

## REASONED OPINION

### Modification of the existing MRLs for prosulfocarb in carrots and celeriac<sup>1</sup>

#### European Food Safety Authority<sup>2</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

According to Article 6(2) of the Regulation (EC) No 396/2005, France received an application from Syngenta AGRO S.A.S. to modify the existing MRLs for prosulfocarb in carrots and celeriac. In order to accommodate the intended GAP in France, the applicant proposes to raise the existing MRL of 0.1 mg/kg to 1.0 mg/kg for carrots and from 0.05 mg/kg (set at the LOQ) to 0.1 mg/kg for celeriac. France as the Evaluating Member State (EMS) drafted an evaluation report according to Article 8 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 29 May 2009.

During the detailed assessment EFSA identified several issues requiring Member State consultation. The draft reasoned opinion was circulated to Member States for commenting and comments as received from France, The Netherlands, Greece and Germany were considered in the final reasoned opinion. EFSA bases its assessment on the evaluation report prepared by France, the EFSA conclusion prepared in the framework of the peer review and the draft assessment report prepared under Directive 91/414/EEC.

The metabolism of prosulfocarb was investigated in three crop groups following post- and pre-emergence application of the active substance (root and tuber vegetables, cereals, pulses and oilseeds). Metabolic pathway was considered similar in all plants investigated; neither prosulfocarb nor any structurally-related metabolites were detected. Therefore the peer review concluded that the enforcement and risk assessment residue definition should be established as prosulfocarb only.

The metabolism study in potatoes is the most relevant study regarding the intended use in carrots and celeriac. In the potato metabolism study the application rate is comparable with the intended use on immature carrots (baby carrots), but the PHI is significantly longer. Considering the fact that the supervised field trials on baby carrots clearly indicate that significant residues of parent prosulfocarb are present in the edible part of the crop, further information regarding the characterisation and quantification of TRR at earlier growth stages should be provided. The conclusion reached in the peer review for the representative uses needs to be reconsidered for the given applications. EFSA concludes that sufficient information on the metabolism of prosulfocarb applied on crops with a long vegetation period is available, but further information is needed investigating the nature of residues in root crops with a short vegetation period. Adequate analytical method with the LOQ of 0.01 mg/kg is available to enforce the MRLs in carrots and celeriac.

---

1 On request from the European Commission, Question No EFSA-Q-2009-00636, issued on 05 November 2009.

2 Correspondence: [praper.mrl@efsa.europa.eu](mailto:praper.mrl@efsa.europa.eu)

Suggested citation: European Food Safety Authority; Modification of the existing MRLs for prosulfocarb in carrots and celeriac on request from the European Commission. EFSA Journal 2009; 7(11):1373. [24 pp.]. doi:10.2903/j.efsa.2009.1373. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

The submitted supervised field trials data demonstrate that the use on immature carrots leads to significantly higher residues than in mature carrots and should therefore be considered as the critical use for the MRL setting. Therefore a higher MRL of 1.5 mg/kg than proposed by the EMS (1.0 mg/kg) would be necessary to accommodate the intended use on carrots. For celeriac an MRL of 0.1 mg/kg as proposed by the EMS would be required.

No rotational crop studies were performed under the peer review since the potential for residues in succeeding crops was considered to be minimal. EFSA concludes that no residues are expected in rotational crops unless crops with extremely short vegetation period are planted after crop a failure of primary crops treated with prosulfocarb. However, the probability of these cases is very low and no further risk mitigation measures seem to be necessary. Studies on the nature and magnitude of prosulfocarb residues in livestock are not relevant for the current application.

In the peer review it was decided that studies on the effects of processing on the nature and magnitude of prosulfocarb are not required due to very low residues in raw commodities. Since submitted residue trials on carrots now indicate the presence of significant prosulfocarb residues, EFSA is of the opinion that the nature of prosulfocarb residues in processing should be investigated. Regarding effects of processing on the magnitude of residues, specific processing studies are required for a certain crop if the expected total theoretical maximum daily intake exceeds 10 % of the ADI. This trigger value would be exceeded for French infants and toddlers (17.5 and 16.1% of the ADI, respectively) if the total consumption of carrots refers to baby carrots only. However, Member States who provided comments in the framework of the Member State consultation were of the opinion that the major proportion of carrots consumed refers to mature carrots; the consumption of baby carrots is assumed to be of minor relevance. Hence, it is concluded that specific processing studies are not required, unless the hydrolysis study will indicate the formation of a potentially toxic degradation product.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the STMR values for baby carrots and celeriac as obtained from the intended use. The existing MRLs were used as an input values for food commodities other than carrots and celeriac. For the short term intake assessment, the HR values as derived from the intended use on baby carrots and celeriac were used as input values and risk assessment was performed only with regard to these crops.

