelled or unshelled)	**0,05***
120010	Almonds	**0,05***
120020	Brazil nuts	**0,05***
120030	Cashew nuts	**0,05***
120040	Chestnuts	**0,05***
120050	Coconuts	**0,05***
120060	Hazelnuts (Filbert)	**0,05***
120070	Macadamia	**0,05***
120080	Pecans	**0,05***
120090	Pine nuts	**0,05***
120100	Pistachios	**0,05***
120110	Walnuts	**0,05***
120990	Others	**0,05***
130000	(iii) Pome fruit	**0,05***
130010	Apples (Crab apple)	**0,05***
130020	Pears (Oriental pear)	**0,05***
130030	Quinces	**0,05***
130040	Medlar	**0,05***
130050	Loquat	**0,05***
130990	Others	**0,05***
140000	(iv) Stone fruit	**0,05***
140010	Apricots	**0,05***
140020	Cherries (sweet cherries, sour cherries)	**0,05***
140030	Peaches (Nectarines and similar hybrids)	**0,05***
140040	Plums (Damson, greengage, mirabelle)	**0,05***
140990	Others	**0,05***
150000	(v) Berries & small fruit	**0,05***
151000	(a) Table and wine grapes	**0,05***
151010	Table grapes	**0,05***
151020	Wine grapes	**0,05***
152000	(b) Strawberries	**0,05***
153000	(c) Cane fruit	**0,05***
153010	Blackberries	**0,05***
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	**0,05***
153030	Raspberries (Wineberries)	**0,05***
153990	Others	**0,05***
154000	(d) Other small fruit & berries	**0,05***
154010	Blueberries (Bilberries cowberries (red bilberries))	**0,05***
154020	Cranberries	**0,05***
154030	Currants (red, black and white)	**0,05***
154040	Gooseberries (Including hybrids with other ribes species)	**0,05***
154050	Rose hips	**0,05***
154060	Mulberries (arbutus berry)	**0,05***
154070	Azarole (mediteranean medlar)	**0,05***
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	**0,05***
154990	Others	**0,05***
160000	(vi) Miscellaneous fruit	**0,05***
161000	(a) Edible peel	**0,05***
161010	Dates	**0,05***
161020	Figs	**0,05***
161030	Table olives	**0,05***
161040	Kumquats (Marumi kumquats, nagami kumquats)	**0,05***
161050	Carambola (Bilimbi)	**0,05***
161060	Persimmon	**0,05***
161070	Jambolan (java plum) (Java apple	**0,05***
	(water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	
161990	Others	**0,05***
162000	(b) Inedible peel, small	**0,05***
162010	Kiwi	**0,05***
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	**0,05***
162030	Passion fruit	**0,05***
162040	Prickly pear (cactus fruit)	**0,05***
162050	Star apple	**0,05***
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	**0,05***
162990	Others	**0,05***
163000	(c) Inedible peel, large	**0,05***
163010	Avocados	**0,05***
163020	Bananas (Dwarf banana, plantain, apple banana)	**0,05***
163030	Mangoes	**0,05***
163040	Papaya	**0,05***
163050	Pomegranate	**0,05***
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	**0,05***
163070	Guava	**0,05***
163080	Pineapples	**0,05***
163090	Bread fruit (Jackfruit)	**0,05***
163100	Durian	**0,05***
163110	Soursop (guanabana)	**0,05***
163990	Others	**0,05***
200000	2. VEGETABLES FRESH OR FROZEN	**0,05***
210000	(i) Root and tuber vegetables	**0,05***
211000	(a) Potatoes	**0,05***
212000	(b) Tropical root and tuber vegetables	**0,05***
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	**0,05***
212020	Sweet potatoes	**0,05***
212030	Yams (Potato bean (yam bean), Mexican yam bean)	**0,05***
212040	Arrowroot	**0,05***
212990	Others	**0,05***
213000	(c) Other root and tuber vegetables except sugar beet	**0,05***
213010	Beetroot	**0,05***
213020	Carrots	**0,05***
213030	Celeriac	**0,05***
213040	Horseradish	**0,05***
213050	Jerusalem artichokes	**0,05***
213060	Parsnips	**0,05***
213070	Parsley root	**0,05***
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	**0,05***
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	**0,05***
213100	Swedes	**0,05***
213110	Turnips	**0,05***
213990	Others	**0,05***
220000	(ii) Bulb vegetables	**0,05***
220010	Garlic	**0,05***
220020	Onions (Silverskin onions)	**0,05***
220030	Shallots	**0,05***
220040	Spring onions (Welsh onion and similar varieties)	**0,05***
220990	Others	**0,05***
230000	(iii) Fruiting vegetables	**0,05***
231000	(a) Solanacea	**0,05***
231010	Tomatoes (Cherry tomatoes,)	**0,05***
231020	Peppers (Chilli peppers)	**0,05***
231030	Aubergines (egg plants) (Pepino)	**0,05***
231040	Okra, lady's fingers	**0,05***
231990	Others	**0,05***
232000	(b) Cucurbits - edible peel	**0,05***
232010	Cucumbers	**0,05***
232020	Gherkins	**0,05***

