REASONED OPINION

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

European Food Safety Authority[2, 3]

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ABSTRACT

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

KEY WORDS

dichlorprop-P, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, phenoxypropionic, herbicide, plant growth regulator

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SUMMARY

Dichlorprop-P was included in Annex I to Directive 91/414/EEC on 01 June 2007, 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 the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Denmark, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 21 April 2009 and, after having considered several comments made by EFSA, the RMS provided on 02 November 2009 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 10 June 2011 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 19 August 2011 and the confirmatory data required in the framework of Directive 91/414/EEC (evaluation process finalised in October 2013) were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of dichlorprop-P was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.06 mg/kg bw per d and 0.5 mg/kg bw, respectively. Both toxicological reference values were established for dichlorprop-P but they can also apply to dichlorprop which was demonstrated to have the same toxicity as dichlorprop-P.

Primary crop metabolism was investigated following foliar application on wheat and oranges, hereby covering the crop groups of fruits and cereals. The relevant residue for enforcement and risk assessment in these 2 crop groups is defined as the sum of dichlorprop (including dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop. Dichlorprop-P is also authorised for use as soil treatment in several orchards trees which would normally require an additional representative metabolism study with fruits and fruiting vegetables treated *via* soil application. As the DT_{90} values of dichlorprop-P and its soil metabolite 2,4-DCP are below the trigger value of 100 days, and as the treatment in orchard tree is performed prior to flowering, no significant residues are expected in harvested fruits. Hence EFSA proposes that the residue definition derived for foliar treatments also applies to orchard trees following soil application. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.02 mg/kg in dry, acidic, high oil content and high water content commodities.

Regarding the magnitude of residues in all crops reported by the RMS, a sufficient number of supervised residues trials is available, which allowed EFSA to estimate the expected residue concentrations in all crops under consideration and to derive appropriate MRLs.

The effects of processing on the nature of dichlorprop-P residues have not been investigated during the peer review of the active substance and no new studies have been submitted. Nevertheless, such studies are not required as the overall chronic exposure represents less than 10 % of the ADI. Although not required, studies investigating the effect of processing on the magnitude of dichlorprop-P residues in the processed fractions of oranges were submitted in the framework of a previous MRL application. However, as the nature of residues in processed commodities is not addressed and as only two processing studies are available, the processing factors derived from these studies are considered indicative only. With regard to the risk assessment, further processing studies are not required because they are not expected to affect the outcome of the risk assessment. If there would be the intention from risk managers to derive more processing factors for enforcement purposes, additional processing studies might be required

The DT_{90} values of dichlorprop-P and its soil metabolite 2,4-DCP are below the trigger value of 100 days. 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 was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement and risk assessment in these animal products was defined as the sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop. There are indications that this residue definition can be enforced with an LOQ of 0.01 mg/kg in milk, an LOQ of 0.02 mg/kg in meat and fat, and an LOQ of 0.05 mg/kg liver and kidney, but a confirmatory method is still required. Tentative MRLs in pig and ruminant commodities were also derived from the metabolism study. For poultry products, no MRLs are required because there is no significant exposure of poultry to dichlorprop-P residues.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 1.7 % of the ADI (Dutch child) and the highest acute exposure amounted to 4 % of the ARfD (orange).

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 summary table). All MRL values listed in the table as 'Recommended' are sufficiently supported by data and can in principle be proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- a confirmatory method for enforcement in animal commodities.

It is also noted by EFSA that the MRL proposals in cereal grains, swine kidney, ruminant liver and ruminant kidney are driven by authorisations for cereals and grass that will need to be withdrawn or modified by Member States in line with Regulation (EU) No 1166/2013. It is therefore recommended to review these MRL proposals when authorisations have been modified at national level and residue trials according to the modified GAPs (in particular for cereals) can be made available to EFSA.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition (existing): sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop **Enforcement residue definition (proposed):** sum of dichlorprop (including dichlorprop-p), its salts, esters and conjugates, expressed as dichlorprop				
0110000	Oranges	0.2	0.3	Recommended [(a)]
0130010	Apples	0.05*	0.02*	Recommended [(a)]
0130020	Pears	0.05*	0.02*	Recommended [(a)]
0140020	Cherries	0.05*	0.02*	Recommended [(a)]
0140040	Plums	0.05*	0.02*	Recommended [(a)]
0500010	Barley grain	0.2	0.1	Recommended [(a)]

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
0500050	Oats grain	0.2	0.1	Recommended [(a)]
0500070	Rye grain	0.2	0.1	Recommended [(a)]
0500090	Wheat grain	0.2	0.1	Recommended [(a)]
Enforcement residue definition (existing): sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop **Enforcement residue definition (proposed):** sum of dichlorprop (including dichlorprop-p) and its salts, expressed as dichlorprop				
1011010	Swine meat	0.05*	0.02*	Further consideration needed [(b)]
1011020	Swine fat	0.05*	0.02*	Further consideration needed [(b)]
1011030	Swine liver	0.05*	0.05*	Further consideration needed [(b)]
1011040	Swine kidney	0.1	0.1	Further consideration needed [(b)]
1012010	Bovine meat	0.05*	0.02*	Further consideration needed [(b)]
1012020	Bovine fat	0.05*	0.02*	Further consideration needed [(b)]
1012030	Bovine liver	0.1	0.06	Further consideration needed [(b)]
1012040	Bovine kidney	0.7	0.7	Further consideration needed [(b)]
1013010	Sheep meat	0.05*	0.02*	Further consideration needed [(b)]
1013020	Sheep fat	0.05*	0.02*	Further consideration needed [(b)]
1013030	Sheep liver	0.1	0.06	Further consideration needed [(b)]
1013040	Sheep kidney	0.7	0.7	Further consideration needed [(b)]
1014010	Goat meat	0.05*	0.02*	Further consideration needed [(b)]
1014020	Goat fat	0.05*	0.02*	Further consideration needed [(b)]
1014030	Goat liver	0.1	0.06	Further consideration needed [(b)]
1014040	Goat kidney	0.7	0.7	Further consideration needed [(b)]
1020010	Cattle milk	0.05*	0.01*	Further consideration needed [(b)]
1020020	Sheep milk	0.05*	0.01*	Further consideration needed [(b)]
1020030	Horse milk	0.05*	0.01*	Further consideration needed [(b)]
-	Other products of plant and animal origin	See App. C	-	Further consideration needed [(c)]

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).

(c): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates 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 dichlorprop-P was included in Annex I to the above mentioned directive on 01 June 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-525 was included in the EFSA Register of Questions.

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

In order to gain an overview 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 inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

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

Denmark, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for dichlorprop-P. The requested information was submitted to EFSA on 21 April 2009 and subsequently checked for completeness. On 02 November 2009, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 10 June 2011 and submitted to Member States (MS) for commenting. All MS comments received by 19 August 2011 and the confirmatory data required in the framework of Directive 91/414/EEC (evaluation process finalised in October 2013) were considered by EFSA in the finalisation of the reasoned opinion.

TERMS OF REFERENCE

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

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;

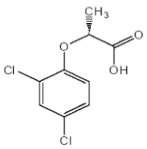
[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

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

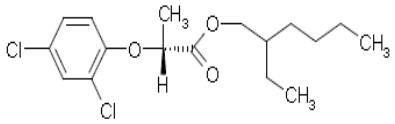
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Dichlorprop-P is the ISO common name for (*R*)-2-(2,4-dichlorophenoxy) propionic acid (IUPAC). Dichlorprop-P may be manufactured as different variants such as salts (e.g. dichlorprop-P-dimethylammonium[6]) and esters (e.g. dichlorprop-P-2-ethylhexyl[7]), but dichlorprop-P (acid compound) is considered to be the active component. Dichlorprop, which is the unresolved isomeric mixture of dichlorprop-P and its S-isomer, was already introduced as a pesticide active substance before dichlorprop-P. This racemic mixture is however no longer authorised within the EU.



dichlorprop-P



dichlorprop-P-2-ethylhexyl

Dichlorprop-P belongs to the group of phenoxy propionic compounds. It is a selective, systemic, foliar hormone herbicide absorbed by leaves and translocated to roots; it is used to control broad leaved weeds. Dichlorprop-P induces a series of morphological effects which include decreases in root and shoot growth. It also acts as growth regulator as it is thought to increase cell-wall plasticity, biosynthesis of proteins, and the production of ethylene.

