**Modification of the existing maximum residue level for tebuconazole in beans with pods**

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**Abstract**

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant ADAMA Agricultural Solutions Ltd submitted a request to the competent national authority in Denmark to set an import tolerance for the active substance tebuconazole in beans with pods. The data submitted in support of the request were found to be sufficient to derive a maximum residue level (MRL) proposal of 3 mg/kg for beans with pods imported from Kenya. Adequate analytical methods for enforcement are available to control the residues of tebuconazole on this commodity. Based on the risk assessment results and assuming no change in the isomeric ratio, EFSA concluded that the short-term and long-term intake of residues of tebuconazole resulting from its use according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agricultural Solutions Ltd submitted an application to the competent national authority in Denmark [evaluating Member State (EMS)] to set an import tolerance for the active substance tebuconazole in beans with pods. 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 2 August 2016. The EMS proposed to increase the existing maximum residue level (MRL) for beans with pods to 3 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS, the draft assessment report (DAR) and its addenda prepared under Directive 91/414/EEC, the Commission review report on tebuconazole, the conclusions on the peer review of the pesticide risk assessment of the active substance tebuconazole, the Joint Meeting on Pesticide Residues (JMPR) evaluation reports, as well as the conclusions from previous EFSA opinions including a Reasoned opinion on the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) and scientific reports on tebuconazole.

The metabolism of tebuconazole following foliar applications was investigated in crops belonging to the groups of fruit crops, cereals and pulses/oilseeds. Studies investigating the effect of processing on the nature of tebuconazole (hydrolysis studies) demonstrated that the active substance is stable. As the notified use of tebuconazole is on an imported crop, investigations of residues in rotational crops are not relevant.

Based on the metabolic pattern identified in metabolism studies and the toxicological significance of metabolites, the residue definition for monitoring was provisionally proposed as the sum of enantiomers of tebuconazole, pending the outcome of a global risk assessment approach for triazole derivative metabolites (TDMs). For risk assessment, the residue definition was proposed as tebuconazole (sum of enantiomers), but EFSA highlighted that an additional separate residue definition is needed for TDMs, harmonised for all active substances of the triazole chemical class. EFSA concludes that for the crop assessed in this application, the metabolism of tebuconazole in primary crops and the nature of residues in processed products have been sufficiently addressed and that the previously derived residue definitions are applicable.

Sufficiently validated analytical methods are available to quantify residues in beans with pods according to the enforcement residue definition. The methods enable quantification of residues at or above the limit of quantification (LOQ) of 0.02 mg/kg. The available residue trials are sufficient to derive a MRL proposal of 3 mg/kg for beans with pods.

Specific studies investigating the magnitude of tebuconazole residues in processed commodities are not required as the contribution of the residues in this crop to the overall dietary consumer exposure is low. Residues of tebuconazole in commodities of animal origin were also not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of tebuconazole was evaluated in the framework of Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day and acute reference dose (ARfD) of 0.03 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). Assuming no change in the isomeric ratio had occurred in the residues at harvest, EFSA concluded that the reported use of tebuconazole on beans with pods will not result in a consumer exposure exceeding the toxicological reference values for the active substance and therefore is unlikely to pose a risk to consumer health. However, at the hypothetically possible worst case of a complete change from the racemic mixture into one of its isomers in the residue at harvest and the assumption that the toxicity of tebuconazole is attributed to this isomer, this could lead to an acute exposure estimate higher than the acute toxicological reference value (114% of ARfD). The long-term dietary risk estimation was still not exceeding the chronic toxicological reference value.

EFSA emphasises that the above assessment does not yet take into consideration TDMs. As these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available. Additionally, no information is available on the possible preferential degradation/metabolism of the constituents of the racemic mixture of tebuconazole and further investigations of the isomeric composition of the residues in plants at harvest are required. It is acknowledged that guidance...
on how to address the dietary risk assessment in case of a changed isomeric composition of the residue is not yet available. EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA proposes to amend the existing MRL as reported in the summary table below.

| Code\(^{(a)}\) | Commodity                | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|--------------|--------------------------|-------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0260010      | Beans (with pods)        | 2                       | 3                       | Import tolerance from Kenya supported. However, no information on the MRL value set in Kenya for the requested import tolerance was provided even if evidence of the registration of the plant protection product on beans with pods is available. Risk for consumers unlikely assuming no change in isomeric ratio (1:1) in the final residue. Nevertheless, risk managers should be aware that at the hypothetically possible worst case of a residue composition at harvest of one single isomer to which the entire toxicity is attributed could lead to an acute exposure estimate higher than the ARfD (114%). The consumer risk assessment of TDMs has not been conducted. |

MRL: maximum residue level; ARfD: acute reference dose; TDM: triazole derivative metabolites.