Code number	Groups and examples of individual products to which the MRLs apply (a)	2,4-D (sum of 2,4-D and its esters expressed as 2,4-D)
232030	Courgettes (Summer squash, marrow (patisson))	**0,05***
232990	Others	**0,05***
233000	(c) Cucurbits-inedible peel	**0,05***
233010	Melons (Kiwano)	**0,05***
233020	Pumpkins (Winter squash)	**0,05***
233030	Watermelons	**0,05***
233990	Others	**0,05***
234000	(d) Sweet corn	**0,05***
239000	(e) Other fruiting vegetables	**0,05***
240000	(iv) Brassica vegetables	**0,05***
241000	(a) Flowering brassica	**0,05***
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	**0,05***
241020	Cauliflower	**0,05***
241990	Others	**0,05***
242000	(b) Head brassica	**0,05***
242010	Brussels sprouts	**0,05***
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	**0,05***
242990	Others	**0,05***
243000	(c) Leafy brassica	**0,05***
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	**0,05***
243020	Kale (Borecole (curly kale), collards)	**0,05***
243990	Others	**0,05***
244000	(d) Kohlrabi	**0,05***
250000	(v) Leaf vegetables & fresh herbs	**0,05***
251000	(a) Lettuce and other salad plants including Brassicacea	**0,05***
251010	Lamb´s lettuce (Italian cornsalad)	**0,05***
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	**0,05***
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	**0,05***
251040	Cress	**0,05***
251050	Land cress	**0,05***
251060	Rocket, Rucola (Wild rocket)	**0,05***
251070	Red mustard	**0,05***
251080	Leaves and sprouts of Brassica spp (Mizuna)	**0,05***
251990	Others	**0,05***
252000	(b) Spinach & similar (leaves)	**0,05***
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	**0,05***
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	**0,05***
252030	Beet leaves (chard) (Leaves of beetroot)	**0,05***
252990	Others	**0,05***
253000	(c) Vine leaves (grape leaves)	**0,05***
254000	(d) Water cress	**0,05***
255000	(e) Witloof	**0,05***
256000	(f) Herbs	**0,05***
256010	Chervil	**0,05***
256020	Chives	**0,05***
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	**0,05***
256040	Parsley	**0,05***
256050	Sage (Winter savory, summer savory,)	**0,05***
256060	Rosemary	**0,05***
256070	Thyme (marjoram, oregano)	**0,05***
256080	Basil (Balm leaves, mint, peppermint)	**0,05***
256090	Bay leaves (laurel)	**0,05***
256100	Tarragon (Hyssop)	**0,05***
256990	Others	**0,05***
260000	(vi) Legume vegetables (fresh)	**0,05***
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	**0,05***
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	**0,05***
260030	Peas (with pods) (Mangetout (sugar peas))	**0,05***
260040	Peas (without pods) (Garden pea, green pea, chickpea)	**0,05***
260050	Lentils	**0,05***
260990	Others	**0,05***
270000	(vii) Stem vegetables (fresh)	**0,05***
270010	Asparagus	**0,05***
270020	Cardoons	**0,05***
270030	Celery	**0,05***
270040	Fennel	**0,05***
270050	Globe artichokes	**0,05***
270060	Leek	**0,05***
270070	Rhubarb	**0,05***
270080	Bamboo shoots	**0,05***
270090	Palm hearts	**0,05***
270990	Others	**0,05***
280000	(viii) Fungi	**0,05***
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	**0,05***
280020	Wild (Chanterelle, Truffle, Morel ,)	**0,05***
280990	Others	**0,05***
290000	(ix) Sea weeds	**0,05***
300000	3. PULSES, DRY	**0,05***
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	**0,05***
300020	Lentils	**0,05***
300030	Peas (Chickpeas, field peas, chickling vetch)	**0,05***
300040	Lupins	**0,05***
300990	Others	**0,05***
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	**0,1***
401010	Linseed	**0,1***
401020	Peanuts	**0,1***
401030	Poppy seed	**0,1***
401040	Sesame seed	**0,1***
401050	Sunflower seed	**0,1***
401060	Rape seed (Bird rapeseed, turnip rape)	**0,1***
401070	Soya bean	**0,1***
401080	Mustard seed	**0,1***
401090	Cotton seed	**0,1***
401100	Pumpkin seeds	**0,1***
401110	Safflower	**0,1***
401120	Borage	**0,1***
401130	Gold of pleasure	**0,1***
401140	Hempseed	**0,1***
401150	Castor bean	**0,1***
401990	Others	**0,1***
402000	(ii) Oilfruits	
402010	Olives for oil production	**0,05***
402020	Palm nuts (palmoil kernels)	**0,1***
402030	Palmfruit	**0,1***
402040	Kapok	**0,1***
402990	Others	**0,1***
500000	5. CEREALS	**0,05***
500010	Barley	**0,05***
500020	Buckwheat	**0,05***
500030	Maize	**0,05***
500040	Millet (Foxtail millet, teff)	**0,05***
500050	Oats	**0,05***
500060	Rice	**0,05***
500070	Rye	**0,05***
500080	Sorghum	**0,05***
500090	Wheat (Spelt Triticale)	**0,05***
500990	Others	**0,05***
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	**0,1***
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	**0,1***
620000	(ii) Coffee beans	**0,1***
630000	(iii) Herbal infusions (dried)	**0,1***
631000	(a) Flowers	**0,1***
631010	Camomille flowers	**0,1***
631020	Hybiscus flowers	**0,1***
631030	Rose petals	**0,1***
631040	Jasmine flowers	**0,1***
631050	Lime (linden)	**0,1***
631990	Others	**0,1***
632000	(b) Leaves	**0,1***
632010	Strawberry leaves	**0,1***
632020	Rooibos leaves	**0,1***
632030	Maté	**0,1***
632990	Others	**0,1***
633000	(c) Roots	**0,1***
633010	Valerian root	**0,1***
633020	Ginseng root	**0,1***
633990	Others	**0,1***
639000	(d) Other herbal infusions	**0,1***
640000	(iv) Cocoa (fermented beans)	**0,1***

