

## REASONED OPINION

### Reasoned opinion on the review of the existing maximum residue levels (MRLs) for propanil according to Article 12 of Regulation (EC) No 396/2005<sup>1</sup>

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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 propanil. Considering that this active substance is no longer authorised within the European Union, that no MRLs are established by the Codex Alimentarius Commission, and that no import tolerances were notified to EFSA, residues of propanil are not expected to occur in any plant or animal commodity. Available data were also not sufficient to derive a residue definition or an LOQ for enforcement against potential illegal uses.

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#### KEY WORDS

propanil, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, anilide, herbicide, 3,4-dichloroaniline

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## SUMMARY

A decision not to include propanil in Annex I to Directive 91/414/EEC entered into force on 22 October 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(1) of Regulation (EC) No 396/2005. Considering that the use of propanil is no longer authorised within the European Union and that no import tolerances were notified by the designated rapporteur Member State (Italy), EFSA based its assessment mainly on the conclusions derived by EFSA in the framework of Directive 91/414/EEC.

On 05 April 2013 EFSA issued a draft reasoned opinion that was circulated to Member States' experts for consultation. No comments were received by 07 June 2013 and the following conclusions are derived.

The toxicological profile of propanil was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.02 mg/kg bw per d and 0.07 mg/kg bw, respectively. It was also concluded that major metabolite 3,4-dichloroaniline (3,4-DCA) had a higher acute toxicity than propanil. Nevertheless, no toxicological reference values could be derived for this metabolite.

Considering that the use of propanil is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of propanil are not expected to occur in any plant commodity or livestock. Nevertheless, primary crop metabolism of propanil was investigated in cereals (rice). These data indicate that parent propanil is extensively metabolised and that metabolite 3,4-DCA is the principal component of the residue in consumable crop parts. Therefore, although parent compound propanil can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in acidic and high water content commodities and an LOQ of 0.02 mg/kg in dry commodities, this compound would not be a good indicator for enforcement against a potential illegal use of propanil. However, enforcement of all compounds containing the 3,4-DCA moiety, free and conjugated, is also not considered to be the most appropriate because 3,4-DCA is a metabolite of other authorised compounds such as linuron and measurable levels of 3,4-DCA would not be specific to the illegal use of propanil. Moreover, there is not sufficient evidence that residues of compounds containing the 3,4-DCA moiety can be enforced in food of plant origin and no toxicological reference values are available for 3,4-DCA. Due to the limited data EFSA is not in a position to conclude on the most appropriate option.

The nature of propanil residues in commodities of animal origin was also investigated in lactating cows and laying hens. These data indicate that parent propanil is extensively metabolised to numerous conjugates of propanil and 3,4-DCA. As propanil was not found in plant commodities, animals will never be exposed to parent compound residues and propanil will not be present in livestock commodities. Therefore, although there are indications that propanil can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs, parent compound would not be a good indicator for enforcement against a potential illegal use of propanil in livestock commodities. However, enforcement of all compounds containing the 3,4-DCA moiety, free and conjugated, is also not considered to be the most appropriate due to the same considerations as for plant commodities and, also for commodities of animal origin, EFSA is not in a position to conclude on the most appropriate option.

A risk assessment is in principle not required considering that the use of propanil is no longer authorised within the EU, that no CXLs are available and that no import tolerances have been notified but a theoretical exposure calculation was carried out indicating that the LOQ values of 0.02 mg/kg and 0.01 mg/kg for plant and livestock commodities respectively provide a satisfactory level of protection for the European consumers regarding parent propanil. In case of illegal use, the occurrence

of metabolites containing the 3,5-DCA moiety can not be excluded, even if parent residues levels remain below the LOQ. However, a calculation for these metabolites could not be carried out as no toxicological reference values were derived for 3,4-DCA.

Consequently the existing EU MRLs established for parent propanil are in principle no longer required. Nevertheless, it is noted that neither parent propanil nor metabolites containing the 3,4-DCA moiety can be considered as satisfactory markers for the enforcement against illegal use of propanil. Also considering that the enforcement against potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend the most adequate enforcement measures. However, if propanil is chosen as residue definition for enforcement, available data indicate that LOQs of 0.02 mg/kg and 0.01 mg/kg for plant and livestock commodities respectively would be sufficiently protective for European consumers. If the sum of all compounds containing the 3,4-DCA moiety, free and conjugated, is chosen as residue definition for enforcement, EFSA recommends to await the review of MRLs for linuron according to Article 12 of Regulation (EC) No 396/2005 in order to set MRLs for the sum of compounds taking into consideration the residues generated by the use of linuron. Risk managers could then enforce against the potential illegal use of propanil without prejudice to 3,4-DCA residues resulting from the legal use of linuron.

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## BACKGROUND

Regulation (EC) No 396/2005<sup>4</sup> establishes the rules governing the setting and review of pesticide MRLs at European level. Article 12(1) of that regulation stipulates that EFSA shall provide, within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC<sup>5</sup>, a reasoned opinion on the review of the existing MRLs for that active substance. As a decision not to include propanil in Annex I to Directive 91/414/EEC entered into force on 22 October 2008, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2009-00020 was included in the EFSA Register of Questions.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that the few representative uses evaluated in the framework of that directive might no longer be relevant because the use of active substances that are not included in Annex I is not allowed within the EU. Moreover, non-included substances might still be authorised in third countries, requiring the establishment of import tolerances in Regulation (EC) No 396/2005.

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

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

Italy, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for propanil and to prepare a supporting evaluation report. However, submission of the requested information was not considered necessary as no import tolerances were notified to the RMS.