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

Regulation (EC) No 396/20051 (hereinafter referred to as 'the MRL regulation') establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC,2 repealed by Regulation (EC) No 1107/20093, shall submit an application to a Member State to set an import tolerance in accordance with the provisions of Article 7 of the MRL regulation.

The applicant ADAMA Agricultural Solutions Ltd4 submitted an application to the competent national authority in Denmark, hereafter referred to as the evaluating Member State (EMS), to set an import tolerance for the active substance tebuconazole in beans with pods imported from Kenya. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 2 August 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00493 and the following subject:

Tebuconazole – IT MRL in beans with pods.

Denmark proposed to raise the existing MRL of tebuconazole in beans with pods from 2 mg/kg to 3 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within 3 months from the date of receipt of the application.

The evaluation report submitted by the EMS (Denmark, 2016) 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. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

The active substance and its use pattern

The detailed description of the use in beans with pods of the active substance tebuconazole, which is the basis for the current MRL application, is reported in Appendix A.

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1 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
4 ADAMA Agricultural Solutions Ltd, Golan Street, 7019990 Airport City, Israel.
Tebuconazole is the ISO common name for (R5)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol (IUPAC). Tebuconazole consists of two enantiomers. The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Tebuconazole was evaluated in the framework of Council Directive 91/414/EEC with Denmark, designated as rapporteur Member State (RMS), for the representative uses as foliar applications on wheat, barley, oat, rye and grape and seed dressing for barley. Tebuconazole was approved5 for the use as a fungicide on 1 September 2009. On 14 September 2015, Commission Implementing Regulation (EU) No 921/20144 amended the conditions of approval of the active substance tebuconazole in accordance with Implementing Regulation (EU) No 540/2011, to extend the use of tebuconazole also as plant growth regulator. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2008, 2014).

The EU MRLs for tebuconazole are established in Annex II 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, 2011) and the proposed modifications have been implemented in the MRL legislation.7 After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for tebuconazole. The proposals from these reasoned opinions have been considered in recent regulations8,9,10 for EU MRL legislation.

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Denmark, 2016), the DAR and its addenda prepared under Council Directive 91/414/EEC (Denmark, 2007, 2008, 2012, 2013), the European Commission review report on tebuconazole as revised in July 2014 (European Commission, 2008, 2014), the conclusions on the peer review of the pesticide risk assessment of the active substance tebuconazole (EFSA, 2008, 2014), the Joint Meeting on Pesticide Residues (JMPR) evaluation reports (FAO, 2011, 2015), as well as the conclusions from previous EFSA opinions including a Reasoned opinion on the review of the existing MRLs according to Article 12 of Regulation EC) No 396/2005 (MRL review); and scientific reports on tebuconazole (EFSA, 2011, 2012a,b, 2013, 2015a,b, 2016).

No information on the MRL value set in Kenya for the requested import tolerance was provided. Evidence of the registration of the plant protection product on beans with pods (French beans)11 and its commercial label are available.

For this application, the data requirements established in Regulation (EU) No 544/201112 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, 2016; OECD, 2011). The assessment is performed in

5 Commission Directive 2008/125/EC of 19 December 2008 amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, magnesium phosphide, cymoxanil, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrione, tebuconazole and triadimenol as active substances. OJ L 344, 20.12.2008, p. 78–88
6 Commission Implementing Regulation (EU) No 921/2014 of 25 August 2014 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance tebuconazole Text with EEA relevance. OJ L 252, 26.8.2014, p. 3–5
7 Commission Regulation (EU) No 61/2014 of 24 January 2014 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 cyromazine, fenpropidin, formetanate, oxamyl and tebuconazole in or on certain products. OJ L 22, 25.1.2014, p. 1–32
8 Commission Regulation (EU) 2015/401 of 25 February 2015 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, chromafenozide, cyazofamid, dicamba, difenconazole, fenpyrazamine, fluazinam, formetanate, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products. OJ L 71, 14.3.2015, p. 114–156
9 Commission Regulation (EU) 2016/1 of 3 December 2015 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 bifenthrane, boscalid, cyazofamid, cyromazine, dodemorph, dithiocarbamates, flazinam, formetanate, heptachlor, hemicarb, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products. OJ L 71, 14.3.2015, p. 114–156
10 Commission Regulation (EU) 2016/1003 of 17 June 2016 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 abamectin, acequinocyl, acetamiprid, bifenazate, boscalid, butolometh, butralin, butylate, cyazofamid, cypermethrin, cyproconazole, diuron, dithiamete, dodemorph, dodine, dithiocarbamates, dithiothion, fenthion, fenpyrazamine, fluazinam, fludioxonil, flusilazole, fosetyl, flupyradol, formetanate, heptachlor, hexachloride, hexythiazox, hexylresorcinol, hexythiazox, nicotine, penconazole, pymetrozine, pyraclostrobin, tau-fluvalinate and tebuconazole in or on certain products. OJ L 167, 24.6.2016, p. 46–103
11 Regulatory agency of Kenya. Pest Control Products Board (PCPB) website: Products Registered for Use on Crops database. PCPB (CR)0547, http://www.pcpb.or.ke/cropproductsviewform.php
12 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.
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.\(^\text{13}\)

