Modification of the existing maximum residue level for epoxiconazole in beetroots

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Zoltan Erdos,
Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia,
Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Ragnor Pedersen,
Hermine Reich, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona,
Anne Theobald, Benedicte Vagenende and Laura Villamar-Bouza

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Agriculture & Horticulture Development Board submitted a request to the competent national authority in the United Kingdom to modify the existing maximum residue level (MRL) for the active substance epoxiconazole in beetroots. The data submitted in support of the request were found to be sufficient to derive a MRL proposal for beetroots. Adequate analytical methods for enforcement are available to control the residues of epoxiconazole in the commodities under evaluation 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 epoxiconazole according to the reported agricultural practice is unlikely to present a risk to consumer health. However, the residue definition for risk assessment was set on a provisional basis, pending the outstanding issues on the overall consumer assessment of the triazole derivative metabolites (TDMs). The reliable end points, appropriate for use in regulatory risk assessment are presented.

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Keywords: epoxiconazole, beetroots, pesticide, MRL, consumer risk assessment, triazole derivative metabolites

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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture & Horticulture Development Board submitted an application to the competent national authority in the United Kingdom (evaluating Member State (EMS)) to modify the existing maximum residue level (MRL) for the active substance epoxiconazole in beetroots. 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 26 April 2018. To accommodate for the intended use of epoxiconazole, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 0.1 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 epoxiconazole following foliar application was investigated in primary crops belonging to the group of fruit crops, root crops and cereals/grass crops after foliar application and in rotational crops in root crops, leafy crops and cereals/grass crops after foliar application during the European Union (EU) pesticides peer review.

Based on the metabolic pattern identified in metabolism studies, the results of the hydrolysis studies, the toxicological significance of metabolites and the capabilities of the analytical methods, the EFSA conclusion in the framework of the peer review was that the enforcement residue definition should be parent epoxiconazole and that the risk assessment residue definition as parent epoxiconazole should also need to consider triazole derivative metabolites (TDMs). This conclusion remains unchanged in the current application. The residue definition is applicable to primary crops, including the crops under assessment, rotational crops and processed products. A sufficiently validated analytical method is available for the enforcement of the proposed residue definition in plant commodities at the LOQ of 0.01 mg/kg.

The available residue trials were sufficient to derive a MRL proposal of 0.1 mg/kg for beetroot. Specific studies investigating the magnitude of epoxiconazole residues in processed commodities are not required, as the residue levels expected in raw agricultural commodities are low.

Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels of epoxiconazole are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practice (GAP).

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

The toxicological profile of epoxiconazole 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 0.008 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.023 mg/kg bw. It is noted that epoxiconazole has harmonised classification as toxic for reproduction category 1B and this classification triggers the lack of compliance with the approval criteria set out in the Annex II to Regulation (EC) No 1107/2009. The conclusions reported in this reasoned opinion should be considered as provisional and might need to be reconsidered in the light of the outcome of the ongoing peer review for the renewal of approval.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 58.1% of the ADI (DK, child diet), where the contribution of the residues in beetroots to the total exposure is accounting for 0.006% of ADI. No acute consumer risk was identified in relation to the MRL proposal for beetroots, with the highest calculated acute exposure being 11.4% of the ARfD (NL, child). EFSA emphasises that the above assessment does not take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed.
EFSA concluded that the proposed use of epoxiconazole on beetroots 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 MRL as reported in the summary table below. Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code<sup>(a)</sup> | Commodity          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|--------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0.213010          | Beetroots          | 0.05*                   | 0.1                     | The submitted data are sufficient to derive a MRL of 0.1 mg/kg for the NEU use. Residues in beetroots related to the use of epoxiconazole in accordance with the assessed GAP are not expected to pose a risk to EU consumers. However, the assessment does not yet take into consideration triazole derivative metabolites (TDMs). |

MRL: maximum residue level; NEU: northern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
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Assessment

The detailed description of the intended use of epoxiconazole which is the basis for the current maximum residue level (MRL) application is reported in Appendix A.