A draft reasoned opinion was issued by EFSA on 05 April 2013 and submitted to Member States (MS) for commenting. No comments were received by 07 June 2013.

## TERMS OF REFERENCE

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

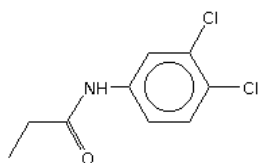
- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;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

<sup>4</sup> 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.

<sup>5</sup> 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 ACTIVE SUBSTANCE AND ITS USE PATTERN

Propanil is the ISO common name for 3',4'-dichloropropionanilide (IUPAC).



Propanil belongs to the group of anilide compounds which are used, among others, as herbicide. Propanil is a post-emergence, foliar contact herbicide which is absorbed by leaves only. It can act against many species of grasses, broad leaved weeds and sedges in field crops, through inhibition of photosynthesis. Herbicidal activity symptoms rapidly appear, usually within hours. Susceptible plants stop growing and leaves become necrotic beginning at the tip of the leaves first.

Propanil was evaluated in the framework of Directive 91/414/EEC with Italy being the designated rapporteur Member State (RMS). The representative use supported for the initial submission was the outdoor post-emergence foliar spray application on rice, twice at 4000 g a.s./ha with a PHI of 90 days, on drained paddy fields in Southern Europe. Following the examination of the Draft Assessment Report (DAR) by the Commission of the European Communities in accordance with Article 11a of Regulation (EC) No 1490/2002<sup>6</sup>, it was concluded that there were clear indications of harmful effects. Indeed, concerns were identified with regard to the operator exposure and to the risk to aquatic organisms, non target arthropods and birds. A first decision on non-inclusion of the active substance in Annex I to Directive 91/414/EEC was therefore published by means of Commission Decision 2008/769/EC<sup>7</sup>, which entered into force on 22 October 2008. According to this Commission Decision, any period of grace granted by Member States in accordance with the provisions of Article 4(6) of Directive 91/414/EEC should have expired on 30 March 2010 at the latest. In accordance with Article 13 of Regulation (EC) No 33/2008<sup>8</sup>, propanil was then subject to a resubmission procedure and a peer-review was carried out by EFSA. The representative use evaluated during this resubmission was the same but with a reduced application rate of 500 g a.s./ha. However, the additional data and information provided did not allow eliminating the concerns which led to the non-inclusion. Indeed, critical areas of concerns were identified in the toxicology, ecotoxicology, environment and residue sections. Consequently, a final decision not to approve propanil under Regulation (EC) No 2009/1107<sup>9</sup>, replacing Directive 91/414/EEC, was published by means of Commission Regulation (EU) No 2011/1078<sup>10</sup>.

The EU MRLs for propanil are established in Annexe IIIA of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the parent compound only, are summarised in Appendix B to this document. CXLs for propanil are not available.

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

<sup>7</sup> 2008/769/EC: Commission Decision of 30 September 2008 concerning the non-inclusion of propanil in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance. OJ L 263, 2.10.2008, p. 14-15.

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

<sup>9</sup> 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.

<sup>10</sup> Commission Implementing Regulation (EU) No 1078/2011 of 25 October 2011 concerning the non-approval of the active substance propanil, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 279, 26.10.2011, p. 1–2.

According to the decision of non-inclusion in Annex I of Directive 91/414/EEC, plant protection products containing propanil are no longer authorised in EU Member States (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion). For the purpose of this MRL review, the RMS did not report any use authorised in third countries that might have a significant impact on international trade.

## ASSESSMENT

Considering that the use of propanil is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, European consumers are not expected to be exposed to residues of this active substance and a consumer risk assessment is, in principle, not required. Risk managers might have the interest, however, to enforce against the potential illegal use of propanil within the EU as well as the presence of illegitimate residue levels in imported products. In order to assist risk managers in applying the most appropriate enforcement measures, EFSA assessed the available data with particular attention to the analytical methods, the toxicological reference values and the nature of residues in plants and livestock. The assessment of EFSA is mainly based on the conclusion on the peer review of the pesticide risk assessment of the active substance propanil (EFSA, 2011), the Draft Assessment Report (DAR), the Additional Report to the DAR and its addendum prepared under Council Directive 91/414/EEC (Italy, 2006, 2010, 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 LC-MS, and its ILV were evaluated and validated for the determination of all compounds containing the 3,4-dichloroaniline (3,4-DCA)<sup>11</sup> moiety in plant matrices with an LOQ of 0.01 mg/kg in dry commodities (rice grain) (Italy, 2011). This method has not been confirmed and the hydrolysis rate has not been demonstrated.

In addition, an analytical method using LC-MS/MS as well as a method using GC-MS were evaluated and validated for the determination of parent propanil with LOQ of 0.01 mg/kg for LC and 0.05 mg/kg for GC in dry commodities (rice grain) and straw (Italy, 2011). These methods have not been confirmed and no ILV is available.

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for analysis of the parent propanil only with an LOQ of 0.01 mg/kg in high water content and acidic commodities and an LOQ of 0.02 mg/kg in dry commodities (EURL, 2013).

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<sup>11</sup> See Appendix B.



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

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Acidic	0.01	98.2	10.7	16	2
	0.10	95.5	6.1	27	
Dry (cereals, dry pulses)	≤ 0.02	89.7	8.2	16	2
	≤ 0.20	97.1	7.7	16	
High water content	≤ 0.01	80.9	5.6	11	2
	0.10	91.7	5.7	11	

Hence, it is concluded that propanil can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in acidic and high water content commodities and an LOQ of 0.02 mg/kg in dry commodities. Nevertheless, there is not sufficient evidence that the sum of compounds containing the 3,4-DCA moiety can be enforced in food of plant origin.