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of residue studies submitted in support of the current MRL application, are presented in Appendix B.

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 tebuconazole in primary crops has been investigated after foliar applications in the groups of fruits, cereals and pulses/oilseeds and after seed treatment in cereals in the framework of the peer review and the MRL review (Denmark, 2008; EFSA, 2008, 2011, 2014). In the crops tested, parent compound represented the main residue component, except in cereal grain and nut kernel, where tebuconazole was extensively metabolised to the triazole derivative metabolites (TDMs).

For the reported use of tebuconazole on beans with pods, the metabolic behaviour in primary crops is sufficiently addressed. Nevertheless, the preferential metabolism/degradation of the enantiomers in plants needs to be investigated as requested during the peer review (EFSA, 2014).

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

Investigations of residues in rotational crops are not required for imported crops.

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

The effect of processing on the nature of tebuconazole was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2011, 2014). These studies showed that tebuconazole is hydrolytically stable under standard processing conditions.

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of tebuconazole residues in plant commodities were assessed during the EU pesticides peer review and the MRL review (Denmark, 2008; EFSA, 2008, 2011). The multiresidue DFG-S19 was concluded to be sufficiently validated in plants at or above the LOQ of 0.02 mg/kg. In addition, the multiresidue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method was concluded to be sufficiently validated at or above the LOQ of 0.01 mg/kg in plants (EFSA, 2011, 2012b, 2013, 2015a,b). These methods quantify residues of tebuconazole as sum of its enantiomers (not stereoselective).

EFSA concludes that sufficiently validated analytical methods are available for the crop under consideration, which belongs to the high water content crop group.

1.1.5. **Stability of residues in plants**

The storage stability of tebuconazole in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (Denmark, 2008; EFSA, 2008, 2011). It was demonstrated that in the crop assessed in the framework of this application, residues were stable for at least 30 months when stored at \(-20^\circ\text{C}\).

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, the capabilities of enforcement analytical methods, the following residue definitions were proposed during the peer review:

- residue definition for risk assessment: 1. tebuconazole (sum of enantiomers); 2. TDMs
- residue definition for enforcement: tebuconazole (sum of enantiomers)

\(^{13}\) 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.
The current residue definition set in Regulation (EC) No 396/2005 refers to the active substance tebuconazole without explicitly stating that it applies to the sum of enantiomers. The residue definitions were set provisionally pending the outcome of a global risk assessment approach for TDMs (EFSA, 2008, 2014). EFSA concludes that these residue definitions are applicable to the crop under consideration and no further information is required.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the results of eight supervised residue trials performed in beans with pods according to the good agricultural practices (GAP) were submitted. Trials were conducted over two seasons in Kenya and Senegal. There was one extremely high residue value (1.5 mg/kg), which was detected as outlier (Dixon’s Q-test). Since no information was provided to explain this high value, it was not disregarded from the calculations. The samples were analysed for the parent compound only.

According to the assessment of the EMS, the methods of analysis used were sufficiently validated and fit for purpose. The samples of these residue trials were stored for a maximum of about 3 months under conditions for which integrity of the samples has been demonstrated (Denmark, 2016).

1.2.2. Magnitude of residues in rotational crops

Not relevant for imported crops.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crop under assessment were not provided and are not required since the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the ADI.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive a MRL proposal as well as risk assessment values for beans with pods imported from Kenya (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on this crop resulting from the notified use are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as imported beans with pods are usually not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). 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 tebuconazole used in the risk assessment (i.e. ADI and ARfD values) were derived in the framework of the EU pesticides peer review (European Commission, 2008).

3.1. Short-term (acute) dietary risk assessment

The short-term exposure assessment for tebuconazole was performed for beans with pods in accordance with the internationally agreed methodology (FAO, 2016). The calculation was based on the highest residue derived from supervised field trials assuming no change in the isomeric ratio in the residue at harvest, and the input value can be found in Appendix D.2.

The short-term exposure did not exceed the ARfD for the crop assessed in this application (see Appendix C).

