

REASONED OPINION

Modification of existing MRLs for valifenalate (valiphenal) in tomatoes and aubergines¹

European Food Safety Authority²

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

According to Article 6 of the Regulation (EC) No 396/2005, Hungary received two applications from Isagro S.p.A to modify the existing MRLs for valifenalate (former name *valiphenal*) in tomatoes and aubergines. In order to accommodate for intended outdoor uses in Italy, it is proposed to raise existing MRLs in tomatoes and aubergines from 0.01 mg/kg (set at the limit of quantification) to 0.2 mg/kg. Hungary drafted two separate evaluation reports according to Article 8 of Regulation (EC) No 396/2005 which were submitted to the European Commission and forwarded to EFSA on 20 July 2009.

EFSA derived the following conclusions based on the above mentioned evaluation report and the Draft Assessment Report (DAR) prepared by Hungary under Directive 91/414/EEC.

According to the evaluation of the RMS, the data package was complete to derive an ADI of 0.07 mg/kg bw/d. Valifenalate is considered of a low acute toxicity and therefore no ARfD is proposed by the RMS.

Metabolism of valifenalate in primary plants was investigated in grapes (fruits and fruiting vegetables), potatoes (root and tuber vegetables) and lettuce and tomato leaves (leafy vegetables). Results of the metabolism studies indicate that the metabolic pathway in all crops investigated proceeds in a similar way. The RMS proposal for the risk assessment and enforcement residue definition is parent valifenalate only. Pending the outcome of the peer review, EFSA accepts the proposed residue definition as a provisional one, but notes that parent valifenalate might not be a suitable marker residue in fruits and fruiting vegetables as well as in root and tuber vegetables taking into account the amount of identified metabolites.

For the control of the compliance of the proposed MRLs in tomatoes and aubergines, an adequate analytical method is available with the LOQ of 0.01 mg/kg.

A sufficient number of supervised residue field trials was submitted to support the proposed extrapolation of residue data from tomatoes to aubergines. Data from the residue trials indicate that a lower MRL of 0.1 mg/kg than proposed by the RMS (0.2 mg/kg) is sufficient to accommodate the intended GAP on tomatoes and aubergines.

1 On request from the European Commission, Question No EFSA-Q-2009-00726 and EFSA-Q-2009-00727, issued on 23 November 2009.

2 Correspondence: praper.mrl@efsa.europa.eu

Suggested citation: European Food Safety Authority; Modification of existing MRLs for valifenalate (valiphenal) in tomatoes and aubergines on request. EFSA Journal 2009; 7(11):1388. [20 pp.]. doi:10.2903/j.efsa.2009.1388. Available online: www.efsa.europa.eu

No studies are available investigating the effects of the processing on the nature and magnitude of valifenalate residues. However, these are not necessary taking into account the low consumer exposure to valifenalate residues. The possible occurrence of valifenalate residue in rotational or succeeding crops was investigated. EFSA concludes that a significant amount of valifenalate residues is not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

Tomatoes and aubergines are not livestock feeding items according to the EU Guidance document and therefore the nature and magnitude of valifenalate residues in livestock was not investigated.

Consumer intake assessment was performed with revision 2 of the EFSA PRIMo. The existing MRLs as established in Regulation (EC) No 396/2005 and the STMR values as derived for the intended use on tomatoes and aubergines were used as input values in the chronic exposure assessment. Acute intake assessment was not undertaken since no ARfD is established for valifenalate.

No chronic consumer intake concerns were identified for any of the European diets. Total calculated intake values accounted for a maximum of 1.3 % of the ADI with the contribution of tomatoes and aubergines being below 0.1% of the ADI.

Consequently EFSA concludes that the intended uses of valifenalate on tomatoes and aubergines are acceptable as they will not result in consumer health concerns.

In addition, EFSA recommends amending the existing name of the active substance from *valiphenal* to *valifenalate* according to the proposal made by ISO. The MRL proposals are presented below:

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: valifenalate (former name <i>valiphenal</i>)			
Tomatoes	0.01*	0.1	The proposed MRLs are sufficiently supported by data and no risk for consumers was identified for the proposed uses. MRL proposals are based on the SEU outdoor use only.
Aubergines	0.01*	0.1	

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

As the DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

KEY WORDS

Valifenalate, valiphenal, tomatoes, aubergines, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, acylamino acid fungicide, valifenalate acid.

TABLE OF CONTENTS

Summary	1
Table of contents	3
Background	4
Terms of reference	4
The active substance and its use pattern	5
Assessment	6
1. Methods of analysis	6
1.1. Methods for enforcement of residues in food of plant origin	6
1.2. Methods for enforcement of residues in food of animal origin	6
2. Mammalian toxicology	6
3. Residues	6
3.1. Nature and magnitude of residues in plant	6
3.1.1. Primary crops	6
3.1.2. Rotational crops	10
3.2. Nature and magnitude of residues in livestock	10
4. Consumer risk assessment	10
Conclusions and recommendations	12
References	13
Appendix A – Good Agricultural Practices (GAPs)	14
Appendix B – Pesticide Residues Intake Model (PRIMo)	15
Appendix C – Existing EC MRLs	16
Abbreviations	19

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.