Code number	Groups and examples of individual products to which the MRLs apply (a)	2,4-D (sum of 2,4-D and its esters expressed as 2,4-D)
650000	(v) Carob (st johns bread)	**0,1***
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	**0,1***
800000	8. SPICES	**0,1***
810000	(i) Seeds	**0,1***
810010	Anise	**0,1***
810020	Black caraway	**0,1***
810030	Celery seed (Lovage seed)	**0,1***
810040	Coriander seed	**0,1***
810050	Cumin seed	**0,1***
810060	Dill seed	**0,1***
810070	Fennel seed	**0,1***
810080	Fenugreek	**0,1***
810090	Nutmeg	**0,1***
810990	Others	**0,1***
820000	(ii) Fruits and berries	**0,1***
820010	Allspice	**0,1***
820020	Anise pepper (Japan pepper)	**0,1***
820030	Caraway	**0,1***
820040	Cardamom	**0,1***
820050	Juniper berries	**0,1***
820060	Pepper, black and white (Long pepper, pink pepper)	**0,1***
820070	Vanilla pods	**0,1***
820080	Tamarind	**0,1***
820990	Others	**0,1***
830000	(iii) Bark	**0,1***
830010	Cinnamon (Cassia)	**0,1***
830990	Others	**0,1***
840000	(iv) Roots or rhizome	**0,1***
840010	Liquorice	**0,1***
840020	Ginger	**0,1***
840030	Turmeric (Curcuma)	**0,1***
840040	Horseradish	**0,1***
840990	Others	**0,1***
850000	(v) Buds	**0,1***
850010	Cloves	**0,1***
850020	Capers	**0,1***
850990	Others	**0,1***
860000	(vi) Flower stigma	**0,1***
860010	Saffron	**0,1***
860990	Others	**0,1***
870000	(vii) Aril	**0,1***
870010	Mace	**0,1***
870990	Others	**0,1***
900000	9. SUGAR PLANTS	**0,05***
900010	Sugar beet (root)	**0,05***
900020	Sugar cane	**0,05***
900030	Chicory roots	**0,05***
900990	Others	**0,05***
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	**0,05***
1011020	Fat free of lean meat	**0,05***
1011030	Liver	**0,05***
1011040	Kidney	**1**
1011050	Edible offal	**0,05***
1011990	Others	**0,05***
1012000	(b) Bovine	
1012010	Meat	**0,05***
1012020	Fat	**0,05***
1012030	Liver	**0,05***
1012040	Kidney	**1**
1012050	Edible offal	**0,05***
1012990	Others	**0,05***
1013000	(c) Sheep	
1013010	Meat	**0,05***
1013020	Fat	**0,05***
1013030	Liver	**0,05***
1013040	Kidney	**1**
1013050	Edible offal	**0,05***
1013990	Others	**0,05***
1014000	(d) Goat	
1014010	Meat	**0,05***
1014020	Fat	**0,05***
1014030	Liver	**0,05***
1014040	Kidney	**1**
1014050	Edible offal	**0,05***
1014990	Others	**0,05***
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	**0,05***
1015020	Fat	**0,05***
1015030	Liver	**0,05***
1015040	Kidney	**1**
1015050	Edible offal	**0,05***
1015990	Others	**0,05***
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	**0,05***
1016010	Meat	**0,05***
1016020	Fat	**0,05***
1016030	Liver	**0,05***
1016040	Kidney	**0,05***
1016050	Edible offal	**0,05***
1016990	Others	**0,05***
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	**0,05***
1017020	Fat	**0,05***
1017030	Liver	**0,05***
1017040	Kidney	**1**
1017050	Edible offal	**0,05***
1017990	Others	**0,05***
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	**0,01***
1020010	Cattle	**0,01***
1020020	Sheep	**0,01***
1020030	Goat	**0,01***
1020040	Horse	**0,01***
1020990	Others	**0,01***
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	**0,01***
1030010	Chicken	**0,01***
1030020	Duck	**0,01***
1030030	Goose	**0,01***
1030040	Quail	**0,01***
1030990	Others	**0,01***
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination

APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for 2,4-d in plant commodities																
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation			
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
110010	Grapefruit	2,4-D	1	2,4-D	0,3	n.a.	1	n.c.	0,305	0,61	n.k.	1	1998, 2001	No	Post-harvest treatment in USA and Uruguay. Trials on oranges and lemons to support citrus CXLs. Whole fruit analysed, no data on peel/pulp distribution. See comment on residue definition.
110020	Oranges	2,4-D	1	2,4-D	0,3	n.a.	1	n.c.	0,305	0,61	n.k.	1	1998, 2001	No	
110030	Lemons	2,4-D	1	2,4-D	0,3	n.a.	1	n.c.	0,305	0,61	n.k.	1	1998, 2001	No	
110040	Limes	2,4-D	1	2,4-D	0,3	n.a.	1	n.c.	0,305	0,61	n.k.	1	1998, 2001	No	
110050	Mandarins	2,4-D	1	2,4-D	0,3	n.a.	1	n.c.	0,305	0,61	n.k.	1	1998, 2001	No	
120010	Almonds	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	Based on USA GAP. Trials on almond kernel, hazlenut, pistachio and pecans to support tree nut MRL. Hazlenut trials generated according to different GAP but still used to support CXL. See comment for grapefruit on residue definition.
120020	Brazil nuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120030	Cashew nuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120040	Chestnuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120050	Coconuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120060	Hazelnuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120070	Macadamia	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120080	Pecans	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120090	Pine nuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120100	Pistachios	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
120110	Walnuts	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,160	n.a.	1	1998	No	
130010	Apples	2,4-D	0,01 *	2,4-D	0	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	Trials were all conducted in the USA to support the USA GAP (less critical GAPs for NL and Poland were also supported). Trials on apple and pear used to support a Pome CXLs. See comment for grapefruit on residue definition.
130020	Pears	2,4-D	0,01 *	2,4-D	0	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	
130030	Quinces	2,4-D	0,01 *	2,4-D	0	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	
130040	Medlar	2,4-D	0,01 *	2,4-D	0	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	
130050	Loquat	2,4-D	0,01 *	2,4-D	0	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	
140010	Apricots	2,4-D	0,05 *	2,4-D	0	n.a.	1	n.c.	0,01	0,05	n.a.	1	1998	No	Trials were all conducted in the USA to support the USA GAP (less critical GAP for NL was also supported). Trials on cherry, peach & plum used to support a Stone Fruit CXLs. See comment for
140020	Cherries	2,4-D	0,05 *	2,4-D	0	n.a.	1	n.c.	0,01	0,05	n.a.	1	1998	No	
140030	Peaches	2,4-D	0,05 *	2,4-D	0	n.a.	1	n.c.	0,01	0,05	n.a.	1	1998	No	
140040	Plums	2,4-D	0,05 *	2,4-D	0	n.a.	1	n.c.	0,01	0,05	n.a.	1	1998	No	