3.2. Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed for tebuconazole, assuming no change in the isomeric ratio in the residue at harvest and
taking into account the existing uses at EU level and acceptable Codex maximum residue limit (CXLs) (EFSA, 2011). EFSA updated this risk assessment considering the median values derived from the residue trials conducted on beans with pods and the median residue values reported in EFSA reasoned opinions issued after the MRL review (EFSA, 2012b, 2013, 2015a,b). CXLs implemented in the EU legislation were also taken into account (FAO, 2011, 2015; EFSA, 2012a, 2016). The complete list of input values is presented in Appendix D.2.

The estimated long-term dietary intake was in the range of 0–16% of the ADI. The contribution of residues expected in beans with pods to the overall long-term exposure is presented in more detail in Appendix C.

Conclusions and recommendations

The data submitted in support of this import tolerance application were found to be sufficient to derive a MRL proposal for beans with pods.

Adequate analytical methods for enforcement are available to control the residues of tebuconazole in the commodity under consideration.

Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of tebuconazole according to the reported agricultural practice is unlikely to present a risk to consumer health.

However, the above consumer risk assessment was performed disregarding the possible impact of plant and livestock metabolism on the enantiomers ratio of the active substance. Considering that the active substance is a racemic mixture (1:1) and that the toxicological studies were carried out according to these specifications (EFSA, 2014), a change of ratio in residues might, in the worst case situation, lead to a duplication of the toxicological burden of the residue. For the use assessed in the framework of this application, EFSA concluded that the hypothetically possible change of isomer ratio in the final residue is unlikely to be of chronic exposure concerns (calculations represented less than 50% of the ADI), but could lead to an acute exposure estimate higher than the ARfD (114%). This leads to additional uncertainty in the risk assessment and further investigations of possible changes in the isomeric ratio in plants at harvest are required to refine this uncertainty. It is acknowledged that guidance on how to address the dietary risk assessment in case of a changed isomeric composition of the residue is not yet available. EFSA recommends that this issue is reconsidered when such guidance is available.

EFSA emphasises that the above consumer assessment does not yet take into consideration TDMs. Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Directive 91/414/EEC have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

The MRL recommendation is summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CCPR Codex Committee on Pesticide Residues
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DALA days after last application
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
EW emulsion, oil in water.
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-ECD gas chromatography with electron capture detector
GS growth stage
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
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern Europe
STMR supervised trials median residue
TDM triazole derivative metabolites
TMDI theoretical maximum daily intake
WHO World Health Organization
### Appendix A – Summary of reported GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Conc. a.s. | Method kind | Range of growth stages & season | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-----------|------------|-----------------------------|----------------|--------------------------------|-----------------------------|------------|---------|
| Beans with pods       | KE                      | F Rust (Uromyces appendiculatus)   | EW          | 250 g/L   | Spray      | BBCH 51–79                 | 1–3           | 7                                | 33.3, 600, 200 | 7         | –       |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; KE: Kenya; EW: emulsion, oil in water; a.s.: active substance.

(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.

(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 selected 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) | Crops groups | Crops          | Applications                      | Sampling                  |
|----------------------------------|--------------|----------------|-----------------------------------|---------------------------|
| Fruit crops                      | Grape        | Foliar, 1 × 280 g/ha | 0, 3, 7, 14, 21, 28 DAT          |
| Cereals/grass                    | Wheat        | Foliar, 1 × 500 g/ha | 0, 7, 14, 21, 28, 50 DAT         |
|                                 | Seed, 11 g/100 kg seed | 38, 66 days after planting |
| Pulses/oilseeds                 | Peanut       | Foliar, 3 × 250 g/ha, 14 days interval | 49 DALA                  |
|                                 |              | Foliar, 3 × 250 g/ha, 14 days intervals | 98 DALA                  |
|                                 |              | Foliar, 7 × 82.6 g/ha, 14 days intervals (total ca 593 g/ha) | 14 DALA (100 DAT₁)       |

Comments: [phenyl-UL-14C]-tebuconazole (grape), [triazole-3,5-14C]-tebuconazole or [chlorophenyl-UL-14C]-tebuconazole (peanut), [triazole-3,5-14C]-tebuconazole (wheat) Reference: Denmark, 2008

| Rotational crops (available studies) | Crops groups | Crops | Conditions | Investigated |
|-------------------------------------|--------------|-------|------------|--------------|
| Processing commodities (hydrolysis study) |              |       | Pasteurisation (20 min, 90°C, pH 4) | Y             |
|                                     |              |       | Baking, brewing and boiling (60 min, 100°C, pH 5) | Y             |
|                                     |              |       | Sterilisation (20 min, 120°C, pH 6) | Y             |
|                                     |              |       | Comment: [phenyl-UL-14C]-tebuconazole. Reference: Denmark, 2008 |

DAT: days after treatment; DAT₁: days after 1st treatment; DALA: days after last application; PBI: plant back interval.

