

## REASONED OPINION

**Reasoned opinion on the modification of the existing MRL for tebuconazole in poppy seed<sup>1</sup>****European Food Safety Authority<sup>2</sup>**

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**ABSTRACT**

In accordance with Article 6 of Regulation (EC) No 396/2005, the Czech Republic, hereafter referred to as the evaluating Member State (EMS), received an application from Bayer s.r.o to modify the existing MRL for the active substance tebuconazole in poppy seed. In order to accommodate for the intended use of tebuconazole, the EMS proposed to raise the existing MRL from the limit of quantification 0.05 mg/kg to the proposed MRL of 0.5 mg/kg. 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. According to EFSA the data are sufficient to derive a MRL proposal of 0.2 mg/kg for the proposed use on poppy seed. Adequate analytical enforcement methods are available to control the residues of tebuconazole in the commodity under consideration. Based on the risk assessment results, EFSA concludes that the proposed use of tebuconazole on poppy seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

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**KEY WORDS**

Tebuconazole, poppy seed, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, triazole fungicide, triazole derivative metabolites.

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## SUMMARY

In accordance with Article 6 of Regulation (EC) No 396/2005, the Czech Republic, hereafter referred to as the evaluating Member State (EMS), received an application from Bayer s.r.o to modify the existing MRL for the active substance tebuconazole in poppy seed. In order to accommodate for the intended use of tebuconazole, the EMS proposed to raise the existing MRL from the limit of quantification 0.05 mg/kg to the proposed MRL of 0.5 mg/kg. 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 04 December 2012.

EFSA bases its assessment on the evaluation report submitted by the EMS, the Draft Assessment Report (DAR) (and its addendum/addenda) prepared under Council Directive 91/414/EEC, the Commission Review Report on tebuconazole, the conclusion on the peer review of the pesticide risk assessment of the active substance tebuconazole, the JMPR Evaluation report as well as the conclusions from previous EFSA opinions on tebuconazole.

The toxicological profile of tebuconazole was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.03 mg/kg bw per day and an ARfD of 0.03 mg/kg bw.

The metabolism of tebuconazole in primary crops was investigated in grapes (fruit crops), peanuts (pulses/oilseeds) and wheat (cereals). From these studies the peer review concluded to establish the residue definition for enforcement and for risk assessment as tebuconazole. For the use on poppy seed, EFSA concludes that the metabolism of tebuconazole in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.2 mg/kg for the proposed use on poppy seed. Adequate analytical enforcement methods are available to control the residues of tebuconazole in the commodity under consideration at the validated LOQ of 0.02 mg/kg.

Studies investigating the nature of tebuconazole residues in processed commodities were assessed in the peer review and showed that the compound is hydrolytically stable under processing conditions representative of pasteurisation, boiling/cooking and sterilisation. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable. Considering the low dietary intake of tebuconazole residues via poppy seed, specific studies investigating the magnitude of tebuconazole residues in processed commodities are not considered necessary.

The occurrence of tebuconazole residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, it was concluded that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on poppy seed according to the proposed GAP (Good Agricultural Practice).

Residues of tebuconazole in commodities of animal origin were not assessed in the framework of this application, since poppy seed is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). In the framework of the review of the existing MRLs for tebuconazole according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of tebuconazole at EU level and the existing acceptable CXLs supported by data. EFSA now updates this risk assessment with the median residue values as derived from the supervised residue trials on oilseed rape extrapolated to poppy seed and the median residue values reported in a previously issued EFSA reasoned opinion. In addition, the

exposure calculation was updated taking into account the relevant input values corresponding to Codex MRLs which were recently included in EU legislation. The acute exposure assessment was performed only with regard to poppy seed. The estimated exposure was then compared with the derived toxicological reference values.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for tebuconazole under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for up to 16.5 % of the ADI (WHO cluster diet B). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. No acute consumer risk was identified in relation to the MRL proposal.

EFSA concludes that the proposed use of tebuconazole on poppy seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

EFSA emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (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 Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

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

### Summary table

| Code number <sup>(a)</sup>                          | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Justification for the proposal   |
|---|------------|-------------------------|-------------------------|--|
| <b>Enforcement residue definition: tebuconazole</b> |            |                         |                         |  |
| 401030  | Poppy seed | 0.05*                   | 0.2                     | The MRL proposal reflects the intended use in the Czech Republic which is sufficiently supported by data and no risk was identified for consumers. |

(a): According to Annex I of Regulation (EC) No 396/2005.