Summary of CXLs for 2,4-d in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
151010	Table grapes	2,4-D	0,1	2,4-D	0	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	Where it was stated in the JMPR report, trials were conducted in the USA to support the USA GAP (GAPs in Canada and NL were also supported). Trials on blueberry, cranberry, grapes, raspberry and strawberry were used to support a Berries and other small fruit CXL. See comment for grapefruit on residue definition.
151020	Wine grapes	2,4-D	0,1	2,4-D	0	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
152000	Strawberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
153010	Blackberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
153020	Dewberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
153030	Raspberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154010	Blueberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154020	Cranberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154030	Currants (red, black and white)	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154040	Gooseberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154050	Rose hips	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154060	Mulberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154070	Azarole (mediteranean medlar)	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
154080	Elderberries	2,4-D	0,1	2,4-D	0,05	n.a.	1	n.c.	0,05	0,11	n.a.	1	1998	No	
211000	Potatoes	2,4-D	0,2	2,4-D	0,05	n.a.	1	n.c.	0,05	0,13	n.a.	1,00	1998	No	Trials on potato were conducted in the USA according to the USA GAP (a more critical Australia GAP does not appear to have been supported). See comment for grapefruit on residue definition.
234000	Sweet corn	2,4-D	0,05 *	2,4-D	0,05	n.a.	1	n.c.	0,05	0,05	n.a.	1	1998	No	Trials on sweetcorn (whole without husk) were conducted in the USA according to the USA GAP (an Australia GAP was also supported). See comment for grapefruit on residue definition.

Summary of CXLs for 2,4-d in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
401070	Soya bean	2,4-D	0,01 *	2,4-D	0	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	Based on a USA GAP and supported by USA trials. See comment for grapefruit on residue definition.
500030	Maize grain	2,4-D	0,05	2,4-D	0,01	n.a.	1	n.c.	0,01	0,04	n.a.	1	1998	No	The trials are conducted according to the critical USA GAP however this covers additional EU and non-EU GAPs. See comment for grapefruit on residue definition.
500060	Rice grain	2,4-D	0,1	2,4-D	0,01	n.a.	1	n.c.	0,01	0,05	n.a.	1	1998	No	The trials are conducted according to the critical USA GAP (covers less critical Thailand GAP). Husked rice was analysed. See comment for grapefruit on residue definition.
500070	Rye grain	2,4-D	2	2,4-D	0,22	n.a.	1	n.c.	0,22	1,40	n.a.	1	1998	No	Extrapolated from wheat.
500080	Sorghum grain	2,4-D	0,01 *	2,4-D	0,01	n.a.	1	n.c.	0,01	0,01	n.a.	1	1998	No	Trials conducted in the USA according to GAP. See comment for grapefruit on residue definition.
500090	Wheat grain	2,4-D	2	2,4-D	0,22	n.a.	1	n.c.	0,22	1,40	n.a.	1	1998	No	The majority of trials were conducted in the USA according to the USA GAP. See comments on grapefruit for residue definition.
900020	Sugar cane	2,4-D	0,05	2,4-D	0,01	n.a.	1	None	0,01	0,02	n.a.	1	1998	No	All trials were conducted in the USA accroding to the relevant GAP.