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

During the peer review under Directive 91/414/EEC, an analytical method using LC-MS/MS was evaluated and validated for the determination of parent propanil in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs (Italy, 2011). This method has not been confirmed and no ILV is available.

Hence there are indications that parent propanil can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs but ILV and confirmatory method are missing. Moreover, there is no evidence that all compounds containing the 3,4-DCA moiety can be enforced in food of animal origin.

## 2. Mammalian toxicology

The toxicological assessment of propanil was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2011). These toxicological reference values are summarised in Table 2-1.

**Table 2-1:** Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
<b>Propanil</b>					
ADI	EFSA	2011	0.02 mg/kg bw per d	1-year dog study	300
ARfD	EFSA	2011	0.07 mg/kg bw	30-day dog study	100

The toxicity of the 3,4-DCA metabolite was discussed during the peer review of propanil. Considering that this metabolite has a higher acute toxicity than propanil (i.e. 3,4-DCA is *toxic by inhalation, in contact with skin and if swallowed*, whereas propanil is *harmful if swallowed*), the experts agreed that its toxicity is not covered by the reference values set for propanil. Nevertheless, no toxicological reference values could be set for the metabolite 3,4-DCA (EFSA, 2011).



### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

Metabolism of propanil was investigated for foliar and soil applications in cereals (rice) using <sup>14</sup>C-ring-labelled propanil (EFSA, 2011; Italy, 2010). The characteristics of this study 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 <sup>(a)</sup>	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Cereals	Rice <sup>(b)</sup>	<sup>14</sup> C-ring-labelled propanil	soil treatment and foliar application (on the same day, at 4-5 leaf growth stage), G	- soil treatment <sup>(c)</sup> : 3.36	1	- immature plants (foliage, shoots): 28 and 56	Sources: EFSA, 2011; Italy, 2010
				- foliar application: 3.80	1	- at maturity (straw, rough grain): 110 <sup>(d)</sup>	

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

(b): Rice grown in pots.

(c): The soil application was performed by distribution onto the surface of each pot, of a thin layer of soil previously mixed with <sup>14</sup>C ring labelled-propanil. Pots were flooded the next day after treatments and until harvest.

(d): Rough grains were then processed to hulls and brown rice, which was further processed to bran and milled rice (white rice).

Significant TRR levels were observed in immature shoots (7.02 mg eq./kg 28 DAT, 1.135 mg eq./kg 56 DAT) and at maturity: up to 1.510 mg eq./kg in shoots, 1.218 mg eq./kg in straw, 1.551 mg eq./kg in bran, 0.718 mg/kg in hulls, 0.483 mg/kg in rough rice and 0.245 mg eq./kg in milled rice.

In all plant parts, most of the radioactivity remained unextracted accounting from 60 % TRR (immature shoots, 28 DAT) to 92 % TRR (milled rice). After enzymatic and chemical procedures, this radioactivity was identified to be composed of bound residues incorporated into natural products (protein, starch, lignin, hemicelluloses, etc.). The extracted radioactivity (10 - 35 % TRR) was shown to be composed of numerous fractions where only two metabolites were identified: 3,4-dichloroaniline (3,4-DCA) (*c.a.* 0.3 % TRR in bran and hulls and 7 % TRR in immature shoots) and 3,4-dichloroglucosylamine<sup>12</sup>, accounting for less than 2 % TRR in hulls and straw and up to 4 % TRR in immature shoots. Following alkaline hydrolysis, 20 % of the TRR in straw, rough grain, hulls and bran, was released as 3,4-DCA, suggesting that residues in the extracted fractions were mainly composed of (conjugated) 3,4-DCA and 3,4-DCA analogs.

Furthermore, in order to better understand the metabolic fate of propanil in rice, straw and bran samples were re-analysed 34 months after harvest using more accurate analytical methods. TRR distribution in extractable and non-extractable fractions in rice bran and straw samples were similar to the values previously determined. Parent propanil was confirmed not to be present. Only two metabolites were identified (3,4-DCA and 3,4-dichloroacetanilide<sup>13</sup>, *c.a.* 3 % TRR in straw). The extracted radioactivity was shown to be mainly composed of a total of 14 unidentified compounds (metabolites A to N), mostly polar in nature and yielding 3,4-DCA after alkaline hydrolysis (*c.a.* 20 % TRR). Therefore, even if not supported by reliable storage stability data, this new investigation

<sup>12</sup> See Appendix C.

<sup>13</sup> See Appendix C.

confirms that propanil is not present in rice samples, where the extracted radioactivity is mainly composed of 3,4-DCA and conjugates of 3,4-DCA accounting for about 20 % of the TRR.

In rice, propanil is extensively metabolised. After cleavage, the primary metabolite 3,4-DCA subsequently undergoes conjugation with a glucose moiety to form 3,4-dichloroglucosylamine. Besides, it appears that 3,4-DCA can be oxidized in the aromatic ring followed by conjugation with endogenous plant constituents, such as lignin and carbohydrates.