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

## TABLE OF CONTENTS

|   |    |
|---|----|
| Abstract .....  | 1  |
| Summary .....   | 2  |
| Table of contents .....   | 4  |
| Background .....  | 5  |
| Terms of reference.....   | 5  |
| The active substance and its use pattern.....                           | 6  |
| Assessment .....  | 7  |
| 1. Method of analysis.....  | 7  |
| 1.1. Methods for enforcement of residues in food of plant origin .....  | 7  |
| 1.2. Methods for enforcement of residues in food of animal origin ..... | 7  |
| 2. Mammalian toxicology.....  | 7  |
| 3. Residues.....  | 8  |
| 3.1. Nature and magnitude of residues in plant.....                     | 8  |
| 3.1.1. Primary crops.....   | 8  |
| 3.1.2. Rotational crops.....  | 11 |
| 3.2. Nature and magnitude of residues in livestock .....                | 11 |
| 4. Consumer risk assessment .....                                       | 12 |
| Conclusions and recommendations .....                                   | 15 |
| References .....  | 17 |
| Appendices .....  | 20 |
| Abbreviations .....   | 30 |

## BACKGROUND

Regulation (EC) No 396/2005<sup>3</sup> establishes the rules governing the setting of pesticide MRLs at European Union level. Article 6 of that 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<sup>4</sup>, repealed by Regulation (EC) No 1107/2009<sup>5</sup>, shall submit to a Member State, when appropriate, an application to modify a MRL in accordance with the provisions of Article 7 of that Regulation.

The Czech Republic, hereafter referred to as the evaluating Member State (EMS), received an application from the company Bayer s.r.o.<sup>6</sup> to modify the existing MRL for the active substance tebuconazole in poppy seed. This application was notified to the European Commission and EFSA, and was subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 04 December 2012.

The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2012-00980 and the following subject:

*Modification of MRL for tebuconazole in poppy seed.*

The Czech Republic proposed to raise the existing MRL of tebuconazole in poppy seed from the limit of quantification 0.05 mg/kg to 0.5 mg/kg.

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

## TERMS OF REFERENCE

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

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

In this particular case the deadline for providing the reasoned opinion is 04 March 2012.

<sup>3</sup> Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005. OJ L 70, 16.03.2005, p. 1-16.

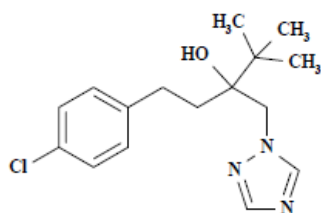
<sup>4</sup> Council Directive 91/414/EEC of 15 July 1991. OJ L 230, 19.08.1991, p. 1-32.

<sup>5</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009. OJ L 309, 24.11.2009, p. 1-50.

<sup>6</sup> Bayer s.r.o., Siemsensova 2717/4, 155 00, Praha 5 – Stodulky, Czech Republic.

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Tebuconazole is the ISO common name for (*RS*)-1-*p*-chlorophenyl-4,4-dimethyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-pentan-3-ol (IUPAC). The chemical structure of the compound is reported below.



Molecular weight: 307.8 g/mol

Tebuconazole is a systemic fungicide belonging to the class of triazoles. The compound acts as an ergosterol biosynthesis inhibitor (EBI). The lack of normal sterol production inhibits the growth of the fungus, hereby effectively preventing further infection and/or invasion of host tissues. The active substance is used against a wide range of fungal pathogens in a high number of agricultural crops.

Tebuconazole was evaluated in the framework of Council Directive 91/414/EEC with Denmark designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2008/125/EC<sup>7</sup> which entered into force on 01 September 2009 for use as fungicide only. In accordance with Commission Implementing Regulation (EU) No 540/2011<sup>8</sup> tebuconazole is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC.

The representative uses evaluated in the peer review were outdoor foliar applications on grapes and cereals in northern and southern Europe and seed treatment on barley in northern Europe. The Draft Assessment Report (DAR) of tebuconazole has been peer reviewed by EFSA (EFSA, 2008).

The EU MRLs for tebuconazole are established in Annex IIIA of Regulation (EC) No 396/2005 (Appendix C). EU MRLs for tebuconazole in products of plant and animal origin have been set for the first time in 2008 by means of Regulation (EC) No 149/2008<sup>9</sup> which were based on MRLs previously established at national level. Following MRLs applications, EFSA recommended the modification of the MRLs for swedes, turnip, mandarin, passion fruit, various citrus fruits and pulses (EFSA, 2009a, 2009b, 2010, 2011b) which were legally implemented in several regulations<sup>10, 11, 12</sup>. The most recent recommendations for citrus (except oranges), lettuce and other salad plants, parsley and chives (EFSA, 2012) were included in a regulation which was voted in the SCFCAH on 23 February but which is not yet published (SANCO/10065/2013). In this regulation also the acceptable Codex MRLs adopted by CAC in July 2012 were taken into account.

In 2011, EFSA reviewed the existing MRLs for tebuconazole according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2011a); the implementation of the EFSA recommendations is currently discussed in the Standing Committee on the Food Chain and Animal Health (SCFCAH) (Doc. SANCO/12783/2011). The existing EU MRLs (including the MRLs voted in February 2012) as well as the EFSA recommendations resulting from the MRL review are summarized in Appendix C. The existing EU MRL for tebuconazole on poppy seed is set at the LOQ of 0.05 mg/kg. Codex Alimentarius has established CXLs for a wide range of commodities, but no CXLs have been set for the crop under consideration.

<sup>7</sup> Commission Directive 2008/125/EC of 19 December 2008, OJ L 344, 20.12.2008, p. 78-88.