(*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

n.k.: not known

Summary of CXLs for 2,4-d in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	2,4-D	no	0,2	2,4-D	0,125	n.a.	1998	no	Intakes based on US grass forage trials.
1011030	Swine liver	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1011040	Swine kidney	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1011050	Swine edible offal	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1012010	Bovine meat	2,4-D	no	0,2	2,4-D	0,125	n.a.	1998	no	Intakes based on US grass forage trials.
1012030	Bovine liver	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1012040	Bovine kidney	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1012050	Bovine edible offal	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1013010	Sheep meat	2,4-D	no	0,2	2,4-D	0,125	n.a.	1998	no	Intakes based on US grass forage trials.
1013030	Sheep liver	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials.
1013040	Sheep kidney	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials.
1013050	Sheep edible offal	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1014010	Goat meat	2,4-D	no	0,2	2,4-D	0,125	n.a.	1998	no	Intakes based on US grass forage trials.
1014030	Goat liver	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1014040	Goat kidney	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1014050	Goat edible offal	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney

Summary of CXLs for 2,4-d in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1015010	Horses, asses, mules or hinnies meat	2,4-D	no	0,2	2,4-D	0,125	n.a.	1998	no	Intakes based on US grass forage trials.
1015030	Horses, asses, mules or hinnies liver	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1015040	Horses, asses, mules or hinnies kidney	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1015050	Horses, asses, mules or hinnies edible offal	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1016010	Poultry meat	2,4-D	no	0,05 *	2,4-D	0	n.a.	1998	no	Intakes based on US wheat and rye grain residues.
1016030	Poultry liver	2,4-D	n.a.	0,05 *	2,4-D	0	n.a.	1998	no	Intakes based on US wheat and rye grain residues.
1016040	Poultry kidney	2,4-D	n.a.	0,05 *	2,4-D	0	n.a.	1998	no	Intakes based on US wheat and rye grain residues.
1016050	Poultry edible offal	2,4-D	n.a.	0,05 *	2,4-D	0	n.a.	1998	no	Intakes based on US wheat and rye grain residues. Based on kidney residues - to include liver and kidney
1017010	Other farm animals meat	2,4-D	no	0,2	2,4-D	0,125	n.a.	1998	no	Intakes based on US grass forage trials.
1017030	Other farm animals liver	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials.
1017040	Other farm animals kidney	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials.
1017050	Other farm animals edible offal	2,4-D	n.a.	5	2,4-D	2,745	n.a.	1998	no	Intakes based on US grass forage trials. Based on kidney residues - to include liver and kidney
1020010	Cattle milk	2,4-D	no	0,01	2,4-D	0,043	n.a.	1998	no	Intakes based on US grass forage trials. Data support CXL of 0.1 increased from 0.05. Instead the CXL was lowered from 0.05 to 0.01 in 2004. Thee reasons for are unclear, there is no STMR/HR therefore. 0.043 and 0.098 are appropriate based on the data.
1020020	Sheep milk	2,4-D	no	0,01	2,4-D	0,043	n.a.	1998	no	
1020030	Goat milk	2,4-D	no	0,01	2,4-D	0,043	n.a.	1998	no	
1020040	Horse milk	2,4-D	no	0,01	2,4-D	0,043	n.a.	1998	no	
1030000	Birds' eggs	2,4-D	n.a.	0,01 *	2,4-D	0	n.a.	1998	no	Intakes based on US wheat and rye grain residues. No residue >0.002 mg/kg expected in eggs based on a theoretical calculation.