No long-term intake concerns were identified with regard to the intake of carrots and celeriac. The total calculated intake values range from 11.4 - 81.2% of the ADI. The contribution of carrots to the total dietary intake accounts for 17.5% of the ADI for French infant diet if it is assumed that the total amount of carrots consumed consists of immature baby carrots. However, this assumption is considered as a gross overestimation. If the consumed carrots consist only of mature carrots, the intake of prosulfocarb residues from treated carrots accounts only for 0.5% of the ADI. Celeriac contributes only for up to 0.025% of the ADI for French toddler diet and Irish adult diet.

No acute consumer intake concerns were identified for carrots (47.6% of the ARfD) and celeriac (3.3% of the ARfD).

The following is concluded:

- 1) A metabolism study investigating the nature of prosulfocarb in root crops with a short vegetation period has to be performed
- 1) A study regarding the stability of prosulfocarb under conditions simulating baking/brewing/boiling, pasteurization and sterilization has to be performed.

EFSA recommends establishing the following temporary MRLs in Annex III of Regulation (EC) No 396/2005:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: prosulfocarb</b>			
Carrots	0.1	1.5	The intended uses of prosulfocarb on carrots and celeriac are acceptable with regard to consumer safety.
Celeriac	0.05*	0.1	

\*indicates the limit of analytical quantification

The requested data have to be evaluated in the framework of Article 12 (1) of Regulation (EC) No 396/2005 and if necessary the conclusions reached in this reasoned opinion have to be revised.

#### KEY WORDS

Prosulfocarb, carrots, celeriac, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, thiocarbamates herbicide.

## TABLE OF CONTENTS

Summary .....	1
Table of contents .....	4
Background .....	5
Terms of reference.....	5
The active substance and its use pattern.....	6
Assessment .....	7
1. Methods of analysis .....	7
1.1. Methods for enforcement of residues in food of plant origin .....	7
1.2. Methods for enforcement of residues in food of animal origin .....	7
2. Mammalian toxicology .....	7
3. Residues.....	7
3.1. Nature and magnitude of residues in plant.....	7
3.1.1. Primary crops.....	7
3.1.2. Rotational crops.....	12
3.2. Nature and magnitude of residues in livestock .....	12
4. Consumer risk assessment .....	12
Conclusions and recommendations .....	14
References .....	15
Appendix A – Good Agricultural Practices (GAPs) .....	16
Appendix B – Pesticide Residues Intake Model (PRIMo).....	17
Appendix C – Existing EC MRLs.....	20
Abbreviations .....	23

## BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

France, hereafter referred to as the evaluating Member State (EMS), received an application from Syngenta AGRO S.A.S.<sup>3</sup> to modify the existing MRLs for the active substance prosulfocarb in carrots and celeriac. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00636 and the following subject:

*Prosulfocarb - Application to modify the existing MRLs for prosulfocarb in carrots from 0.1 mg /kg to 1 mg/kg and in celeriac from 0.05\*mg/kg to 0.1 mg/kg.*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

During the detailed assessment EFSA identified several issues requiring Member State consultation. The draft reasoned opinion was circulated to Member States for commenting on 22 September 2009. By the deadline (7 October 2009), comments were received from France, The Netherlands, Greece and Germany. The final reasoned opinion reflects the considerations and comments received from the commenting Member States.

## TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

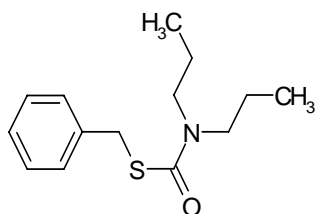
In this particular case the calculated deadline for providing the reasoned opinion is 29 August 2009.

---

<sup>3</sup> Syngenta AGRO S.A.S., Avenue des Pres 1, CS 10537, 7828, Guyancourt cedex, France

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Prosulfocarb is the ISO common name for S-benzyl dipropylthiocarbamate (IUPAC):



Molecular mass: 251.4 g/mol

Prosulfocarb is a herbicide belonging to the chemical class of thiocarbamates. Prosulfocarb (pre-emergence and early post-emergence applications) is used for the selective control of a wide range of grass and broad-leaved weeds. It is absorbed by the leaves and roots of the plant and it acts by inhibiting growth in the meristematic region. It causes dark greening, twisting, inhibition of shoots and roots, and a failure of leaf emergence from coleoptiles.

Prosulfocarb was assessed in stage three of the peer review according to Commission Directive 91/414/EEC. Sweden is the designated Rapporteur Member State. The peer review of prosulfocarb is finalized and an EFSA conclusion was issued on 27 July 2007 (EFSA, 2007). Prosulfocarb was included in Annex I to Directive 91/414/EEC by Commission Directive 2007/76/EC which entered into force on 1 November 2008. The representative uses evaluated under the peer review cover pre-emergence application of the active substance on wheat and potatoes.

Temporary EU MRLs have been established for prosulfocarb in Annex III of Regulation (EC) No 396/2005 (Appendix C) which were derived from previously established national MRLs. All MRLs are established at the LOQ of 0.05 mg/kg, except the MRLs for carrots and several other root and tuber vegetables which are set at 0.1 mg/kg. Significant higher MRLs were also set for celery, herbal infusions (2 mg/kg) and certain spices. Prosulfocarb has not been evaluated by the JMPR and no CXLs are therefore set for the active substance.