Epoxiconazole is the ISO common name for (2RS,3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1H-1,2,4-triazole (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Epoxiconazole was evaluated in the framework of Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on cereals and sugar beet. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority EFSA (2008). Epoxiconazole was approved2 for the use as a fungicide on 1 May 2009.

The European Union (EU) MRLs for epoxiconazole are established in Annexes III of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has previously issued several reasoned opinions on the modification of MRLs for epoxiconazole. The proposals from these reasoned opinions have been considered in recent regulation4 for EU MRL legislation. No Codex maximum residue limits (CXLs) are established for epoxiconazole.

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture & Horticulture Development Board submitted an application to the competent national authority in the United Kingdom (EMS) to modify the existing MRL for the active substance epoxiconazole in beetroots. 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 EFSA on 26 April 2018.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2018), the DAR (and its addendum/addenda) (Germany, 2005, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on epoxiconazole (European Commission, 2016), the conclusion on the peer review of the pesticide risk assessment of the active substance epoxiconazole (EFSA, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance epoxiconazole in light of confirmatory data (EFSA, 2015) as well as the conclusions from previous EFSA opinions on epoxiconazole (EFSA, 2011, 2012).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 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 546/20116.

As the EU pesticides peer review for the renewal of the active substance in accordance with Regulation (EC) No 1107/2009 and the review of the existing MRLs under Article 12 of Regulation 396/2005 are not yet finalised, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review and the MRL review. It is furthermore noted that epoxiconazole has harmonised classification as toxic for reproduction category 1B and this classification triggers the lack of compliance with the approval criteria set out in points the Annex II to Regulation (EC) No 1107/2009.

EFSA emphasises that the above assessment does not take into consideration triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs

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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 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances. OJ L 316, 26.11.2008, p. 4–11.
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: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
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.
arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018).

As an outcome of the EU peer review of epoxiconazole, a data gap was identified to elucidate the impact of different isomer ratios on the consumer risk assessment of epoxiconazole (EFSA 2008). Nonetheless, the relevance of the enantiomer change on the consumer dietary risk assessment was addressed by EFSA (2015).

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, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (United Kingdom, 2018) 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. **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 epoxiconazole in primary crops was evaluated by the RMS (Germany, 2005) and reviewed by EFSA (2008) in the framework of the peer review under Directive 91/414/EEC. The overview of the metabolism study designs is presented in Appendix B. The metabolism of epoxiconazole has been investigated in wheat, bananas, coffee beans and sugar beets after foliar application. The metabolic pathway in wheat proceeds through hydroxylation of the chlorophenyl and oxirane rings, cleavage of the oxirane ring and further conjugation processes. Two to three months after application, unchanged epoxiconazole represents at least 75% of the organic extract in straw. The total radioactive residue (TRR) in grains was low (0.05 mg eq/kg). A great part of the radioactivity was associated to the starch fraction and no parent epoxiconazole was detected. Triazole alanine and triazole acetic acid levels were not reported.

In other tested plants, only epoxiconazole was identified as a predominant component of the residue. A metabolism study in sugar beets indicates a small translocation of residues from leaves into roots. All these studies suggest that after foliar application parent epoxiconazole accounts for the major component of the residues.

1.1.2. **Nature of residues in rotational crops**

Epoxiconazole is proposed to be used on beetroot that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, epoxiconazole demonstrated medium to very high persistence in soil (DT90 > 1 year) (EFSA, 2008). A minor soil metabolite of epoxiconazole was 1,2,4-triazole, which itself is very rapidly degraded into soil with a half-life of 8 days. As the DT90 value of epoxiconazole exceeds the trigger values of 100 days, further studies investigating the nature and magnitude of the compound uptake in rotational crops are required. The metabolism of epoxiconazole in rotational crops was assessed in the DAR prepared under Directive 91/414/EEC and in the conclusion on the peer review (Germany, 2005; EFSA, 2008). Overall, the peer review concluded that the metabolic pathways in rotational crops are similar to those observed in primary crops. For the proposed uses assessed in the present application, no further information is required. Details of the studies are presented in Appendix B.