Can a general residue definition be proposed for primary crops? Yes
Rotational crop and primary crop metabolism similar? Not considered under current assessment
Residue pattern in processed commodities similar to residue pattern in raw commodities? The study has been performed with radioactive labelled tebuconazole only parent compound was found
Plant residue definition for monitoring (RD-Mo) Sum of enantiomers contained in tebuconazole (primary and rotational crops) (provisional, pending outcome of a global risk assessment on TDMs)
Plant residue definition for risk assessment (RD-RA) Sum of enantiomers contained in tebuconazole (primary and rotational crops)
An additional residue definition is needed for TDMs, harmonised for all active substances of the triazole chemical class

| Conversion factor (monitoring to risk assessment) |
|---------------------------------------------------|
| Not applicable                                    |

| 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:     |
| GC-ECD (DFG-S19 method), LOQ 0.02 mg/kg (EFSA, 2014)                                        |

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

| Plant products (available studies) | Category          | Commodity               | T (°C) | Stability (Months) |
|-----------------------------------|-------------------|-------------------------|--------|-------------------|
| Apple, cherry, peach,             | High water content| –20                     | 30     |
| Peanut                            | High oil content  | –20                     | 30     |
| Wheat grain, straw                | Dry / High starch | –20                     | 30     |
| Grape                             | High acid content | –20                     | 30     |

Comment: Storage stability in certain processed products available. Reference: Denmark, 2008; EFSA, 2014
### B.1.2. Magnitude of residues in plants

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

| Crop (supervised trials) | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations) | MRL proposals (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|--------------------------|-----------------------------|----------------------------------------------------------------|-----------------------------|----------------------|------------------------|---------------------------|-------------|
| Beans with pods          | KE                          | 0.13; 0.17; 0.20; 0.24; 0.39; 0.45; 0.47; **1.5** TDMs: not analysed for | Underlined: mean of two replicate values MRL<sub>OECD</sub>: 2.23/3.00 | 3                    | 1.5                    | 0.32                      | 1           |

KE: Kenya; MRL: maximum residue level; OECD: Organisation for Economic Co-operation and Development; TDM: triazole derivative metabolites.

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

(b): Highest residue according to the residue definition for monitoring.

(c): Supervised trials median residue according to the residue definition for monitoring.

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Conversion factors for risk assessment in plant products
Not relevant.

B.1.2.3. Residues in succeeding crops
Not relevant (import tolerance request).

B.1.2.4. Processing factors
Not relevant.

B.2. Residues in livestock
Not relevant.

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock
Not relevant.

B.2.2. Stability of residues in livestock
Not relevant.

B.2.2.1. Summary of the residue data from livestock feeding studies
Not relevant.

B.3. Consumer risk assessment

| ARfD                  | 0.03 mg/kg bw (European Commission, 2008) |
|-----------------------|------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Beans with pods: 57% of ARfD |
| Assumptions made for the calculations | The calculation is based on the highest residue levels of tebuconazole expected in the raw agricultural commodity assuming no change in residues isomer ratio (1:1) |

| ADI                   | 0.03 mg/kg bw per day (European Commission, 2008) |
|-----------------------|--------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 16% of ADI (WHO Cluster diet B) Contribution of beans with pods: 1.18% of ADI |
| Assumptions made for the calculations | The calculation is based on the median residue levels of tebuconazole derived for raw agricultural commodities (or tentative MRL when median value was not available) assuming no change in residues isomer ratio (1:1). Peeling factor for citrus and passion fruits were applied. The contribution of commodities where no safe use was reported in the framework of the MRL review and subsequent EFSA opinions and scientific reports were not included in the calculation |
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|------------|-------------------------|-------------------------|------------------------|
| 0260010           | Beans (with pods) | 2                       | 3                       | Import tolerance from Kenya supported. However, no information on the MRL value set in Kenya for the requested import tolerance was provided even if evidence of the registration of the plant protection product on beans with pods is available. Risk for consumers unlikely assuming no change in isomeric ratio (1:1) in the final residue. Nevertheless, risk managers should be aware that at the hypothetically possible worst case of a residue composition at harvest of one single isomer to which the entire toxicity is attributed could lead to an acute exposure estimate higher than the ARfD (114%). The consumer risk assessment of TDMs has not been conducted. |

Enforcement residue definition: Tebuconazole

MRL: maximum residue level; ARfD: acute reference dose; TDM: triazole derivative metabolites.