Hungary, hereafter referred to as the evaluating Member State (EMS), received two applications from the company Isagro S.p.A³ to modify the existing MRLs for the active substance valifenalate in tomatoes and aubergines. Both applications were 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 applications, the evaluation report and the supporting dossier to EFSA on 20 July. Both applications were included in the EFSA Register of Question with the reference numbers EFSA-Q-2009-00726 and EFSA-Q-2009-00727 and the following subjects:

Valifenalate - Application to modify the existing MRL in tomatoes.

Valifenalate - Application to modify the existing MRL in aubergines.

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

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.

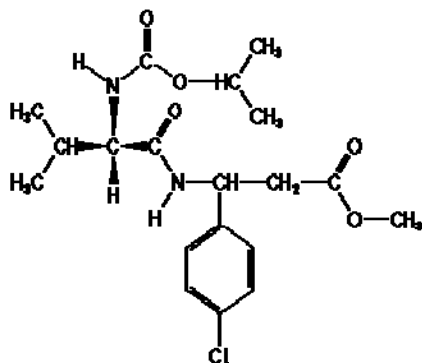
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 20 October 2009.

³ Isagro S.p.A, Via Caldera 21, Centro Uffici San Diro – Ed.D, Ala 3, 20153, Milan Italy

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Valifenalate is the provisionally approved ISO common name for methyl N-(isopropoxycarbonyl)-L-valyl-(3RS)-3-(4-chlorophenyl)- β -alaninate (IUPAC) and its chemical structure is as follows:



Molecular weight: 398.89

Valifenalate (in the existing EC legislation named as “valiphenal”) is an acylamino acid fungicide. It acts systemically. It is used to control a wide range of fungi belonging to the class of Oomycetes. Valifenalate interferes with the cell-wall synthesis thus affecting the growth stages of the pathogens controlled, both outside (on the spores) or inside the plant (on the mycelium).

Valifenalate is a new active substance (NAS) according to the classification of Directive 91/414/EEC. With a view to obtain the inclusion of valifenalate in the Annex I of Directive 91/414/EEC, a Draft Assessment Report (DAR) was prepared by Hungary as the designated rapporteur Member State and submitted to EFSA in February 2008. The representative use supported in the framework of the peer review is a foliar application of the active substance on grapes at an application rate of 0.09 to 0.72 kg a.s./ha with the PHI of 42 days. The peer review of valifenalate has not yet been finalized.

The EC MRLs for valifenalate have been set at the LOQ of 0.01 mg/kg or 0.02 mg/kg for plant commodities. No EC MRLs are set for commodities of animal origin. It should be noted that the MRLs for valifenalate according to Regulation (EC) No 396/2005 have been set under the former name of the active substance - *valiphenal*. The current MRLs for tomatoes and aubergines are set at the LOQ of 0.01 mg/kg. No CXLs are set for valifenalate.

The GAP for which the authorization is requested in Italy, refers to an outdoor foliar application of valifenalate three times on tomatoes and aubergines (BBCH 17-79) at a dose rate of 0.150 kg a.s./ha. The minimum PHI is 3 days. The table with intended GAP is provided in Appendix A.

EFSA bases its assessment on the evaluation report (Hungary, 2009) as well as the Draft Assessment Report prepared in the framework of the peer review of Directive 91/414/EEC (Hungary, 2008).

As the DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

ASSESSMENT

1. Methods of analysis

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

The analytical enforcement methods for the determination of parent valifenalate in plant matrices have been investigated in the framework of the peer review and are reported in the DAR (Hungary, 2008). The analytical methods were validated at the LOQ of 0.01 mg/kg for commodities with high water and high acid content (grape, and potato tubers) and wine. The determination was carried out by high performance liquid chromatography and tandem mass spectrometric detection (LC-MS/MS) or by HPLC with a mass detector (LC-MS).

Tomatoes and aubergines belong to a crop group with high water content and therefore it is concluded that a sufficiently validated enforcement method is available to control the compliance of the proposed MRLs.

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

Tomatoes and aubergines are not livestock feeding items and therefore the availability of an analytical enforcement method for the determination of valifenalate residues in matrices of animal origin was not investigated.

2. Mammalian toxicology

Toxicity studies presented by the manufacturer were assessed by the RMS who concluded that the data were sufficient to derive an ADI. Because of the low acute toxicity no ARfD was considered necessary (Hungary, 2008).