Based on the results of the metabolism study, radioactive residues in rice samples at harvest are exclusively composed of metabolite 3,4-DCA and its conjugates. Although parent compound propanil can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in acidic and high water content commodities and an LOQ of 0.02 mg/kg in dry commodities, this compound is not a good indicator for enforcement against a potential illegal use of propanil, because it was not found in rice samples at harvest at all. However, enforcement of all compounds containing the 3,4-DCA moiety, free and conjugated, is also not considered to be the most appropriate because 3,4-DCA is a metabolite of other authorised compounds such as linuron and measurable levels of 3,4-DCA would not be specific to the illegal use of propanil. Moreover, there is not sufficient evidence that residues of compounds containing the 3,4-DCA moiety can be enforced in food of plant origin (see also section 1.1) and no toxicological reference values are available for 3,4-DCA (see also section 2).

Due to the limited data EFSA is not in a position to conclude on the most appropriate option but EFSA considers that only one of these two possibilities can be chosen by risk managers. In case the latter option is considered the most appropriate by risk managers, the review of MRLs for linuron according to Article 12 of Regulation (EC) No 396/2005 should be awaited in order to set MRLs for the sum of compounds taking into consideration the residues generated by linuron. Risk managers could then enforce against the potential illegal use of propanil without prejudice to 3,4-DCA residues resulting from the legal use of linuron.

### **3.2. Nature and magnitude of residues in livestock**

Considering that the use of propanil is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of propanil are also not expected to occur in any products of animal origin. Nevertheless, the nature of propanil residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC. Reported metabolism studies include one study in lactating goats and one study in laying hens using <sup>14</sup>C ring labelled-propanil. (EFSA, 2011; Italy, 2010). The characteristics of these studies are summarised in Table 3-2.

In goats, 96 % to around 100 % of the applied radioactivity (AR) was readily eliminated in urine (83.2 to 91.5 % AR) and faeces (10.7 to 12.8 % AR). The highest TRR was found in tissue samples in liver (1.62 – 1.74 mg eq/kg) and kidney (1.59 – 1.86 mg eq/kg), followed by fat. In milk, the level of TRR reached at the 3<sup>rd</sup> day 0.512 – 0.528 mg eq./kg. Loin muscle and leg muscle contained the lowest TRR among all tissues (0.068 – 0.091 mg eq/kg).

Parent compound propanil was detected in all matrices, except in milk. Higher levels of TRR were measured in fat (up to 3.21 % TRR of fat) and liver (up to 5.56 % TRR of liver). Furthermore, data indicate that propanil was generally readily metabolised in goats by hydrolysis and oxidation and was converted to a number of conjugated metabolites related to both parent compound and 3,4-DCA, in milk and tissues.

**Table 3-2:** 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	<sup>14</sup> C-ring-labelled propanil	3 (2 treated, 1 control)	1.5 <sup>(a)</sup>	5	Milk	Daily
						Urine and faeces	Daily
						Tissues	At sacrifice
Laying poultry	Hens	<sup>14</sup> C-ring-labelled propanil	46 (26 treated, 20 controls)	3.98 <sup>(b)</sup>	8	Eggs	Daily
						Excreta	Daily
						Tissues	At sacrifice <sup>(c)</sup>

(a) One gelatin capsule administered daily by balling gun.

(b) Oral administration (in the feed).

(c) Control hens were sacrificed on day 7.

In hens, a major part of the applied radioactivity (AR) was obtained from the excreta. TRR levels found in liver, kidney, muscle and fat were respectively 3.82 mg eq./kg, 3.78 mg eq./kg, 0.23 - 0.40 mg eq./kg and 2.08 mg eq./kg. Levels of radioactivity in eggs were found up to 0.845 mg eq./kg (on the 8<sup>th</sup> day).

Analyses of the metabolites in eggs and tissues showed that parent propanil was detected in all matrices. Higher levels were measured in fat (up to 11.25 % TRR of fat). Furthermore, the most significant metabolites were generally 3,4-dichloroacetanilide and 3,4-dichloroaniline-N-sulfamic acid<sup>14</sup>. In addition to these metabolites, eggs showed significant quantities of 3,4-dichlorolactanilide<sup>15</sup> and 3,4-DCA. Therefore, after ingestion by laying hens, propanil was readily metabolised, initially by hydrolysis and oxidation and subsequently converted to metabolites related to both parent compound and 3,4-DCA. Then, conjugation of these metabolites also occurred. Incorporation of radioactive residues into natural constituents such as lipids, carbohydrates and proteins was insignificant.

The results of the metabolism studies performed with propanil show that radioactive residues in animal samples are composed of both (conjugated) parent compound and (conjugated) metabolite 3,4-DCA. As propanil was not found in plant commodities, animals will never be exposed to parent compound residues and propanil will not be present in livestock commodities. Therefore, although there are indications that propanil can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs, parent compound would not be a good indicator for enforcement against a potential illegal use of propanil in livestock commodities. However, enforcement of all compounds containing the 3,4-DCA moiety, free and conjugated, is also not considered to be the most appropriate because 3,4-DCA is a metabolite of other authorised compounds such as linuron and measurable levels of 3,4-DCA would not be specific to the illegal use of propanil. Moreover, there is not sufficient evidence that residues of compounds containing the 3,4-DCA moiety can be enforced in food of plant origin (see also section 1.1) and no toxicological reference values are available for 3,4-DCA (see also section 2).

Due to the limited data EFSA is not in a position to conclude on the most appropriate option but EFSA considers that only one of these two possibilities can be chosen by risk managers. In case the latter option is considered the most appropriate by risk managers, the review of MRLs for linuron according to Article 12 of Regulation (EC) No 396/2005 should be awaited in order to set MRLs for the sum of

<sup>14</sup> See Appendix C.