1.1.3. **Nature of residues in processed commodities**

The effect of processing on the nature of epoxiconazole residues was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 min at 90°C, pH 4; 60 min at 100°C, pH 5; 20 min at 120°C, pH 6). The peer review concluded that the compound is hydrolytically stable under the representative processing conditions (EFSA, 2008).
1.1.4. Methods of analysis in plants

Analytical methods for the determination of epoxiconazole residues in plant commodities were assessed in the DAR and in the conclusion on the peer review under Directive 91/414/EEC (Germany, 2005; EFSA, 2008).

Further validation data for the high-performance liquid chromatography with mass spectrometry (HPLC–MS) and high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) method in high water content matrices (beetroot roots and beetroot leaves/tops) were assessed in the framework of the current MRL application (United Kingdom, 2018). These methods are sufficiently validated and able to quantify epoxiconazole at or above the LOQ of 0.01 mg/kg.

1.1.5. Stability of residues in plants

The storage stability of epoxiconazole in primary crops was investigated in the framework of the peer review DAR (Germany, 2005; EFSA, 2008). Residues of epoxiconazole were found to be stable at ≤18°C for up to 24 months in matrices with high water, high fat content as well as in dry matrices.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions for enforcement and risk assessment were proposed in the EU peer review:

- residue for risk assessment: (1) epoxiconazole and (2) TDMs (provisionally, pending the definition of a common and harmonised approach for all the active substances of the triazole class);
- residue definition for enforcement: epoxiconazole.

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

For the uses on the crop under consideration, EFSA concludes that the metabolism of epoxiconazole is addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable. The same residue definitions are applicable to rotational crops and processed products.

Sufficiently validated analytical methods are available to monitor the proposed residue definition in the commodity under assessment.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted eight trials on sugar beet performed over two seasons in the Northern Europe. The extrapolation of residue data from sugar beet to beetroots is possible (European Commission, 2017). Samples of sugar beet roots and tops were analysed for epoxiconazole (United Kingdom, 2018). The available trials were overdosed and therefore the proportionality approach was applied (OECD, 2016). The residue results from the trials have been scaled by an appropriate factor (0.702–0.758) based on total application rate. Detailed information of the residue levels can be found in Table B.1.2.1. The data were sufficient to calculate MRL and risk assessment values.

As the supervised residue trial samples were stored under conditions for which integrity of the samples was demonstrated, it is concluded that the residue data are valid with regard to storage stability. The samples were analysed by using a sufficiently validated method.

1.2.2. Magnitude of residues in rotational crops

Rotational crop residue trials investigating the level of epoxiconazole residues in leafy vegetables, root and tuber vegetables, cereals and pulses and oilseed were assessed in the DAR and in the conclusion of the peer review (Germany, 2005; EFSA, 2008). The magnitude of TDMs in rotational crops has not been investigated.

In study 1, after the harvest of wheat (treated 2 × 0.125 kg a.s./ha), the fields were treated with the active substance at an application rate of 3 × 0.375 kg a.s./ha (6N compared to the intended application rate on beetroot). Rice, cucumbers, spinach, potato, radish, soybean and sugar beet were
sown. Epoxiconazole was detected in samples of rice forage and rice straw at levels of 0.01–0.05 mg/kg. In all other crops, the residues were < 0.005 mg/kg.

In study II, cereals were sprayed with 3–4 × 0.125–0.188 kg a.s./ha (4N compared to the intended application rate on beetroot). Winter cereals, oilseed rape, turnips and potatoes were planted following the harvest of cereals. Residues in rotational crops at all sampling intervals were < 0.05 mg/kg.