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

#### Tebuconazole

| Status of the active substance: | Approved |
|---------------------------------|----------|
| LOQ (mg/kg):                   | Proposed LOQ |
| Toxicological end points:      |            |
| ADI (mg/kg bw per day):        | 0.03      |
| Source of ADI:                 | COM       |
| Year of evaluation:            | 2008      |
| ARfD (mg/kg bw):               | 0.03      |
| Source of ARfD:                | COM       |
| Year of evaluation:            | 2008      |

Year of evaluation: 2008

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (% of ADI) | pTMRLs at LOQ (% of ADI) |
|--------------------------------|-----------------|--------------------------|
| Wheat                          | 7.3             | 0.9                      |
| Barley                         | 7.1             | 1.1                      |
| Apples                         | 6.8             | 0.9                      |
| Swine: Meat                    | 5.8             | 1.0                      |
| Tomatoes                       | 5.7             | 1.1                      |
| Oats                           | 5.6             | 1.2                      |
| Wine grapes                    | 5.5             | 1.3                      |
| Beets (without pods)           | 5.4             | 1.4                      |
| Rice                           | 5.3             | 1.5                      |
| Apples                         | 5.2             | 1.6                      |
| Barley                         | 5.1             | 1.7                      |
| Wine grapes                    | 5.0             | 1.8                      |
| Beets (without pods)           | 4.9             | 1.9                      |
| Rice                           | 4.8             | 2.0                      |
| Apples                         | 4.7             | 2.1                      |
| Barley                         | 4.6             | 2.2                      |
| Wine grapes                    | 4.5             | 2.3                      |
| Beets (without pods)           | 4.4             | 2.4                      |
| Rice                           | 4.3             | 2.5                      |
| Apples                         | 4.2             | 2.6                      |
| Barley                         | 4.1             | 2.7                      |
| Wine grapes                    | 4.0             | 2.8                      |
| Beets (without pods)           | 3.9             | 2.9                      |
| Rice                           | 3.8             | 3.0                      |
| Apples                         | 3.7             | 3.1                      |
| Barley                         | 3.6             | 3.2                      |
| Wine grapes                    | 3.5             | 3.3                      |
| Beets (without pods)           | 3.4             | 3.4                      |
| Rice                           | 3.3             | 3.5                      |
| Apples                         | 3.2             | 3.6                      |
| Barley                         | 3.1             | 3.7                      |
| Wine grapes                    | 3.0             | 3.8                      |
| Beets (without pods)           | 2.9             | 3.9                      |
| Rice                           | 2.8             | 4.0                      |
| Apples                         | 2.7             | 4.1                      |
| Barley                         | 2.6             | 4.2                      |
| Wine grapes                    | 2.5             | 4.3                      |
| Beets (without pods)           | 2.4             | 4.4                      |
| Rice                           | 2.3             | 4.5                      |
| Apples                         | 2.2             | 4.6                      |
| Barley                         | 2.1             | 4.7                      |
| Wine grapes                    | 2.0             | 4.8                      |
| Beets (without pods)           | 1.9             | 4.9                      |
| Rice                           | 1.8             | 5.0                      |
| Apples                         | 1.7             | 5.1                      |
| Barley                         | 1.6             | 5.2                      |
| Wine grapes                    | 1.5             | 5.3                      |
| Beets (without pods)           | 1.4             | 5.4                      |
| Rice                           | 1.3             | 5.5                      |
| Apples                         | 1.2             | 5.6                      |
| Barley                         | 1.1             | 5.7                      |
| Wine grapes                    | 1.0             | 5.8                      |
| Beets (without pods)           | 0.9             | 5.9                      |
| Rice                           | 0.8             | 6.0                      |
| Apples                         | 0.7             | 6.1                      |
| Barley                         | 0.6             | 6.2                      |
| Wine grapes                    | 0.5             | 6.3                      |
| Beets (without pods)           | 0.4             | 6.4                      |
| Rice                           | 0.3             | 6.5                      |
| Apples                         | 0.2             | 6.6                      |
| Barley                         | 0.1             | 6.7                      |
| Wine grapes                    | 0.0             | 6.8                      |

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI. A long-term intake of residues of Tebuconazole 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) | No of commodities for which ARfD/ADI is exceeded (ESTI 1) | No of commodities for which ARfD/ADI is exceeded (ESTI 2) |
|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|----------------------------------------------------------|
| Highest % of ARfD/ADI Commodities                        | pTMRL/threshold MRL (mg/kg)                              | Highest % of ARfD/ADI Commodities                        | pTMRL/threshold MRL (mg/kg)                              |
| 56.7 Beans (with pods) 1.5*                              | 56.7 Beans (with pods) 1.5*                              | 26.5 Beans (with pods) 1.5*                              | 26.5 Beans (with pods) 1.5*                              |