The GAPs for which the authorizations are requested in France refer to a single application of prosulfocarb with an application rate of 4 kg a.s./ha on carrots and celeriac at a growth stage of BBCH 12-14. The minimum waiting period (PHI) is 49 days for short cycle carrots, 80 days for medium cycle carrots and 100 days for celeriac. The details of the GAPs are outlined in Appendix A.

EFSA bases its assessment on the evaluation report submitted by France (2009), EFSA conclusion of the peer review of prosulfocarb (EFSA, 2007) and the draft assessment report prepared under Directive 91/414/EEC (Sweden, 2005).

## ASSESSMENT

### 1. Methods of analysis

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

Analytical enforcement methods for the determination of prosulfocarb residues in plant matrices were evaluated in the framework of the peer review of 91/414/EEC (Sweden, 2005). The multi-residue method DFG-S19 is sufficiently validated at the LOQ of 0.01 mg/kg for the determination of prosulfocarb residues in plant matrices with high acid, high water and high oil content as well as in dry matrices. EFSA therefore concludes that an adequate analytical method is available for the determination of prosulfocarb residues in carrots and celeriac.

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

Carrots and celeriac are not normally used as livestock feed items therefore analytical methods for the determination of prosulfocarb residues in commodities of animal origin are not of relevance for the current MRL application.

### 2. Mammalian toxicology

The toxicological reference values were derived in the framework of the peer review and are compiled in the table below (EFSA, 2007).

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

	Source	Year	Value	Study relied upon	Safety factor
Prosulfocarb					
ADI	EFSA	2007	0.005 mg/kg bw/d	2 yr rat oral toxicity, supported by the multi-generation study	100
ARfD	EFSA	2007	0.1 mg/kg bw	Rat, developmental toxicity	100

### 3. Residues

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

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

The metabolism of prosulfocarb was investigated under the peer review of Directive 91/141/EEC in the following crop categories (Sweden, 2005):

- cereals: post-emergence application on winter wheat (3.64 kg a.s./ha. PHI=283 d) and post emergence application in winter barley (4 kg a.s./ha, sampling 7, 14, and 161 days after the application).



- pulses and oilseeds: pre-emergence application- peas (4.05 kg a.s./ha)
- root and tuber vegetables: potatoes – pre-emergence application at a rate of 3.42 kg a.s./ha (PHI=105 d)

The metabolism studies were performed using [<sup>14</sup>C]-phenyl radiolabelled prosulfocarb.

The TRR in winter wheat grain and straw contained in total 0.012 mg/kg and 0.036 mg/kg prosulfocarb equivalents respectively. The radioactive residues in grain were separated into four fractions, all at levels less than 0.01 mg/kg prosulfocarb equivalents.

Immature barley foliage samples were analyzed at BBCH 12-22 (7 and 14 PHI); barley straw and grain samples were analyzed at full maturity 237 PHI. Results indicate that parent prosulfocarb was the major component of the TRR in immature foliage 7 PHI (10.9% TRR or 4.6 mg/kg, in hexane fraction) along with several metabolites in aqueous phase (2B<sup>4</sup> (10.5% TRR), 2C<sup>5</sup> (6.9% TRR), 2D<sup>6</sup> (6.9% TRR)). Results with immature barley indicate that amount of parent prosulfocarb tends to decrease with longer PHI (3.7% TRR or 1.85 mg/kg at 14 PHI) while the number of metabolites, due to extensive metabolism, tends to increase at 14 DAT. At the PHI of 161 days the amount of metabolites has significantly decreased, being below 10% TRR. Results indicate no presence of prosulfocarb and any prosulfocarb specific metabolites in mature grain and straw.

The TRR in mature peas was 0.05 mg/kg prosulfocarb equivalents. The majority of the residue (0.03 mg/kg prosulfocarb equivalents) was associated with readily extractable proteins and 0.01 mg/kg prosulfocarb equivalents were released by enzymatic digestion, indicating the incorporation of radioactivity into carbohydrates.

In potato tubers, the total radioactive residue (TRR) measured was low accounting for 0.096 mg/kg prosulfocarb equivalents. Some of this residue results from the incorporation of radioactivity into potato starch. Neither prosulfocarb nor any related metabolites were detected. A trace level of benzoic acid (0.003 mg/kg) was detected in the organosoluble fraction and there were at least seven other compounds in this fraction, but none exceeded 0.01 mg/kg. No information was provided regarding the nature of residues at earlier growth stages.