<sup>8</sup> Commission Implementing Regulation (EU) No 540/2011 of 23 May 2011, OJ L 153, 11.06.2011, p. 1-186.

<sup>9</sup> Commission Regulation (EC) 149/2008 of 29 January 2008, OJ L 58, 1.3.2008, p. 1-398.

<sup>10</sup> Commission Regulation (EC) 459/2010 of 27 May 2010, OJ L 129, 28.5.2010, p. 3-49.

<sup>11</sup> Commission Regulation (EU) 750/2010 of 07 July 2010, OJ L 220, 21.8.2010, p. 1-56.

<sup>12</sup> Commission Regulation (EU) 524/2011 of 26 May 2011, OJ L 142, 28.5.2011, p. 1-56.

The details of the intended GAP for tebuconazole are given in Appendix A.

## ASSESSMENT

EFSA bases its assessment on the evaluation report submitted by the EMS (Czech Republic, 2012), the Draft Assessment Report (DAR) (and its addendum/addenda) prepared under Council Directive 91/414/EEC (Denmark, 2008a, 2008b), the Commission Review Report on tebuconazole (EC, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance tebuconazole (EFSA, 2008), the JMPR Evaluation report (FAO, 1994, 2009a, 2009b, 2010, 2011) as well as the conclusions from previous EFSA opinions on tebuconazole (EFSA, 2009a, 2009b, 2010, 2011a, 2011b, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011<sup>13</sup> and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011; OECD, 2011).

### 1. Method of analysis

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

Analytical methods for the determination of tebuconazole residues in plant commodities were assessed in the DAR and during the peer review under Directive 91/414/EEC (Denmark, 2008a; EFSA, 2008).

The multi-residue method DFG-S19 using GC-MS and its ILV were evaluated and adequately validated for the determination of parent tebuconazole in plant matrices with a LOQ of 0.02 mg/kg in high water content (tomato, onion, cauliflower), high fat content (rape), acidic (orange) and dry (wheat) commodities (Denmark, 2008a).

The multi-residue QuEChERS method using HPLC-MS/MS described in the European Standard EN 15662:2008 is also applicable for the determination of tebuconazole in high water content, acidic and dry commodities (CEN, 2008).

Since the commodity under consideration belongs to the group of high fat content commodities, EFSA concludes that sufficiently validated analytical methods for enforcing the proposed MRL for tebuconazole on the poppy seed are available.

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

Analytical methods for the determination of residues in food of animal origin are not assessed in the current application, since poppy seed is normally not fed to livestock.

### 2. Mammalian toxicology

The toxicological profile of the active substance tebuconazole was assessed in the framework of the peer review under Directive 91/414/EEC (EFSA, 2008). The data were sufficient to derive toxicological reference values for tebuconazole which are compiled in Table 2-1.

Metabolism studies in both mammals and plants have shown that active substances belonging to the chemical class of triazoles are degraded/metabolized to a certain extent to common metabolites known as triazole derivative metabolites (TDMs), the major ones being the metabolites 1,2,4-triazole<sup>14</sup>, triazole alanine<sup>15</sup>, triazole lactic acid<sup>16</sup> and triazole acetic acid<sup>17</sup>. In 2007 the toxicological profile of TDMs was discussed by the experts in the EFSA Pesticide Risk Assessment Peer Review (PRAPeR)

<sup>13</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

<sup>14</sup> 1H-[1,2,4]triazole (see Appendix E).

<sup>15</sup> 2-amino-3-[1,2,4]triazol-1-yl-propionic acid (see Appendix E).

<sup>16</sup> [1,2,4]triazol-1-yl-lactic acid (see Appendix E).

<sup>17</sup> [1,2,4]triazol-1-yl-acetic acid (see Appendix E).



Expert Meeting 14. The proposed toxicological reference values for the TDMs were finally published in the EFSA conclusion on difenoconazole, another active substance belonging to the triazole class (EFSA, 2011c).

**Table 2-1:** Overview of the toxicological reference values

|  | Source | Year  | Value                 | Study relied upon  | Safety factor |
|--|--------|-------|-----------------------|--|---------------|
| <b>Tebuconazole (sum of enantiomers)</b>                                       |        |       |                       |  |               |
| ADI  | EFSA   | 2008  | 0.03 mg/kg bw per day | Dog, 1 year toxicity study (supported by developmental mouse study; safety factor 300) | 100           |
| ARfD   | EFSA   | 2008  | 0.03 mg/kg bw         | Mouse, developmental study   | 300           |
| <b>Metabolites: 1,2,4-triazole, triazole acetic acid, triazole lactic acid</b> |        |       |                       |  |               |
| ADI  | EFSA   | 2011c | 0.02 mg/kg bw per day | Rat, multigeneration study   | 1000          |
| ARfD   | EFSA   | 2011c | 0.06 mg/kg bw         | Rat, developmental study   | 500           |
| <b>Metabolite: triazole alanine</b>  |        |       |                       |  |               |
| ADI  | EFSA   | 2011c | 0.10 mg/kg bw per day | Rat, developmental study   | 1000          |
| ARfD   | EFSA   | 2011c | 0.10 mg/kg bw         | Rat, developmental study   | 1000          |

It is noted that JMPR established an ADI of 0.03 mg/kg bw per day and ARfD of 0.3 mg/kg bw for tebuconazole (FAO, 2010).