<sup>15</sup> See Appendix C.

compounds taking into consideration the residues generated by linuron. Risk managers could then enforce against the potential illegal use of propanil without prejudice to 3,4-DCA residues resulting from the legal use of linuron.

#### 4. Consumer risk assessment

A risk assessment is in principle not required considering that the use of propanil is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), that no CXLs are available and that no import tolerances have been notified. However, in order to assess whether the reported LOQ values are sufficiently protective for European consumers, acute and chronic intake calculations were performed using revision 2 of the EFSA PRIMo (EFSA, 2007). Although the sum of all compounds containing the 3,4-DCA moiety, free and conjugated, is the only residues which could be found in plant and livestock commodities in case of misuses of propanil, no toxicological reference values were derived for metabolite 3,4-DCA. Therefore, intake calculations were performed considering the ARfD and ADI derived for propanil and using the LOQ for propanil of 0.02 mg/kg in all products of plant origin and of 0.01 mg/kg in all products of animal origin.

The detailed results of the acute and chronic intake calculations are reported in Appendix A to this document. The highest chronic exposure was calculated for UK toddlers, representing 5.5 % of the ADI and the highest acute exposure was calculated for potatoes, representing 4.4 % of the ARfD. EFSA highlights that the above calculation does not reflect real exposure of consumers to propanil residues; it is a theoretical calculation indicating that the LOQ values of 0.02 mg/kg and 0.01 mg/kg for plant and livestock commodities respectively provide a satisfactory level of protection for the European consumers regarding parent propanil. However, in case of illegal use, the occurrence of metabolites containing the 3,5-DCA moiety can not be excluded, even if parent residues levels remain below the LOQ.

#### CONCLUSIONS AND RECOMMENDATIONS

The toxicological profile of propanil was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI and an ARfD being established at 0.02 mg/kg bw per d and 0.07 mg/kg bw, respectively. It was also concluded that major metabolite 3,4-dichloroaniline (3,4-DCA) had a higher acute toxicity than propanil. Nevertheless, no toxicological reference values could be derived for this metabolite.

Considering that the use of propanil is no longer authorised within the EU (authorisations for emergency situations in plant protection granted in application of Article 53 of Regulation (EC) No 1107/2009 are not considered in the context of this Reasoned Opinion), that no CXLs are available for this active substance and that no uses authorised in third countries were notified to the RMS, residues of propanil are not expected to occur in any plant commodity or livestock. Nevertheless, primary crop metabolism of propanil was investigated in cereals (rice). These data indicate that parent propanil is extensively metabolised and that metabolite 3,4-DCA is the principal component of the residue in consumable crop parts. Therefore, although parent compound propanil can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in acidic and high water content commodities and an LOQ of 0.02 mg/kg in dry commodities, this compound would not be a good indicator for enforcement against a potential illegal use of propanil. However, enforcement of all compounds containing the 3,4-DCA moiety, free and conjugated, is also not considered to be the most appropriate because 3,4-DCA is a metabolite of other authorised compounds such as linuron and measurable levels of 3,4-DCA would not be specific to the illegal use of propanil. Moreover, there is not sufficient evidence that residues of compounds containing the 3,4-DCA moiety can be enforced in food of plant origin and no toxicological reference values are available for 3,4-DCA. Due to the limited data EFSA is not in a position to conclude on the most appropriate option.

The nature of propanil residues in commodities of animal origin was also investigated in lactating cows and laying hens. These data indicate that parent propanil is extensively metabolised to numerous conjugates of propanil and 3,4-DCA. As propanil was not found in plant commodities, animals will never be exposed to parent compound residues and propanil will not be present in livestock commodities. Therefore, although there are indications that propanil can be enforced in food of animal origin with an LOQ of 0.01 mg/kg in milk, meat, fat, liver, kidney and eggs, parent compound would not be a good indicator for enforcement against a potential illegal use of propanil in livestock commodities. However, enforcement of all compounds containing the 3,4-DCA moiety, free and conjugated, is also not considered to be the most appropriate due to the same considerations as for plant commodities and, also for commodities of animal origin, EFSA is not in a position to conclude on the most appropriate option.

A risk assessment is in principle not required considering that the use of propanil is no longer authorised within the EU, that no CXLs are available and that no import tolerances have been notified but a theoretical exposure calculation was carried out indicating that the LOQ values of 0.02 mg/kg and 0.01 mg/kg for plant and livestock commodities respectively provide a satisfactory level of protection for the European consumers regarding parent propanil. In case of illegal use, the occurrence of metabolites containing the 3,5-DCA moiety can not be excluded, even if parent residues levels remain below the LOQ. However, a calculation for these metabolites could not be carried out as no toxicological reference values were derived for 3,4-DCA.

Consequently the existing EU MRLs established for parent propanil are in principle no longer required. Nevertheless, it is noted that neither parent propanil nor metabolites containing the 3,4-DCA moiety can be considered as satisfactory markers for the enforcement against illegal use of propanil. Also considering that the enforcement against potential illegal uses falls under the remit of risk managers, EFSA is not in a position to recommend to recommend the most adequate enforcement measures. However, if propanil is chosen as residue definition for enforcement, available data indicate that LOQs of 0.02 mg/kg and 0.01 mg/kg for plant and livestock commodities respectively would be sufficiently protective for European consumers. If the sum of all compounds containing the 3,4-DCA moiety, free and conjugated, is chosen as residue definition for enforcement, EFSA recommends to await the review of MRLs for linuron according to Article 12 of Regulation (EC) No 396/2005 in order to set MRLs for the sum of compounds taking into consideration the residues generated by the use of linuron. Risk managers could then enforce against the potential illegal use of propanil without prejudice to 3,4-DCA residues resulting from the legal use of linuron.

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**APPENDIX A – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)**

<b>propanil</b>			
Status of the active substance:	<b>not approved</b>	Code no.:	
LOQ (mg/kg bw):		proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0,02</b>	ARfD (mg/kg bw):	<b>0,07</b>
Source of ADI:	<b>EFSA</b>	Source of ARfD:	<b>EFSA</b>
Year of evaluation:	<b>2011</b>	Year of evaluation:	<b>2011</b>

<b>Chronic risk assessment</b>								
		TMDI (range) in % of ADI minimum - maximum						
		1                      6						
		<b>No of diets exceeding ADI:</b>						
		---						
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	pTMRs at LOQ (in % of ADI)
5,5	UK Toddler	2,3	SUGAR PLANTS	1,2	PRODUCTS OF ANIMAL ORIGIN	0,6	FRUIT (FRESH OR FROZEN)	
5,4	FR toddler	2,2	PRODUCTS OF ANIMAL ORIGIN	1,7	VEGETABLES	1,2	FRUIT (FRESH OR FROZEN)	
5,1	FR infant	2,1	VEGETABLES	1,5	FRUIT (FRESH OR FROZEN)	1,4	PRODUCTS OF ANIMAL ORIGIN	
5,0	UK Infant	2,1	PRODUCTS OF ANIMAL ORIGIN	1,0	SUGAR PLANTS	0,7	VEGETABLES	
4,9	NL child	1,6	PRODUCTS OF ANIMAL ORIGIN	1,5	FRUIT (FRESH OR FROZEN)	1,1	VEGETABLES	
4,8	DE child	2,3	FRUIT (FRESH OR FROZEN)	1,2	PRODUCTS OF ANIMAL ORIGIN	0,7	VEGETABLES	
4,3	WHO Cluster diet B	1,4	VEGETABLES	1,2	CEREALS	0,7	FRUIT (FRESH OR FROZEN)	
3,4	DK child	1,1	PRODUCTS OF ANIMAL ORIGIN	1,0	CEREALS	0,7	VEGETABLES	
3,1	IE adult	1,1	FRUIT (FRESH OR FROZEN)	0,9	VEGETABLES	0,7	CEREALS	
3,0	SE general population 90th percentile	1,0	VEGETABLES	0,9	PRODUCTS OF ANIMAL ORIGIN	0,6	FRUIT (FRESH OR FROZEN)	
2,7	WHO cluster diet E	0,9	VEGETABLES	0,6	CEREALS	0,6	FRUIT (FRESH OR FROZEN)	
2,7	ES child	0,9	PRODUCTS OF ANIMAL ORIGIN	0,6	FRUIT (FRESH OR FROZEN)	0,5	CEREALS	
2,5	WHO cluster diet D	0,9	VEGETABLES	0,8	CEREALS	0,4	PRODUCTS OF ANIMAL ORIGIN	
2,2	WHO regional European diet	0,9	VEGETABLES	0,5	PRODUCTS OF ANIMAL ORIGIN	0,4	CEREALS	
2,2	WHO Cluster diet F	0,7	VEGETABLES	0,5	CEREALS	0,4	FRUIT (FRESH OR FROZEN)	
1,8	PT General population	0,6	FRUIT (FRESH OR FROZEN)	0,5	VEGETABLES	0,5	CEREALS	
1,8	NL general	0,6	VEGETABLES	0,5	FRUIT (FRESH OR FROZEN)	0,4	PRODUCTS OF ANIMAL ORIGIN	
1,8	UK vegetarian	0,4	SUGAR PLANTS	0,4	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
1,6	IT kids/toddler	0,8	CEREALS	0,4	VEGETABLES	0,4	FRUIT (FRESH OR FROZEN)	
1,6	FR all population	0,6	FRUIT (FRESH OR FROZEN)	0,4	VEGETABLES	0,3	CEREALS	
1,6	ES adult	0,4	FRUIT (FRESH OR FROZEN)	0,4	PRODUCTS OF ANIMAL ORIGIN	0,4	VEGETABLES	
1,6	UK Adult	0,4	SUGAR PLANTS	0,3	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
1,4	DK adult	0,4	PRODUCTS OF ANIMAL ORIGIN	0,4	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
1,3	LT adult	0,5	VEGETABLES	0,3	PRODUCTS OF ANIMAL ORIGIN	0,3	CEREALS	
1,2	IT adult	0,5	CEREALS	0,4	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
1,1	FI adult	0,3	PRODUCTS OF ANIMAL ORIGIN	0,3	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	
1,0	PL general population	0,6	VEGETABLES	0,3	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	

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



Acute risk assessment /children				Acute risk assessment / adults / general population								
<p>The acute risk assessment is based on the ARfD.</p> <p>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.</p> <p>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.</p> <p>In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.</p> <p><b>Threshold MRL</b> is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.</p>												
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)
	4,4	Potatoes	0,02 / -	4,3	Melons	0,02 / -	1,5	Pumpkins	0,02 / -	1,5	Pumpkins	0,02 / -
	4,3	Melons	0,02 / -	3,5	Watermelons	0,02 / -	1,2	Watermelons	0,02 / -	1,2	Watermelons	0,02 / -
3,8	Oranges	0,02 / -	3,1	Potatoes	0,02 / -	1,1	Melons	0,02 / -	1,1	Melons	0,02 / -	
3,5	Watermelons	0,02 / -	2,9	Pineapples	0,02 / -	1,0	Chinese cabbage	0,02 / -	1,0	Chinese cabbage	0,02 / -	
2,9	Pineapples	0,02 / -	2,7	Oranges	0,02 / -	0,9	Cauliflower	0,02 / -	0,9	Cauliflower	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:			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)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	1,5	Apple juice	0,02 / -	0,3	Orange juice	0,02 / -	0,2	Apple juice	0,02 / -	0,1	Bread/pizza	0,02 / -
	1,4	Orange juice	0,02 / -	0,2	Apple juice	0,02 / -	0,1	Wine	0,02 / -	0,1	Pineapples preserved	0,02 / -
1,2	Carrot, juice	0,02 / -										
0,9	Grape juice	0,02 / -										
0,5	Peach juice	0,02 / -										
<p>*) 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 &gt; 90% of ARfD are reported.</p> <p>**) pTMRL: provisional temporary MRL</p> <p>***) pTMRL: provisional temporary MRL for unprocessed commodity</p>												
<p><b>Conclusion:</b></p> <p>For propanil 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.</p> <p>For processed commodities, no exceedance of the ARfD/ADI was identified.</p>												

## APPENDIX B – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLs)

(Pesticides - Web Version - EU MRLs - File created on 01/03/2013 14:55)

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,1*
110000	(i) Citrus fruit	0,1*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,1*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,1*
110030	Lemons (Citron, lemon )	0,1*
110040	Limes	0,1*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,1*
110990	Others	0,1*
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	0,1*
130010	Apples (Crab apple)	0,1*
130020	Pears (Oriental pear)	0,1*
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	0,1*
140010	Apricots	0,1*
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	0,1*
140040	Plums (Damson,	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
	greengage, mirabelle)	
140990	Others	0,1*
150000	(v) Berries & small fruit	0,1*
151000	(a) Table and wine grapes	0,1*
151010	Table grapes	0,1*
151020	Wine grapes	0,1*
152000	(b) Strawberries	0,1*
153000	(c) Cane fruit	0,1*
153010	Blackberries	0,1*
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,1*
153030	Raspberries (Wineberries )	0,1*
153990	Others	0,1*
154000	(d) Other small fruit & berries	0,1*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*
154020	Cranberries	0,1*
154030	Currants (red, black and white)	0,1*
154040	Gooseberries (Including hybrids with other ribes species)	0,1*
154050	Rose hips	0,1*
154060	Mulberries (arbutus berry)	0,1*
154070	Azarole (mediteranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,1*
154990	Others	0,1*
160000	(vi) Miscellaneous fruit	0,1*
161000	(a) Edible peel	0,1*
161010	Dates	0,1*
161020	Figs	0,1*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
	kumquats)	
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (java plum) (Java apple (water apple), pomeraç, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,1*
161990	Others	0,1*
162000	(b) Inedible peel, small	0,1*
162010	Kiwi	0,1*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*
162030	Passion fruit	0,1*
162040	Prickly pear (cactus fruit)	0,1*
162050	Star apple	0,1*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,1*
162990	Others	0,1*
163000	(c) Inedible peel, large	0,1*
163010	Avocados	0,1*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*
163030	Mangoes	0,1*
163040	Papaya	0,1*
163050	Pomegranate	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,1*
163070	Guava	0,1*
163080	Pineapples	0,1*
163090	Bread fruit (Jackfruit)	0,1*
163100	Durian	0,1*
163110	Soursop (guanabana)	0,1*
163990	Others	0,1*
200000	2. VEGETABLES FRESH OR FROZEN	0,1*
210000	(i) Root and tuber	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
	vegetables	
211000	(a) Potatoes	0,1*
212000	(b) Tropical root and tuber vegetables	0,1*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*
212020	Sweet potatoes	0,1*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*
212040	Arrowroot	0,1*
212990	Others	0,1*
213000	(c) Other root and tuber vegetables except sugar beet	0,1*
213010	Beetroot	0,1*
213020	Carrots	0,1*
213030	Celeriac	0,1*
213040	Horseradish	0,1*
213050	Jerusalem artichokes	0,1*
213060	Parsnips	0,1*
213070	Parsley root	0,1*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,1*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,1*
213100	Swedes	0,1*
213110	Turnips	0,1*
213990	Others	0,1*
220000	(ii) Bulb vegetables	0,1*
220010	Garlic	0,1*
220020	Onions (Silverskin onions)	0,1*
220030	Shallots	0,1*
220040	Spring onions (Welsh onion and similar varieties)	0,1*
220990	Others	0,1*
230000	(iii) Fruiting vegetables	0,1*
231000	(a) Solanacea	0,1*
231010	Tomatoes (Cherry tomatoes, )	0,1*
231020	Peppers (Chilli peppers)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
231030	Aubergines (egg plants) (Pepino)	0,1*
231040	Okra, lady's fingers	0,1*
231990	Others	0,1*
232000	(b) Cucurbits - edible peel	0,1*
232010	Cucumbers	0,1*
232020	Gherkins	0,1*
232030	Courgettes (Summer squash, marrow (patisson))	0,1*
232990	Others	0,1*
233000	(c) Cucurbits-inedible peel	0,1*
233010	Melons (Kiwano )	0,1*
233020	Pumpkins (Winter squash)	0,1*
233030	Watermelons	0,1*
233990	Others	0,1*
234000	(d) Sweet corn	0,1*
239000	(e) Other fruiting vegetables	0,1*
240000	(iv) Brassica vegetables	0,1*
241000	(a) Flowering brassica	0,1*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1*
241020	Cauliflower	0,1*
241990	Others	0,1*
242000	(b) Head brassica	0,1*
242010	Brussels sprouts	0,1*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,1*
242990	Others	0,1*
243000	(c) Leafy brassica	0,1*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,1*
243020	Kale (Borecole (curly kale), collards)	0,1*
243990	Others	0,1*
244000	(d) Kohlrabi	0,1*
250000	(v) Leaf vegetables & fresh herbs	0,1*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,1*
251010	Lamb's lettuce (Italian	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
	cornsalad)	
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,1*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,1*
251040	Cress	0,1*
251050	Land cress	0,1*
251060	Rocket, Rucola (Wild rocket)	0,1*
251070	Red mustard	0,1*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,1*
251990	Others	0,1*
252000	(b) Spinach & similar (leaves)	0,1*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,1*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,1*
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*
252990	Others	0,1*
253000	(c) Vine leaves (grape leaves)	0,1*
254000	(d) Water cress	0,1*
255000	(e) Witloof	0,1*
256000	(f) Herbs	0,1*
256010	Chervil	0,1*
256020	Chives	0,1*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiaceae)	0,1*
256040	Parsley	0,1*
256050	Sage (Winter savory, summer savory, )	0,1*
256060	Rosemary	0,1*
256070	Thyme ( marjoram, oregano)	0,1*
256080	Basil (Balm leaves, mint,	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
	peppermint)	
256090	Bay leaves (laurel)	0,1*
256100	Tarragon (Hyssop)	0,1*
256990	Others	0,1*
260000	(vi) Legume vegetables (fresh)	0,1*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,1*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,1*
260030	Peas (with pods) (Mangetout (sugar peas))	0,1*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1*
260050	Lentils	0,1*
260990	Others	0,1*
270000	(vii) Stem vegetables (fresh)	0,1*
270010	Asparagus	0,1*
270020	Cardoons	0,1*
270030	Celery	0,1*
270040	Fennel	0,1*
270050	Globe artichokes	0,1*
270060	Leek	0,1*
270070	Rhubarb	0,1*
270080	Bamboo shoots	0,1*
270090	Palm hearts	0,1*
270990	Others	0,1*
280000	(viii) Fungi	0,1*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,1*
280020	Wild (Chanterelle, Truffle, Morel .)	0,1*
280990	Others	0,1*
290000	(ix) Sea weeds	0,1*
300000	3. PULSES, DRY	0,1*
300010	Beans (Broad beans, navy beans, flageolet, jack beans, lima beans, field beans, cowpeas)	0,1*
300020	Lentils	0,1*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
300040	Lupins	0,1*
300990	Others	0,1*
400000	4. OILSEEDS AND OILFRUITS	0,1*
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*
402990	Others	0,1*
500000	5. CEREALS	
500010	Barley	0,1*
500020	Buckwheat	0,1*
500030	Maize	0,1*
500040	Millet (Foxtail millet, teff)	0,1*
500050	Oats	0,1*
500060	Rice	0,2
500070	Rye	0,1*
500080	Sorghum	0,1*
500090	Wheat (Spelt Triticale)	0,1*
500990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*