On the basis of the metabolism studies assessed in the peer review, the experts concluded that the TRR in edible plant parts is extremely low and mainly associated to endogenous plant materials. Neither prosulfocarb nor any structurally-related metabolites were detected in significant concentrations in cereal grain, mature potatoes and mature peas. On the basis of the residue pattern found in immature barley the metabolic pathway was suggested to consist of several routes involving hydrolysis, oxidation and dealkylation of the parent compound. Nine compounds including parent were in total identified. In the peer review it was concluded that the residue definition for enforcement and risk assessment should be established as prosulfocarb only since metabolism studies indicate that representative uses do not lead to quantifiable levels of any residual compound structurally related to the parent compound in the edible parts of these commodities.

The metabolism study in potatoes is the most relevant study with regard to the intended use in carrots and celeriac. In this study the application rate was comparable with the intended use (0.85 N), but the PHI is significantly longer (105 days instead of 49 days, 80 days or 100 days for immature carrots, mature carrots and celeriac, respectively). Considering the fact that the supervised field trials on immature carrots clearly indicate that significant residues of parent prosulfocarb are present in the edible part of the crop (see 3.1.1.2), further information regarding the characterisation and quantification of the TRR at earlier growth stages should be provided. Thus, the conclusion reached in

---

<sup>4</sup> 2B: 3-phenylmethanesulfinyl-2-(3,4,5-trihydroxy-6-hydroxymethyl-tetrahydro-pyran-2-yloxy)-propionic acid

<sup>5</sup> 2C: 6-(2-benzoyloxy-1-hydroxymethyl-ethoxy)-3,4,5-trihydroxy-tetrahydro-pyran-2-yloxy)propionic acid

<sup>6</sup> 2D: 3-benzylsulfonyl-2-(3,4,5-trihydroxy-6-hydroxy-tetrahydro-pyran-2-yloxy)propionic acid



the peer review for the representative uses - that no quantifiable residues of parent compound or metabolites are expected - needs to be reconsidered for the given applications in carrots and celeriac.

EFSA concludes that sufficient information on the metabolism of prosulfocarb applied on crops with a long vegetation period is available, but further information is needed investigating the nature of residues in root crops with a short vegetation period.

#### 3.1.1.2. Magnitude of residues

In support of the proposed GAPs, the applicant submitted 15 supervised residue field trials on carrots for the use in the NEU (8 on medium vegetation cycle (mature) carrots and 7 on short vegetation cycle (immature) carrots or “baby carrots”) and 11 residue trials for the use in the SEU (8 on mature carrots and 3 on immature carrots). The data demonstrate that the use on immature carrots leads to significantly higher residues and should therefore be considered as the critical use for the MRL setting. Although the number of trials for the use on “baby carrots” grown in Southern Europe is not sufficient, a tentative MRL proposal is derived for the use on baby carrots in Northern EU.

In support of the proposed GAP on celeriac the applicant submitted four residue trials representing the residue situation in the crop following the NEU use. Taking into account that the use is intended in France (covering Northern and Southern European regions), additional trials on celeriac would be required. France addressed this data request by providing summary residue data on potatoes where samples were taken 75 – 125 days after the last treatment. Additional residue trials for potatoes are reported in the DAR which can be used as supporting data. The combined data set – trials on celeriac, potatoes and mature carrots - was used to derive a MRL proposal for celeriac.

All the residues trials data and the proposed MRLs are summarized in Table 3-1.

The storage stability of prosulfocarb has been investigated under the peer review in cereal grain, straw, forage, potato and legumes (peas, dry beans). Residues of prosulfocarb in matrices with high water content are stable for at least 18 months when stored at  $<-18^{\circ}\text{C}$ . Residues of prosulfocarb in peas and dry beans are stable for at least 23 months and in straw and forage for at least 25 months when stored at  $<-18^{\circ}\text{C}$  (Sweden, 2005). An additional storage stability study of prosulfocarb residues in carrots and sunflower seeds is reported by the EMS (Sweden, 2009). Study indicates that the residues of prosulfocarb in analyzed matrices will be stable for at least 14 months when stored deep frozen. The supervised residue trial samples prior analyses were stored deep frozen for a maximum of 12 months thereby not exceeding the demonstrated storage stability period of the active substance.

According to the EMS, supervised field trials data are considered valid with regard to analytical performance.