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

The metabolism of tebuconazole in primary crops was evaluated by Denmark (Denmark, 2008a) and reviewed by EFSA (EFSA, 2008) in the framework of the peer review under Directive 91/414/EEC. The details of the metabolism studies are reported in the DAR and the EFSA reasoned opinion on the review of the existing MRLs (Denmark, 2008a; EFSA, 2011a).

The peer review proposed parent tebuconazole (sum of isomers) as provisional residue definition for monitoring and risk assessment purposes for all categories of crops (EFSA, 2008). These residue definitions were confirmed in the framework of the MRL review (EFSA, 2011a). The current enforcement residue definition in Regulation (EC) No 396/2005 is parent tebuconazole.

In addition, it was concluded that a risk assessment needs to be performed for the triazole derivative metabolites (TDMs). Since these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommended that this risk assessment should be performed 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 triazole derivative metabolites is available (EFSA, 2011a).



For the uses on poppy seed, EFSA concludes that the metabolism of tebuconazole is sufficiently addressed and the residue definitions for enforcement and risk assessment agreed in the peer review are applicable.

#### 3.1.1.2. Magnitude of residues

In support of the intended GAP on poppy seeds in NEU the applicant submitted eight GAP compliant outdoor residue trials (2 x 160 g a.s./ha, PHI 56d) conducted on oilseed rape. The trials were performed during 2002 and 2006 in Germany, United Kingdom, France and Sweden. The applicant proposed to extrapolate the results of the residue trials to poppy seeds. The extrapolation is acceptable according to the EU guidance document (EC, 2011).

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposal are summarised in Table 3-1.

The storage stability of tebuconazole in primary crops was investigated in the DAR under Directive 91/414/EEC (Denmark, 2008a). Residues of tebuconazole were found to be stable at typically  $\leq -20^{\circ}\text{C}$  for up to 30 months in matrices with high water-, high acid-, and high fat content as well as in dry matrices. 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.

According to the EMS, the analytical methods used to analyse the supervised residue trial samples have been sufficiently validated and were proven to be fit for the purpose (Czech Republic, 2012).

EFSA concludes that the data are sufficient to derive a MRL proposal of 0.2 mg/kg for the intended use on poppy seed in NEU.

It is noted that in the framework of the MRL review a use on poppy seeds was assessed (FR/NEU: 2 x 250 g a.s. /ha, 90 d PHI). As the available trials did not match with the GAP (eleven outdoor residue trials conducted on oilseed rape in northern Europe with 2 x 375 g/ha, PHI 56-76d were available) EFSA derived a tentative MRL proposal (0.05 mg/kg), noting that 4 residue trials complying with the northern GAP on poppy seed would be required (EFSA, 2011). Since the studies presented in the framework of the current MRL application resulted in a higher MRL proposal of 0.2 mg/kg, this value is recommended to be included in the EU legislation.

**Table 3-1:** Overview of the available residues trials data

| Commodity              | Residue region<br>(a) | Outdoor /Indoor | Individual trial results (mg/kg)        |   | Median residue (mg/kg)<br>(b) | Highest residue (mg/kg)<br>(c) | MRL proposal (mg/kg) | Median CF<br>(d) | Comments<br>(e)   |
|------------------------|-----------------------|-----------------|---|---|-------------------------------|--------------------------------|----------------------|------------------|---|
|                        |                       |                 | Enforcement (tebuconazole)              | Risk assessment (tebuconazole)          |                               |                                |                      |                  |   |
| Rape seed → poppy seed | NEU                   | Outdoor         | <0.02; 0.02; 2x0.03; 2x0.04; 0.07; 0.11 | <0.02; 0.02; 2x0.03; 2x0.04; 0.07; 0.11 | 0.035                         | 0.11                           | 0.2                  | 1                | R <sub>ber</sub> =0.125<br>R <sub>max</sub> =0.143<br>MRL <sub>OECD</sub> = 0.168/0.2 |

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e. indoor use) or Import (country code) (EC, 2011).

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.

(e): Statistical estimation of MRLs according to the EU methodology (R<sub>ber</sub>, R<sub>max</sub>; EC, 1997g) and unrounded/rounded values according to the OECD methodology (OECD, 2011).

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

### 3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of tebuconazole was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 minutes at 100°C pH 5; 20 minutes at 120°C, pH 6). The studies were reported in the DAR and in the conclusion on the peer review (Denmark, 2008a; EFSA, 2008). EFSA concluded that the compound is hydrolytically stable under the representative processing conditions. Thus, for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable (EFSA, 2008).

No processing studies have been submitted investigating the effects of processing on the magnitude of tebuconazole residues in processed poppy seed. Considering the low dietary exposure of consumers and the insignificant contribution of poppy seed to the total dietary intake such studies are not required. Taking into account the high fat solubility of tebuconazole (log Pow = 3.7, EFSA, 2008), it is expected that accumulation of tebuconazole residues may occur in plant oils (e.g. poppy seed oil).