No of critical MRLs (ESTI 1)  ---

No of critical MRLs (ESTI 2)  ---

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# Acute risk assessment/adults/general population – refined calculations

Processed commodities

| No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|--------------------------------------------------|--------------------------------------------------|
| Highest % of ARfD/ADI Processed commodities      | pTMRL/threshold MRL (mg/kg)                       |
|                                                 |                                                 |

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

Conclusion:

For Tebuconazole, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

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

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

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*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

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Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations
Not relevant

D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment                           |
| Risk assessment residue definition (plant commodities): Tebuconazole (sum of enantiomers) |
| Beans with pods            | 0.32 STMR               |                       | 1.5 HR              |
| Citrus (except orange)    | 0.24 STMR-peel F (EFSA, 2012b) | Acute risk assessment undertaken only with regard to beans with pods |
| Oranges                   | 0.05 STMR (EFSA, 2011)  |                       |                      |
| Tree nuts                 | 0.05 STMR (EFSA, 2011)  |                       |                      |
| Pome fruits (except apple, pear) | 0.19 STMR (EFSA, 2011) |                       |                      |
| Apples, pears             | 0.13 STMR (EFSA, 2011)  |                       |                      |
| Apricots, peaches         | 0.16 STMR (EFSA, 2011)  |                       |                      |
| Cherries                  | 0.34 STMR (EFSA, 2011)  |                       |                      |
| Plums                     | 0.11 STMR (EFSA, 2011)  |                       |                      |
| Table grapes              | 0.17 STMR (EFSA, 2011)  |                       |                      |
| Wine grapes               | 0.37 STMR (EFSA, 2011)  |                       |                      |
| Strawberries              | 0.02 STMR (EFSA, 2011)  |                       |                      |
| Cane fruits               | 0.11 STMR (EFSA, 2011)  |                       |                      |
| Other small fruits and berries | 0.52 STMR (EFSA, 2011) |                       |                      |
| Table olives              | 0.05 STMR (EFSA, 2011)  |                       |                      |
| Passion fruits            | 0.03 STMR-peel F (EFSA, 2011) |                       |                      |
| Banana                    | 0.07 STMR (FAO, 2015)   |                       |                      |
| Mango                     | 0.05 STMR (EFSA, 2011)  |                       |                      |
| Papaya                    | 0.36 STMR (EFSA, 2011)  |                       |                      |
| Carrots, Horseradish      | 0.15 STMR (EFSA, 2011)  |                       |                      |
| Celeriac                  | 0.08 STMR (EFSA, 2011)  |                       |                      |
| Parsnips, parley root, salsify | 0.15 STMR (EFSA, 2011) |                       |                      |
| Swedes, turnips           | 0.12 STMR (EFSA, 2011)  |                       |                      |
| Garlic                    | 0.04 STMR (EFSA, 2011)  |                       |                      |
| Onion, shallot            | 0.06 STMR (FAO, 2015)   |                       |                      |
| Spring onion              | 0.10 STMR (FAO, 2015)   |                       |                      |
| Tomatoes                  | 0.23 STMR (EFSA, 2011)  |                       |                      |
| Peppers                   | 0.26 STMR (EFSA, 2011)  |                       |                      |
| Aubergines                | 0.11 STMR (EFSA, 2011)  |                       |                      |
| Cucumbers, courgette      | 0.08 STMR (EFSA, 2015a) |                       |                      |
| Melons                    | 0.09 STMR (EFSA, 2011)  |                       |                      |
| Pumpkins, watermelons     | 0.04 STMR (EFSA, 2011)  |                       |                      |
| Sweet corn                | 0.06 STMR (FAO, 2011, 2015) |                       |                      |
| Broccoli                  | 0.04 STMR (EFSA, 2011)  |                       |                      |
| Cauliflower               | 0.05 STMR (EFSA, 2011)  |                       |                      |
| Brussels sprout           | 0.06 STMR (EFSA, 2011)  |                       |                      |
| Head cabbage              | 0.05 STMR (EFSA, 2011)  |                       |                      |
### Chronic risk assessment