Therefore, based on the available rotational crop field studies and considering the application rates proposed in the framework of this application (2 × 0.9375 kg a.s./ha), it is concluded that no significant uptake of epoxiconazole is expected in rotational crops, provided the active substance is applied according to the intended Good Agricultural Practice (GAP).

Possible uptake of triazole metabolites cannot be excluded and should be considered further when a methodology for TDMs assessment is available.

1.2.3. Magnitude of residues in processed commodities

Not triggered by the current application. Specific studies to assess the magnitude of epoxiconazole and its residues in processed commodities of beetroots are not considered necessary as the residue levels in the raw agricultural commodity (RAC) did not exceed the trigger value of 0.1 mg/kg in the raw agricultural commodity (European Commission, 1997d).

1.2.4. Proposed MRLs

EFSA concludes that sufficient information was provided to derive an MRL of 0.1 mg/kg in support of the proposed northern Europe (NEU) outdoor GAP on beetroots. In Section 3, the risk to consumers related to the calculated MRL is assessed.

2. Residues in livestock

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

3. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The PRIMo model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007). The toxicological reference values for epoxiconazole used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD)) were derived in the framework of the EU pesticides peer review (EFSA, 2008).

The relevance of the enantiomer change on the consumer dietary risk assessment was addressed by EFSA (2015).

The short-term exposure assessment has been performed using the highest residue (HR) for epoxiconazole observed in the supervised residue trials for beetroots. No acute consumer risk was identified in relation to the MRL proposal for beetroots. The calculated maximum short-term (acute) exposure accounted for 11.4% of the ARfD (NL, child). For the chronic risk assessment of epoxiconazole, supervised trial median residues (STMR) were used for all those commodities previously assessed by EFSA (EFSA, 2011, 2012), including the median residue (STMR) for epoxiconazole observed in the supervised residue trials for beetroots. For the other commodities, the existing MRLs set in Regulation (EU) No 978/20117 have been used for exposure calculations. The calculated exposure was then compared with the toxicological reference values as derived for epoxiconazole (EFSA, 2008). No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 58.1% of the ADI (DK, child diet) with the contribution of the residues in beetroots to the total exposure accounting for 0.006% of ADI.

7 Commission Regulation (EU) No 978/2011 of 3 October 2011 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 acetamiprid, biphenyl, captan, chlorantraniliprole, cyflufenamid, cymoxanil, dichlorprop-P, difenoconazole, dimethomorph, dithiocarbamates, epoxiconazole, ethephon, flutriafol, flupyradolu, isopyrazam, propamocarb, pyraclostrobin, pyrimethanil and spirotetramat in or on certain products. OJ L 258, 4.10.2011, p. 12-69.
The input values used for the dietary exposure calculation are summarised in Appendix D and for further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

EFSA concludes that the proposed use of epoxiconazole on beetroots will not result in a consumer exposure exceeding the toxicological reference values of epoxiconazole. However, EFSA emphasises that the above residue definitions do not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA was asked to perform a comprehensive dietary risk assessment for TDMs considering data for several triazole fungicides submitted in the framework of the confirmatory data assessment. However, currently, an overall consumer exposure assessment to relevant TDMs arising from all triazole fungicides could not be concluded on until the outstanding issues and general recommendations highlighted in the assessment are addressed (EFSA, 2018).

As the EU pesticides peer review for the renewal of the active substance in accordance with Regulation (EC) No 1107/2009 and the review of the existing MRLs under Article 12 of Regulation 396/2005 are not yet finalised, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review and the MRL review. It is furthermore noted that epoxiconazole has harmonised classification as toxic for reproduction category 1B and this classification triggers the lack of compliance with the approval criteria set out in points the Annex II to Regulation (EC) No 1107/2009.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for beetroots.