### 3.1.2. Rotational crops

Poppy seed can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed (EC, 1997c). However, since the application rate of tebuconazole on poppy seed is less critical compared with the uses assessed in the framework of the article 12 MRLs review (EFSA, 2011a), no significant levels of tebuconazole residues are expected in crops grown in rotation with the crop under consideration, provided that tebuconazole is applied according to the intended GAP on poppy seed.

## 3.2. Nature and magnitude of residues in livestock

Since poppy seed and its by-products are not normally fed to livestock, the nature and magnitude of tebuconazole residues in livestock is not assessed in the framework of this application (EC, 1996).

#### 4. Consumer risk assessment

In the framework of the review of the existing MRLs for tebuconazole according to Article 12 of Regulation (EC) No 396/2005 a comprehensive long-term exposure assessment was performed taking into account the existing uses of tebuconazole at EU level. EFSA now updates this risk assessment with the median residue values as derived from the supervised residue trials on oilseed rape extrapolated to poppy seed (see Table 3-1) and the median residue values reported in a previously issued EFSA reasoned opinion (EFSA, 2012). In addition, STMR values derived by JMPR were taken into account (only for those crops where the JMPR derived higher values compared to the input values derived in the MRL review or where no specific median values were derived by EFSA).

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population<sup>18</sup> (EFSA, 2007).

The model assumptions for the long-term exposure assessment are considered to be sufficiently conservative for a first tier exposure assessment, assuming that all food items consumed have been treated with the active substance under consideration. In reality, it is not likely that all food consumed will contain residues at the MRL or at levels of the median residue values identified in supervised field trials. However, if this first tier exposure assessment does not exceed the toxicological reference value for long-term exposure (i.e. the ADI), a consumer health risk can be excluded with a high probability.

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

The input values used for the dietary exposure calculation are summarised in Table 4-1.

**Table 4-1:** Input values for the consumer dietary exposure assessment

| Commodity   | Chronic exposure assessment |  | Acute exposure assessment  |  |
|---|-----------------------------|--|--|--|
|   | Input value (mg/kg)         | Comment  | Input value (mg/kg)  | Comment                                    |
| <b>Risk assessment residue definition: tebuconazole</b> |                             |  |  |  |
| Poppy seed  | 0.04                        | Median residue (Table 3.1)                           | 0.11   | Highest residue <sup>(1)</sup> (Table 3.1) |
| Citrus fruit (except oranges)                           | 0.24                        | Median residue x PF peeling (1.31x0.18) (EFSA, 2012) | Acute risk assessment was undertaken only with regard to the crop under consideration. |  |
| Lettuce and other salad plants including Brassicaceae   | 0.05                        | Median residue (EFSA, 2012)                          |  |  |
| Chives, parsley   | 0.58                        | Median residue (EFSA, 2012)                          |  |  |

<sup>18</sup> The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from MS surveys is used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

| Commodity  | Chronic exposure assessment |                  | Acute exposure assessment |         |
|--|-----------------------------|------------------|---------------------------|---------|
|  | Input value (mg/kg)         | Comment          | Input value (mg/kg)       | Comment |
| Plums  | 0.08                        | STMR (FAO, 2011) |                           |         |
| Elderberries   | 0.345                       | STMR (FAO, 2011) |                           |         |
| Bananas  | 0.01                        | STMR (FAO, 2011) |                           |         |
| Papaya   | 0.18                        | STMR (FAO, 2011) |                           |         |
| Carrots  | 0.11                        | STMR (FAO, 2011) |                           |         |
| Garlic   | 0.02                        | STMR (FAO, 2011) |                           |         |
| Onions   | 0.02                        | STMR (FAO, 2011) |                           |         |
| Courgettes   | 0.05                        | STMR (FAO, 2011) |                           |         |
| Sweet corn   | 0.06                        | STMR (FAO, 2011) |                           |         |
| Cauliflower  | 0.05                        | STMR (FAO, 2011) |                           |         |
| Head cabbage   | 0.05                        | STMR (FAO, 2011) |                           |         |
| Globe artichokes   | 0.145                       | STMR (FAO, 2011) |                           |         |
| Bean (dry)   | 0.05                        | STMR (FAO, 2011) |                           |         |
| Peanut   | 0.035                       | STMR (FAO, 2011) |                           |         |
| Soya bean (dry)  | 0.02                        | STMR (FAO, 2011) |                           |         |
| Cotton seed  | 0.05                        | STMR (FAO, 2011) |                           |         |
| Olives for oil production  | 0.05                        | STMR (FAO, 2011) |                           |         |
| Barley   | 0.085                       | STMR (FAO, 2011) |                           |         |
| Oats   | 0.085                       | STMR (FAO, 2011) |                           |         |
| Rice   | 0.275                       | STMR (FAO, 2011) |                           |         |
| Rye  | 0.05                        | STMR (FAO, 2011) |                           |         |
| Coffee beans   | 0.04                        | STMR (FAO, 2011) |                           |         |
| Hops   | 9.65                        | STMR (FAO, 2011) |                           |         |
| Liver, kidney, edible offal/ruminants, pigs and other farm animals | 0.06                        | STMR (FAO, 2011) |                           |         |
| Other commodities of plant and animal origin                       | See Appendix D.             |                  |                           |         |

(1) Normally for oilseeds the STMR should be used for the calculation of the short term exposure. However, since poppy seed is a speciality crop which might be marketed directly, EFSA uses the HR for the worst case exposure calculation, assuming that a consumer consumes poppy seeds from one producer, without having been mixed or bulked with products from different provenance.