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Valifenalate					
ADI	DAR	2008	0.07	1 yr dog	100
ARfD	DAR	2008		n.n.	

n.n. - not necessary

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 valifenalate in primary plants was investigated in the framework of the peer review on following crops (Hungary, 2008):

- fruits and fruiting vegetables: grapes (foliar application 4 x 15 g/hL(1N) and 4 x 75 g/hL(5N))
- root and tuber vegetables: potatoes (foliar application 3 x 0.15 kg a.s./ha)
- leafy vegetables: lettuce (foliar application 3 x 0.15 kg a.s./ha), tomato leaves (foliar application 1 x 250 mg/L)

Grape fruits were sampled at harvest and washed. The TRR was quantified in surface washes as well as in the grape. In grapes at 1N rate, the total TRR accounted for 0.189 mg/kg (0.079 mg/kg in surface washes and 0.110 mg/kg in washed grapes). At 5N rate the total TRR in grapes accounted for a maximum of 1.67 mg/kg (1.178 mg/kg in washes and 0.492 mg/kg in washed grape). The identification of the TRR in 1 N samples revealed that parent valifenalate was the major component of the TRR accounting for up to 66% TRR (0.125 mg/kg) in grapes. The acid form of parent valifenalate (valifenalate acid⁴) was identified accounting for 13.23 % TRR (0.025 mg/kg) or 20% of the amount of parent valifenalate. Two other minor metabolites (also isolated and identified in potato leaves) were found in grape extracts: glucosyl ester of valifenalate acid⁵ which amounted to 0.012 mg/kg (6.35% TRR) and a conjugate of β -pCl-phenylalanine- N-glucoside, which amounted to 0.006 mg/kg (3.17% of TRR).

The metabolism study with tomatoes investigated the metabolic pathway of valifenalate in tomato leaves. No data are available on the nature of the active substance in tomato fruit. The characterisation of the TRR indicated that in treated tomato leaves 28 DAT parent valifenalate is the main component of the TRR (94.77 %) with all other metabolites being below 1.5 % TRR (0.188 mg/kg). In new leaves 28 DAT parent valifenalate was major component of the TRR accounting for 44.82 % (0.375 mg/kg) along with valifenalate acid which accounted for 19.29% TRR (0.16 mg/kg) and lower amounts of glucosyl ester of valifenalate acid (9.85% TRR). Results indicated that valifenalate penetrates and translocates from the treated leaves to new leaves grown after spraying.

The metabolism study with potatoes indicates that only small amount of the applied radioactivity was translocated in mature potato tubers (0.0133 mg/kg). The majority of the TRR was found in treated potato leaves (58.27 mg/kg). In potato tubers unchanged parent compound was not present above the LOD. The major components of the identified radioactivity in potato tubers was characterised as follows: valifenalate acid 15.04% TRR (0.0020 mg/kg), glucosyl ester of valifenalate acid 15.79% TRR (0.0021mg/kg) and β -4-chlorophenylalanine 32.33% TRR (0.0043 mg/kg). According to the proposed metabolic pathway in potatoes, β -4-chlorophenylalanine is an intermediate metabolism product of primary metabolism product valifenalate acid and is further metabolized to β -pCl-phenylalanine-N-glucoside.

In mature lettuce samples the total radioactivity amounted for 3.58 mg/kg. The majority of the radioactivity could be washed off with water (67.97% TRR) and the surface wash contained 32% TRR. The characterization of the TRR from washed leaves indicated that parent valifenalate is the major component of the TRR (96.12%; 3.44 mg/kg) with no other metabolites exceeding 3% TRR.

Available metabolism studies indicate, that the metabolic pathway in all crops investigated generally proceeds in a similar way. The primary metabolite of valifenalate is in all cases valifenalate acid which after the cleavage forms β -pCl-phenylalanine and glucosyl ester of valifenalate acid. Parent valifenalate is the major compound found on the surface and extracts of the treated leaves. After penetrating the plant tissues, valifenalate is metabolized to valifenalate acid which always accounted for more than 10% of the TRR in non-leafy parts of the crops (grapes, potato tubers).

⁴ Valifenalate acid: *RS*- β -alanine, N-[(1-methylethoxy)carbonyl]-L-valyl-3-(4-chlorophenyl)

⁵ Glucosyl ester of valifenalate acid: *RS*- β -alanine, N-[(1-methylethoxy)carbonyl]-L-valyl-3-(4-chlorophenyl) glucosyl ester

The RMS proposal for the risk assessment and enforcement residue definition is parent valifenalate only.

EFSA accepts this residue definition and considers it as a provisional residue definition, pending the outcome of the peer review. This residue definition is as established in Annex III of Regulation (EC) No 396/2005. It is noted, however, that parent valifenalate might not be a suitable marker residue in fruits and fruiting vegetables as well as in root and tuber vegetables taking into account the amount of identified metabolites.

All conclusions reached in this reasoned opinion are provisional and might be reconsidered in the light of the outcome of the peer review.

3.1.1.2. Magnitude of residues

In support of the intended outdoor use of valifenalate on tomatoes and aubergines in Italy, the applicant submitted a number of supervised field trials on tomatoes. An extrapolation of the residue data to aubergines is proposed. All residue trials were designed as residue decline studies. Only four residue trials were compliant with the intended GAP in terms of the relevant PHI of 3 days. From the remaining trials EFSA selected four, which represent the residue situation in the crop on the day of application, 1, 5 and 7 days after the last application. For three trials by interpolation EFSA obtained residue values that may be expected in the crop at the PHI of 3 days. In two trials the residue value within a trial was higher with a longer PHI of 5 or 7 days.

The applicant had submitted also data on indoor residue trials but these were not taken into consideration by EFSA since the intended GAP refers to an outdoor use only.

Summary of residue trials is available in Table 3-1.