Dichlorprop-P was evaluated in the framework of Directive 91/414/EEC with Denmark being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were broadcast outdoor treatments in cereals and grass at an application rate of 1.5 kg a.s./ha in early post-emergence, both in northern and southern Europe. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2006/74/EC[8], which entered into force on 01 June 2007. According to Regulation (EU) No 540/2011[9], dichlorprop-P is deemed to have been approved under Regulation (EC) No 1107/2009[10]. This approval was initially restricted to uses as herbicide only and included a requirement for the notifier to provide further confirmatory information on livestock metabolism and risk assessment for birds and herbivorous mammals. Confirmatory data were submitted, evaluated by the RMS and a peer review was carried out by EFSA. Considering that a high acute risk for birds and mammals could not be excluded by EFSA, further restrictions to the approval have been established by means of Commission Implementing Regulation (EU) No

[6] (2R)-2-(2,4-dichlorophenoxy)propionic acid – dimethylamine (1:1)

[7] (2RS)-2-ethylhexyl (2R)-2-(2,4-dichlorophenoxy)propionate, dichlorprop-P-2-EHE or dichlorprop-P-EHE

[8] Commission Directive 2006/74/EC of 21 August 2006 amending Council Directive 91/414/EEC to include dichlorprop-P, metconazole, pyrimethanil and triclopyr as active substances. OJ L 235, 30.8.2006, p. 17–22.

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

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

1166/2013[11]. These restrictions stipulate that the use on grasslands shall no longer be authorised and that, as regards cereals, only applications in spring shall be authorised at application rates not exceeding 0.8 kg a.s./ha per application. Member States shall amend or withdraw authorisations in line with these restrictions by 09 June 2014 and any period of grace granted by Member States for disposal of stocks shall expire by 09 June 2015 at the latest.

The EU MRLs for dichlorprop-P are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for oranges, liver and kidney (EFSA, 2011) which was legally implemented by Regulation (EU) No 978/2011[12]. All existing EU MRLs, which are established for dichlorprop including dichlorprop-P, are summarised in Appendix C to this document. CXLs for dichlorprop-P are not available.

For the purpose of this MRL review, the critical uses of dichlorprop-P currently authorised within the EU, have been collected by the RMS and reported in the PROFile (see Appendix A). They include herbicide treatments by foliar application on cereals and grass at a rate up to 1.5 kg a.s./ha or by soil application in orchards at a rate up to 1.09 kg/ha. Foliar treatments as growth regulator are also authorised on oranges at a rate up to 0.06 kg a.s./ha. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

According to the European Commission (2001), uses as plant growth regulator fall under the general area of herbicide uses; the use of dichlorprop-P in orchards and oranges is therefore compliant with the restrictions of approval for this active substance. The current authorisations for grass and cereals are no longer compliant with those restrictions and Member States are required to revise these authorisations by 09 June 2014 (see above). Considering however that a period of grace until 09 June 2015 may still be grated by Member States, these authorisations were still included in the present MRL review.

[11] Commission Implementing Regulation (EU) No 1166/2013 of 18 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance dichlorprop-P. OJ L 309, 19.11.2013, p. 22–24

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

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addenda prepared under Council Directive 91/414/EEC (Denmark, 2005a, 2005b, 2011), the conclusions on the peer review of the pesticide risk assessment of the active substance dichlorprop-P (EFSA, 2005, 2012) and the previous reasoned opinion on dichlorprop-P (EFSA, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[13] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a-g, 2000, 2010a, b, 2011; OECD, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-MS and its ILV were evaluated for determination of dichlorprop (including dichlorprop-P), its salts, its esters and its conjugates in plant matrices with, for the sum of compounds, an LOQ of 0.02 mg/kg in dry (wheat grain) commodities and an LOQ of 0.05 mg/kg in high water content commodities (wheat forage). Nevertheless, this hydrolysis step was not validated for esters and conjugates (Denmark, 2005a; EFSA, 2005).

Additionally, an analytical method using GC-MS and its ILV were evaluated and validated for the determination of dichlorprop (including dichlorprop-P), its salts, its esters and its conjugates in plant matrices with, for the sum of compounds, an LOQ of 0.02 mg/kg in dry (wheat grain), acidic (citrus), high water (wheat green) and high oil content (oil seed rape) commodities. This method involves a hydrolysis of all esters and conjugates to the parent compound which is fully validated (EFSA, 2011).

Hence it is concluded that dichlorprop (including dichlorprop-P), its salts, esters and conjugates can be enforced with a combined LOQ of 0.02 mg/kg in dry, acidic, high oil content and high water content commodities.

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

During the peer review under Directive 91/414/EEC, an analytical method using HPLC-MS and its ILV were evaluated and validated for determination of dichlorprop (including dichlorprop-P) and its salts in food of animal origin with an LOQ of 0.01 mg/kg in milk, 0.02 mg/kg in poultry and beef muscle, fat and eggs and 0.05 mg/kg in liver and kidney (Denmark, 2005a; EFSA, 2005). The LOQs apply to the sum of compounds. Although these methods were previously considered acceptable by EFSA, it is noted that according to the latest guidance document on this matter (EC, 2010b) this method is no longer regarded as highly specific; a confirmatory method is therefore still required.

Hence it is concluded that dichlorprop (including dichlorprop-P) and its salts can be enforced in food of animal origin with an LOQ of 0.02 mg/kg in muscle, fat and eggs, an LOQ of 0.01 mg/kg in milk and an LOQ of 0.05mg/kg in liver and kidney. Nevertheless, a confirmatory method is still missing.

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

2. Mammalian toxicology

The toxicological assessment of dichlorprop-P was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2005). These toxicological reference values are summarised in Table 2-1. During the peer review, it was agreed that the bridging concept was acceptable for dichlorprop-P and the racemic mixture dichlorprop. Therefore the toxicological properties of both isomers can be considered as similar. For dichlorprop-P-2-ethylhexyl (dichlorprop-p-2-EHE or dichlorprop-P-EHE), considering that ingested and absorbed dichlorprop-p-2-EHE is rapidly and completely hydrolysed to dichlorprop-P acid, the results obtained from the short and long term toxicity study conducted with dichlorprop-P acid are relevant and can be used to characterise dichlorprop-p-2-EHE.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Dichlorprop-P					
ADI	EFSA	2005	0.06 mg/kg bw per d	18-month feeding study mouse	100
ARfD	EFSA	2005	0.5 mg/kg bw	Teratogenicity study rabbit	100

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 dichlorprop-P was investigated after foliar application on cereals (wheat) using U-^{14}C-phenyl labelled dichlorprop-P with a chiral purity of 90.7 % R-isomer and 9.3 % S-isomer (Denmark, 2005a). Metabolism of dichlorprop-P was also investigated on fruits and fruiting vegetables (oranges) using U-^{14}C-phenyl labelled dichlorprop-P-EHE (EFSA, 2011). The characteristics of these studies are summarised in Table 3-1.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Oranges	U-^{14}C-phenyl dichlorprop-P-2-EHE	Foliar treatment, F	7.66 mg a.s./tree	2	After 1st application : 0,30, 159 After 2nd application: 0, 46	Application at BBCH 71-73 and 81. Rates equivalent to 4.79 g a.s./hL and 3.56 g a.s./hL.

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate	No	Sampling (DAT)	Remarks
Cereals	Wheat	U-^{14}C-phenyl dichlorprop-P	Foliar treatment, F	0.75 kg a.s./ha	1	0[(b)], 28, 89	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): 1 hour after treatment

The application rate in the wheat study was 0.5N compared to the intended rate for the uses on cereals and grass. Total radioactive residue (TRR) in grain at maturity was 0.02 mg/kg, whereof 60 % was non extractable. No further work on identification or characterisation of grain residue was done due to the low extractable residue levels (0.008 mg/kg). In straw at maturity unchanged dichlorprop-P accounted for the majority of the TRR (19 %). Metabolites 8 and 11 were found to be the major metabolites each accounting for 14 % of the TRR. Metabolite 8 was found to be conjugates of dichlorprop-P and released several components when treated with acid, including dichlorprop-P and the hydroxy derivate of dichlorprop-P[14] (EFSA, 2005). Metabolite 11 was further identified as dichlorprop-P methylester[15] and its identity was confirmed by mass spectrometry. This metabolite was considered as an artefact formed during the prolonged frozen storage of the straw extracts under acidic methanol conditions where methylation reactions may occur resulting in an esterification step (EFSA, 2012).