**Table 3-1.** Overview of the available residues trials data

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (Prosulfocarb)	Risk assessment (Prosulfocarb)					
Carrots (mature) (PHI 80 d)	NEU	Outdoor	4 x <0.01; 0.01; 2 x 0.02; 0.06	4 x <0.01; 0.01; 2 x 0.02; 0.06	<b>0.01</b>	<b>0.06</b>	<b>0.1</b>	<b>1.0</b>	Residue trials data indicate that no MRL modification is necessary. $R_{ber\ NEU}=0.04$ mg/kg $R_{max\ NEU}=0.074$ mg/kg $R_{ber\ SEU}=0.055$ mg/kg $R_{max\ SEU}=0.055$ mg/kg
	SEU	Outdoor	3 x < 0.01; 2 x 0.01; 0.02; 0.03; 0.04*	3 x < 0.01; 2 x 0.01; 0.02; 0.03; 0.04*	0.01	0.04	0.1	1.0	
Carrots (immature) (PHI 49 d)	NEU	Outdoor	<0.01; 0.02; 0.04; 0.33; 0.34; 0.57; 0.75	<0.01; 0.02; 0.04; 0.33; 0.34; 0.57; 0.75	<b>0.33</b>	<b>0.75</b>	<b>1.5</b>	<b>1.0</b>	Residue trials indicate that the use of prosulfocarb on immature carrots results in a more critical residue situation in the crop (indicated in bold) and therefore these data were used for deriving the MRL proposal and risk assessment values for carrots. $R_{ber\ NEU}=1.14$ mg/kg $R_{max\ NEU}=1.28$ mg/kg $R_{ber\ SEU}=1.08$ mg/kg $R_{max\ SEU}=1.701$ mg/kg
	SEU	Outdoor	0.19; 0.34; 0.54	0.19; 0.34; 0.54	0.34	0.54	1.5	1.0	
Celeriac (carrots, potatoes)	NEU	Outdoor	Celeriac: 2 x <0.02; 0.027; 0.035 Carrots: 4 x <0.01; 0.01; 2 x 0.02; 0.06 Potatoes: 14 x <0.01; 4 x 0.02	Celeriac: 2 x <0.02; 0.027; 0.035 Carrots: 4 x <0.01; 0.01; 2 x 0.02; 0.06 Potatoes: 14 x < 0.01; 4 x 0.02	<b>0.01</b>	<b>0.06</b>	<b>0.1</b>	<b>1.0</b>	Residue trials data following the NEU use of prosulfocarb on celeriac, carrots and potatoes were combined. Insufficient data are for the SEU use. Taking into account the low

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STM (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement (Prosulfocarb)	Risk assessment (Prosulfocarb)					
	SEU	Outdoor	Carrots: 3 x < 0.01; 2 x 0.01; 0.02; 0.03; 0.04* Potatoes: 2 x <0.01 Celeriac : n.a.	Carrots: 3 x < 0.01; 2 x 0.01; 0.02; 0.03; 0.04* Potatoes: 2 x <0.01 Celeriac: n.a.	0.01	0.04	0.1	1.0	residue levels, data could be combined to derive an MRL proposal for celeriac.

(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.

(\*): Residue value at longer PHI of 103 days

### 3.1.1.3. Effect of industrial processing and/or household preparation

For the representative uses evaluated under the peer review of 91/414/EEC (potatoes and wheat), metabolism studies and supervised field trials indicated that prosulfocarb residues are unlikely to be found in raw agricultural commodity when prosulfocarb is applied according to the proposed GAP (Sweden, 2005). Thus, processing studies were not considered necessary.

No additional information was submitted in support of this MRL application, although the results of the supervised residue field trials provide evidence that the assumption made in the peer review for waiving processing studies is not applicable for carrots. EFSA therefore concludes that the nature of prosulfocarb residues in processing should be investigated in a hydrolysis study simulating the effect of pasteurisation, boiling and sterilisation.

According to the guidance document on processing studies (European Commission, 1997), specific processing studies are required for a certain crop if the expected total theoretical maximum daily intake exceeds 10 % of the ADI. This trigger value would be exceeded for French infants and toddlers (17.5 and 16.1% of the ADI, respectively) if the total consumption of carrots refers to baby carrots only which contain residues at the level of 0.33 mg/kg (STMR for NEU baby carrots). However, Member States who provided comments in the framework of the Member State consultation were of the opinion that the major proportion of carrots consumed refers to mature carrots; the consumption of baby carrots is assumed to be of minor relevance. Hence, specific processing studies are not required, unless the hydrolysis study will indicate the formation of a potentially toxic degradation product.

### 3.1.2. Rotational crops

Carrots and celeriac are crops for which a crop rotation is relevant. Degradation of prosulfocarb in soil was investigated in the framework of the peer review of Directive 91/414/EEC (Sweden, 2005). According to field studies the maximum  $DT_{90}$  for prosulfocarb is 48 days. Prosulfocarb in soil forms a minor soil metabolite prosulfocarb sulfoxide<sup>7</sup>, which exhibits low persistence (max  $DT_{90lab}$  = 13 d). Peer review concluded that, taking into account the relatively rapid degradation of prosulfocarb and its breakdown products in soil and the delay in planting subsequent crops, the potential for residues in following crops is considered minimal. Therefore the need for rotational crop studies was considered as irrelevant and no studies were requested.

EFSA concludes that no residues are expected in rotational crops unless crops with extremely short vegetation period are planted after crop a failure of primary crops treated with prosulfocarb. However, the probability of these cases is very low and no further risk mitigation measures seem to be necessary.

## 3.2. Nature and magnitude of residues in livestock

Carrots and celeriac are not typical livestock feeding items therefore the nature and magnitude of prosulfocarb residues in livestock is not further discussed under the current opinion.