The estimated exposure was then compared with the toxicological reference values derived for tebuconazole (see Table 2-1). The results of the intake calculation are presented in Appendix B to this reasoned opinion.

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 up to 16.5 % of the ADI (WHO cluster diet B). The contribution of residues in poppy seed to the total consumer exposure accounted for a maximum of 0.05 % of the ADI (WHO regional European diet).

No acute consumer risk was identified in relation to the MRL proposal for poppy seed. The calculated maximum exposure in percentage of the ARfD was 0.4 % (DE child, variability factor 1).

EFSA concludes that the intended use of tebuconazole on poppy seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a public health concern.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

The toxicological profile of tebuconazole was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an ADI of 0.03 mg/kg bw per day and an ARfD of 0.03 mg/kg bw.

The metabolism of tebuconazole in primary crops was investigated in grapes (fruit crops), peanuts (pulses/oilseeds) and wheat (cereals). From these studies the peer review concluded to establish the residue definition for enforcement and for risk assessment as tebuconazole. For the use on poppy seed, EFSA concludes that the metabolism of tebuconazole in primary crops is sufficiently addressed and that the derived residue definitions are applicable.

EFSA concludes that the submitted supervised residue trials are sufficient to derive a MRL proposal of 0.2 mg/kg for the proposed use on poppy seed. Adequate analytical enforcement methods are available to control the residues of tebuconazole in the commodity under consideration at the validated LOQ of 0.02 mg/kg.

Studies investigating the nature of tebuconazole residues in processed commodities were assessed in the peer review and showed that the compound is hydrolytically stable under processing conditions representative of pasteurisation, boiling/cooking and sterilisation. Therefore for processed commodities the same residue definition as for raw agricultural commodities (RAC) is applicable. Considering the low dietary intake of tebuconazole residues via poppy seed, specific studies investigating the magnitude of tebuconazole residues in processed commodities are not considered necessary.

The occurrence of tebuconazole residues in rotational crops was investigated in the framework of the peer review. Based on the available information on the nature and magnitude of residues in succeeding crops, it was concluded that significant residue levels are unlikely to occur in rotational crops provided that the compound is used on poppy seed according to the proposed GAP (Good Agricultural Practice).

Residues of tebuconazole in commodities of animal origin were not assessed in the framework of this application, since poppy seed is normally not fed to livestock.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). In the framework of the review of the existing MRLs for tebuconazole according to Article 12 of Regulation (EC) No 396/2005, a comprehensive long-term exposure assessment was performed taking into account the existing uses of tebuconazole at EU level and the existing acceptable CXLs supported by data. EFSA now updates this risk assessment with the median residue values as derived from the supervised residue trials on oilseed rape extrapolated to poppy seed and the median residue values reported in a previously issued EFSA reasoned opinion. In addition, the exposure calculation was updated taking into account the relevant input values corresponding to Codex MRLs which were recently included in EU legislation. The acute exposure assessment was performed only with regard to poppy seed. The estimated exposure was then compared with the derived toxicological reference values.

It is noted that the long-term consumer exposure calculation is based on the conclusions and recommendations derived in the review of the existing MRLs for tebuconazole under Article 12 of Regulation (EC) No 396/2005. Under the assumption that the MRLs will be amended as proposed in the Article 12 review, the total calculated intake accounted for up to 16.5 % of the ADI (WHO cluster diet B). Thus, no long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. No acute consumer risk was identified in relation to the MRL proposal.



EFSA concludes that the proposed use of tebuconazole on poppy seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a consumer health risk.

EFSA emphasises that the above assessment does not yet take into consideration triazole derivative metabolites (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 Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their triazole derivative metabolites is available.

#### RECOMMENDATIONS

| Code number <sup>(a)</sup>                          | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Justification for the proposal   |
|---|------------|-------------------------|-------------------------|--|
| <b>Enforcement residue definition: tebuconazole</b> |            |                         |                         |  |
| 401030  | Poppy seed | 0.05*                   | 0.2                     | The MRL proposal reflects the intended use in the Czech Republic which is sufficiently supported by data and no risk was identified for consumers. |

(a): According to Annex I of Regulation (EC) No 396/2005.

