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Modification of the existing maximum residue levels for proquinazid in currants and gooseberries

European Food Safety Authority (EFSA)

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Germany received an application from Landwirtschaftliches Technologiezentrum Augustenberg to modify the existing maximum residue levels (MRLs) for the active substance proquinazid in currants (black, red and white) and in gooseberries (green, red and yellow). Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA. According to EFSA the data are sufficient to derive a MRL proposal of 1.5 mg/kg for the proposed northern Europe use of proquinazid on currants and gooseberries, based on the residue trials on black currants. Adequate analytical methods are available to control proquinazid residues in the berries under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of proquinazid on currants and gooseberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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Keywords: proquinazid, currants, gooseberries, MRL application, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the evaluating Member State (EMS) Germany received an application from Landwirtschaftliches Technologiezentrum Augustenberg to modify the existing maximum residue levels (MRLs) for the active substance proquinazid in currants (black, red and white) and in gooseberries (green, red and white). Germany drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 September 2015.

EFSA bases its assessment on the evaluation report submitted by the EMS Germany, the DAR prepared under Directive 91/414/EEC, the conclusions on the peer review of the pesticide risk assessment and the conclusions from previous EFSA opinions on the active substance proquinazid.

The toxicological profile of proquinazid was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg bw per day and an acute reference dose (ARfD) of 0.2 mg/kg bw.

The metabolism of proquinazid in primary crops was investigated in the fruit (grapes) and cereals/grass (wheat) crop groups. Slightly different metabolic pathways were observed between both crops, since residues in wheat were mostly composed of proquinazid and its metabolite IN-MW977, while the metabolite IN-MW977 was not identified in grapes. Based on these data the residue definition for risk assessment in both crop groups was proposed by the peer review as 'proquinazid and metabolite IN-MW977, expressed as proquinazid' and as 'proquinazid' alone for monitoring. For the uses on berries, EFSA concludes that the metabolism of proquinazid is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

EFSA concludes that the submitted supervised residue trials on black currants are sufficient to derive a MRL proposal of 1.5 mg/kg on currants (black, red and white), extrapolated to gooseberries (green, red and white). Adequate analytical enforcement methods are available to monitor the residues of proquinazid in commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg.

Proquinazid is stable under standard hydrolysis conditions and therefore for processed commodities the same residue definition as for raw commodities is applicable. Processing studies on berries were not provided and are not requested.

As the proposed uses of proquinazid are on permanent crops and since berries are normally not fed to livestock, the investigation of residues in rotational crops and in livestock is not required.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). To calculate the chronic exposure, EFSA used median residue values (STMR) derived from the residue trials conducted on black currants. The acute exposure assessment was performed only with regard to the berries under consideration. The highest calculated chronic intake accounted for 12 % of the ADI (WHO Cluster B). An acute consumer risk was not identified in relation to the MRL proposals for currants and gooseberries, the highest calculated acute intake being 3 % of the ARfD for currants (DE, Child).

EFSA concludes that the intended use of proquinazid on currants (black, red and white) and gooseberries (green, red and white) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health. Thus, EFSA proposes to amend the existing MRLs as reported in the summary table below.

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Proquinazid				
0154030	Currants (black, red & white)	0.02*	1.5	NEU trials.
0154040	Gooseberries (green, red & yellow)	0.02*	1.5	Extrapolation from currants.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

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Background

Regulation (EC) No 396/2005¹ establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the Regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,² repealed by Regulation (EC) No 1107/2009,³ shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of the Regulation.

Germany, hereafter referred to as the evaluating Member State (EMS), received an application from Landwirtschaftliches Technologiezentrum Augustenberg⁴ to modify the existing MRLs for the active substance proquinazid in currants (black, red and white) and in gooseberries (green, red and white). This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation. After completion, the evaluation report was submitted to the European Commission and to EFSA on 2 September 2015.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2015-00503 and the following subject:

Proquinazid: Application to modify existing MRLs in currants and gooseberries

Germany proposed to raise the existing MRLs of proquinazid in currants and gooseberries from the limit of quantification of 0.02 mg/kg to 1.5 mg/kg.

EFSA proceeded with the assessment of the application and the evaluation report as required by Article 10 of the Regulation.

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

In accordance with Article 11 of the Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within three months (which may be extended to six months if more detailed evaluations need to be carried out) from the date of receipt of the application. If EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

The active substance and its use pattern

Proquinazid is the ISO common name for 6-iodo-2-propoxy-3-propylquinazolin-4(3*H*)-one (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix C.

Proquinazid was evaluated in the framework of Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2010/25/EU⁵ which entered into force on 1 August 2010 for use as a fungicide only. In accordance with Commission Regulation (EU) No 540/2011⁶ proquinazid is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

¹ Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.

² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.08.1991, p. 1–32.

³ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

⁴ Landwirtschaftliches Technologiezentrum Augustenberg, Nebelstr.23-31, 76227, Karlsruhe, Germany

⁵ Commission Directive 2010/25/EU of 18 March 2010 amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spirodiclofen as active substances. OJ L 69, 19.3.2010, p. 11–15.

⁶ Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.06.2011, p. 1–186.

The representative uses evaluated in the peer review were foliar applications on cereals and grapes against powdery mildew. The draft assessment report (DAR) has been peer reviewed by EFSA (EFSA, 2009).

The EU MRLs for proquinazid are established in Annex IIIA of Regulation (EC) No 396/2005. Since the entry into force of this regulation, EFSA has issued two reasoned opinions on the modification of MRLs for proquinazid. The proposals from these reasoned opinions have been considered in the preparation of EU legislation. The MRL changes that were reported in the EU legislation since the entry into force of the regulation are summarised in Table 1. The review of the existing MRLs for proquinazid according to Article 12 of Regulation (EC) No 396/2005 has not been finalised yet.

Table 1: Overview of the MRL changes since the entry into force of Regulation (EC) No 396/2005

Procedure ^(a)	Considered by Regulation	Remarks
Art. 10 (EFSA, 2010)	(EC) No 508/2011	strawberries
Art. 10 (EFSA, 2012)	(EC) No 251/2013	tomatoes, aubergines, cucurbits with edible peel

(a): Art. 10: Assessment of MRL application according to Article 6 to 10 of Regulation (EC) No 396/2005

No Codex MRLs (CXLs) are established for proquinazid.

The details of the intended German GAPs for proquinazid on currants and gooseberries are given in Appendix A.

Assessment

EFSA bases its assessment on the evaluation report submitted by the EMS (Germany, 2015), the DAR prepared under Directive 91/414/EEC (United Kingdom, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance proquinazid (EFSA, 2009), and the conclusions from previous EFSA opinions on proquinazid (EFSA, 2010, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁷ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1996, 1997a–g, 2000, 2010a, b, 2011; OECD, 2011).

1. Method of analysis

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

Analytical methods for the determination of proquinazid residues in plant commodities were assessed during the peer review under Directive 91/414/EEC (EFSA, 2009). The current enforcement residue definition in plant commodities is 'proquinazid'.

According to the peer review, residues of proquinazid in food of plant origin can be monitored by the modified multi-residue enforcement method DFG S19, with GC-MS quantification at LOQs of 0.01 mg/kg in high water (apple), high acid (grape) and in dry/starch (wheat grain) matrices, 0.02 mg/kg in high oil content matrices (rapeseed) and 0.1 mg/kg for wheat straw (EFSA, 2009).

As berries belong to the high acid content commodity group, EFSA concludes that sufficiently validated analytical methods are available for control residues of proquinazid in currants and gooseberries.

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

Analytical methods for the determination of residues in food of animal origin were not assessed in the current application, since berries under consideration are normally not fed to livestock.

⁷ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127–175.

2. Mammalian toxicology

The toxicological profile of the active substance proquinazid was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2009). The data were sufficient to derive toxicological reference values compiled in Table 2.

Table 2: Overview of the toxicological reference values

	Source	Year	Value	Study	Safety factor
Proquinazid					
ADI	EFSA	2009	0.01 mg/kg bw per day*	rat, 2 yr study	100
ARfD	EFSA	2009	0.2 mg/kg bw*	dog, 90 d study	100

*The ADI and ARfD for proquinazid are also considered acceptable to the metabolite IN-MW977 (EFSA, 2009).

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

Nature of residues

The metabolism of proquinazid in primary crops was evaluated in the framework of the peer review under Directive 91/414/EEC in the cereals/grass and fruits crop groups (United Kingdom, 2006; EFSA, 2009). An overview of the available metabolism studies is presented in Table 3.

Table 3: Summary of available metabolism studies in plants

Crop group	Crops	Application	Sampling ^(a) (day, DAT)	Comments
Fruit	Grapes	Foliar (3x 200 g/ha, BBCH 75; 79 and 85)	14, 28 DAT ₃	
Cereal/Grass	Wheat	Foliar, (3x 100 g/ha, BBCH 31/32; 37 and 71)	13 DAT ₁ (forage), 16 DAT ₂ (hay), 26 DAT ₃ (straw, grain)	

(a): DAT_x, days after treatment x.

The overall picture of the metabolism was found to be slightly different in wheat and grapes (EFSA, 2009), since residues in wheat fractions were mostly composed of proquinazid and its metabolite IN-MW977, while metabolite IN-MW977 was not identified in grapes.

Based on these data, the residue definition for risk assessment in the cereals and fruit crop groups was proposed as the 'sum proquinazid and metabolite IN-MW977 (and its isomer also called IN-MW977), expressed as proquinazid' in the conclusion of the peer review (EFSA, 2009). A conversion factor (CF) of 2 was derived for cereals from the supervised residues trials where IN-MW977 was measured in similar levels to proquinazid. No conversion factor was deemed necessary for grapes (CF 1) as metabolite IN-MW977 was concluded not to be relevant for grapes.

The residue definition for monitoring for cereals and fruit crop groups was proposed as 'proquinazid' only and is identical to the residue definition established under Regulation (EC) No 396/2005.

For the uses on the berries under consideration, EFSA concludes that the metabolism of proquinazid is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed during the peer review are applicable.

Magnitude of residues

In support of the MRL application the applicant submitted 5 GAP compliant residue trials on black currants, which were performed in Germany in 2011 and 2012. Samples were analysed according to the enforcement residue definition (proquinazid only), and no data were available for the metabolite IN-MW977. However, this is not considered a data gap as, according to metabolism studies,

metabolite IN-MW977 is not relevant for the fruit crop group. The data are sufficient to derive an MRL proposal of 1.5 mg/kg on currants, extrapolated to gooseberries.

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Table 4.

The stability of proquinazid residues in plant matrices under storage conditions prior to analysis was assessed during the peer review under Directive 91/414/EEC (EFSA, 2009). Residues of proquinazid were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 19 months in high acid content matrices (grapes); residues of proquinazid and IN-MW977 were found to be stable at $\leq -18^{\circ}\text{C}$ for up to 18 months in dry/starch content matrices (wheat grain, straw) and in high water content matrices (wheat forage) (EFSA, 2009).

As the trial samples were stored for a maximum period of 6 months under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability.

According to the EMS, the analytical method used to analyse the residue trial samples has been sufficiently validated and was proven to be fit for purpose (Germany, 2015).

EFSA concludes that the data are sufficient to derive the following MRL proposals:

- 1.5 mg/kg currants (black, red and white) in NEU,
- 1.5 mg/kg gooseberries (green, red and white) in NEU (extrapolation from trials on black currants)

Table 4: Overview of the available residues trials data

Crop (GAPs)	Region/ Indoor ^(a)	Residue levels observed in the supervised residue trials ^(b) (mg/kg)	Recommendations/comments ^(c)	MRL proposal (mg/kg)	HR ^(d) (mg/kg)	STMR ^(e) (mg/kg)
Black currants (2 x 75 g/ha, PHI 7 days)	NEU (outdoor)	Mo: 0.29; 0.31; <u>0.43</u> ; <u>0.49</u> ; 0.74 RA: samples not analysed for risk assessment*	<u>Underlined values</u> refer to higher residues in samples collected at a later PHI of 14 days MRL _{OECD} : 1.36/1.50 Extrapolation to gooseberries	1.5	0.74	0.43

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Individual residue levels considered for MRL calculation are reported in ascending order

Mo: residue level according to the monitoring residue definition (proquinazid)

RA: residue level according to the residue definition for risk assessment (sum proquinazid and metabolite IN-MW977 expressed as proquinazid)

(c): Any information/comment supporting the decision and OECD MRL calculation (unrounded/rounded values)

(d): HR: Highest residue level according to the residue definition for risk assessment.

(e): STMR: Median residue level according to residue definition for risk assessment.

*: No data provided for the risk assessment. However, according to the peer review, a conversion factor is not requested for the fruit crop group (CF 1)

Effect of industrial processing and/or household preparation

Standard hydrolysis studies investigating the effect of processing on the nature of proquinazid residues were investigated in the framework of the peer review, which concluded that proquinazid is hydrolytically stable (EFSA, 2009). Thus, for processed commodities, the same residue definition as for raw agricultural commodities is applicable.

Studies on the magnitude of proquinazid residues during the processing have been assessed in the framework of the peer review and processing factors were proposed for wine and raisins (EFSA, 2009). Processing studies on the berries under consideration were not submitted and are not required, as their contribution to the consumer intake is less than 10% of the ADI.

3.1.2. Rotational crops

As the proposed use of proquinazid is on permanent crops, the investigation of residues in rotational crops is not required and was therefore not considered in this reasoned opinion.

3.2. Nature and magnitude of residues in livestock

As currants and gooseberries or their by-products are not normally fed to livestock, the nature and magnitude of proquinazid residues in livestock was not assessed in the framework of this application (European Commission, 1996).

4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population⁸ (EFSA, 2007).

To calculate the chronic exposure, EFSA used median residue values (STMRs) derived from the residue trials conducted on black currants in the framework of the current application (Table 4). For several crops the STMR values as reported in the EFSA conclusion and in previous EFSA opinions were available to refine the calculation (EFSA, 2009, 2010, 2012). For the remaining commodities of plant and animal origin, the existing MRLs as established in Regulation (EU) No 251/2013⁹ were used as input values. EFSA notes that the conversion factors to express residues according to the risk assessment have not been applied as the only commodities for which MRLs are currently set above the LOQ in Regulation (EC) No 251/2013 are fruits and fruiting vegetables, for which the conversion factor of 1 is applicable.

The acute exposure assessment was performed only with regard to the berries under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest residue level (HR) as observed in supervised field trials (see Table 4). A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in the calculation, when required (EFSA, 2007).

The estimated exposures were then compared with the toxicological reference values derived for proquinazid (see Table 2). The results of the intake calculation are presented in Appendix B of this reasoned opinion.

The input values used for the dietary exposure calculation are summarised in Table 5.

⁸ The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

⁹ Commission Regulation (EU) No 251/2013 of 22 March 2013 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for aminopyralid, bifenthrin, captan, fluazinam, fluopicolide, folpet, kresoxim-methyl, penthiopyrad, proquinazid, pyridate and tembotrione in or on certain products. OJ L 88, 27.3.2013, p. 1–44.

Table 5: Input values for the consumer dietary exposure assessment

Commodity	Chronic exposure assessment		Acute exposure assessment	
	Input (mg/kg)	Comment	Input (mg/kg)	Comment
Risk assessment residue definition: proquinazid and the metabolite IN-MW977, expressed as proquinazid				
Currants	0.43	STMR (Table 4)	0.74	HR (Table 4)
Gooseberries	0.43	STMR black currants (Table 4)	0.74	HR black currants (Table 4)
Tomatoes, aubergines	0.04	STMR (EFSA, 2012)	Acute risk assessment undertaken only with regard to the berries under consideration	
Cucurbits(edible peel)	0.02	STMR (EFSA, 2012)		
Strawberries	0.06	STMR (EFSA, 2010)		
Grapes	0.15	STMR (EFSA, 2009)		
Other plant and animal commodities	MRL	MRL values as listed under Regulation (EU) No 251/2013		

The highest calculated chronic intake was estimated to be 12 % of the ADI (WHO Cluster B). The contribution of residues in gooseberries and currants to the total consumer exposure accounted for a maximum of 0.9 % of the ADI (WHO Cluster B) and 0.6 % of the ADI (NL child), respectively.

An acute consumer risk was not identified in relation to the MRL proposals for currants and gooseberries, the highest calculated acute intake being 3 % of the ARfD for currants (DE, Child).

EFSA concludes that the intended use of proquinazid on currants (black, red and white) and gooseberries (green, red and white) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

Conclusions and recommendations

Code ^(a)	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/Justification
Enforcement residue definition: Proquinazid				
0154030	Currants (black, red & white)	0.02*	1.5	NEU trials
0154040	Gooseberries (green, red & yellow)	0.02*	1.5	Extrapolation from currants

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005

(*): indicates that the MRL is set at the limit of analytical quantification (LOQ)

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Abbreviations

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement to risk assessment residue definition
CXL	Codex maximum residue limit (Codex MRL)
DAR	draft assessment report
DAT	days after treatment
EC	emulsifiable concentrate
EMS	evaluating Member State
GAP	good agricultural practice
GC	gas chromatography
GCPF	Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products (GIFAP))
HR	highest residue
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue level
MS	mass spectrometry detector
MW	molecular weight
NEU	northern Europe
NL	The Netherlands
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RD	residue definition
RMS	rapporteur Member State
STMR	supervised trials median residue
WHO	World Health Organization
wk	week
yr	year

Appendix A – Good Agricultural Practice (GAP)

Crop and/or situation ^(a)	MS or NEU/SEU or Country	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. a.s. ⁽ⁱ⁾	Method kind ^(f-h)	Growth stage & season ^(j)	Number min-max ^(k)	Interval min-max	g/hL min-max	Water L/ha min-max			g/ha min-max
Currants and Gooseberries	Germany	F	<i>Sphaeroteca mors uvae</i>	EC	200 g/L	Foliar spraying	Up to BBCH 85	2	7-10 days	7.5	1000	75	7	-

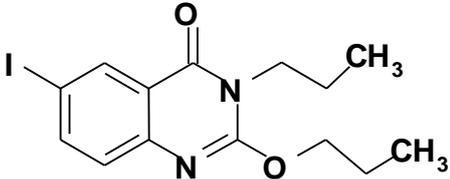
Remarks:

- (a): For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the usage 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 sucking insects, soil-born insects, foliar fungi, weeds
- (d): e.g. wettable powder (WP), water soluble granule (WG)
- (e): GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f): all abbreviations must be explained
- (g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h): Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants. type of equipment used must be indicated

- (i): g/kg or µg/L
- (j): Growth stage at last treatment, 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

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)
	3	Currants (red, black)	0,74 / -	3,4	Currants (red, black)	0,74 / -	1,0	Currants (red, black)	0,74 / -	1,0	Currants (red, black and white)	0,74 / -
2	Gooseberries	0,74 / -	2,3	Gooseberries	0,74 / -	0,8	Gooseberries	0,74 / -	0,8	Gooseberries	0,74 / -	
No of critical MRLs (IESTI 1)						No of critical MRLs (IESTI 2)						
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Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---			---			---		
	Highest % of ARfD/ADI		Processed commodities	Highest % of ARfD/ADI		Processed commodities	Highest % of ARfD/ADI		Processed commodities	Highest % of ARfD/ADI		Processed commodities
			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)
*) 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 Proquinazid 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 – Used compound codes

Code/Trivial name	Chemical name	Structural formula
Proquinazid	6-Iodo-2-propoxy-3-propyl-3 <i>H</i> -quinazolin-4-one MW: 372.21	
IN-MW977	2-(2-Hydroxypropoxy)-6-iodo-3-propyl-4(3 <i>H</i>)-quinazolinone	