| Commodity                        | Input value (mg/kg) | Comment               |
|----------------------------------|---------------------|-----------------------|
| Lettuce and other salad plants including Brassicaceae | 0.05 | STMR (EFSA, 2012b)   |
| Witloof                          | 0.05                | STMR (EFSA, 2011)    |
| Chives, parsley                  | 0.58                | STMR (EFSA, 2012b)   |
| Beans without pods               | 2.00                | MRL = LOQ (EFSA, 2011)|
| Peas with pods                   | 2.00                | MRL = LOQ (EFSA, 2011)|
| Asparagus                        | 0.02                | STMR (EFSA, 2011)    |
| Celery                           | 0.19                | STMR (EFSA, 2011)    |
| Globe artichokes                 | 0.15                | STMR (EFSA, 2011)    |
| Leek                             | 0.21                | STMR (EFSA, 2011)    |
| Pulses (expect lentils)          | 0.07                | STMR (EFSA, 2011)    |
| Lentils                          | 0.05                | STMR (EFSA, 2011)    |
| Linseeds                         | 0.14                | STMR (EFSA, 2011)    |
| Peanuts                          | 0.04                | STMR (FAO, 2011, 2015)|
| Poppy seeds                      | 0.04                | STMR (EFSA, 2013)    |
| Rape seeds                       | 0.09                | STMR (FAO, 2011, 2015)|
| Soya beans                       | 0.02                | STMR (EFSA, 2011)    |
| Mustard seeds                    | 0.05                | STMR (EFSA, 2011)    |
| Cotton seeds                     | 0.05                | STMR (FAO, 2011, 2015)|
| Gold of pleasure                 | 0.10                | STMR (EFSA, 2011)    |
| Olives for oil production        | 0.05                | STMR (EFSA, 2011)    |
| Barley, oats                     | 0.68                | STMR (EFSA, 2011)    |
| Rice                             | 0.28                | STMR (EFSA, 2011)    |
| Wheat, Rye                       | 0.03                | STMR (EFSA, 2015b)   |
| Coffee beans                     | 0.04                | STMR (FAO, 2011, 2015)|
| Ginseng root                     | 0.05                | STMR (FAO, 2015)     |
| Hops                             | 9.65                | STMR (EFSA, 2011)    |
| Spices (seeds)                   | 0.40                | STMR (EFSA, 2011)    |
| Caraway                          | 0.40                | STMR (EFSA, 2011)    |

### Acute risk assessment

| Commodity                        | Input value (mg/kg) | Comment               |
|----------------------------------|---------------------|-----------------------|
| Lettuce and other salad plants including Brassicaceae | - | -                      |
| Witloof                          | -                   | -                     |
| Chives, parsley                  | -                   | -                     |
| Beans without pods               | -                   | -                     |
| Peas with pods                   | -                   | -                     |
| Asparagus                        | -                   | -                     |
| Celery                           | -                   | -                     |
| Globe artichokes                 | -                   | -                     |
| Leek                             | -                   | -                     |
| Pulses (expect lentils)          | -                   | -                     |
| Lentils                          | -                   | -                     |
| Linseeds                         | -                   | -                     |
| Peanuts                          | -                   | -                     |
| Poppy seeds                      | -                   | -                     |
| Rape seeds                       | -                   | -                     |
| Soya beans                       | -                   | -                     |
| Mustard seeds                    | -                   | -                     |
| Cotton seeds                     | -                   | -                     |
| Gold of pleasure                 | -                   | -                     |
| Olives for oil production        | -                   | -                     |
| Barley, oats                     | -                   | -                     |
| Rice                             | -                   | -                     |
| Wheat, Rye                       | -                   | -                     |
| Coffee beans                     | -                   | -                     |
| Ginseng root                     | -                   | -                     |
| Hops                             | -                   | -                     |
| Spices (seeds)                   | -                   | -                     |
| Caraway                          | -                   | -                     |

### Risk assessment residue definition (animal commodities):

Sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole.

| Commodity                        | Input value (mg/kg) | Comment               |
|----------------------------------|---------------------|-----------------------|
| Liver, kidney, edible offal      | 0.06                | STMR (FAO, 2011, 2015, EFSA, 2012a) |
| Other animal origin products    | MRLs as in Regulation (EU) No 2017/626 |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; LOQ: limit of quantification.
## Appendix E – Used compound codes

| Code/trivial name | Chemical name | Structural formula |
|-------------------|---------------|--------------------|
| Tebuconazole      | (RS)-1-p-Chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)-pentan-3-ol | ![Tebuconazole 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)-D,L-alanine | ![Triazole Alanine Structural Formula](image) |
| Triazole lactic acid | (R,S)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl) propanoic acid | ![Triazole Lactic Acid Structural Formula](image) |
| 1,2,4 Triazole    | 1H-1,2,4-triazole (free triazole) | ![1,2,4 Triazole Structural Formula](image) |
| Triazole acetic acid | 1H-1,2,4-triazol-1-yl acetic acid | ![Triazole Acetic Acid Structural Formula](image) |