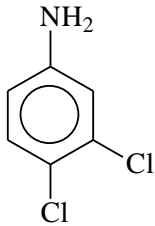
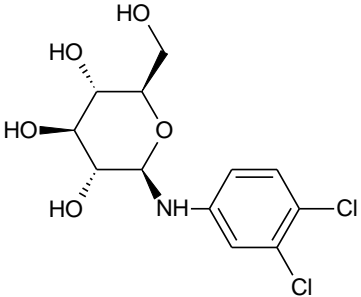
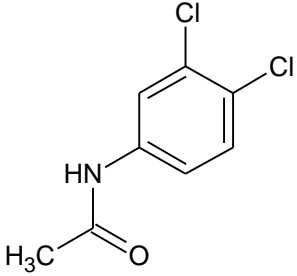
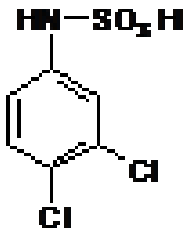
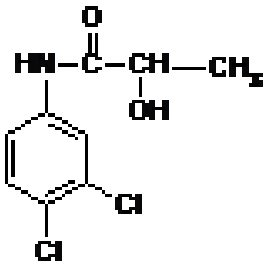
Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	
900010	Sugar beet (root)	
900020	Sugar cane	
900030	Chicory roots	
900990	Others	
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	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	

Code number	Groups and examples of individual products to which the MRLs apply <sup>(a)</sup>	Propanil
1020040	Horse	
1020990	Others	
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	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	0,1*

(\* ) Indicates lower limit of analytical determination

**APPENDIX C – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA**

Common name	IUPAC name	Structural formula
3,4-DCA	3,4-dichloroaniline	
3,4-dichloroglucosylamine  or  <i>N</i> -3,4-dichlorophenyl-glucosylamine	<i>N</i> -(3,4-dichlorophenyl)-β-D-glucopyranosylamine	
-	3,4-dichloroacetanilide	
-	3,4-dichloroaniline- <i>N</i> -sulfamic acid	
-	3,4-dichlorolactanilide	

## ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
AR	applied radioactivity
ARfD	acute reference dose
bw	body weight
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
GC-MS	gas chromatography with mass spectrometry
ha	hectare
ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
LC-MS	liquid chromatography with mass spectrometry
LC-MS/MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
PHI	pre-harvest interval

PROFile	(EFSA) Pesticide Residues Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
RMS	rapporteur Member State
TRR	total radioactive residue