EFSA concluded that the proposed use of epoxiconazole on beetroots 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.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CAS Chemical Abstract Service
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DT₉₀ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
eq residue expressed as a.s. equivalent
GAP Good Agricultural Practice
HPLC–MS high-performance liquid chromatography with mass spectrometry
HPLC–MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MS Member States
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PHI pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
| Abbreviation | Description                                      |
|--------------|--------------------------------------------------|
| RA           | risk assessment                                  |
| RAC          | raw agricultural commodity                       |
| RD           | residue definition                               |
| RMS          | rapporteur Member State                          |
| SANCO        | Directorate-General for Health and Consumers      |
| SC           | suspension concentrate                           |
| SEU          | southern Europe                                  |
| STMR         | supervised trials median residue                 |
| TDM          | triazole derivative metabolite                   |
| TRR          | total radioactive residue                         |
# 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<sup>(a)</sup> | Pests or group of pests controlled | Preparation Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages and season<sup>(c)</sup> | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|-------------------------|------------------------|-----------------------------------|-------------------------------|-----------|-------------|--------------------------------|-----------------|-----------------------------|--------------------------------|--------------|---------|
| Beetroots             | NEU                     | F                      | Cercospora                        | SC                           | 125 g/L   | Spraying    | BBCH 39–49 (June–November) | 1–2 (per year) | 28                          | 23–47 200–400 93.75 g/ha 28 |             |         |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. 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                      | Coffee beans | Foliar 2 × 0.15 kg a.s./ha and Foliar 2 × 0.1 kg a.s./ha | 3 months (harvest) | Radiolabelled active substance: fluorophenyl-14C-epoxiconazole and chlorophenyl-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Fruit crops                      | Bananas     | Foliar 4 × 0.15 kg a.s./ha | Ripe and unripe fruit | Radiolabelled active substance: fluorophenyl-14C-epoxiconazole and chlorophenyl-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Root crops                       | Sugar beets | Foliar 2 × 0.15 kg a.s./ha | Before 2nd appl.; after 2nd appl., at harvest | Radiolabelled active substance: fluorophenyl-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Cereals/grass (spring)           | Wheat       | Foliar 1 × 0.25 kg a.s./ha BBCH 29 | 0, 19, 40, 82 (harvest) | Radiolabelled active substance: oxirane-2-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Cereals/grass (spring)           | Wheat       | Foliar 2 × 0.12 kg a.s./ha BBCH 37 and 47-49 | 0, 64 (harvest) | Radiolabelled active substance: triazole-3(5)-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Carrots     | Bare soil, 0.51 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: triazole-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Root/tuber crops                    | Radish      | Bare soil, 0.4 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: fluorophenyl-14C-epoxiconazole and chlorophenyl-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Leafy crops                         | Lettuce     | Bare soil, 0.51 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: triazole-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Leafy crops                         | Lettuce     | Bare soil, 0.4 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: fluorophenyl-14C-epoxiconazole and chlorophenyl-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Leafy crops                         | Cabbage     | Bare soil, 0.51 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: triazole-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Cereal (small grain)                | Wheat       | Bare soil, 0.51 kg a.s./ha | 30, 120, 365 | Radiolabelled active substance: triazole-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
### Rotational crops (available studies)

| Crop groups                  | Crop(s)       | Application(s)                | PBI (DAT) | Comment/source                                      |
|------------------------------|---------------|-------------------------------|-----------|-----------------------------------------------------|
| Cereal (small grain)         | Wheat         | n.r. (not reported)           | 30        | Radiolabelled active substance: triazole-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |
| Pulses and oilseeds          | Green beans   | Bare soil, 0.51 kg a.s./ha    | 30, 120, 365 | Radiolabelled active substance: triazole-14C-epoxiconazole (Germany, 2005; EFSA, 2008) |

### Processed commodities (hydrolysis study)

| Conditions                        | Stable? | Comment/source |
|-----------------------------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4) | Yes     | EFSA (2008)    |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | EFSA (2008)    |
| Sterilisation (20 min, 120°C, pH 6)     | Yes     | EFSA (2008)    |

### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity   | T (°C) | Stability period Value | Stability period Unit | Compounds covered          | Comment/source |
|------------------------------------|-------------------|-------------|--------|------------------------|-----------------------|---------------------------|----------------|
| High water content                 | Banana            | ≤ 18        | 24     | Months                 |                       | Epoxiconazole              | Germany (2005)   |
| Others                             | Coffee beans      | ≤ 18        | 12     | Months                 |                       | Epoxiconazole              | Germany (2005)   |
| Dry/High starch                    | Wheat             | ≤ 18        | 12     | Months                 |                       | Epoxiconazole              | Germany (2005)   |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; HPLC-MS: high-performance liquid chromatography with mass spectrometry; HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
### B.1.2. Magnitude of residues in plants

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

| Commodity  | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                                                                                                                                                 | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|------------|-----------------------------|----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|------------------------|-------------------------|
| Beetroots  | NEU                         | Roots (overdosed) 3 × 0.02, 2 × 0.03, 0.04, 0.06, 0.08 Rescaled residue values (appropriate to the GAP) 2 × 0.01, 3 × 0.02, 0.03, 0.04, 0.06 | Residue trials on sugar beet overdosed compared to the proposed GAP; the proportionality approach has been applied. Residues multiplied by a scaling factor of 0.702–0.758 (United Kingdom, 2018) Extrapolation is possible from sugar beet (0900010) to beetroots (0213010) | 0.1                                  | 0.06                   | 0.02                    |

MRL: maximum residue level; GAP: Good Agricultural Practice; 
*: Indicates that the MRL is proposed at the limit of quantification.  
<a>NEU</a>: 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): Highest residue. 
(c): Supervised trials median residue. 
(d): Supervised trials median residue.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes | In the confined rotational crop study performed at overdosed application (2.1 N the intended maximal application rate for sugar beet) on bare soil (at PBI 30, 120 and 365 days prior to planting radish, lettuce and wheat), the highest residue uptake found in wheat straw was 0.215 mg eq/kg. Significant residues of the parent compound > 0.01 mg/kg is expected when considering the intended GAP |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | No | Field studies were available in the peer review (EFSA, 2008) and showed that under practical conditions parent compound residues are not above 0.01 mg/kg in edible parts of rice, cucumber, spinach, potato, radish, soybean, oilseed rape, turnips and sugar beet cultivated as rotational crop after cereals. The actual transfer of triazole metabolites to rotational crops was not investigated under realistic conditions |

PBI: plant-back interval; GAP: Good Agricultural Practice; eq: residue expressed as a.s. equivalent.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant since the crop under consideration is not fed to livestock.
B.3. Consumer risk assessment

**ARfD**
Highest IESTI, according to EFSA PRIMo
Assumptions made for the calculations

| ARfD | 0.23 mg/kg bw (EFSA, 2008) |
|------|--------------------------|
|       | Beetroots < 11.4% of ARfD (NL, child diet) |
|       | The calculation is based on the highest residue levels expected in raw agricultural commodities (beetroots) based on the GAP-compliant supervised residue trials submitted in support of this MRL application. The above assessment does not yet take into consideration triazole derivative metabolites (TDMs) |

**ADI**
Highest IEDI, according to EFSA PRIMo
Assumptions made for the calculations

| ADI | 0.008 mg/kg bw per day (EFSA, 2008) |
|-----|----------------------------------|
|      | **Risk assessment results for epoxiconazole:** |
|      | 58.1% ADI (DK, child diet) |
|      | Contribution of crops assessed: |
|      | Beetroots: 0.006% of ADI |
|      | **Exposure calculation assumption for epoxiconazole:** |
|      | The chronic calculation is based on the median residue levels (STMR) derived for raw agricultural commodities based on supervised residue trials and the MRLs set in Regulation (EU) No 978/2011. The above assessment does not yet take into consideration triazole derivative metabolites (TDMs) |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; GAP: Good Agricultural Practice; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 0213010 | Beetroots | 0.05*                  | 0.1                     | The submitted data are sufficient to derive a MRL of 0.1 mg/kg for the NEU use. Residues in beetroots related to the use of epoxiconazole in accordance with the assessed GAP are not expected to pose a risk to EU consumers. However, the assessment does not yet take into consideration triazole derivative metabolites (TDMs) |