Stability of valifenalate residues in plant matrices have been investigated in potatoes, grapes, tomatoes, lettuce and wine (Hungary, 2008, 2009). Results indicate that valifenalate is stable in plant matrices with high water and high acid content over a period of 2 years when deep frozen. According to the EMS, residue trial samples prior analyses were stored for a period not exceeding the demonstrated storage stability period of valifenalate.

Supervised residue field trial samples were analysed for parent valifenalate with an LOQ of 0.01 mg/kg and the LOD of 0.007 mg/kg. The residues are determined using HLPC-MS. According to the EMS, the analytical method is sufficiently validated and fit for purpose.

Data from the residue trials indicate that a lower MRL of 0.1 mg/kg than proposed by the RMS (0.2 mg/kg) is required to accommodate the intended GAP on tomatoes and aubergines.

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 ^(d)	Comments
			Enforcement (valifenalate)	Risk assessment (valifenalate)						
Tomatoes → aubergines	SEU	Outdoor	0.014; 0.02; 0.024 ^{int1} ; 0.026 ^e ; 0.032 ^{int2} ; 0.036 ^{int3} ; 0.039; 0.077 ^f	0.014; 0.02; 0.024 ^{int1} ; 0.026 ^e ; 0.032 ^{int2} ; 0.036 ^{int3} ; 0.039; 0.077 ^f	0.029	0.08	0.1	1.0	Residue data on tomatoes are used to derive MRL for aubergines. R _{ber} =0.077 mg/kg R _{max} =0.095 mg/kg	

(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.

^{int1}: derived on a basis of interpolation from the following residue values on 0, 1, 5, 7 PHI respectively: 0.06; 0.032; 0.013; 0.011

^{int2}: derived on a basis of interpolation from the following residue values on 0, 1, 5, 7 PHI respectively: 0.071; 0.061; 0.018; <0.01

^{int3}: derived on a basis of interpolation from the following residue values on 0, 1, 5, 7 PHI respectively: 0.065; 0.033; 0.027; 0.033

^e: residue value was higher with a longer PHI of 5 days

^f: residue value was higher with a longer PHI of 7 days

3.1.1.3. Effect of industrial processing and/or household preparation

No studies are available investigating the effects of the processing on the nature and magnitude of valifenalate residues (Hungary, 2008). Such studies are, however, not necessary taking into account that the total consumer exposure to valifenalate residues accounts for less than 10% of the ADI.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Tomatoes and aubergines are crops for which a crop rotation is relevant. The rate of degradation of valifenalate in the soil was investigated in the framework of the peer review (Hungary, 2008). According to the laboratory studies, the DT_{90} value for valifenalate accounts for a maximum of 40 hours. The relevant soil metabolites of valifenalate were identified as valifenalate acid and 4-chlorobenzoic acid. The relevant DT_{90} values for both metabolites did not exceed 100 days and were less than 55 hours for valifenalate acid and less than 11 days for 4-chlorobenzoic acid.

Even though the rate of degradation of valifenalate and its metabolites in the soil indicate that residues are not expected in rotational crops, a confined rotational crop study is available (see section 3.1.2.2.).

3.1.2.2. Nature of residues

A confined rotational crop study was submitted to Hungary in the framework of the current application. Bare soil was treated with valifenalate (radiolabelled at phenyl ring) at an exaggerated application rate of 1.44 kg a.s./ha (3N the intended application rate on tomatoes and aubergines). 30, 120 and 365 days after the treatment (DAT) lettuce, carrot was planted and wheat was sown. At maturity, the TRR was below 0.03 mg/kg in carrot roots, lettuce and grain and ranged between 0.008 to 0.098 mg/kg in other raw commodities (carrot leaves, forage and straw). The major component of the TRR in all cases was parent valifenalate. Several metabolites - valifenalate acid, glucosyl ester of valifenalate acid as well as β -pCl-phenylalanine-N-glucoside - were identified in trace amounts. The RMS concluded that the metabolism of valifenalate in rotational crops proceeds in a similar pathway as in primary plants.

3.1.2.3. Magnitude of residues

Considering that the intended application rate of valifenalate on tomatoes and aubergines is significantly lower than investigated in the rotational crop studies, EFSA concludes, that significant amount of valifenalate residues is not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

3.2. Nature and magnitude of residues in livestock

Tomatoes and aubergines are not livestock feeding items according to the EU Guidance document and therefore the nature and magnitude of valifenalate residues in livestock was not investigated.

4. Consumer risk assessment

Consumer intake assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model). The existing MRLs as established in Regulation (EC) No 396/2005 and the STMR values as derived for the intended use on tomatoes and aubergines were used as input values. Acute intake assessment was not undertaken since no ARfD has been established for valifenalate. 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: valifenalate				
Tomatoes, aubergines	0.03	STMR	Acute intake assessment was not undertaken since there is no ARfD established for valifenalate.	
Other commodities of plant and animal origin	MRL	See Appendix C		

The summary of consumer intake calculations is available in Appendix B.

No chronic consumer intake concerns were identified for any of the European diets. Total calculated intake values accounted for a maximum of 1.3 % of the ADI with the contribution of tomatoes and aubergines being below 0.1% of the ADI.