## 4. Consumer risk assessment

A provisional consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). In case metabolism studies on crops with short vegetation period give reason to revise the residue definition for risk assessment, the consumer risk assessment has to be revised.

---

<sup>7</sup> prosulfocarb sulfoxide: 1-(benzylsulfinyl)-N, N-dipropylmethanamide

For the chronic intake assessment the STMR value for baby carrots and celeriac as derived from the intended use was used as an input value. The existing MRLs (as established in Annex III Regulation (EC) No 396/2005) were used as input values for food commodities other than carrots and celeriac.

The acute intake assessment was performed only with regard to carrots and celeriac and the HR values as derived for the intended uses were used as input values.

Input values are summarized in table 4-1.

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: <b>prosulfocarb</b>				
Carrots	0.33	STMR (baby carrots, NEU)	0.75	HR
Celeriac	0.01	STMR	0.06	HR
Other commodities	MRL	See Appendix C	Not relevant	

Summary of consumer intake calculations can be found in Appendix B.

No long-term intake concerns were identified with regard to the intake of carrots and celeriac. The total calculated intake values range from 11.4 - 81.2% of the ADI. It should be noted, that the contribution of commodities for which the MRLs are set at the LOQ of 0.05 mg/kg contribute for up to 64.9% of the ADI. The contribution of carrots to the total dietary intake accounts for 17.5% of the ADI for French infant diet if it is assumed that the total amount of carrots consumed consists of immature baby carrots. However, as discussed previously (see section 3.1.1.3), this assumption is considered as a gross overestimation. If the consumed carrots consist only of mature carrots, the intake of prosulfocarb residues from carrots accounts only for 0.5% of the ADI. Celeriac contributes only for up to 0.025% of the ADI for French toddler diet and Irish adult diet.

No acute consumer intake concerns were identified for carrots (47.6% of the ARfD) and celeriac (3.3% of the ARfD).

Consequently EFSA comes to a conclusion that the intended uses of prosulfocarb on carrots and celeriac are acceptable with regard to consumer safety unless the metabolism study on root crops with short vegetation period (see section 3.1.1.1) or the hydrolysis study (see section 3.1.1.3) will reveal the occurrence of toxicologically relevant compounds in significant concentrations.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The metabolism of prosulfocarb was investigated in three crop groups following post- and pre-emergence application of the active substance (root and tuber vegetables, cereals, pulses and oilseeds). Metabolic pathway was considered similar in all plants investigated; neither prosulfocarb nor any structurally-related metabolites were detected. Therefore the peer review concluded that the enforcement and risk assessment residue definition should be established as prosulfocarb only.

The metabolism study in potatoes is the most relevant study regarding the intended use in carrots and celeriac. In the potato metabolism study the application rate is comparable with the intended use on immature carrots (baby carrots), but the PHI is significantly longer. Considering the fact that the supervised field trials on baby carrots clearly indicate that significant residues of parent prosulfocarb are present in the edible part of the crop, further information regarding the characterisation and quantification of TRR at earlier growth stages should be provided. The conclusion reached in the peer review for the representative uses needs to be reconsidered for the given applications. EFSA concludes that sufficient information on the metabolism of prosulfocarb applied on crops with a long vegetation period is available, but further information is needed investigating the nature of residues in root crops with a short vegetation period. Adequate analytical method with the LOQ of 0.01 mg/kg is available to enforce the MRLs in carrots and celeriac.

The submitted supervised field trials data demonstrate that the use on immature carrots leads to significantly higher residues than in mature carrots and should therefore be considered as the critical use for the MRL setting. Therefore a higher MRL of 1.5 mg/kg than proposed by the EMS (1.0 mg/kg) would be necessary to accommodate the intended use on carrots. For celeriac an MRL of 0.1 mg/kg as proposed by the EMS would be required.

No rotational crop studies were performed under the peer review since the potential for residues in succeeding crops was considered to be minimal. EFSA concludes that no residues are expected in rotational crops unless crops with extremely short vegetation period are planted after crop a failure of primary crops treated with prosulfocarb. However, the probability of these cases is very low and no further risk mitigation measures seem to be necessary. Studies on the nature and magnitude of prosulfocarb residues in livestock are not relevant for the current application.

In the peer review it was decided that studies on the effects of processing on the nature and magnitude of prosulfocarb are not required due to very low residues in raw commodities. Since submitted residue trials on carrots now indicate the presence of significant prosulfocarb residues, EFSA is of the opinion that the nature of prosulfocarb residues in processing should be investigated. Regarding effects of processing on the magnitude of residues, specific processing studies are required for a certain crop if the expected total theoretical maximum daily intake exceeds 10 % of the ADI. This trigger value would be exceeded for French infants and toddlers (17.5 and 16.1% of the ADI, respectively) if the total consumption of carrots refers to baby carrots only. However, Member States who provided comments in the framework of the Member State consultation were of the opinion that the major proportion of carrots consumed refers to mature carrots; the consumption of baby carrots is assumed to be of minor relevance. Hence, it is concluded that specific processing studies are not required, unless the hydrolysis study will indicate the formation of a potentially toxic degradation product.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. For the chronic intake assessment EFSA used the STMR values for baby carrots and celeriac as obtained from the intended use. The existing MRLs were used as an input values for food commodities other than carrots and celeriac. For the short term intake assessment, the HR values as derived from the intended use on

baby carrots and celeriac were used as input values and risk assessment was performed only with regard to these crops.