MRL: maximum residue level; NEU: northern Europe; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Epoxiconazole

Status of the active substance: Included

Code no.: Proposed LOQ:

Toxicological end points

ADI (mg/kg bw per day): 0.008
Source of ADI: EFSA
Year of evaluation: 2008

ARfD (mg/kg bw): 0.023
Source of ARfD: EFSA
Year of evaluation: 2008

No of diets exceeding ADI:

8
28

Chronic risk assessment – refined calculations

TMDI (range) in % of ADI
minimum – maximum

Epoxiconazole

Table: Highest calculated TMDI values in % of ADI

| Commodity/group of commodities | MS Diet | 2nd contributor to MS diet | 3rd contributor to MS diet |
|--------------------------------|---------|---------------------------|---------------------------|
| Rye                            | 33.1    | 7.4 Oats                  | 7.1 Bananas               |
| Sugar beet (root)              | 28.6    | 6.7 Bananas               | 2.2 Potatoes              |
| Bananas                        | 9.7     | 7.5 Apples                | 5.9 Rye                   |
| Rye                            | 3.5     | 6.7 Oats                  | 4.7 Oats                  |
| Banana                         | 10.6    | 4.0 Apples                | 3.7 Potatoes              |
| Sugar beet (root)              | 4.9     | 3.4 Oats                  | 2.9 Maze                  |
| Wheat                          | 4.3     | 3.1 Oats                  | 2.0 Bananas               |
| Rye                            | 11.3    | 2.6 Potatoes              | 2.2 Rye                   |
| Bananas                        | 3.5     | 2.6 Apples                | 2.8 Oats                  |
| Wheat                          | 3.2     | 2.4 Potatoes              | 2.3 Bananas               |
| Rye                            | 3.0     | 2.5 Oats                  | 2.5 Potatoes              |
| Wheat                          | 6.3     | 2.2 Wheat                 | 1.4 Oranges               |
| Rye                            | 2.0     | 2.0 Potatoes              | 1.7 Oats                  |
| Potato                         | 3.3     | 2.1 Bananas               | 2.0 Wheat                 |
| Potato                         | 2.5     | 2.4 Bananas               | 1.5 Wheat                 |
| Potato                         | 4.5     | 2.6 Potatoes              | 1.7 Carrots               |
| Rye                            | 5.1     | 2.4 Bananas               | 2.2 Oats                  |
| Sugar beet (root)              | 4.7     | 2.4 Bananas               | 1.0 Wheat                 |
| Rye                            | 3.3     | 2.2 Bananas               | 1.9 Other cereal          |
| Banana                         | 5.0     | 2.2 Bananas               | 0.9 Potatoes              |
| Sugar beet (root)              | 2.0     | 1.7 Potatoes              | 1.0 Wheat                 |
| Wheat                          | 2.0     | 1.6 Oats                  | 1.6 Bananas               |
| Wine grapes                    | 2.5     | 1.6 Wheat                 | 1.6 Bananas               |
| Wheat                          | 2.1     | 1.3 Bananas               | 0.9 Other cereal          |
| Potato                         | 2.1     | 1.3 Apples                | 1.2 Bananas               |

Commodity/group of commodities

Wheat
Bananas
Rye
Sugar beet (root)
Apples
Potatoes
Carrots
Oats
Wheat
Other cereal

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Epoxiconazole is unlikely to present a public health concern.
Acute risk assessment/children – 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 lead to an exposure equivalent to 100% of the ARfD.