Consequently EFSA concludes that intended uses of valifenalate on tomatoes and aubergines are acceptable as they will not result in consumer health concerns.

It should be noted that all conclusions reached in this reasoned opinion are provisional and might be reconsidered in the light of the outcome of the peer review.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

According to the evaluation of the RMS, the data package was complete to derive an ADI of 0.07 mg/kg bw/d. Valifenalate is considered of a low acute toxicity and therefore no ARfD is proposed by the RMS.

Metabolism of valifenalate in primary plants was investigated in grapes (fruits and fruiting vegetables), potatoes (root and tuber vegetables) and lettuce and tomato leaves (leafy vegetables). Results of the metabolism studies indicate that the metabolic pathway in all crops investigated proceeds in a similar way. The RMS proposal for the risk assessment and enforcement residue definition is parent valifenalate only. Pending the outcome of the peer review, EFSA accepts the proposed residue definition as a provisional one, but notes that parent valifenalate might not be a suitable marker residue in fruits and fruiting vegetables as well as in root and tuber vegetables taking into account the amount of identified metabolites.

For the control of the compliance of the proposed MRLs in tomatoes and aubergines, an adequate analytical method is available with the LOQ of 0.01 mg/kg.

A sufficient number of supervised residue field trials was submitted to support the proposed extrapolation of residue data from tomatoes to aubergines. Data from the residue trials indicate that a lower MRL of 0.1 mg/kg than proposed by the RMS (0.2 mg/kg) is sufficient to accommodate the intended GAP on tomatoes and aubergines.

No studies are available investigating the effects of the processing on the nature and magnitude of valifenalate residues. However, these are not necessary taking into account the low consumer exposure to valifenalate residues. The possible occurrence of valifenalate residue in rotational or succeeding crops was investigated. EFSA concludes that a significant amount of valifenalate residues is not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

Tomatoes and aubergines are not livestock feeding items according to the EU Guidance document and therefore the nature and magnitude of valifenalate residues in livestock was not investigated.

Consumer intake assessment was performed with revision 2 of the EFSA PRIMo. The existing MRLs as established in Regulation (EC) No 396/2005 and the STMR values as derived for the intended use on tomatoes and aubergines were used as input values in the chronic exposure assessment. Acute intake assessment was not undertaken since no ARfD is established for valifenalate.

No chronic consumer intake concerns were identified for any of the European diets. Total calculated intake values accounted for a maximum of 1.3 % of the ADI with the contribution of tomatoes and aubergines being below 0.1% of the ADI.

Consequently EFSA concludes that the intended uses of valifenalate on tomatoes and aubergines are acceptable as they will not result in consumer health concerns. EFSA additionally recommends amending the existing name of the active substance from *valiphenal* to *valifenalate* according to the ISO proposal. The MRL proposals are presented below:

RECOMMENDATIONS

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: valifenalate (former name <i>valiphenal</i>)			
Tomatoes	0.01*	0.1	The proposed MRLs are sufficiently supported by data and no risk for consumers was identified for the proposed uses. MRL proposals are based on the SEU outdoor use only.
Aubergines	0.01*	0.1	

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

As the DAR has not yet been peer reviewed by EFSA, the conclusions reached in this reasoned opinion have to be considered as provisional and might be reconsidered in the light of the outcome of the peer review.

REFERENCES

- Hungary, 2009. Evaluation report on the modification of MRLs for valifenalate in tomatoes and aubergine prepared by the evaluating Member State Hungary under Article 8 of Regulation (EC) No 396/2005, 30 June, 2009.
- Hungary, 2008. Draft Assessment Report (DAR) on the active substance valiphenal prepared by the rapporteur Member State Hungary in the framework of Directive 91/414/EEC, January 2008.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and / or situation (a)	F G or I (b)	Pest or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (k)	Remarks: (l)
			Type (d - f)	Conc. of a.i. (i)	method, kind (f - h)	growth stage (j)	number (range)	interval between appl. (days)	kg a.i./hl	water l/ha	kg a.i./ha		
Tomato Aubergines	F	<i>Phytophthora infestans</i> (Late blight)	WG	60 g/kg	Foliar spray	17 to 79	3	7-10	0.015-0.075	200 - 1000	0.150	3	

(a) In case of group of crops the Codex classification should be used

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) e.g. biting and sucking insects, soil born insects, foliar fungi

(d) e.g. wettable powder (WP), emulsifiable concentration (EC), granule (GR)

(e) Use CIPAC/FAO Codes where appropriate

(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

(i) g/kg or g/l

(j) Growth stage at last treatment

(k) PHI = Pre-harvest interval

(l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Valifenalate			
Status of the active substance:	NAS	Code no.	#N/A
LOQ (mg/kg bw):	0.01	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.07	ARfD (mg/kg bw):	n.n.
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2008	Year of evaluation:	2008