No long-term intake concerns were identified with regard to the intake of carrots and celeriac. The total calculated intake values range from 11.4 - 81.2% of the ADI. The contribution of carrots to the total dietary intake accounts for 17.5% of the ADI for French infant diet if it is assumed that the total amount of carrots consumed consists of immature baby carrots. However, this assumption is considered as a gross overestimation. If the consumed carrots consist only of mature carrots, the intake of prosulfocarb residues from treated carrots accounts only for 0.5% of the ADI. Celeriac contributes only for up to 0.025% of the ADI for French toddler diet and Irish adult diet. No acute consumer intake concerns were identified for carrots (47.6% of the ARfD) and celeriac (3.3% of the ARfD).

The following is concluded:

- 1) A metabolism study investigating the nature of prosulfocarb in root crops with a short vegetation period has to be performed
- 2) A study regarding the stability of prosulfocarb under conditions simulating baking/brewing/boiling, pasteurization and sterilization has to be performed.

EFSA recommends establishing the following temporary MRLs in Annex III of Regulation (EC) No 396/2005:

#### RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<b>Enforcement residue definition: prosulfocarb</b>			
Carrots	0.1	1.5	The intended uses of prosulfocarb on carrots and celeriac are acceptable with regard to consumer safety.
Celeriac	0.05*	0.1	

\*indicates the limit of analytical quantification

The requested data have to be evaluated in the framework of Article 12 (1) of Regulation (EC) No 396/2005 and if necessary the conclusions reached in this reasoned opinion have to be revised.

#### REFERENCES

- France, 2009. Evaluation report on the modification of MRLs for prosulfocarb in carrots and celeriac prepared by the evaluating Member State France under Article 8 of Regulation (EC) No 396/2005, 8 March 2009.
- Sweden, 2005. Draft Assessment Report (DAR) on the active substance prosulfocarb prepared by the Rapporteur Member State Sweden in the framework of Directive 91/414/EEC, April, 2005.
- EFSA (European Food Safety Authority), 2007. Conclusion regarding the peer review of the pesticide risk assessment of the active substance prosulfocarb EFSA Scientific Report (2007), 111, 1-81.
- European Commission, 1997. Appendix E: Processing studies, SANCO/7035/VI/95rev 5, 22 July 1997.
- Sweden, 2009. Evaluation report for prosulfocarb prepared under Article 12(1) of Regulation (EC) NO 396/2005. March 2009.



**APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)**

Crop and / or situation (a)	Country and/or region	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application			Application rate per treatment			PHI (days) (l)	Remarks: (m)
				Type (d - f)	Conc. of as (i)	method kind (f - h)	growth stage & season (j)	number min max (k)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Carrots	France	F	Weeds	EC	800 g/l	Low volume spraying	BBCH 12-14	1			4	49d for short cycle carrots; 80d for medium cycle carrots	2-3 leaves unfolded
Celeriac	France	F	Weeds	EC	800 g/l	Low volume spraying	BBCH 12-14 [or 5-10 d after planting]	1			4	100	2-3 leaves unfolded

- Remarks:**
- (a) For crops, Codex (or other, e.g. EU) classifications should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
  - (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
  - (f) All abbreviations used must be explained
  - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions

## APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Prosulfocarb			
Status of the active substance:	included	Code no.	136
LOQ (mg/kg bw):	0.05	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.005	ARfD (mg/kg bw):	0.1
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2007	Year of evaluation:	2007

Input values: carrots- STMR=0.33 mg/kg; HR=0.75 mg/kg; celeriac- STMR=0.01 mg/kg; HR=0.06 mg/kg