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

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APPENDICES

Appendix A. GOOD AGRICULTURAL PRACTICE (GAPS)

| Crop and/or situation<br>(a) | Member State or Country | F G or I (b) | Pest or group of pests controlled (c)  | Formulation  |                         | Application         |                           |                    |                  | Application rate per treatment |                    |                           | PHI (days)<br>(l) | Remarks (m)   |
|------------------------------|-------------------------|--------------|--|--------------|-------------------------|---------------------|---------------------------|--------------------|------------------|--------------------------------|--------------------|---------------------------|-------------------|---|
|                              |                         |              |  | type (d - f) | conc. of a.s. (i)       | method kind (f - h) | growth stage & season (j) | number min max (k) | interval min max | kg as/hL min max               | water L/ha min max | kg a.s./ha min max        |                   |   |
| Poppy seed                   | CZ                      | F            | Foliar poppy diseases ( <i>Pleospora calvescens</i> , <i>Sclerotinia spp.</i> , <i>Alternaria brassicae</i> ), Growth regulation effect. | EC           | 160 G/L<br>TEBUCONAZOLE | Foliar spray        | BBCH 15-69                | 1-2                |                  | 0.02-0.08<br>tebuconazole      | 200-600            | 0.12-0.16<br>tebuconazole | 56                | Product dose rate: 0.75-1.0 l/ha, combi product containing 80 g/L prothioconazole |

- Remarks:
- (a) For crops, EU or other classifications, e.g. Codex, should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
  - (b) of a structure)
  - (c) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
  - (e) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
  - (g) GCPF Technical Monograph No 2, 4<sup>th</sup> Ed., 1999 or other codes, e.g. OECD/CIPAC, should be used  
All abbreviations used must be explained  
Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
  - (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
  - (i) g/kg or g/l
  - (j) Growth stage at last treatment (Growth stages of mono- and dicotyledonous plants. BBCH Monograph, 2<sup>nd</sup> Ed., 2001), including where relevant, information on season at time of application
  - (k) The minimum and maximum number of application possible under practical conditions of use must be provided
  - (l) PHI - minimum pre-harvest interval
  - (m) Remarks may include: Extent of use/economic importance/restrictions (i.e. feeding, grazing)

## Appendix B. Pesticide Residue Intake Model (PRIMO)

| Tebuconazole                    |          |                     |      |
|---------------------------------|----------|---------------------|------|
| Status of the active substance: | Included | Code no.            |      |
| LOQ (mg/kg bw):                 | 0.02     | proposed LOQ:       |      |
| Toxicological end points        |          |                     |      |
| ADI (mg/kg bw/day):             | 0.03     | ARfD (mg/kg bw):    | 0.03 |
| Source of ADI:                  | EFSA     | Source of ARfD:     | EFSA |
| Year of evaluation:             | 2008     | Year of evaluation: | 2008 |