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum 0 - 1						
		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)		3rd contributor to MS diet (in % of ADI)		pTMRLs at LOQ (in % of ADI)
				Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	
1.3	FR all population	1.1	Wine grapes	0.0	Wheat	0.0	Table grapes	0.1
1.3	WHO Cluster diet B	0.5	Wine grapes	0.1	Tomatoes	0.1	Wheat	0.5
1.1	PT General population	0.7	Wine grapes	0.1	Table grapes	0.1	Potatoes	0.2
0.9	DE child	0.4	Table grapes	0.2	Apples	0.1	Wheat	0.5
0.9	IE adult	0.4	Wine grapes	0.1	Table grapes	0.1	Sweet potatoes	0.4
0.8	WHO cluster diet E	0.5	Wine grapes	0.1	Wheat	0.1	Potatoes	0.3
0.7	NL child	0.2	Table grapes	0.1	Apples	0.1	Potatoes	0.4
0.7	UK Toddler	0.3	Sugar beet (root)	0.1	Table grapes	0.1	Wheat	0.6
0.6	DK adult	0.4	Wine grapes	0.0	Wheat	0.0	Table grapes	0.1
0.5	UK Adult	0.3	Wine grapes	0.1	Sugar beet (root)	0.0	Wheat	0.2
0.5	WHO cluster diet D	0.1	Wine grapes	0.1	Wheat	0.1	Potatoes	0.3
0.5	WHO Cluster diet F	0.2	Wine grapes	0.1	Wheat	0.0	Potatoes	0.2
0.5	UK vegetarian	0.2	Wine grapes	0.1	Sugar beet (root)	0.0	Tomatoes	0.2
0.5	NL general	0.2	Wine grapes	0.1	Table grapes	0.0	Potatoes	0.2
0.4	FR toddler	0.1	Potatoes	0.1	Table grapes	0.0	Apples	0.3
0.4	UK Infant	0.1	Sugar beet (root)	0.0	Potatoes	0.0	Wheat	0.4
0.4	WHO regional European diet	0.1	Wine grapes	0.1	Potatoes	0.1	Tomatoes	0.2
0.4	DK child	0.1	Wheat	0.1	Rye	0.1	Table grapes	0.3
0.3	ES adult	0.1	Wine grapes	0.0	Tomatoes	0.0	Wheat	0.2
0.3	IT kids/toddler	0.1	Wheat	0.1	Tomatoes	0.0	Table grapes	0.2
0.3	ES child	0.1	Wheat	0.0	Tomatoes	0.0	Oranges	0.2
0.3	SE general population 90th percentile	0.1	Potatoes	0.0	Wheat	0.0	Tomatoes	0.3
0.3	FR infant	0.1	Potatoes	0.0	Carrots	0.0	Apples	0.2
0.3	PL general population	0.1	Table grapes	0.0	Potatoes	0.0	Tomatoes	0.1
0.3	IT adult	0.1	Wheat	0.1	Tomatoes	0.0	Table grapes	0.2
0.2	FI adult	0.1	Wine grapes	0.0	Tomatoes	0.0	Potatoes	0.1
0.2	LT adult	0.0	Potatoes	0.0	Tomatoes	0.0	Apples	0.1

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

APPENDIX C – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	Valiphenal
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,01*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, uglı and other hybrids)	0,01*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,01*
110030	Lemons (Citron, lemon)	0,01*
110040	Limes	0,01*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,01*
110990	Others	0,01*
120000	(ii) Tree nuts (shelled or unshelled)	0,01*
120010	Almonds	0,01*
120020	Brazil nuts	0,01*
120030	Cashew nuts	0,01*
120040	Chestnuts	0,01*
120050	Coconuts	0,01*
120060	Hazelnuts (Filbert)	0,01*
120070	Macadamia	0,01*
120080	Pecans	0,01*
120090	Pine nuts	0,01*
120100	Pistachios	0,01*
120110	Walnuts	0,01*
120990	Others	0,01*
130000	(iii) Pome fruit	0,01*
130010	Apples (Crab apple)	0,01*
130020	Pears (Oriental pear)	0,01*
130030	Quinces	0,01*
130040	Medlar	0,01*
130050	Loquat	0,01*
130990	Others	0,01*
140000	(iv) Stone fruit	0,01*
140010	Apricots	0,01*
140020	Cherries (sweet cherries, sour cherries)	0,01*
140030	Peaches (Nectarines and similar hybrids)	0,01*

140040	Plums (Danson, greengage, mirabelle)	0,01*
140990	Others	0,01*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0,2
151010	Table grapes	0,2
151020	Wine grapes	0,2
152000	(b) Strawberries	0,01*
153000	(c) Cane fruit	0,01*
153010	Blackberries	0,01*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,01*
153030	Raspberries (Wineberries)	0,01*
153990	Others	0,01*
154000	(d) Other small fruit & berries	0,01*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,01*
154020	Cranberries	0,01*
154030	Currants (red, black and white)	0,01*
154040	Gooseberries (Including hybrids with other ribes species)	0,01*
154050	Rose hips	0,01*
154060	Mulberries (arbutus berry)	0,01*
154070	Azarole (mediteranean medlar)	0,01*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawallowthorn), hawthorn, service berries, and other treeberries)	0,01*
154990	Others	0,01*
160000	(vi) Miscellaneous fruit	0,01*
161000	(a) Edible peel	0,01*
161010	Dates	0,01*
161020	Figs	0,01*
161030	Table olives	0,01*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,01*
161050	Carambola (Bilimbi)	0,01*
161060	Persimmon	0,01*
161070	Jambolan (java plum) (Java apple (water apple), pomereac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,01*
161990	Others	0,01*
162000	(b) Inedible peel, small	0,01*
162010	Kiwi	0,01*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,01*