| No of commodities for which ARfD/ADI is exceeded (ESTI 1): | No of commodities for which ARfD/ADI is exceeded (ESTI 2): |
|-----------------------------------------------------------|-----------------------------------------------------------|
| commodities                                              | commodities                                              |
| pTMRL/threshold MRL (mg/kg)                               | pTMRL/threshold MRL (mg/kg)                               |
| Highest % of ARfD/ADI                                     | Highest % of ARfD/ADI                                     |
| Beetroot                                                  | Beetroot                                                  |
| 11.4                                                      | 8.9                                                      |
| 0.06/-                                                    | 0.06/-                                                    |

No of critical MRLs (ESTI 1): ---

No of critical MRLs (ESTI 2): ---

Processed commodities

| No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|---------------------------------------------------|---------------------------------------------------|
| commodities                                      | commodities                                      |
| pTMRL/threshold MRL (mg/kg)                       | pTMRL/threshold MRL (mg/kg)                       |
| Highest % of ARfD/ADI                             | Highest % of ARfD/ADI                             |
| Apple juice                                      | Apple juice                                      |
| 11.1                                             | 1.4                                             |
| 0.06/-                                           | 0.05/-                                          |
| Orange juice                                     | Orange juice                                     |
| 10.8                                             | 0.8                                             |
| 0.05/-                                           | 0.05/-                                          |
| Carrot, juice                                    | Wine                                             |
| 9.3                                              | 0.8                                             |
| 0.05/-                                           | 0.05/-                                          |
| Grape juice                                      | Bread/pizza                                      |
| 7.2                                              | 0.8                                             |
| 0.05/-                                           | 0.04/-                                          |
| Peach juice                                      | Pineapples preserved                             |
| 3.9                                              | 0.6                                             |
| 0.05/-                                           | 0.06/-                                          |

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

---

Conclusion:
For Epoxiconazole, 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.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity          | Chronic risk assessment | Acute risk assessment |
|--------------------|-------------------------|-----------------------|
|                    | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Beetroots          | 0.02<sup>(a)</sup>     | STMR (Table B.1.2.1)  | 0.06                | HR (Table B.1.2.1)   |
| Wheat, rye         | 0.04<sup>(a)</sup>     | STMR (EFSA, 2012)     |                      |                       |
| Barley, oats       | 0.13<sup>(a)</sup>     | STMR (EFSA, 2012)     |                      |                       |
| Ruminant kidney    | 0.01<sup>(a)</sup>     | STMR (EFSA, 2012)     |                      |                       |
| Milk               | 0.001<sup>(a)</sup>    | STMR (EFSA, 2012)     |                      |                       |
| All other          | EU MRL                 | Reg. (EU) No 978/2011 |                      |                       |
| commodities        |                         |                       |                      |                       |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
(a): residues were not considering the TDMs; therefore a realistic consumer dietary risk assessment is provisional pending the finalisation of an EU harmonised assessment for TDMs (EFSA, 2012; United Kingdom, 2018).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|----------------------------------|
| **Epoxiconazole**              | (2RS,3SR)-1-[3-(2-chlorophenyl)-2,3-epoxy-2-(4-fluorophenyl)propyl]-1H-1,2,4-triazole MW: 329.76 g/mol | ![Structural formula](image) |
| **1,2,4-triazole**             | 1H-1,2,4-triazole (free triazole) (CAS number 288-88-0) | ![Structural formula](image) |
| **Triazole alanine**           | (RS)-2-amino-3-(1H-1,2,4 triazol-1-yl)propanoic acid or 3-(1H-1,2,4-triazol-1-yl)-αL-alanine (CAS number 86362-20-1) | ![Structural formula](image) |
| **Triazole acetic acid**       | 1H-1,2,4-triazol-1-yl acetic acid (CAS number 28711-29-7) | ![Structural formula](image) |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Keys; MW: molecular weight; CAS: Chemical Abstract Service.

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).