Following foliar application in oranges dichlorprop-P-EHE undergoes de-esterification forming dichlorprop-P acid. The acid is then rapidly conjugated. At maturity combined residues of dichlorprop-P-EHE, dichlorprop-P and conjugated dichlorprop-P accounted for a maximum of 53.6-75.6 % TRR (0.148-0.545 mg/kg equivalent as dichlorprop-P) in orange leaves and 72.1-76.6 % of the TRR (0.014-0.086 mg/kg) in fruits. Dichlorprop-P-EHE in fruits was the major component of the TRR immediately after the first application (89.3 %), whereas at the harvest dichlorprop-P conjugates comprised the majority of the TRR (48.8 %; 0.055mg/kg) with lower amounts of dichlorprop-P-EHE (12.1 %; 0.014 mg/kg) and dichlorprop-P (15.7 %; 0.017 mg/kg) (EFSA, 2011).

It is concluded by EFSA, that the metabolic pattern in citrus fruits and cereals is qualitatively similar. Consequently, as i) dichlorprop-P is used under its ester form, ii) no significant residues other than dichlorprop were identified (including all isomers, salts, esters and conjugates), iii) dichlorprop and dichlorprop-P have similar toxicities, and iv) from an analytical point of view it is not necessary to distinguish the different isomers, salts, esters and conjugates, the residue definition for enforcement and risk assessment in cereals and in fruits and fruiting vegetables is defined as the sum of dichlorprop (including dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop.

EFSA points out that no metabolism study for the soil treatment in orchard trees is available. However, considering that the DT_{90} values of dichlorprop-P and its relevant soil metabolite (2,4-DCP[16]) are below the trigger value of 100 days (EFSA, 2005) and that according to the RMS the treatment in orchard trees should be performed prior to flowering, no significant residues are expected in harvested fruits. Hence the residue definition for cereals and fruits and fruiting vegetables following foliar application can be applied also to orchard fruits when treated by soil application.

Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). It is noted that the available method include the use of a hydrolytic step which might not be easy to implement for routine enforcement purposes. Also considering that dichlorprop under

[14] (*R*)3-hydoxy-2-(2,4-dichlorophenoxy) propionic acid. See Appendix E.
[15] (R)-2-(2,4-dichlorophenoxy) propanoic acid, methyl ester. See Appendix E.
[16] 2,4-dichlorophenol. See Appendix E.

its acidic form represented a significant part of the residue, the possibility to derive an enforcement residue definition without esters and conjugates should be further investigated. However all available residues trials data refer to the sum of all compounds (including esters and conjugates) and EFSA is currently not in a position to propose a simplified residue definition for enforcement purposes.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance dichlorprop-P is authorised for foliar application in cereals, oranges and grass and for soil application in apples, pears, cherries and plums (see Appendix A). To assess the magnitude of dichlorprop-P 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 (EFSA, 2005) and in the framework of a previous MRL application (EFSA, 2011). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residues trials and extrapolations were evaluated in view of the European Guidelines on comparability, extrapolation group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment except for orchard trees (apples, pears, cherries, plums) where no residue trials were submitted. Nevertheless, considering that the DT_{90} for dichlorprop-P is lower than 100 days and that the applications are performed early in the growing season, significant residues above the LOQ of 0.02 mg/kg are not expected in harvested fruits. Consequently a waiver for residue trials and metabolism study can be accepted.

The potential degradation of residues during storage of the residues trials samples was also assessed in the framework of the peer review. Storage stability of dichlorprop-P was demonstrated for 18 months at -18 °C in commodities with high water content (cereal forage) and in dry commodities (cereals grain) (Denmark, 2005a). In addition, EFSA recently reviewed a storage stability study demonstrating that dichlorprop-P-EHE and dichlorprop-P are stable in high acid content for a period of 12 months at -18 °C (EFSA, 2011). According to the RMS, all residue trials samples were stored according to the above reported storage conditions. Degradation of residues during storage of the trial samples of oranges, cereals and grass is therefore not expected.

Consequently, the available residue data are considered sufficient to derive adequate MRL proposals as well as risk assessment values for all commodities under assessment (see also Table 3-1). In case where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in the table. Tentative MRLs were derived for grass and cereal straws in view of the future need to set MRLs in feed items.

EFSA highlights that MRL proposals for cereals and grass are based on authorisations that will need to be withdrawn or modified by Member States in line with Regulation (EU) No 1166/2013. It is therefore recommended to review these MRL proposals when authorisations have been modified at national level and residue trials according to the modified GAPs (in particular for cereals) can be made available to EFSA.

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 dichlorprop (incl. dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop)	**Risk assessment** (sum of dichlorprop (incl. dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop)					
Oranges	SEU	Outdoor (foliar)	0.05; 2x0.06; 0.07[e]; 0.08[e]; 0.10[e]; 0.11; 0.15	0.05; 2x0.06; 0.07[e]; 0.08[e]; 0.10[e]; 0.11; 0.15	0.075	0.15	0.3	1.00	Trials compliant with the GAP, despite minor deviation (48-54.4 g as/ha; PHI = 58 days) R_{ber} = 0.22 R_{max} = 0.15 MRL_{OECD} = 0.26
Apples Pears Cherries Plums	NEU	Outdoor (soil)	-	-	0.02	0.02	0.02*	1.00	No residues trials are needed based on the degradation of dichlorprop-P in soil.
Barley grain Oats grain Rye grain Wheat grain	NEU	Outdoor	Barley: 3x <0.02; 10x <0.05; 0.05, 0.07 Rye: 4x <0.05 Wheat: 8 x <0.02; 0.02, 8 x <0.05	Barley: 3x <0.02; 10x <0.05; 0.05, 0.07 Rye: 4x <0.05 Wheat: 8 x <0.02; 0.02, 8 x <0.05	0.05	0.07	**0.1**	1.00	Combined dataset on wheat (17), rye (4) and barley (15) supporting the critical GAP for all small grain cereals. R_{ber} = 0.10 R_{max} = 0.07 MRL_{OECD} = 0.10
	SEU	Outdoor	9x <0.05	9x <0.05	0.05	0.05	0.05	1.00	Combined dataset on wheat (5) and barley (4) supporting the critical GAP for all small grain cereals.

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 dichlorprop (incl. dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop)	**Risk assessment** (sum of dichlorprop (incl. dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop)					
Barley straw Oat straw Rye straw Wheat straw	NEU	Outdoor	0.03, 3x <0.05, 0.06, 2x 0.07, 0.08, 2x 0.11, 0.12, 0.21, 0.36, 0.5	0.03, 3x <0.05, 0.05, 0.06, 2x 0.07, 0.08, 2x 0.11, 0.12, 0.21, 0.5	0.08	0.5	0.7	1.00	Combined dataset on wheat (6) and barley (8) supporting the critical GAP for all small grain cereals. R_{ber} = 0.28 R_{max} = 0.49 MRL_{OECD} = 0.68
	SEU	Outdoor	<0.05, 0.06, 2x 0.07, 0.08, 0.97, 1.06, 1.45, 6.64	<0.05, 0.06, 2x 0.07, 0.08, 0.97, 1.06, 1.45, 6.64	0.08	6.64	10	1.00	Combined dataset on wheat (5) and barley (4) supporting the critical GAP for all small grain cereals. R_{ber} = 2.51 R_{max} = 7.61 MRL_{OECD} = 9.66
Grass	NEU	Outdoor	3.25; 3.49; 4.14; 6.0; 6.1; 6.2; 7.14; 8.7	3.25; 3.49; 4.14; 6.0; 6.1; 6.2; 7.14; 8.7	6.05	8.70	20	1.00	Trials compliant with GAP. R_{ber} = 13.81 R_{max} = 11.63 MRL_{OECD} = 16.88

(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.
(e): Residue values higher at a longer PHI interval of 43-44 days.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of dichlorprop-P residues has not been investigated, neither in the framework of the peer review nor in the framework of a routine MRL application. Nevertheless, investigation on the nature of residues is not required as the overall chronic exposure amounts to less than 10 % of the ADI.

Studies investigating the magnitude of dichlorprop-P residues in processed commodities of oranges were evaluated in the framework of MRL application (EFSA, 2011). Oranges were treated at an exaggerated application rate of 0.25 kg a.s./ha at BBCH 45. At harvest, 45 days after application (BBCH 89), oranges were collected and processed into juice, canned oranges and jam. From one trial, the distribution between peel and pulp was also assessed. Residues in raw oranges accounted for 0.3-0.4 mg/kg. A peeling factor of 0.13 indicates that the majority of residues is present in the peel. In juice residues were below the LOQ of 0.02mg/kg. A reduction of residues is observed also in canned oranges (PF of 0.09) and orange jam (PF of 0.19). An overview of all available processing studies is available in Table 3-3. The processing factors reported for the remaining commodities should be considered indicative as the nature of residues in processed commodities is not addressed and as only two processing studies are available.

Nevertheless, with regard to the risk assessment, further processing studies are not required because they are not expected to affect the outcome of the risk assessment. If there would be the intention from risk managers to derive more processing factors for enforcement purposes, additional processing studies might be required

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement and risk assessment residue definition : sum of dichlorprop (incl. dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop				
Indicative processing factors (limited dataset)				
Oranges, peeled	1	0.13	1	-
Oranges, pasteurised juice	2	<0.05	1	Residue level below the LOQ of 0.02 mg/kg in juice
Oranges, marmalade	2	0.19	1	-
Oranges, canned fruits	2	0.09	1	-

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

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

3.1.2. Rotational crops

All crops under consideration, except permanent crops, may be grown in rotation but, according to the soil degradation studies evaluated in the framework of the peer review, DT_{90} values of dichlorprop-P and its soil metabolite 2,4-DCP are shorter than 100 days (EFSA, 2005). 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

Dichlorprop-P is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996).The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-4. For grass hay, cereal bran and fruit pomace, the respective default processing factors of 4, 8 and 2.5 have been included in the calculation in order to consider potential concentration of residues in these processed commodities.

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Risk assessment residue definition: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop				
Grass (fresh and silage)	6.05	Median residue	8.70	Highest residue
Orange pomace	0.188	Median residue x 2.5	0.188	Median residue x 2.5
Apple pomace	0.13	Median residue x 2.5	0.13	Median residue x 2.5
Grass hay	24.20	Median residue x 4	34.80	Highest residue x 4
Cereal 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	0.08	Median residue	6.64	Highest residue

The results of the calculations are reported in Table 3-5. The calculated dietary burdens for ruminants and pigs were found to exceed the trigger value of 0.1 mg/kg DM/d. Further investigation of residues is therefore only required for these groups of livestock.

EFSA highlights that the calculated dietary burden is driven by authorisations for cereals and grass that will need to be withdrawn or modified by Member States in line with Regulation (EU) No 1166/2013. It is therefore recommended to review the livestock dietary burden when authorisations have been modified at national level and residue trials according to the modified GAPs (in particular for cereals) can be made available to EFSA.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop					
Dairy ruminants	1.10	1.58	Grass (fresh)	44	Y
Meat ruminants	1.30	1.86	Grass (fresh)	43	Y
Poultry	0.004	0.004	Cereal bran	0.07	N
Pigs	0.19	0.27	Grass silage	6.6	Y

3.2.2. Nature of residues

The nature of dichlorprop-P residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Denmark, 2005a). Reported metabolism studies include a study in lactating goats using U-^{14}C-phenyl labelled dichlorprop-P. The basic characteristics of the study design used in the metabolism studies are summarised in Table 3-6.

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

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	U-^{14}C-phenyl	2	1st goat : 0.16-0.18$^{(a)}$ 2nd goat: 1.5$^{(a)}$	7	Milk	Twice daily
						Urine and faeces	Once a day
						Tissues	At sacrifice (16 h after last dose)

(a): calculated by RMS on the bases of value expressed in mg/kg of diet.

Two lactating goats received twice daily oral administration of U-^{14}C-phenyl labelled dichlorprop-P in gelatine capsules over a period of seven consecutive days at daily doses equivalent to 5 mg/kg and 50 mg/kg in dry feed. According to the RMS, the highest dose corresponds to 1.5 mg/kg bw per d which is close to the 1N exposure for meat ruminants. Therefore, only the results for the highest dose are discussed. This metabolism study shows that dichlorprop-P is rapidly excreted in ruminants (93.2 % of the administered dose), mainly as the unchanged parent compound. Excretion via milk was minor as only 0.01 % of the administered dose was detected (TRR below 0.01 mg eq/kg in all samples). The highest TRR in tissues were found in kidney (0.49 mg eq/kg) and liver (0.047 mg eq/kg). Further analysis showed that dichlorprop-P was the major compound in these organs, accounting for 0.42 mg/kg (85.9 % TRR) in kidney and 0.025 mg eq/kg (53.2 % TRR) in liver. TRR in fat and muscle only accounted to 0.011 mg eq/kg and 0.008 mg eq/kg, respectively. There is no evidence of accumulation in tissues.

EFSA highlights that the goats were not dosed with all the compounds including in the residue definition for risk assessment in feed items. Consequently, the fate of the esters and conjugates in ruminants was not investigated in the available study. However, dichlorprop-P was the main identified

compound in straw from the metabolism study on cereals and it was also demonstrated that hydrolysis from esters to acid occurs in rats. Consequently, ruminants are expected to be mainly exposed to unchanged dichlorprop-P and further data on the fate of residues of this substance are therefore not required.

Since the metabolism of dichlorprop-P in rats and ruminants was demonstrated to be similar, the findings in ruminants can also be extrapolated to pigs.

Based on the above findings, it is proposed to define the residue in ruminants and pigs as the sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop for both monitoring and risk assessment. There are indications that this residue definition can be enforced in animal commodities, but a confirmatory method is required (see section 1.2).

As the log $P_{o/w}$ of dichlorprop-P is lower than 3 (Denmark, 2005a) and no accumulation of residues in fat was observed, EFSA concludes that the proposed residue definition for commodities of animal origin is not fat soluble.

No metabolism study is available on laying hens but it is not required as the calculated dietary burden of poultry to dichlorprop-P residues amounted to less than 0.1 mg/kg DM.

3.2.3. Magnitude of residues

No feeding study on ruminants is available. During the peer review under Directive 91/414/EEC the magnitude of dichlorprop-P residues in livestock was calculated based on the metabolism study with lactating goats (see section 3.2.2). This approach was considered acceptable because the goat metabolism study was performed at a dose rate (1.5 mg/kg bw per d) comparable to the maximum intake of dichlorprop-P by ruminants (1.86 mg/kg bw per d) and TRR values in liver and kidneys comprised mainly of the parent compound (54-86 %). The peer review concluded that no further information would be gained by conducting a new feeding study with dichlorprop-P and confirmed that MRL proposals could be derived on the basis of the metabolism study (EFSA, 2012). Results derived of the metabolism study on lactating goat are summarised in Table 3-7.

Storage stability of dichlorprop-P in animal products was not evaluated under the peer review of Directive 91/414/EEC (Denmark, 2005a). Nevertheless, storage stability studies can be considered as non relevant in this case as MRLs are anyhow derived from TRR levels which are not impacted by degradation of residues.

Based on the available metabolism study, MRLs and risk assessment values in ruminant and pig products were calculated in compliance with the latest international recommendations on this matter (WHO/FAO, 2009). It is concluded that MRLs above the LOQ are expected only in pig and ruminant kidney and in ruminant liver. As a confirmatory method for enforcement in animal commodities is still missing, these MRLs are considered tentative.

EFSA highlights that the MRL proposals for commodities of animal origin are mainly driven by authorisations for cereals and grass that will need to be withdrawn or modified by Member States in line with Regulation (EU) No 1166/2013. It is therefore recommended to review the MRL proposals in livestock when authorisations have been modified at national level and residue trials according to the modified GAPs (in particular for cereals) can be made available to EFSA.

MRLs for poultry products are not required because poultry are not exposed to significant levels of dichlorprop-P.