162030	Passion fruit	0,01*
162040	Prickly pear (cactus fruit)	0,01*
162050	Star apple	0,01*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,01*
162990	Others	0,01*
163000	(c) Inedible peel, large	0,01*
163010	Avocados	0,01*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,01*
163030	Mangoes	0,01*
163040	Papaya	0,01*
163050	Pomegranate	0,01*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,01*
163070	Guava	0,01*
163080	Pineapples	0,01*
163090	Bread fruit (Jackfruit)	0,01*
163100	Durian	0,01*
163110	Soursop (guanabana)	0,01*
163990	Others	0,01*
200000	2. VEGETABLES FRESH OR FROZEN	0,01*
210000	(i) Root and tuber vegetables	0,01*
211000	(a) Potatoes	0,01*
212000	(b) Tropical root and tuber vegetables	0,01*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,01*
212020	Sweet potatoes	0,01*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,01*
212040	Arrowroot	0,01*
212990	Others	0,01*
213000	(c) Other root and tuber vegetables except sugar beet	0,01*
213010	Beetroot	0,01*
213020	Carrots	0,01*
213030	Celeriac	0,01*
213040	Horseradish	0,01*
213050	Jerusalem artichokes	0,01*
213060	Parsnips	0,01*
213070	Parsley root	0,01*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,01*

213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,01*
213100	Swedes	0,01*
213110	Turnips	0,01*
213990	Others	0,01*
220000	(ii) Bulb vegetables	0,01*
220010	Garlic	0,01*
220020	Onions (Silverskin onions)	0,01*
220030	Shallots	0,01*
220040	Spring onions (Welsh onion and similar varieties)	0,01*
220990	Others	0,01*
230000	(iii) Fruiting vegetables	0,01*
231000	(a) Solanacea	0,01*
231010	Tomatoes (Cherry tomatoes,)	0,01*
231020	Peppers (Chilli peppers)	0,01*
231030	Aubergines (egg plants) (Pepino)	0,01*
231040	Okra, lady's fingers	0,01*
231990	Others	0,01*
232000	(b) Cucurbits - edible peel	0,01*
232010	Cucumbers	0,01*
232020	Gherkins	0,01*
232030	Courgettes (Summer squash, marrow (patisson))	0,01*
232990	Others	0,01*
233000	(c) Cucurbits-inedible peel	0,01*
233010	Melons (Kiwano)	0,01*
233020	Pumpkins (Winter squash)	0,01*
233030	Watermelons	0,01*
233990	Others	0,01*
234000	(d) Sweet corn	0,01*
239000	(e) Other fruiting vegetables	0,01*
240000	(iv) Brassica vegetables	0,01*
241000	(a) Flowering brassica	0,01*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,01*
241020	Cauliflower	0,01*
241990	Others	0,01*
242000	(b) Head brassica	0,01*
242010	Brussels sprouts	0,01*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,01*
242990	Others	0,01*
243000	(c) Leafy brassica	0,01*

243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsay), cow cabbage)	0,01*
243020	Kale (Borecole (curly kale), collards)	0,01*
243990	Others	0,01*
244000	(d) Kohlrabi	0,01*
250000	(v) Leaf vegetables & fresh herbs	0,01*
251000	(a) Lettuce and other salad plants including Brassicacea	0,01*
251010	Lamb's lettuce (Italian comsalad)	0,01*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,01*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,01*
251040	Cress	0,01*
251050	Land cress	0,01*
251060	Rocket, Rucola (Wild rocket)	0,01*
251070	Red mustard	0,01*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,01*
251990	Others	0,01*
252000	(b) Spinach & similar (leaves)	0,01*
252010	Spinach (New Zealand spinach, tumip greens (tumip tops))	0,01*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,01*
252030	Beet leaves (chard) (Leaves of beetroot)	0,01*
252990	Others	0,01*
253000	(c) Vine leaves (grape leaves)	0,01*
254000	(d) Water cress	0,01*
255000	(e) Witloof	0,01*
256000	(f) Herbs	0,01*
256010	Chervil	0,01*
256020	Chives	0,01*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,01*
256040	Parsley	0,01*

256050	Sage (Winter savory, summer savory,)	0,01*
256060	Rosemary	0,01*
256070	Thyme (majoram, oregano)	0,01*
256080	Basil (Balm leaves, mint, peppermint)	0,01*
256090	Bay leaves (laurel)	0,01*
256100	Tarragon (Hyssop)	0,01*
256990	Others	0,01*
260000	(vi) Legume vegetables (fresh)	0,01*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,01*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,01*
260030	Peas (with pods) (Mangetout (sugar peas))	0,01*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,01*
260050	Lentils	0,01*
260990	Others	0,01*
270000	(vii) Stem vegetables (fresh)	0,01*
270010	Asparagus	0,01*
270020	Cardoons	0,01*
270030	Celery	0,01*
270040	Fennel	0,01*
270050	Globe artichokes	0,01*
270060	Leek	0,01*
270070	Rhubarb	0,01*
270080	Bamboo shoots	0,01*
270090	Palm hearts	0,01*
270990	Others	0,01*
280000	(viii) Fungi	0,01*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,01*
280020	Wild (Chanterelle, Truffle, Morel,)	0,01*
280990	Others	0,01*
290000	(ix) Sea weeds	0,01*
300000	3. PULSES, DRY	0,01*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,01*
300020	Lentils	0,01*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,01*
300040	Lupins	0,01*

300990	Others	0,01*
400000	4. OILSEEDS AND OILFRUITS	0,01*
401000	(i) Oilseeds	0,01*
401010	Linseed	0,01*
401020	Peanuts	0,01*
401030	Poppy seed	0,01*
401040	Sesame seed	0,01*
401050	Sunflower seed	0,01*
401060	Rape seed (Bird rapeseed, tumip rape)	0,01*
401070	Soya bean	0,01*
401080	Mustard seed	0,01*
401090	Cotton seed	0,01*
401100	Pumpkin seeds	0,01*
401110	Safflower	0,01*
401120	Borage	0,01*
401130	Gold of pleasure	0,01*
401140	Hempseed	0,01*
401150	Castor bean	0,01*
401990	Others	0,01*
402000	(ii) Oilfruits	0,01*
402010	Olives for oil production	0,01*
402020	Palm nuts (palmoil kernels)	0,01*
402030	Palmfruit	0,01*
402040	Kapok	0,01*
402990	Others	0,01*
500000	5. CEREALS	0,01*
500010	Barley	0,01*
500020	Buckwheat	0,01*
500030	Maize	0,01*
500040	Millet (Foxtail millet, teff)	0,01*
500050	Oats	0,01*
500060	Rice	0,01*
500070	Rye	0,01*
500080	Sorghum	0,01*
500090	Wheat (Spelt Triticale)	0,01*
500990	Others	0,01*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,02*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,02*
620000	(ii) Coffee beans	0,02*
630000	(iii) Herbal infusions (dried)	0,02*
631000	(a) Flowers	0,02*
631010	Camomile flowers	0,02*
631020	Hybiscus flowers	0,02*
631030	Rose petals	0,02*
631040	Jasmine flowers	0,02*
631050	Line (linden)	0,02*
631990	Others	0,02*

632000	(b) Leaves	0,02*
632010	Strawberry leaves	0,02*
632020	Rooibos leaves	0,02*
632030	Maté	0,02*
632990	Others	0,02*
633000	(c) Roots	0,02*
633010	Valerian root	0,02*
633020	Ginseng root	0,02*
633990	Others	0,02*
639000	(d) Other herbal infusions	0,02*
640000	(iv) Cocoa (fermented beans)	0,02*
650000	(v) Carob (st johns bread)	0,02*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,02*
800000	8. SPICES	0,02*
810000	(i) Seeds	0,02*
810010	Anise	0,02*
810020	Black caraway	0,02*
810030	Celery seed (Lovage seed)	0,02*
810040	Coriander seed	0,02*
810050	Cumin seed	0,02*
810060	Dill seed	0,02*
810070	Fennel seed	0,02*
810080	Fenugreek	0,02*
810090	Nutmeg	0,02*
810990	Others	0,02*
820000	(ii) Fruits and berries	0,02*
820010	Allspice	0,02*
820020	Anise pepper (Japan pepper)	0,02*
820030	Caraway	0,02*
820040	Cardamom	0,02*
820050	Juniper berries	0,02*
820060	Pepper, black and white (Long pepper, pink pepper)	0,02*
820070	Vanilla pods	0,02*
820080	Tamarind	0,02*
820990	Others	0,02*
830000	(iii) Bark	0,02*
830010	Cinnamon (Cassia)	0,02*
830990	Others	0,02*
840000	(iv) Roots or rhizome	0,02*
840010	Liquorice	0,02*
840020	Ginger	0,02*
840030	Turmeric (Curcuma)	0,02*
840040	Horseradish	0,02*
840990	Others	0,02*
850000	(v) Buds	0,02*
850010	Cloves	0,02*
850020	Capers	0,02*
850990	Others	0,02*

860000	(vi) Flower stigma	0,02*
860010	Saffron	0,02*
860990	Others	0,02*
870000	(vii) Aril	0,02*
870010	Mace	0,02*
870990	Others	0,02*
900000	9. SUGAR PLANTS	0,01*
900010	Sugar beet (root)	0,01*
900020	Sugar cane	0,01*
900030	Chicory roots	0,01*
900990	Others	0,01*
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	
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	
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	

(*) 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
CIPAC	Collaborative International Pesticide Analytical Council Limited
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EDI	estimated daily intake
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
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
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

K _{oc}	organic carbon adsorption coefficient
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10 ⁻⁶)
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
UVD	ultra-violet detection
WG	water dispersible granule
WHO	World Health Organisation