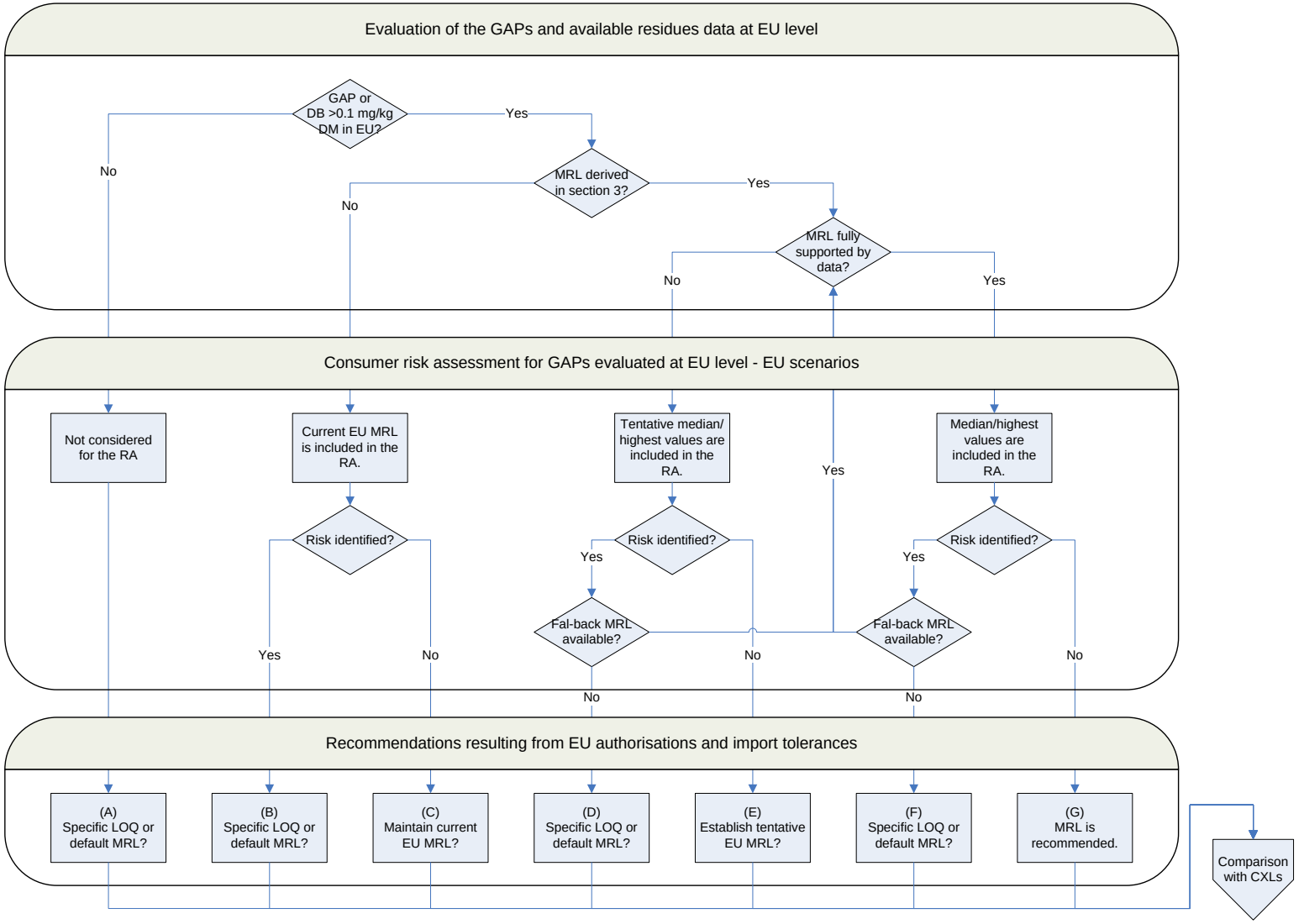
(*) Indicates the lower limit of analytical quantification.

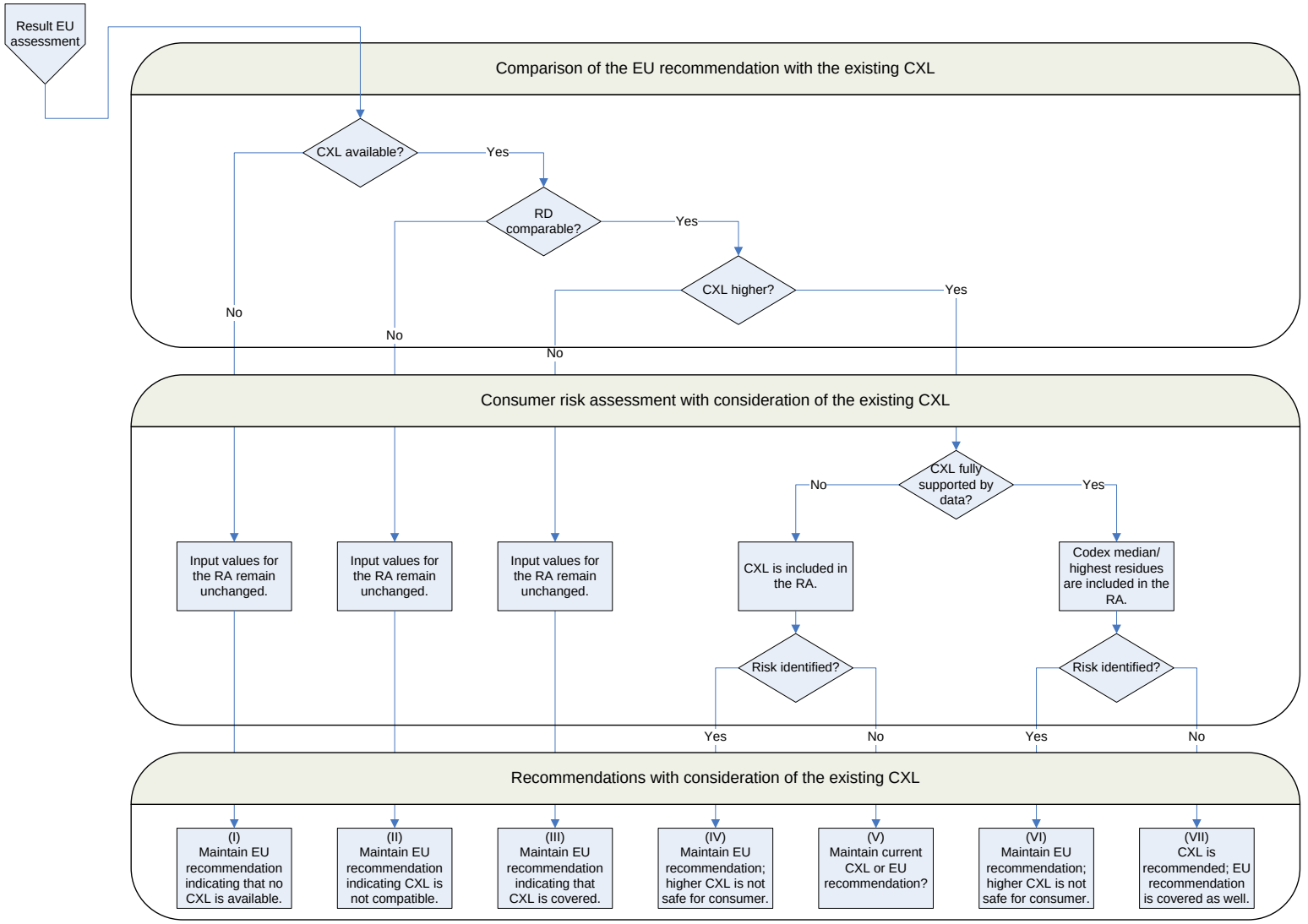
n.a.: not applicable

n.c.: not considered

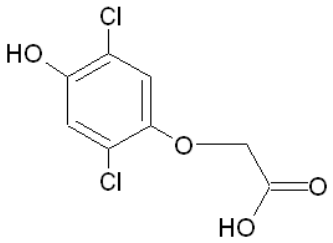
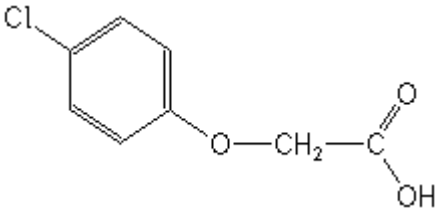
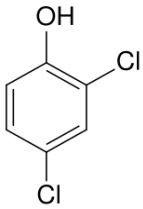
n.k.: not known

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




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

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
4-OH-2,5-D	4-hydroxy-2,5-dichlorophenoxyacetic acid	
4-CPA	4-chlorophenoxyacetic acid	
2,4-DCP	2,4-dichlorophenol	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detection
GC-MS	gas chromatography with mass spectrometry
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry

ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organization for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residue Overview file
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
RSD	relative standard deviation
SC	suspension concentrate
SEU	Southern European Union
SL	soluble concentrate
TRR	total radioactive residue
WHO	World Health Organisation