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		11 --- 81						
		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	pTMRs at LOQ (in % of ADI)
81.2	FR toddler	39.6	Milk and cream,	16.1	Carrots	5.1	Potatoes	64.9
76.1	UK Infant	38.7	Milk and cream,	10.1	Sugar beet (root)	8.7	Carrots	66.4
70.4	NL child	29.3	Milk and cream,	6.3	Apples	5.9	Potatoes	66.1
67.3	UK Toddler	22.9	Sugar beet (root)	20.7	Milk and cream,	3.9	Wheat	62.3
60.9	DE child	14.3	Milk and cream,	12.1	Apples	6.8	Carrots	52.1
59.2	FR infant	25.7	Milk and cream,	17.5	Carrots	4.1	Potatoes	41.8
48.5	DK child	12.6	Milk and cream,	9.1	Carrots	5.5	Wheat	39.1
48.1	WHO Cluster diet B	8.5	Wheat	3.2	Milk and cream,	3.1	Tomatoes	45.5
44.9	IE adult	5.1	Celery	3.5	Sweet potatoes	2.8	Milk and cream,	36.4
37.9	SE general population 90th percentile	12.4	Milk and cream,	5.6	Carrots	4.2	Potatoes	31.4
36.4	ES child	12.5	Milk and cream,	4.4	Wheat	2.2	Oranges	35.1
32.5	WHO cluster diet E	3.9	Wheat	3.8	Potatoes	3.0	Milk and cream,	28.5
30.7	WHO cluster diet D	6.5	Wheat	5.0	Milk and cream,	4.1	Potatoes	27.7
30.2	WHO regional European diet	4.8	Milk and cream,	4.0	Potatoes	3.0	Wheat	26.3
27.9	WHO Cluster diet F	4.0	Milk and cream,	3.6	Wheat	3.4	Potatoes	24.8
24.4	PT General population	5.3	Potatoes	4.4	Carrots	3.9	Wheat	20.0
24.4	NL general	6.6	Milk and cream,	2.7	Potatoes	2.1	Wheat	22.4
20.9	ES adult	5.0	Milk and cream,	2.3	Wheat	1.3	Oranges	19.8
20.6	FR all population	4.0	Wine grapes	3.3	Wheat	2.7	Milk and cream,	18.1
20.3	UK vegetarian	3.8	Sugar beet (root)	3.3	Milk and cream,	2.0	Wheat	17.4
20.0	DK adult	5.4	Milk and cream,	2.9	Carrots	2.0	Wheat	16.7
18.5	IT kids/toddler	6.6	Wheat	1.5	Other cereal	1.4	Tomatoes	16.2
17.8	UK Adult	4.0	Sugar beet (root)	3.0	Milk and cream,	1.7	Wheat	16.0
17.1	LT adult	4.0	Milk and cream,	3.2	Potatoes	1.9	Apples	16.0
15.3	FI adult	5.7	Milk and cream,	1.3	Carrots	1.2	Potatoes	14.0
13.8	IT adult	4.1	Wheat	1.2	Tomatoes	0.9	Carrots	11.9
11.4	PL general population	3.4	Potatoes	2.0	Apples	2.0	Carrots	9.3

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.  
A long-term intake of residues of Prosulfocarb 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 variability 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)
47.6	Carrots	0.75 / -	34.0	Carrots	0.75 / -	8.9	Carrots	0.75 / -	7.1	Carrots	0.75 / -	
3.3	Celeriac	0.06 / -	3.3	Celeriac	0.06 / -	1.0	Celeriac	0.06 / -	1.0	Celeriac	0.06 / -	
<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---			

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)
14.6	Carrot, juice	0.34 / -	0.5	Orange juice	0.05 / -	
2.5	Apple juice	0.05 / -	0.3	Apple juice	0.05 / -	
2.5	Orange juice	0.05 / -	0.2	Bread/pizza	0.05 / -	
1.6	Grape juice	0.05 / -	0.2	Wine	0.05 / -	
1.3	Celeriac juice	0.1 / -	0.1	Pineapples preserved	0.05 / -	

\*) 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 Prosulfocarb 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 EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	Prosulfocarb
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, uglis and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
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*
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 cloudberrys)	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 (mediterranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*

160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomeac, rose apple, Brazilian 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 mammy sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*

163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
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	0,1
213030	Celeriac	0,05*
213040	Horse radish	0,1
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,1
213070	Parsley root	0,1
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,1
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)	0,1
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes, )	0,05*

231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano )	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*

251000	(a) Lettuce and other salad plants including Brassicaceae	0,05*
251010	Lamb's lettuce (Italian comsalad)	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, glasswort)	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 cicely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory, )	0,05*
256060	Rosemary	0,05*
256070	Thyme ( marjoram, oregano)	0,05*

256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	2
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel )	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*

300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	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	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, tefi)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	2

631000	(a) Flowers	2
631010	Camomille flowers	2
631020	Hybiscus flowers	2
631030	Rose petals	2
631040	Jasmine flowers	2
631050	Lime (linden)	2
631990	Others	2
632000	(b) Leaves	2
632010	Strawberry leaves	2
632020	Rooibos leaves	2
632030	Maté	2
632990	Others	2
633000	(c) Roots	2
633010	Valerian root	2
633020	Ginseng root	2
633990	Others	2
639000	(d) Other herbal infusions	2
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st Johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	
810000	(i) Seeds	
810010	Anise	0,05*
810020	Black caraway	0,2
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,2
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	0,5
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	Tumeric (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	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*

1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
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)	0,05*

1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
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)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

(\* ) Indicates lower limit of analytical determination



## ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
Bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
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 Directive 91/414/eeC)
DM	dry matter
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EC	emulsifiable concentrate
EFSA	European Food Safety Authority
EMS	evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GS	growth stage
ha	hectare
hL	hectolitre
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States

NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue