Modification of the existing maximum residue levels for proquinazid in blueberries and cranberries

EFSA (European Food Safety Authority), Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service (FPS) Health, Food chain Safety and Environment submitted a request on behalf of Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance proquinazid in blueberries and cranberries. The data submitted in support of the request were found to be sufficient to derive MRL proposals for blueberries and cranberries. Adequate analytical methods for enforcement are available to control the residues of proquinazid in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of proquinazid according to the reported agricultural practices is unlikely to present a risk to consumer health.

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: proquinazid, blueberries, cranberries, fungicide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2021-00325

Correspondence: pesticides.mrl@efsa.europa.eu
Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgements: EFSA wishes to thank Stathis Anagnos, Laszlo Bura, Andrea Mioc, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Scarlato AP, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the modification of the existing maximum residue levels for proquinazid in blueberries and cranberries. EFSA Journal 2021;19(9):6835, 23 pp. https://doi.org/10.2903/j.efsa.2021.6835

ISSN: 1831-4732

© 2021 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Federal Public Service (FPS) Health, Food chain Safety and Environment submitted a request on behalf of Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance proquinazid in blueberries and cranberries. The EMS 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 3 June 2021. To accommodate for the intended uses in Northern Europe (NEU) of proquinazid, the EMS proposed to raise the existing MRLs in blueberries and cranberries from the limit of quantification (LOQ) of 0.02 to 1.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of proquinazid following foliar application was investigated in crops belonging to the groups of fruit crops and cereals/grass.

As the proposed uses of proquinazid are on permanent crops, investigations of residues in rotational crops are not required.

Studies investigating the effect of processing on the nature of proquinazid (hydrolysis studies) demonstrated that the active substance is stable.

Sufficiently validated analytical multiresidue methods based on gas chromatography are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (limit of quantification – LOQ).

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for fruit crops and cereals were proposed by the MRL review as the ‘sum of proquinazid and metabolite IN-MW977, expressed as proquinazid’ for risk assessment and as ‘proquinazid’ for enforcement. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, metabolism of proquinazid in plants, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are applicable.

The available residue trials are sufficient to derive MRL proposals of 1.5 mg/kg for blueberries and cranberries.

Specific studies investigating the magnitude of proquinazid residues in processed blueberries and cranberries have not been submitted and are not relevant, considering the low individual exposure to residues from the intake of these berries. Processing factors for grapes were derived in the framework of the EU pesticides peer review and can be extrapolated to the commodities under assessment, should further exposure refinement be needed.

Residues of proquinazid in commodities of animal origin were not assessed since the commodities under consideration in this MRL application are normally not fed to livestock.

The toxicological profile of proquinazid was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.01 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.2 mg/kg bw. The metabolite included in the risk assessment residue definition is of similar toxicity to the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). The short-term exposure assessment was performed only for the commodities assessed in this application. The calculations were based on the highest residue (HR) values derived from supervised field trials. The short-term exposure did not exceed the ARfD for any of the plant commodities assessed (3.4% of the ARfD for blueberries and 1.7% of ARfD for cranberries).

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level. EFSA updated these calculations with the relevant median residue (STMR) values derived from the residue trials submitted in support of the present MRL application for blueberries and cranberries. The estimated long-term dietary intake accounted for 20% of the ADI (NL toddler diet). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is minimal.
EFSA concluded that the proposed use of proquinazid on blueberries and cranberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------|-----------|-------------------------|-------------------------|-----------------------|
| 0154010       | Blueberries | 0.02*                   | 1.5                     | The submitted data are sufficient to derive MRL proposals for the NEU uses. Risk for consumers unlikely. |
| 0154020       | Cranberries | 0.02*                   | 1.5                     |                       |

Enforcement residue definition: Proquinazid

MRL: maximum residue level; NEU: northern Europe.

*: Limit of quantification (LOQ). It is noted that a lower MRL at the LOQ of 0.01 mg/kg is proposed to be implemented according to Draft Regulation SANTE/10034/2020.

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Table of contents

Abstract ................................................................................................................................................... 1
Summary .................................................................................................................................................. 3
Assessment ............................................................................................................................................. 6
1. Residues in plants .......................................................................................................................... 7
   1.1. Nature of residues and methods of analysis in plants ................................................................. 7
   1.1.1. Nature of residues in primary crops ............................................................................................. 7
   1.1.2. Nature of residues in rotational crops ........................................................................................... 7
   1.1.3. Nature of residues in processed commodities .............................................................................. 7
   1.1.4. Methods of analysis in plants ....................................................................................................... 7
   1.1.5. Storage stability of residues in plants ............................................................................................ 7
   1.1.6. Proposed residue definitions ....................................................................................................... 8
   1.2. Magnitude of residues in plants ..................................................................................................... 8
   1.2.1. Magnitude of residues in primary crops ......................................................................................... 8
   1.2.2. Magnitude of residues in rotational crops ..................................................................................... 8
   1.2.3. Magnitude of residues in processed commodities ......................................................................... 8
   1.2.4. Proposed MRLs ............................................................................................................................ 9
2. Residues in livestock ....................................................................................................................... 9
3. Consumer risk assessment .............................................................................................................. 9
4. Conclusion and Recommendations .................................................................................................. 9
References ............................................................................................................................................... 9
Abbreviations ........................................................................................................................................... 11
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ..................... 13
Appendix B – List of end points ......................................................................................................... 14
Appendix C – Pesticide Residue Intake Model (PRIMo) ........................................................................ 19
Appendix D – Input values for the exposure calculations ..................................................................... 21
Appendix E – Used compound codes .................................................................................................. 23
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for proquinazid in blueberries and cranberries. The detailed description of the intended NEU uses of proquinazid, which are the basis for the current MRL application, is reported in Appendix A.

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

Proquinazid was evaluated in the framework of Directive 91/414/EEC with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on grapes and cereals (winter and spring wheat and winter and spring barley, oats, triticale, winter rye). The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2009). Proquinazid was approved for the use as fungicide on 1 August 2010.

The EU MRLs for proquinazid are established in Annex III of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2020) and the proposed modifications have been voted at the Standing Committee on Plants, Animals, Food and Feed (PAFF committee) but are currently not implemented in Regulation yet (draft Regulation SANTE/10034/2020).

In accordance with Article 6 of Regulation (EC) No 396/2005, Federal Public Service (FPS) Health, Food chain Safety and Environment submitted a request on behalf of Belgium (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance proquinazid in blueberries and cranberries. The EMS 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 3 June 2021. To accommodate for the intended uses of proquinazid, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) of 0.02 to 1.5 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Belgium, 2021), the draft assessment report (DAR) and its addendum (United Kingdom, 2006, 2009) prepared under Council Directive 91/414/EEC, the Commission review report on proquinazid (European Commission, 2010a), the conclusion on the peer review of the pesticide risk assessment of the active substance proquinazid (EFSA, 2009), the conclusions from previous EFSA opinions on proquinazid (EFSA, 2015), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2020).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010b,c, 2017; OECD, 2011). 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 546/2011.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously is presented in Appendix B.

The evaluation report submitted by the EMS (Belgium, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

---

1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Directive 2010/25/EU of 18 March 2010 amending Council Directive 91/414/EEC to include penoxsulam, proquinazid and spirodichlofen as active substances. OJ L 69, 19.3.2010, p. 11–15.
3 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, 16.3.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
6 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, 11.6.2011, p. 127–175.
1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of proquinazid was investigated using phenyl-labelled proquinazid after foliar treatment in fruits crops (grapes and apples) and in cereals (wheat). Metabolism studies on grapes and wheat were assessed in the framework of the peer review (EFSA, 2009). The apple study was reported in the final addendum to the DAR (United Kingdom, 2009); however, due to its late submission in the process, it was not peer reviewed but further considered in the framework of the MRL review (EFSA, 2020).

In fruit crops, the parent compound was identified as the main residue. In grapes, proquinazid accounted for the majority of the extractable radioactivity (35–39% total radioactive residue (TRR), 0.08–0.09 mg/kg, day 0–29). In apple fruits, parent proquinazid was the major component identified, declining from 61% of the TRR (0.11 mg eq/kg) for the day 0 samples to 22% of the TRR (0.03 mg eq/kg) for the 28-day samples. Part of the unextracted radioactivity was further extracted with strong alkaline treatment and the majority of this unextractable residue reflected lignin incorporation.

In wheat, parent proquinazid was the main residue in grain (0.12 mg/kg) whereas metabolite IN-MW977 (isomers of mono-hydroxy proquinazid) was the main component of the TRR in forage, hay and straw (0.27 mg eq/kg, 0.40 mg eq/kg and 1.5 mg eq/kg, respectively).

For the intended uses on the berries under consideration, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

As the proposed uses of proquinazid are on permanent crops, investigations of residues in rotational crops are not required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of proquinazid was investigated in the framework of the EU pesticides peer review (EFSA, 2009). Studies demonstrated that proquinazid is hydrolytically stable under standard processing conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of proquinazid residues were assessed during the EU pesticides peer review (EFSA, 2009) and further discussed in the framework of the MRL review (EFSA, 2020). Residues of proquinazid can be enforced by modified multiresidue method DFG S19, with gas chromatography coupled with mass spectrometry (GC-MS) with LOQs of 0.01 mg/kg for apples, grapes and wheat grain, 0.02 mg/kg for oilseed rape and 0.1 mg/kg for wheat straw (EFSA, 2009).

Furthermore, in the framework of the MRL review, it was confirmed by the European Union Reference Laboratories (EURLs) that proquinazid can be monitored in high water content, high acid content, high oil content and dry commodities at 0.01 mg/kg by using QuEChERS multiresidue analytical method (EURLs, 2018; EFSA, 2020).

EFSA notes that the extraction efficiency for the analytical methods applied for enforcement and used for the residue trials is not proven as indicated according to the requirements of the extraction efficiency Guidance (European Commission, 2017). Further investigation on this matter would in principle be required. EFSA would therefore recommend reconsidering this point in the framework of the peer review for the renewal of approval of the active substance.

1.1.5. Storage stability of residues in plants

The storage stability of proquinazid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2009). The storage stability of proquinazid was demonstrated for a period of 18 months at –18°C in plant commodities, including the group to which the crops under assessment belong (high acid content commodities).
1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary and rotational crop metabolism studies, the results of hydrolysis studies and the toxicological significance of metabolites, the following residue definitions were proposed during the EU pesticides peer review (EFSA, 2009) and confirmed in the framework of the MRL review (EFSA, 2020):

- residue definition for risk assessment: sum of proquinazid and IN-MW977, expressed as proquinazid (for fruit crops and cereals).
- residue definition for enforcement: proquinazid (for fruit crops and cereals).

Conversion factors (CF) from enforcement to risk assessment have also been derived considering the metabolism studies and the available residue trials. For fruit crops, a CF of 1 was derived since according to the metabolism studies in apples and grapes, metabolite IN-MW977 is not expected to be present in fruits.

The same residue definitions are applicable to processed products and rotational crops (plant commodity relevant for human consumption), noting that it was not possible to conclude on the residue definition for feed items from rotational crops (EFSA, 2020).

Taking into account the proposed uses assessed in this application, EFSA concluded that these residue definitions and the CF for fruits are applicable and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

Blueberries, cranberries GAP (NEU, outdoor): 2 × 75 g a.s./ha; interval between applications: 7 days; PHI: 7 days

In support of the current MRL application, the applicant refers to residue trials conducted on currants that were previously assessed by EFSA (EFSA, 2015, 2020). Samples were analysed for proquinazid only, which is acceptable since the metabolite IN-MW977 included in the residue definition for risk assessment is not expected to be present in fruits (see Section 1.1.6). Data on five good agricultural practice (GAP) compliant residue trials performed with currants in Northern Europe were resubmitted (Belgium, 2021). These studies have been previously assessed by EFSA and concluded to be sufficient to derive MRL proposals of 1.5 mg/kg for currants and by extrapolation for gooseberries in support of identical GAPs (EFSA, 2015). Storage integrity of the samples has been demonstrated, and the analytical method used to quantify the residues has been sufficiently validated and was proven to be fit for purpose (Belgium, 2021).

Applicant requested to extrapolate residue data from currants to blueberries and cranberries. Such an extrapolation is applicable according to the Technical Guidelines on extrapolation (European Commission, 2020).

EFSA confirms the previous conclusions as valid for the present MRL request in blueberries and cranberries and an MRL of 1.5 mg/kg is proposed for both commodities.

1.2.2. Magnitude of residues in rotational crops

As the proposed uses of proquinazid are on permanent crops, investigations of residues in rotational crops are not required.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment were not submitted and are not required, since the contribution of the commodities under consideration to the theoretical maximum daily intake (TMDI) is < 10% of the acceptable daily intake (ADI) and the estimated daily intake is < 10% of the acute reference dose (ARfD) for any European consumer group diet (see Appendix B.3).

Moreover, the effect of industrial processing and/or household preparation was assessed during the pesticides peer review in studies conducted with grapes (EFSA, 2009) deriving various processing factors (PF). PF for juice making (i.e. < 0.25) could be extrapolated to small berries in case a refinement in consumer risk assessment is necessary (OECD, 2008).
1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for blueberries and cranberries. In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as blueberries and cranberries are generally not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for proquinazid used in the risk assessment (i.e. ADI of 0.01 mg/kg bw per day and ARfD value of 0.2 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2010a). The toxicological reference values of proquinazid were considered applicable for metabolite IN-MW977 included in the residue definition for risk assessment (EFSA, 2009).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodities assessed in this application. The calculations were based on the highest residue (HR) values derived from supervised field trials and the complete list of input values can be found in Appendix D.1. The short-term exposure did not exceed the ARfD for any of the plant commodities assessed in this application (3.4% of the ARfD for blueberries and 1.7% of ARfD for cranberries) (see Appendix B.3).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level (EFSA, 2020). EFSA updated the calculations with the relevant median residue (STMR) values derived from the residue trials submitted in support of the present MRL application for blueberries and cranberries. The crops, on which no uses were reported in the MRL review, were excluded from the exposure calculation, as it was assumed that proquinazid is not authorised on those crops. The input values used in the exposure calculations are summarised in Appendix D.1.

Provided that the existing EU MRLs will be amended as proposed by the MRL review, the estimated long-term dietary intake accounted for 20% of the ADI (NL toddler diet). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is minimal (see Appendix B.3).

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for blueberries and cranberries. EFSA concluded that the proposed use of proquinazid on blueberries and cranberries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

The MRL recommendations are summarised in Appendix B.4.

References

Belgium, 2021. Evaluation report on the modification of MRLs for proquinazid in blueberries and cranberries. April, 2021, 34 pp. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2009. Conclusion on the peer review of the pesticide risk assessment of the active substance proquinazid on request from the European Commission. EFSA Journal 2009;7(10):1350, 132 pp. https://doi.org/10.2903/j.efsa.2009.1350
EFSA (European Food Safety Authority), 2015. Reasoned opinion on the modification of the existing maximum residue levels for proquinazid in currants and gooseberries. EFSA Journal 2015;13(11):4280, 18 pp. https://doi.org/10.2903/j.efsa.2015.4280

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMO revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMO revision 3.1 (update of EFSA PRIMO revision 3). EFSA supporting publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.en-1605

EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned opinion on the review of the existing maximum residue levels for proquinazid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(1):5987, 46 pp. https://doi.org/10.2903/j.efsa.2020.5987

EURL (European Union Reference Laboratories for Pesticide Residues), 2018. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURLs and overall capability of official laboratories to be considered for the review of the existing MRLs for proquinazid. October 2018. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/VI/95-rev.3, 22 July 1997.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95-rev. 2, 22 July 1997.

European Commission, 1997h. Appendix J. Comenium and comparability of residue trials. Annex 2. Classiﬁcation of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997i. Appendix K. Residue analytical methods. For pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414. SANCO/3029/99-rev. 4. 11 July 2000.

European Commission, 2010a. Review report for the active substance proquinazid Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 22 January 2010 in view of the inclusion of proquinazid in Annex I of Directive 91/414/EEC. SANCO/11080/09 ﬁnal, 22 January 2010.

European Commission, 2010b. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010, ﬁnalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010

European Commission, 2000. Residue analytical methods. For pre-registration data requirements for Annex II (part A, section 4) and Annex III (part A, section 5) of Directive 91/414. SANCO/3029/99-rev. 4. 11 July 2000.

European Commission, 2014. Review report of the active substance proquinazid. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 24 March 2010. Available online: www.efsa.europa.eu
United Kingdom, 2009. Final addendum to the draft assessment report on the active substance proquinazid prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, July 2009. Available online: www.efsa.europa.eu

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
CS capsule suspension
CV coefficient of variation (relative standard deviation)
DALA days after last application
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dustable powder
DS powder for dry seed treatment
EC emulsifiable concentrate
EDI estimated daily intake
EMS evaluating Member State
eq residue expressed as a.s. equivalent
EUURL EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC gas chromatography
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GS growth stage
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOD limit of detection
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS mass spectrometry detector
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PAFF Standing Committee on Plants, Animals, Food and Feed
PBI plant back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
| Abbreviation | Description                                          |
|--------------|------------------------------------------------------|
| SC           | suspension concentrate                              |
| SEU          | southern Europe                                     |
| SL           | soluble concentrate                                 |
| SP           | water-soluble powder                                |
| STMR         | supervised trials median residue                    |
| TAR          | total applied radioactivity                         |
| TMDI         | theoretical maximum daily intake                    |
| TRR          | total radioactive residue                            |
| UV           | ultraviolet (detector)                              |
| WHO          | World Health Organization                           |
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pest or group of pests controlled | Preparation | Conc. a.s. (g/L) | Method kind | Range of growth stages and season(c) | Number min–max | Interval between application (days) min | 9 a.s./hl-min–max | Water (L/ha) min–max | Rate max | Unit | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-----------|----------------------------------|-------------|-----------------|------------|----------------------------------------|----------------|----------------------------------------|-----------------|-----------------|---------|------|-------------|---------|
| Blueberries           | NEU F                   | Powdery mildew – Sphaerotheca mors-uvae | EC 200 Foliar treatment – broadcast spraying | – 1–2 | 7.5–18.7 | 400–1,000 | 75 g a.i./ha | 7 | BE expresses rate as a.s/ha leaf wall area with a CF = 2. Hence, BE will authorise a rate of 35 g a.s./ha leaf wall area. |
| Cranberries           | NEU F                   | Powdery mildew – Sphaerotheca mors-uvae | EC 200 Foliar treatment – broadcast spraying | – 1–2 | 7.5–18.7 | 400–1,000 | 75 g a.i./ha | 7 | BE expresses rate as a.s/ha leaf wall area with a CF = 2. Hence, BE will authorise a rate of 35 g a.s./ha leaf wall area. |

**MRL:** maximum residue level; **GAP:** Good Agricultural Practice; **NEU:** northern European Union; **SEU:** southern European Union; **MS:** Member State; **a.s.:** active substance; **EC:** emulsifiable concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to 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.

(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s)       | Application(s) | Sampling (DAT) | Comment/Source                                                                 |
|----------------------------------|-------------|---------------|----------------|----------------|-------------------------------------------------------------------------------|
| Fruit crops                      | Grapes      | Foliar: 3 × 200 g a.s./ha | 0, 14, 29     | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |
|                                  | Apples      | Foliar: 2 × 225 g a.s./ha | 0, 15, 28     | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2009; EFSA, 2020) |
| Cereals/grass                    | Wheat       | Foliar: 3 × 100 g a.s./ha (grain, straw); 2 × 100 g a.s./ha (hay); 1 × 100 g a.s./ha (forage) | 26; 16; 13 | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |

| Rotational crops (available studies) | Crop groups | Crop(s)       | Application(s) | PBI (DAT) | Comment/Source                                                                 |
|--------------------------------------|-------------|---------------|----------------|-----------|-------------------------------------------------------------------------------|
| Root/tuber crops                     | Sugar beet  | Bare soil: 2 × 150 g a.s./ha (interval 30 days) | 45, 210 DALA | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |
| Pulses/oilseeds                     | Oilseed rape, Soybean | Bare soil: 2 × 150 g a.s./ha (interval 30 days) | 45, 210 DALA | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |
| Cereal (small grain)                | Wheat       | Bare soil: 2 × 150 g a.s./ha (interval 30 days) | 45, 210 DALA | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source                                         |
|-----------------------------------------|------------|---------|--------------------------------------------------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4) | Yes     | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |
|                                        | Sterilisation (20 min, 120°C, pH 6) | Yes     | Radiolabelled active substance: phenyl-14C (U) proquinazid (United Kingdom, 2006; EFSA, 2009) |
Can a general residue definition be proposed for primary crops?

No Only for fruits and cereals.

Rotational crop and primary crop metabolism similar?

Inconclusive Since no uptake was observed in the crop parts relevant for human consumption, a specific residue definition for rotational crops is not required for any plant commodity relevant for human consumption. Nevertheless, considering the high persistency of soil metabolite IN-MM671, the significant TRR observed in wheat straw and forage and in soybean straw and the lack of detailed information on the metabolites constituting the radioactivity, it was not possible to conclude on the residue definitions for feed items from rotational crops (EFSA, 2020).

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Yes –

Plant residue definition for monitoring (RD-Mo)
Cereals and fruit crops: proquinazid

Plant residue definition for risk assessment (RD-RA)
Cereals and fruit crops: Sum of proquinazid and metabolite IN-MW977, expressed as proquinazid

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Matrices with high water content, high oil content, high acid content and dry matrices:
- Modified multi-residue enforcement method DFG S19 with GC-MS, LOQ 0.01 mg/kg for apple, grape and wheat grain; 0.02 mg/kg for oilseed rape; 0.1 mg/kg for wheat straw (United Kingdom, 2009).
- Validated on apple, grapes, wheat grain, wheat straw and oilseed rape.
- ILV available for wheat grain, oilseed rape and grapes.
According to the EURLs, the LOQ of 0.01 mg/kg is achievable in all the matrices by using a QuEChERS method during routine analysis (EURLs, 2018; EFSA, 2020).

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (%C) | Stability period Value Unit | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|----------------------------|-------------------|----------------|
| High water content                | Wheat forage | –18 | 18 Months | Proquinazid and IN-MW977 | United Kingdom (2006), EFSA (2009) |
| High acid content                 | Grapes   | –18 | 19 Months | Proquinazid and IN-MW671 | United Kingdom (2006), EFSA (2009) |
| Dry                               | Wheat grains | –18 | 18 Months | Proquinazid and IN-MW977 | United Kingdom (2006), EFSA (2009) |
| Others                            | Wheat straw | –18 | 18 Months | Proquinazid and IN-MW977 | United Kingdom (2006), EFSA (2009) |

DAT: days after treatment; a.s.: active substance; DALA: days after last application; TRR: total radioactive residue; GC-MS: gas chromatography with mass spectrometry; ILV: independent laboratory validation; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; EURL: EU Reference Laboratory.
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity                | Region\(^{(a)}\) | Residue levels observed in the supervised residue trials \((mg/kg)\) | Comments/Source | Calculated MRL \((mg/kg)\) | HR\(^{(b)}\) \((mg/kg)\) | STMR\(^{(c)}\) \((mg/kg)\) | CF\(^{(d)}\) |
|--------------------------|-------------------|---------------------------------------------------------------|-----------------|-----------------------------|----------------|----------------|---------|
| RD-Mo: Proquinazid       |                   |                                                               |                 |                             |                |                |         |
| RD-RA: Sum of Proquinazid and metabolite IN-MW977, expressed as proquinazid |                   |                                                               |                 |                             |                |                |         |
| Blueberries and cranberries | NEU              | **Mo:** 0.29; 0.31; 0.43\(^{(e)}\); 0.49\(^{(e)}\); 0.74 | Trials on currants compliant with intended GAPs. Extrapolation to blueberries and cranberries is applicable. | **1.5**         | 0.74           | 0.43           | 1\(^{(f)}\) |

MRL: maximum residue level; RD-Mo: residue definition for monitoring; RD-RA: residue definition for risk assessment; GAP: Good Agricultural Practice.

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

\(^{(b)}\): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(d)}\): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

\(^{(e)}\): Residue trial value higher at a longer preharvest interval of 14 days.

\(^{(f)}\): The residue trial samples have not been analysed according to the risk assessment residue definition. However, metabolism studies confirm that metabolite IN-MW977 is not expected to be present in fruit crops. Therefore, a CF of 1 is applicable.
B.1.2.2. Residues in rotational crops

The crops under consideration are perennial. Therefore, the assessment on succeeding crops is not relevant in the framework of this MRL application.

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | CFp(b) | Comment/Source |
|---------------------|----------------------------|------------------------|--------|----------------|
| Wine grapes, juice  | 3                          | < 0.17; < 0.25; < 0.71  | < 0.25 | 1 Residues in juice were always below LOD (United Kingdom, 2006; EFSA, 2009) |

PF: processing factor; CFp: Conversion factor for risk assessment in processed commodity (= Residue level in processed commodity expressed according to RD-RA/Residue level in processed commodity expressed according to RD-Mo); LOD: limit of detection.

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): For fruit commodities, a Conversion Factor of 1 can be derived.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

ARfD 0.2 mg/kg bw (European Commission, 2010a)

IESTI, according to EFSA PRIMo

- Blueberries: 3.4% of ARfD (NL adult diet)
- Cranberries: 1.7% of ARfD (NL child diet)

Assumptions made for the calculations

The short-term exposure assessment was performed only for the commodities assessed in this application. The calculations are based on the highest residue levels (HR) expected in blueberries and cranberries according to the submitted residue trials. The conversion factor from enforcement to risk assessment in fruits is 1 (see Section 1.1.6).

Calculations performed with PRIMo revision 3.1.

ADI 0.01 mg/kg bw per day (European Commission, 2010a)

Highest IEDI, according to EFSA PRIMo

- 20% of ADI (NL toddler diet)
- Contribution of crops assessed:
  - Blueberries: 0.13% of ADI (NL toddler diet)
  - Cranberries: 0.09% of ADI (GEMS/Food G10 diet)

Assumptions made for the calculations

The long-term exposure assessment as performed in the recent MRL review (EFSA, 2020) was updated with the median residue levels (STMR) derived for blueberries and cranberries from the submitted residue trials. The conversion factor from enforcement to risk assessment in fruits is 1. The commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: EFSA Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue.
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|------------------|---------------|-------------------------|-------------------------|--------------------------------------------------------------------------------------|
| 0154010          | Blueberries   | 0.02*                   | 1.5                     | The submitted data are sufficient to derive MRL proposals for the NEU uses. Risk for consumers unlikely. |
| 0154020          | Cranberries   | 0.02*                   | 1.5                     |                                                                                                                                 |

Enforcement residue definition: Proquinazid

MRL: maximum residue level; NEU: northern Europe.

*: A lower MRL at the LOQ of 0.01 mg/kg to be implemented according to Draft Regulation SANTE/10034/2020.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
### Appendix C – Pesticide Residue Intake Model (PRMo)

#### Proquinazid (F)

| Commodity | MRL (mg/kg) | LOQ (mg/kg) range from: | Input values |
|------------|-------------|-------------------------|--------------|
| Wheat      | 1.00        | 0.01 to 1.5             |              |
| Currants   | 1.00        | 0.01 to 1.5             |              |

#### Toxological reference values

| ADI (mg/kg bw per day) | Source |
|------------------------|--------|
| EC                     |        |

#### Supplementary results – chronic risk assessment

| Year of evaluation | EC     |
|--------------------|--------|
| 2013               |        |

#### Details – acute risk assessment

| Source of ADI | ARfD (mg/kg bw) |
|---------------|-----------------|
| EC            | Adults          |

#### Input values

**LOQs (mg/kg)** range from: 0.01 to 1.5

**Toxicological reference values assessment**

**Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

| No of diets exceeding the ADI | --- |
|-------------------------------|-----|
| Exposure resulting from commodities not under assessment | 2nd contributor to ADI (in % of ADI) |
| Highest contributor to MS diet (µg/kg bw per day) | 2nd contributor to MS diet (in % of ADI) |
| 3rd contributor to MS (in % of ADI) |

| MS Diet | 20% 2.00 12% 3% 1% Currants (red, black and white) 20% |
|---------|------------------------------------------------------|
| NL toddler | Milk: Cattle  | 11% 1.06 4% 3% 1% Table grapes 11% |
| DE child  | Milk: Cattle  | 10% 1.00 5% 1% 1% Currants (red, black and white) 10% |
| UK infant | Milk: Cattle  | 10% 0.98 8% 0.4% 0.3% Currants (red, black and white) 10% |
| FR toddler 2-3 yr | Milk: Cattle  | 8% 0.81 6% 0.8% 0.3% Wheat 8% |
| FR child 3-15 yr | Milk: Cattle  | 7% 0.74 5% 0.5% 0.4% Apples 7% |
| UK toddler | Milk: Cattle  | 7% 0.67 4% 0.6% 0.4% Currants (red, black and white) 7% |
| FR adult 3-15 yr | Milk: Cattle  | 7% 0.62 3% 1% 0.6% Apples 7% |
| RO general | Milk: Cattle  | 6% 0.60 2% 1% 0.7% Tomatoes 6% |
| SE general | Milk: Cattle  | 5% 0.53 2% 0.9% 0.3% Wheat 5% |
| GEMS/Food G07 | Milk: Cattle  | 5% 0.48 1% 0.9% 0.4% Wheat 5% |
| GEMS/Food G06 | Milk: Cattle  | 5% 0.46 2% 0.9% 0.4% Apples 5% |
| GEMS/Food G08 | Milk: Cattle  | 5% 0.46 1% 0.9% 0.4% Tomatoes 5% |
| ES child  | Milk: Cattle  | 5% 0.45 2% 0.4% 0.1% Strawberries 5% |
| GEMS/Food G10 | Milk: Cattle  | 5% 0.43 1% 0.4% 0.1% Wheat 5% |
| NL general | Milk: Cattle  | 4% 0.38 2% 0.5% 0.3% Apples 4% |
| PT general | Milk: Cattle  | 4% 0.35 2% 0.4% 0.3% Tomatoes 4% |
| IE adult  | Milk: Cattle  | 3% 0.35 1% 0.9% 0.2% Wheat 3% |
| ES adult  | Milk: Cattle  | 3% 0.27 1.0% 0.4% 0.3% Tomatoes 3% |
| UK adult  | Milk: Cattle  | 2% 0.24 0.9% 0.6% 0.2% Wheat 2% |
| FI 3 yr   | Milk: Cattle  | 2% 0.17 0.3% 0.2% 0.2% Tomatoes 2% |
| FI 6 yr   | Milk: Cattle  | 2% 0.17 0.3% 0.2% 0.2% Tomatoes 2% |
| FI adult  | Milk: Cattle  | 2% 0.13 0.3% 0.2% 0.2% Tomatoes 2% |
| FI general | Milk: Cattle  | 2% 0.09 0.3% 0.2% 0.2% Tomatoes 2% |
| FI toddler | Milk: Cattle  | 2% 0.17 0.3% 0.2% 0.2% Tomatoes 2% |
| FI child  | Milk: Cattle  | 2% 0.13 0.3% 0.2% 0.2% Tomatoes 2% |
| FI adult  | Milk: Cattle  | 2% 0.12 0.3% 0.2% 0.2% Tomatoes 2% |
| FI child  | Milk: Cattle  | 2% 0.12 0.3% 0.2% 0.2% Tomatoes 2% |

#### Conclusions

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. 
The long-term intake of residues of Proquinazid (F) is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
### Show results of IESTI calculation only for crops with GAPs under assessment

#### Results for children

| Commodities                              | ARfD/ADI | Exposure (µg/kg bw) |
|-------------------------------------------|----------|---------------------|
| **Processed commodities**                |          |                     |
| Barley (milling (flour))                  | 0.0%     |                     |
| Oat (milling (flakes))                    | 0.0%     |                     |
| Rye (milling (wholemeal)-baking)          | 0.0%     |                     |
| Barley (cooked)                           | 0.0%     |                     |
| Oat (boiled)                              | 0.0%     |                     |
| Rye (boiled)                              | 0.0%     |                     |
| Wheat (milling (flour))                   | 0.0%     |                     |
| Wheat (cooking)                           | 0.0%     |                     |
| Wheat (milling (flour))                   | 0.0%     |                     |
| **Unprocessed commodities**              |          |                     |
| Cucumbers                                 | 0.0%     |                     |
| Courgettes                                | 0.0%     |                     |
| Tomato                                    | 0.0%     |                     |
| Paprika                                   | 0.0%     |                     |

#### Results for adults

| Commodities                              | ARfD/ADI | Exposure (µg/kg bw) |
|-------------------------------------------|----------|---------------------|
| **Processed commodities**                |          |                     |
| Barley (milling (flour))                  | 0.0%     |                     |
| Oat (milling (flakes))                    | 0.0%     |                     |
| Rye (milling (wholemeal)-baking)          | 0.0%     |                     |
| Barley (cooked)                           | 0.0%     |                     |
| Oat (boiled)                              | 0.0%     |                     |
| Rye (boiled)                              | 0.0%     |                     |
| Wheat (milling (flour))                   | 0.0%     |                     |
| Wheat (cooking)                           | 0.0%     |                     |
| Wheat (milling (flour))                   | 0.0%     |                     |
| **Unprocessed commodities**              |          |                     |
| Cucumbers                                 | 0.0%     |                     |
| Courgettes                                | 0.0%     |                     |
| Tomato                                    | 0.0%     |                     |
| Paprika                                   | 0.0%     |                     |

#### No. of processed commodities exceeding the ARfD/ADI in children and adults

| Commodities                              | No. exceeding ARfD/ADI | (IESTI) |
|-------------------------------------------|------------------------|---------|
| **Processed commodities**                |                        |         |
| Barley (milling (flour))                  |                        |         |
| Oat (milling (flakes))                    |                        |         |
| Rye (milling (wholemeal)-baking)          |                        |         |
| Barley (cooked)                           |                        |         |
| Oat (boiled)                              |                        |         |
| Rye (boiled)                              |                        |         |
| Wheat (milling (flour))                   |                        |         |
| Wheat (cooking)                           |                        |         |
| Wheat (milling (flour))                   |                        |         |
| **Unprocessed commodities**              |                        |         |
| Cucumbers                                 |                        |         |
| Courgettes                                |                        |         |
| Tomato                                    |                        |         |
| Paprika                                   |                        |         |

#### No. of processed commodities for which ARfD/ADI is exceeded

| Commodities                              | No. exceeding ARfD/ADI |
|-------------------------------------------|------------------------|
| **Processed commodities**                |                        |
| Barley (milling (flour))                  |                        |
| Oat (milling (flakes))                    |                        |
| Rye (milling (wholemeal)-baking)          |                        |
| Barley (cooked)                           |                        |
| Oat (boiled)                              |                        |
| Rye (boiled)                              |                        |
| Wheat (milling (flour))                   |                        |
| Wheat (cooking)                           |                        |
| Wheat (milling (flour))                   |                        |
| **Unprocessed commodities**              |                        |
| Cucumbers                                 |                        |
| Courgettes                                |                        |
| Tomato                                    |                        |
| Paprika                                   |                        |

### Details – acute risk assessment/adults

A short term intake of residues of Proquinazid (F) is unlikely to present a public health risk.

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

The calculation is based on the large portion of the most critical consumer group.

The acute risk assessment is based on the ARfD, DISCLAIMER: Delayed data from the UK were included in FRMO when the UK was a member of the European Union.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity              | MRLs in SANTE/10034/2020/Proposed MRL (mg/kg) | Source      | Chronic risk assessment | Acute risk assessment |
|------------------------|-----------------------------------------------|-------------|-------------------------|-----------------------|
|                        |                                               |             | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment(a) |
| **Risk assessment residue definition 1:** Sum of proquinazid and IN-MW977, expressed as proquinazid. |                                               |             |                         |                       |             |
| Apples                 | 0.08                                          | EFSA (2020) | 0.024                   | STMR-RAC × CF         | 0.047               | HR-RAC × CF   |
| Pears                  | 0.08                                          | EFSA (2020) | 0.024                   | STMR-RAC × CF         | 0.047               | HR-RAC × CF   |
| Table grapes           | 0.5                                           | EFSA (2020) | 0.085                   | STMR-RAC × CF         | 0.34                | HR-RAC × CF   |
| Wine grapes            | 0.5                                           | EFSA (2020) | 0.085                   | STMR-RAC × CF         | 0.34                | HR-RAC × CF   |
| Strawberries           | 2                                             | EFSA (2020) | 0.06                    | STMR-RAC × CF         | 1.2                 | HR-RAC × CF   |
| Blueberries            | 1.5 Intended use                              |             | 0.43                    | STMR-RAC × CF         | 0.74                | HR-RAC × CF   |
| Cranberries            | 1.5 Intended use                              |             | 0.43                    | STMR-RAC × CF         | 0.74                | HR-RAC × CF   |
| Currants (red, black and white) | 1.5                                      | EFSA (2020) | 0.43  | STMR-RAC × CF         | 0.74                | HR-RAC × CF   |
| Gooseberries (green, red and yellow) | 1.5                                      | EFSA (2020) | 0.43  | STMR-RAC × CF         | 0.74                | HR-RAC × CF   |
| Tomatoes               | 0.15                                          | EFSA (2020) | 0.0375                  | STMR-RAC × CF         | 0.078               | HR-RAC × CF   |
| Aubergines/egg plants  | 0.15                                          | EFSA (2020) | 0.0375                  | STMR-RAC × CF         | 0.078               | HR-RAC × CF   |
| Cucumbers              | 0.05                                          | EFSA (2020) | 0.017                   | STMR-RAC × CF         | 0.024               | HR-RAC × CF   |
| Gherkins               | 0.05                                          | EFSA (2020) | 0.017                   | STMR-RAC × CF         | 0.024               | HR-RAC × CF   |
| Courgettes             | 0.05                                          | EFSA (2020) | 0.017                   | STMR-RAC × CF         | 0.024               | HR-RAC × CF   |
| Barley                 | 0.04                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | STMR-RAC × CF |
| Oat                    | 0.04                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | STMR-RAC × CF |
| Rye                    | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | STMR-RAC × CF |
| Wheat                  | 0.02                                          | EFSA (2020) | 0.01                    | STMR-RAC × CF         | 0.01                | STMR-RAC × CF |
| **Risk assessment residue definition 2:** Sum of proquinazid and metabolites IN-MU210 and IN-MW977 expressed as proquinazid. |                                               |             |                         |                       |             |
| Bovine: Muscle/meat    | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Bovine: Fat tissue     | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Bovine: Liver          | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Bovine: Kidney         | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Sheep: Muscle/meat     | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Sheep: Fat tissue      | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Sheep: Kidney          | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Goat: Muscle/meat      | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Goat: Fat tissue       | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Goat: Liver            | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Goat: Kidney           | 0.02                                          | EFSA (2020) | 0.02                    | STMR-RAC × CF         | 0.02                | HR-RAC × CF   |
| Commodity        | MRLs in SANTE/10034/2020/Proposed MRL (mg/kg) | Source     | Chronic risk assessment | Acute risk assessment |
|------------------|---------------------------------------------|------------|-------------------------|-----------------------|
|                  |                                             |            | Input value (mg/kg)     | Comment              | Input value (mg/kg) | Comment<sup>(a)</sup> |
| Equine: Muscle/meat | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Equine: Fat tissue | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Equine: Liver     | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Equine: Kidney    | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Poultry: Muscle/meat | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Poultry: Fat tissue | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Poultry: Liver    | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |
| Milk: Cattle      | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | STMR-RAC × CF      |
| Milk: Sheep       | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | STMR-RAC × CF      |
| Milk: Goat        | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | STMR-RAC × CF      |
| Milk: Horse       | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | STMR-RAC × CF      |
| Eggs: Chicken     | 0.02                                        | EFSA (2020)| 0.02                   | STMR-RAC × CF        | 0.02               | HR-RAC × CF        |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; CF: conversion factor.

(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
### Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>a</sup> | Structural formula<sup>b</sup> |
|-------------------|-----------------------------------------------|-------------------------------|
| Proquinazid       | 6-iodo-2-propoxy-3-propylquinazolin-4(3H)-one Ic1ccc2N=C(OCCC)N(CCC)=O)c2c1 FLVBVXXXXMLMOX-UHFFFAOYSA-N | ![Structural formula](image) |
|                   | IN-MU210 3-[(6-iodo-4-oxo-3-propyl-3,4-dihydroquinazolin-2-yl)oxy]propanoic acid O=C(O)CCOC1=NC2ccccc(-O)N1CCC YYROMWCBRXFBR-UHFFFAOYSA-N | ![Structural formula](image) |
|                   | IN-MW977 2-(2-hydroxypropoxy)-6-iodo-3-propylquinazolin-4(3H)-one CC(O)COC1=NC2ccccc(-O)N1CCC YCGUJJXFKHHIEK-UHFFFAOYSA-N | ![Structural formula](image) |
|                   | IN-MM671 2-propoxy-3-propylquinazolin-4(3H)-one CCCOC1=NC2cccccc(-O)N1CCC UQWLSCVKSIZLB-UHFFFAOYSA-N | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>a</sup>: ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

<sup>b</sup>: ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).