Table 3-7: Overview of the values derived from the goat metabolism study

Commodity	Dietary burden		Results of the livestock feeding study[(a)]						Median residue (mg/kg)	Highest residue (mg/kg)	MRL proposal (mg/kg)	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Residue definition for enforcement and risk assessment: sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop												
Pig muscle [(b)]	0.19	0.27	1.50	1	0.01	- [(c)]	0.01	- [(c)]	0.02	0.02	0.02* (tentative)	1.00
Pig fat [(b)]			1.50	1	0.01	- [(c)]	0.01	- [(c)]	0.02	0.02	0.02* (tentative)	1.00
Pig liver [(b)]			1.50	1	0.05	- [(c)]	0.05	- [(c)]	0.05	0.05	0.05* (tentative)	1.00
Pig kidney [(b)]			1.50	1	0.49	- [(c)]	0.49	- [(c)]	0.06	0.09	0.1 (tentative)	1.00
Ruminant muscle	1.30	1.86	1.50	1	0.01	- [(c)]	0.01	- [(c)]	0.02	0.02	0.02* (tentative)	1.00
Ruminant fat			1.50	1	0.01	- [(c)]	0.01	- [(c)]	0.02	0.02	0.02* (tentative)	1.00
Ruminant liver			1.50	1	0.05	- [(c)]	0.05	- [(c)]	0.05	0.06	0.06 (tentative)	1.00
Ruminant kidney			1.50	1	0.49	- [(c)]	0.49	- [(c)]	0.42	0.61	0.7 (tentative)	1.00
Milk	1.10	1.58	1.50	12	0.01	- [(d)]	0.01	- [(d)]	0.01	0.01	0.01* (tentative)	1.00

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): results are based on TRR values derived from goat metabolism study.
(b): results of the ruminant metabolism study are extrapolated to pigs but MRLs and risk assessment values are recalculated in view of the pig dietary burden.
(c): not applicable as only one animal was tested; MRL value was therefore calculated on the sole value instead of the highest value.
(d): not applicable as MRLs for milk are always calculated on the basis of the mean residue value.

4. Consumer risk assessment

Chronic and acute exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the intake calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The median residue and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop				
Oranges	0.08	Median residue [(a)]	0.15	Highest residue [(a)]
Apples	0.02*	Median residue [(a)]	0.02*	Highest residue [(a)]
Pears	0.02*	Median residue [(a)]	0.02*	Highest residue [(a)]
Cherries	0.02*	Median residue [(a)]	0.02*	Highest residue [(a)]
Plums	0.02*	Median residue [(a)]	0.02*	Highest residue [(a)]
Barley	0.05	Median residue [(a)]	0.07	Highest residue [(a)]
Oats	0.05	Median residue [(a)]	0.07	Highest residue [(a)]
Rye	0.05	Median residue [(a)]	0.07	Highest residue [(a)]
Wheat	0.05	Median residue [(a)]	0.07	Highest residue [(a)]
Risk assessment residue definition: sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop				
Swine meat	0.02*	Median muscle (tentative) [(b)]	0.02*	Highest muscle (tentative) [(b)]
Swine fat	0.02*	Median residue (tentative) [(b)]	0.02*	Highest residue (tentative) [(b)]
Swine liver	0.05*	Median residue (tentative) [(b)]	0.05*	Highest residue (tentative) [(b)]
Swine kidney	0.06	Median residue (tentative) [(b)]	0.09	Highest residue (tentative) [(b)]
Ruminant meat	0.02*	Median muscle (tentative) [(b)]	0.02*	Highest muscle (tentative) [(b)]
Ruminant fat	0.02*	Median residue (tentative) [(b)]	0.02*	Highest residue (tentative) [(b)]
Ruminant liver	0.05	Median residue (tentative) [(b)]	0.06	Highest residue (tentative) [(b)]
Ruminant kidney	0.42	Median residue (tentative) [(b)]	0.61	Highest residue (tentative) [(b)]
Ruminant milk	0.01*	Median residue (tentative) [(b)]	0.01*	Highest residue (tentative) [(b)]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(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): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for dichlorprop-P (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for Dutch children, representing 1.7 % of the ADI, and the highest acute exposure was calculated for oranges, representing 4 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of dichlorprop-P on crops fully supported by data (footnote (a) in Table 4-1) is acceptable with regard to consumer exposure. For the commodities of animal origin, some uncertainties remain due to the data gap identified in section 3, in particular with regard to the analytical method for enforcement, but considering tentative MRLs in the exposure calculation did not indicate a risk to consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of dichlorprop-P was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.06 mg/kg bw per d and 0.5 mg/kg bw, respectively. Both toxicological reference values were established for dichlorprop-P but they can also apply to dichlorprop which was demonstrated to have the same toxicity as dichlorprop-P.

Primary crop metabolism was investigated following foliar application on wheat and oranges, hereby covering the crop groups of fruits and cereals. The relevant residue for enforcement and risk assessment in these 2 crop groups is defined as the sum of dichlorprop (including dichlorprop-P) its salts, esters and conjugates, expressed as dichlorprop. Dichlorprop-P is also authorised for use as soil treatment in several orchards trees which would normally require an additional representative metabolism study with fruits and fruiting vegetables treated *via* soil application. As the DT_{90} values of dichlorprop-P and its soil metabolite 2,4-DCP are below the trigger value of 100 days, and as the treatment in orchard tree is performed prior to flowering, no significant residues are expected in harvested fruits. Hence EFSA proposes that the residue definition derived for foliar treatments also applies to orchard trees following soil application. Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.02 mg/kg in dry, acidic, high oil content and high water content commodities.

Regarding the magnitude of residues in all crops reported by the RMS, a sufficient number of supervised residues trials is available, which allowed EFSA to estimate the expected residue concentrations in all crops under consideration and to derive appropriate MRLs.

The effects of processing on the nature of dichlorprop-P residues have not been investigated during the peer review of the active substance and no new studies have been submitted. Nevertheless, such studies are not required as the overall chronic exposure represents less than 10 % of the ADI. Although not required, studies investigating the effect of processing on the magnitude of dichlorprop-P residues in the processed fractions of oranges were submitted in the framework of a previous MRL application. However, as the nature of residues in processed commodities is not addressed and as only two processing studies are available, the processing factors derived from these studies are considered indicative only. With regard to the risk assessment, further processing studies are not required because they are not expected to affect the outcome of the risk assessment. If there would be the intention from risk managers to derive more processing factors for enforcement purposes, additional processing studies might be required

The DT_{90} values of dichlorprop-P and its soil metabolite 2,4-DCP are below the trigger value of 100 days. 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 was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for enforcement and risk assessment in these animal products was defined as the sum of dichlorprop (including dichlorprop-P) and its salts, expressed as dichlorprop. There are indications that this residue definition can be enforced with an LOQ of 0.01 mg/kg in milk, an LOQ of 0.02 mg/kg in meat and fat, and an LOQ of 0.05 mg/kg liver and kidney, but a confirmatory method is still required. Tentative MRLs in pig and ruminant commodities were also derived from the metabolism study. For poultry products, no MRLs are required because there is no significant exposure of poultry to dichlorprop-P residues.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 1.7 % of the ADI (Dutch child) and the highest acute exposure amounted to 4 % of the ARfD (orange).

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 summary table). All MRL values listed in the table as 'Recommended' are sufficiently supported by data and can in principle be proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs need to be confirmed by the following data:

- a confirmatory method for enforcement in animal commodities.

It is also noted by EFSA that the MRL proposals in cereal grains, swine kidney, ruminant liver and ruminant kidney are driven by authorisations for cereals and grass that will need to be withdrawn or modified by Member States in line with Regulation (EU) No 1166/2013. It is therefore recommended to review these MRL proposals when authorisations have been modified at national level and residue trials according to the modified GAPs (in particular for cereals) can be made available to EFSA.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition (existing): sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop **Enforcement residue definition (proposed):** sum of dichlorprop (including dichlorprop-p), its salts, esters and conjugates, expressed as dichlorprop				
0110000	Oranges	0.2	0.3	Recommended [(a)]
0130010	Apples	0.05*	0.02*	Recommended [(a)]
0130020	Pears	0.05*	0.02*	Recommended [(a)]
0140020	Cherries	0.05*	0.02*	Recommended [(a)]
0140040	Plums	0.05*	0.02*	Recommended [(a)]
0500010	Barley grain	0.2	0.1	Recommended [(a)]
0500050	Oats grain	0.2	0.1	Recommended [(a)]

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
0500070	Rye grain	0.2	0.1	Recommended [(a)]
0500090	Wheat grain	0.2	0.1	Recommended [(a)]
Enforcement residue definition (existing): sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop **Enforcement residue definition (proposed):** sum of dichlorprop (including dichlorprop-p) and its salts, expressed as dichlorprop				
1011010	Swine meat	0.05*	0.02*	Further consideration needed [(b)]
1011020	Swine fat	0.05*	0.02*	Further consideration needed [(b)]
1011030	Swine liver	0.05*	0.05*	Further consideration needed [(b)]
1011040	Swine kidney	0.1	0.1	Further consideration needed [(b)]
1012010	Bovine meat	0.05*	0.02*	Further consideration needed [(b)]
1012020	Bovine fat	0.05*	0.02*	Further consideration needed [(b)]
1012030	Bovine liver	0.1	0.06	Further consideration needed [(b)]
1012040	Bovine kidney	0.7	0.7	Further consideration needed [(b)]
1013010	Sheep meat	0.05*	0.02*	Further consideration needed [(b)]
1013020	Sheep fat	0.05*	0.02*	Further consideration needed [(b)]
1013030	Sheep liver	0.1	0.06	Further consideration needed [(b)]
1013040	Sheep kidney	0.7	0.7	Further consideration needed [(b)]
1014010	Goat meat	0.05*	0.02*	Further consideration needed [(b)]
1014020	Goat fat	0.05*	0.02*	Further consideration needed [(b)]
1014030	Goat liver	0.1	0.06	Further consideration needed [(b)]
1014040	Goat kidney	0.7	0.7	Further consideration needed [(b)]
1020010	Cattle milk	0.05*	0.01*	Further consideration needed [(b)]
1020020	Sheep milk	0.05*	0.01*	Further consideration needed [(b)]
1020030	Horse milk	0.05*	0.01*	Further consideration needed [(b)]
-	Other products of plant and animal origin	See App. C	-	Further consideration needed [(c)]

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

DOCUMENTATION PROVIDED TO EFSA

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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 waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	NEU	Outdoor	SE	broad leaved weeds	SL	310.0	g/L	Soil treatment - spraying		59	1	1				1.09	kg a.i./ha	n.a.	Not during flowering (latest in May). UK use of 2 x 666 g as/ha; PHI or GS not indicated. SE use seem more cirtical.
Pears	*Pyrus communis*	NEU	Outdoor	SE	broad leaved weeds	SL	310.0	g/L	Soil treatment - spraying		59	1	1				1.09	kg a.i./ha	n.a.	Not during flowering (latest in May). UK use of 2 x 666 g as/ha; PHI or GS not indicated. SE use seem more cirtical.
Cherries	*Prunus cerasus, Prunus avium*	NEU	Outdoor	SE	broad leaved weeds	SL	310.0	g/L	Soil treatment - spraying		59	1	1				1.09	kg a.i./ha	n.a.	Not during flowering (latest in May)
Plums	*Prunus domestica*	NEU	Outdoor	SE	broad leaved weeds	SL	310.0	g/L	Soil treatment - spraying		59	1	1				1.09	kg a.i./ha	n.a.	Not during flowering (latest in May)
Barley	*Hordeum spp.*	NEU	Outdoor	SE, DE	broad leaved weeds	SL	600.0	g/L	Foliar treatment - spraying	13	49	1	1				1.50	kg a.i./ha	n.a.	An approximative PHI of 66 days was reported by SE.
Oats	*Avena fatua*	NEU	Outdoor	SE, DE	broad leaved weeds	SL	600.0	g/L	Foliar treatment - spraying	13	49	1	1				1.50	kg a.i./ha	n.a.	An approximative PHI of 66 days was reported by SE.
Rye	*Secale cereale*	NEU	Outdoor	SE, DE	broad leaved weeds	SL	600.0	g/L	Foliar treatment - spraying	13	49	1	1				1.50	kg a.i./ha	n.a.	An approximative PHI of 66 days was reported by SE.
Wheat	*Triticum aestivum*	NEU	Outdoor	SE, DE	broad leaved weeds	SL	600.0	g/L	Foliar treatment - spraying	13	49	1	1				1.50	kg a.i./ha	n.a.	An approximative PHI of 66 days was reported by SE.
Grass	*not specified*	NEU	Outdoor	SE	broad leaved weeds	SL	600.0	g/L	Foliar treatment - spraying			1	1				1.50	kg a.i./ha	14	Livestock hs to be kept out of treated grassland at least 14 days after treatment

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Oranges	*Citrus sinensis*	SEU	Outdoor	ES	Fruit fall				Foliar treatment - spraying	73	81	1	2			0.02	0.08	kg a.i./ha	20	First application : 37,5 to 75 g a.i./ha, second application: 22,5 to 50 g a.i./ha.
Barley	*Hordeum spp.*	SEU	Outdoor	F	broad leaved weed				Foliar treatment - spraying	29	29	1	1			1.20	1.20	kg a.i./ha	n.a.	
Oats	*Avena fatua*	SEU	Outdoor	F	broad leaved weed				Foliar treatment - spraying	29	29	1	1			1.20	1.20	kg a.i./ha	n.a.	
Rye	*Secale cereale*	SEU	Outdoor	F	broad leaved weed				Foliar treatment - spraying	29	29	1	1			1.20	1.20	kg a.i./ha	n.a.	
Wheat	*Triticum aestivum*	SEU	Outdoor	F	broad leaved weed				Foliar treatment - spraying	29	29	1	1			1.20	1.20	kg a.i./ha	n.a.	

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Dichlorprop-P			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,06**	ARfD (mg/kg bw):	**0,5**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2005**	Year of evaluation:	**2005**

Chronic risk assessment - refined calculations

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

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

Conclusion:

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

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

The acute risk assessment is based on the ARfD.

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

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

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	****)**
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
4,0	Oranges	0,15 / -	2,9	Oranges	0,15 / -	0,8	Oranges	0,15 / -	0,6	Oranges	0,15 / -
0,5	Bovine: Kidney	0,60651428571	0,5	Bovine: Kidney	0,60651428571	0,2	Bovine: Kidney	0,60651428571	0,2	Bovine: Kidney	0,60651428571
0,4	Apples	0,02 / -	0,3	Apples	0,02 / -	0,1	Wheat	0,07 / -	0,1	Wheat	0,07 / -
0,4	Pears	0,02 / -	0,3	Pears	0,02 / -	0,1	Barley	0,07 / -	0,1	Barley	0,07 / -
0,2	Milk and milk	0,01 / -	0,2	Milk and milk	0,01 / -	0,1	Apples	0,02 / -	0,1	Apples	0,02 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		*****)**				*****)**	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
1,5	Orange juice	0,15 / -		0,3	Orange juice	0,15 / -	
0,2	Apple juice	0,02 / -		0,1	Bread/pizza	0,07 / -	
0,2	Wheat flour	0,07 / -		0,0	Apple juice	0,02 / -	
0,1	Pear juice	0,02 / -					
0,1	Plums juice	0,02 / -					

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

Conclusion:

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

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

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS)

(Pesticides - Web Version - EU MRLs (File created on 07/01/2014)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.05*.
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.2.
110030	Lemons (Citron, lemon)	0.05*.
110040	Limes	0.05*.
110050	Mandarins (Clementine, tangerine and other hybrids)	0.05*.
110990	Others	0.05*.
120000	(ii) Tree nuts (shelled or unshelled)	0.05*.
120010	Almonds	0.05*.
120020	Brazil nuts	0.05*.
120030	Cashew nuts	0.05*.
120040	Chestnuts	0.05*.
120050	Coconuts	0.05*.
120060	Hazelnuts (Filbert)	0.05*.
120070	Macadamia	0.05*.
120080	Pecans	0.05*.
120090	Pine nuts	0.05*.
120100	Pistachios	0.05*.
120110	Walnuts	0.05*.
120990	Others	0.05*.
130000	(iii) Pome fruit	0.05*.
130010	Apples (Crab apple)	0.05*.
130020	Pears (Oriental pear)	0.05*.
130030	Quinces	0.05*.
130040	Medlar	0.05*.
130050	Loquat	0.05*.
130990	Others	0.05*.
140000	(iv) Stone fruit	0.05*.
140010	Apricots	0.05*.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
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*.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
161030	Table olives	0.05*.
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.05*.
161050	Carambola (Bilimbi)	0.05*.
161060	Persimmon	0.05*.
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.05*.
161990	Others	0.05*.
162000	(b) Inedible peel, small	0.05*.
162010	Kiwi	0.05*.
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.05*.
162030	Passion fruit	0.05*.
162040	Prickly pear (cactus fruit)	0.05*.
162050	Star apple	0.05*.
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.05*.
162990	Others	0.05*.
163000	(c) Inedible peel, large	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*.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
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	0.05*.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
	similar varieties)	
220990	Others	0.05*.
230000	(iii) Fruiting vegetables	0.05*.
231000	(a) Solanacea	0.05*.
231010	Tomatoes (Cherry tomatoes,)	0.05*.
231020	Peppers (Chilli peppers)	0.05*.
231030	Aubergines (egg plants) (Pepino)	0.05*.
231040	Okra, lady's fingers	0.05*.
231990	Others	0.05*.
232000	(b) Cucurbits - edible peel	0.05*.
232010	Cucumbers	0.05*.
232020	Gherkins	0.05*.
232030	Courgettes (Summer squash, marrow (patisson))	0.05*.
232990	Others	0.05*.
233000	(c) Cucurbits-inedible peel	0.05*.
233010	Melons (Kiwano)	0.05*.
233020	Pumpkins (Winter squash)	0.05*.
233030	Watermelons	0.05*.
233990	Others	0.05*.
234000	(d) Sweet 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*.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
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 corn salad)	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*.

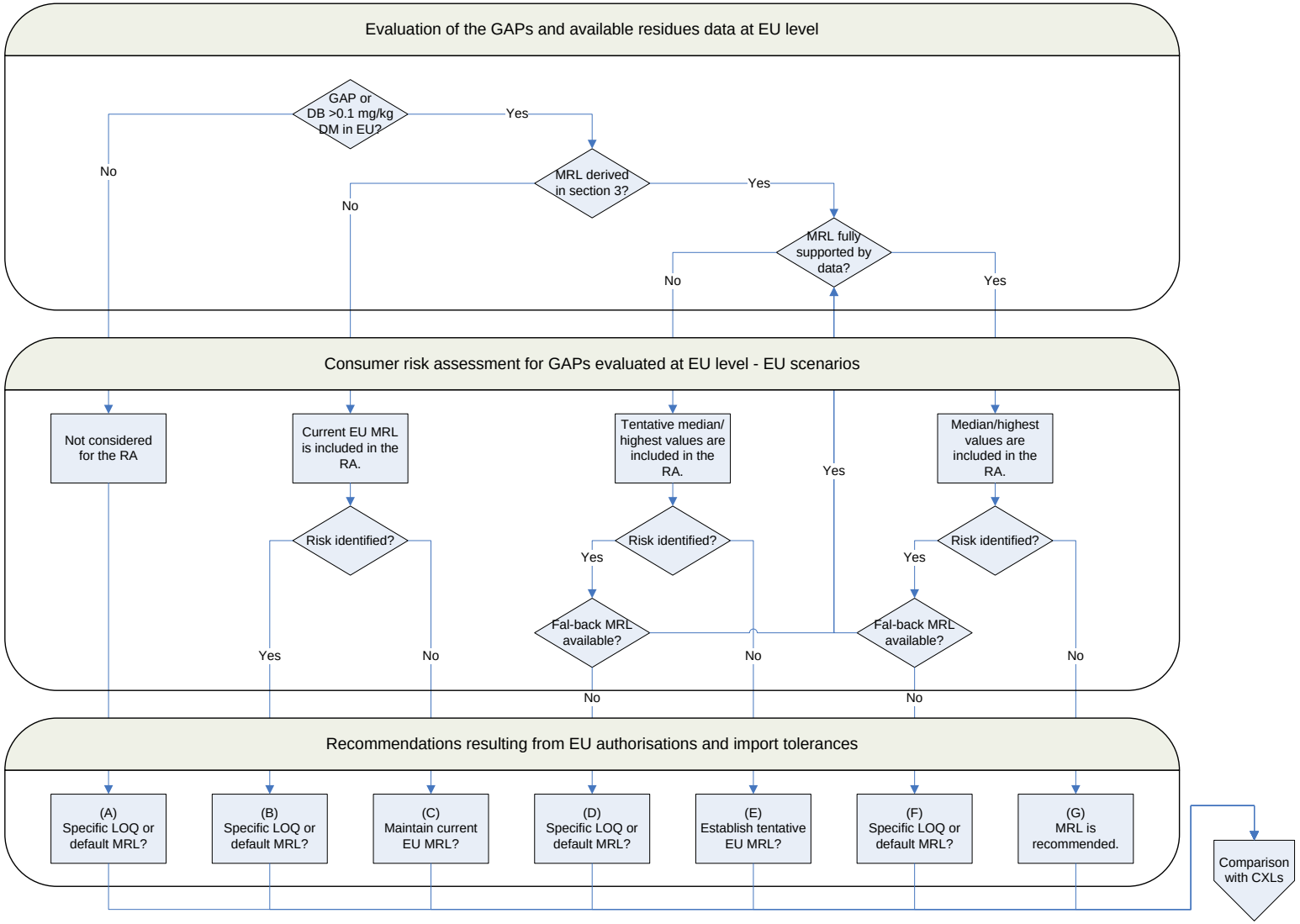
Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
256060	Rosemary	0.05*.
256070	Thyme (marjoram, oregano)	0.05*.
256080	Basil (Balm leaves, mint, peppermint)	0.05*.
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*.

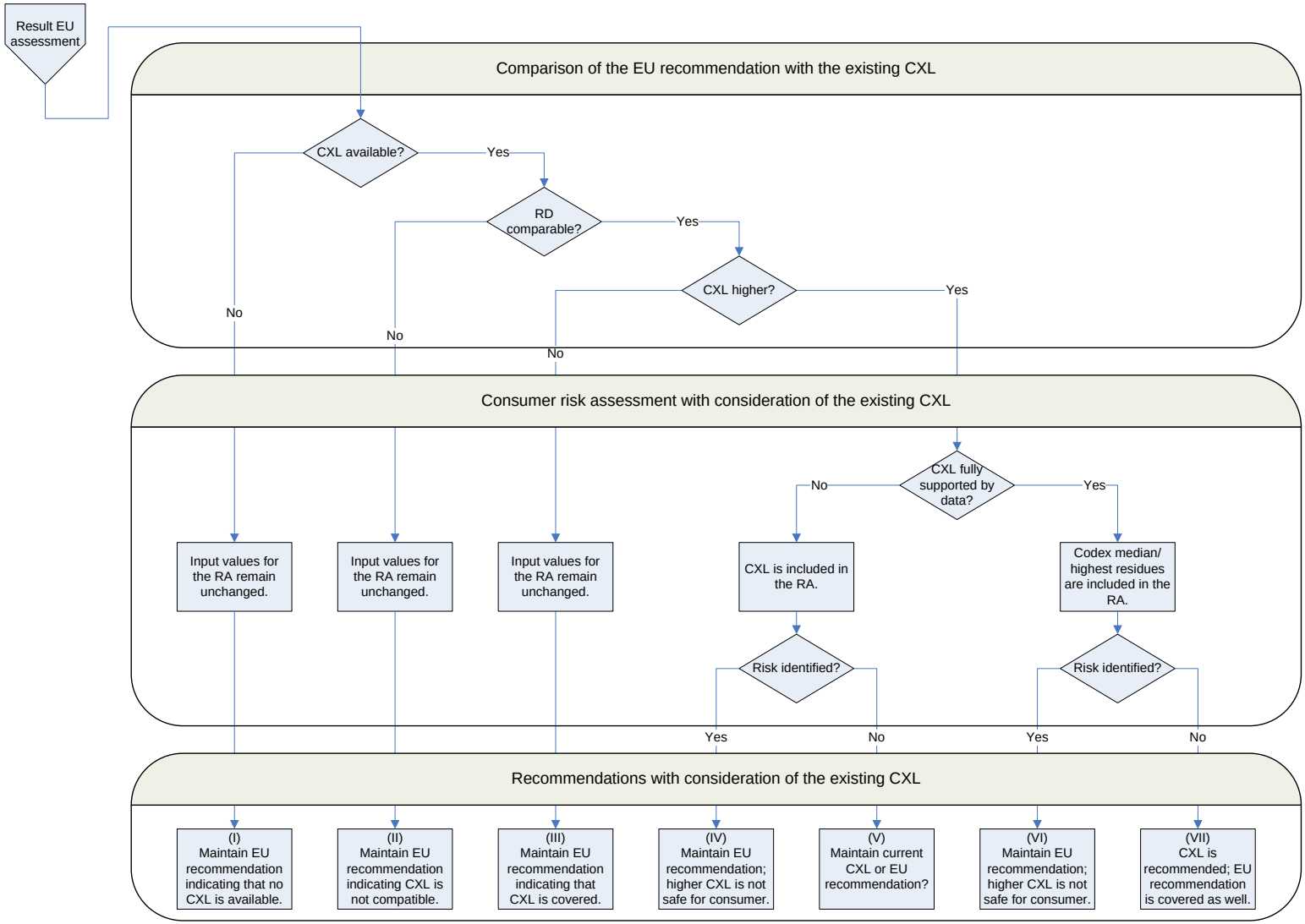
Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
300020	Lentils	0.05*.
300030	Peas (Chickpeas, field peas, chickling vetch)	0.05*.
300040	Lupins	0.05*.
300990	Others	0.05*.
400000	4. OILSEEDS AND OILFRUITS	0.05*.
401000	(i) Oilseeds	0.05*.
401010	Linseed	0.05*.
401020	Peanuts	0.05*.
401030	Poppy seed	0.05*.
401040	Sesame seed	0.05*.
401050	Sunflower seed	0.05*.
401060	Rape seed (Bird rapeseed, turnip rape)	0.05*.
401070	Soya bean	0.05*.
401080	Mustard seed	0.05*.
401090	Cotton seed	0.05*.
401100	Pumpkin seeds	0.05*.
401110	Safflower	0.05*.
401120	Borage	0.05*.
401130	Gold of pleasure	0.05*.
401140	Hempseed	0.05*.
401150	Castor bean	0.05*.
401990	Others	0.05*.
402000	(ii) Oilfruits	0.05*.
402010	Olives for oil production	0.05*.
402020	Palm nuts (palmoil kernels)	0.05*.
402030	Palmfruit	0.05*.
402040	Kapok	0.05*.
402990	Others	0.05*.
500000	5. CEREALS	0.2.
500010	Barley	0.2.
500020	Buckwheat	0.2.
500030	Maize	0.2.
500040	Millet (Foxtail millet, teff)	0.2.
500050	Oats	0.2.
500060	Rice	0.2.
500070	Rye	0.2.
500080	Sorghum	0.2.
500090	Wheat (Spelt Triticale)	0.2.
500990	Others	0.2.

Code number	Groups and examples of individual products to which the MRLs apply (a)	Dichlorprop: sum of dichlorprop (including dichlorprop-P) and its conjugates, expressed as dichlorprop
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.1.
620000	(ii) Coffee beans	0.05*.
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)	0.05*.
650000	(v) Carob (st johns bread)	0.05*.
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0.1.
800000	8. SPICES	0.05*.
810000	(i) Seeds	0.05*.
810010	Anise	0.05*.
810020	Black caraway	0.05*.
810030	Celery seed (Lovage seed)	0.05*.
810040	Coriander seed	0.05*.
810050	Cumin seed	0.05*.
810060	Dill seed	0.05*.
810070	Fennel seed	0.05*.
810080	Fenugreek	0.05*.
810090	Nutmeg	0.05*.
810990	Others	0.05*.
820000	(ii) Fruits and berries	0.05*.
820010	Allspice	0.05*.
820020	Anise pepper (Japan pepper)	0.05*.
820030	Caraway	0.05*.
820040	Cardamom	0.05*.
820050	Juniper berries	0.05*.
820060	Pepper, black and white (Long pepper, pink pepper)	0.05*.
820070	Vanilla pods	0.05*.
820080	Tamarind	0.05*.
820990	Others	0.05*.
830000	(iii) Bark	0.05*.
830010	Cinnamon (Cassia)	0.05*.
830990	Others	0.05*.
840000	(iv) Roots or rhizome	0.05*.
840010	Liquorice	0.05*.
840020	Ginger	0.05*.
840030	Turmeric (Curcuma)	0.05*.
840040	Horseradish	0.05*.
840990	Others	0.05*.
850000	(v) Buds	0.05*.
850010	Cloves	0.05*.
850020	Capers	0.05*.
850990	Others	0.05*.
860000	(vi) Flower stigma	0.05*.
860010	Saffron	0.05*.
860990	Others	0.05*.
870000	(vii) Aril	0.05*.
870010	Mace	0.05*.
870990	Others	0.05*.
900000	9. SUGAR PLANTS	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	0.1
1011050	Edible offal	0.05*.
1011990	Others	0.05*.
1012000	(b) Bovine	
1012010	Meat	0.05*.
1012020	Fat	0.05*.
1012030	Liver	0.1.
1012040	Kidney	0.7.
1012050	Edible offal	0.05*.
1012990	Others	0.05*.
1013000	(c) Sheep	
1013010	Meat	0.05*.
1013020	Fat	0.05*.
1013030	Liver	0.1.
1013040	Kidney	0.7.
1013050	Edible offal	0.05*.
1013990	Others	0.05*.
1014000	(d) Goat	
1014010	Meat	0.05*.
1014020	Fat	0.05*.
1014030	Liver	0.1.
1014040	Kidney	0.7.
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	0.1.
1015040	Kidney	0.7.
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	0.1.
1017040	Kidney	0.7.
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	0.05*.
1020010	Cattle	0.05*.
1020020	Sheep	0.05*.
1020030	Goat	0.05*.
1020040	Horse	0.05*.
1020990	Others	0.05*.
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0.05*.
1030010	Chicken	0.05*.
1030020	Duck	0.05*.
1030030	Goose	0.05*.
1030040	Quail	0.05*.
1030990	Others	0.05*.
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

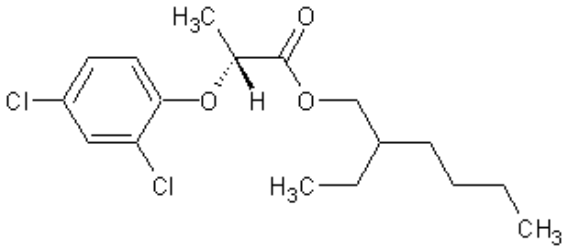
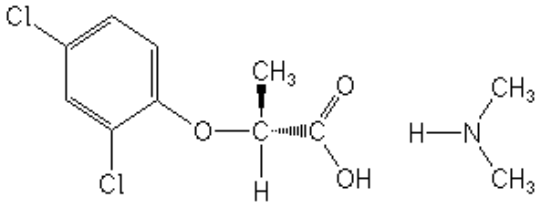
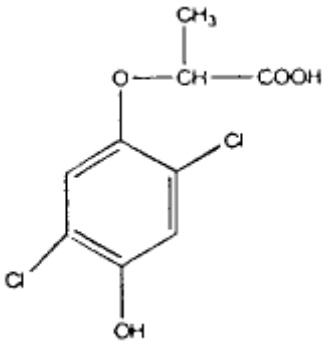
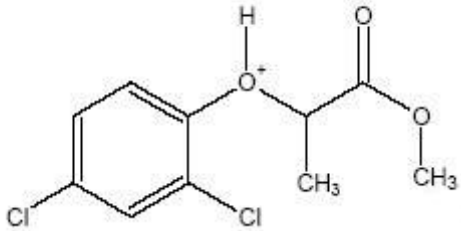
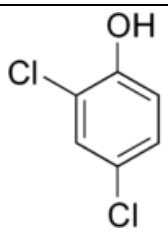
(*) Indicates lower limit of analytical determination

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
dichlorprop-P-2-ethylhexyl dichlorprop-P-2-EHE dichlorprop-P-EHE	(2RS)-2-ethylhexyl (2R)-2-(2,4-dichlorophenoxy) propionate	
dichlorprop-P-dimethylammonium	(2R)-2-(2,4-dichlorophenoxy) propionic acid – dimethylamine (1:1)	
dichlorprop-OH	(*R*)3-hydoxy-2-(2,4-dichlorophenoxy) propionic acid	
dichlorprop-P methyl ester	(R)-2-(2,4-dichlorophenoxy) propanoic acid methyl ester	
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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-MS	gas chromatography with mass spectrometry detection or detector
ha	hectare
HPLC-MS	high performance liquid chromatography with mass spectrometry
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification

MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
$P_{o/w}$	partition coefficient n-octanol/water
PRIMo	(EFSA) Pesticide Residue Intake Model
PROFile	(EFSA) Pesticide Residue Overview File
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organization