Prepare workbook for refined calculations

Undo refined calculations

### Chronic risk assessment - refined calculations

|  |                                       | TMDI (range) in % of ADI<br>minimum - maximum |                                  |  |                                  |  |                                  |                            |
|--|---------------------------------------|---|----------------------------------|--|----------------------------------|--|----------------------------------|----------------------------|
|  |                                       | 2   |                                  | 17                                       |                                  |  |                                  |                            |
|  |                                       | No of diets exceeding ADI:                    |                                  | ---                                      |                                  |  |                                  |                            |
| Highest calculated TMDI values in % of ADI | MS Diet                               | Highest contributor to MS diet (in % of ADI)  | Commodity / group of commodities | 2nd contributor to MS diet (in % of ADI) | Commodity / group of commodities | 3rd contributor to MS diet (in % of ADI) | Commodity / group of commodities | pTMRs at LOQ (in % of ADI) |
| 16.5                                       | WHO Cluster diet B                    | 2.4   | Tomatoes                         | 2.2                                      | Beans (with pods)                | 2.2                                      | Wine grapes                      | 0.3                        |
| 14.9                                       | NL child                              | 3.4   | Beans (with pods)                | 2.7                                      | Apples                           | 2.0                                      | Milk and milk products: Cattle   | 2.1                        |
| 14.0                                       | DE child                              | 5.2   | Apples                           | 1.0                                      | Milk and milk products: Cattle   | 0.7                                      | Tomatoes                         | 1.1                        |
| 13.9                                       | FR toddler                            | 7.4   | Beans (with pods)                | 1.1                                      | Apples                           | 0.9                                      | Carrots                          | 0.1                        |
| 11.5                                       | FR infant                             | 5.6   | Beans (with pods)                | 1.7                                      | Milk and milk products: Cattle   | 1.1                                      | Apples                           | 1.8                        |
| 11.0                                       | IE adult                              | 1.5   | Wine grapes                      | 1.2                                      | Beans (without pods)             | 1.1                                      | Beans (with pods)                | 0.2                        |
| 10.8                                       | WHO cluster diet E                    | 2.0   | Wine grapes                      | 1.9                                      | Beans (with pods)                | 1.5                                      | Beans (without pods)             | 0.3                        |
| 9.1  | FR all population                     | 4.9   | Wine grapes                      | 0.9                                      | Beans (with pods)                | 0.5                                      | Wheat                            | 0.2                        |
| 8.8  | PT General population                 | 3.1   | Wine grapes                      | 1.7                                      | Beans (without pods)             | 0.7                                      | Rice                             | 0.1                        |
| 8.6  | UK Toddler                            | 3.8   | Sugar beet (root)                | 0.7                                      | Apples                           | 0.7                                      | Wheat                            | 0.1                        |
| 8.2  | ES child                              | 1.6   | Beans (with pods)                | 0.8                                      | Milk and milk products: Cattle   | 0.8                                      | Tomatoes                         | 0.9                        |
| 7.2  | WHO regional European diet            | 1.3   | Beans (with pods)                | 0.8                                      | Tomatoes                         | 0.5                                      | Wheat                            | 0.4                        |
| 7.0  | NL general                            | 1.7   | Beans (with pods)                | 0.8                                      | Wine grapes                      | 0.5                                      | Apples                           | 0.5                        |
| 6.5  | ES adult                              | 1.6   | Beans (with pods)                | 0.6                                      | Tomatoes                         | 0.5                                      | Wine grapes                      | 0.4                        |
| 6.4  | SE general population 90th percentile | 0.8   | Milk and milk products: Cattle   | 0.6                                      | Tomatoes                         | 0.6                                      | Beans (with pods)                | 0.9                        |
| 6.1  | WHO cluster diet D                    | 1.1   | Wheat                            | 0.8                                      | Tomatoes                         | 0.5                                      | Rice                             | 0.4                        |
| 6.1  | UK Infant                             | 1.7   | Sugar beet (root)                | 0.7                                      | Apples                           | 0.6                                      | Rice                             | 0.1                        |
| 5.6  | WHO Cluster diet F                    | 0.7   | Wine grapes                      | 0.6                                      | Wheat                            | 0.5                                      | Tomatoes                         | 0.3                        |
| 5.6  | DK child                              | 1.0   | Apples                           | 0.9                                      | Wheat                            | 0.7                                      | Rye                              | 0.1                        |
| 4.7  | UK vegetarian                         | 1.0   | Wine grapes                      | 0.6                                      | Sugar beet (root)                | 0.5                                      | Tomatoes                         | 0.0                        |
| 4.7  | IT kids/toddler                       | 1.1   | Wheat                            | 1.1                                      | Tomatoes                         | 0.6                                      | Beans (with pods)                | 0.0                        |
| 4.4  | UK Adult                              | 1.3   | Wine grapes                      | 0.7                                      | Sugar beet (root)                | 0.3                                      | Rice                             | 0.0                        |
| 4.3  | IT adult                              | 1.0   | Beans (with pods)                | 0.9                                      | Tomatoes                         | 0.7                                      | Wheat                            | 0.0                        |
| 4.1  | DK adult                              | 1.7   | Wine grapes                      | 0.3                                      | Apples                           | 0.3                                      | Wheat                            | 0.0                        |
| 3.5  | LT adult                              | 0.8   | Apples                           | 0.5                                      | Tomatoes                         | 0.3                                      | Swine: Meat                      | 0.3                        |
| 3.0  | PL general population                 | 0.9   | Apples                           | 0.7                                      | Tomatoes                         | 0.4                                      | Beans (without pods)             | 0.0                        |
| 2.4  | FI adult                              | 0.4   | Wine grapes                      | 0.3                                      | Tomatoes                         | 0.3                                      | Beans (with pods)                | 0.0                        |

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

|   |   |
|---|---|
| <b>Acute risk assessment /children - refined calculations</b> | <b>Acute risk assessment / adults / general population - refined calculations</b> |
|---|---|

The acute risk assessment is based on the ARID.

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 ARID.

|                                |  |             |                              |  |             |                              |  |             |                              |  |             |                              |
|--------------------------------|--|-------------|------------------------------|--|-------------|------------------------------|--|-------------|------------------------------|--|-------------|------------------------------|
| <b>Unprocessed commodities</b> | <b>No of commodities for which ARID/ADI is exceeded (IESTI 1):</b> --- |             |                              | <b>No of commodities for which ARID/ADI is exceeded (IESTI 2):</b> --- |             |                              | <b>No of commodities for which ARID/ADI is exceeded (IESTI 1):</b> --- |             |                              | <b>No of commodities for which ARID/ADI is exceeded (IESTI 2):</b> --- |             |                              |
|                                | IESTI 1  | *)          | **)                          | IESTI 2  | *)          | **)                          | IESTI 1  | *)          | **)                          | IESTI 2  | *)          | **)                          |
|                                | Highest % of ARID/ADI  | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARID/ADI  | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARID/ADI  | Commodities | pTMRL/ threshold MRL (mg/kg) | Highest % of ARID/ADI  | Commodities | pTMRL/ threshold MRL (mg/kg) |
|                                | 0.4  | Poppy seed  | 0.11 / -                     | 0.4  | Poppy seed  | 0.11 / -                     | 0.1  | Poppy seed  | 0.11 / -                     | 0.1  | Poppy seed  | 0.11 / -                     |
|                                | <b>No of critical MRLs (IESTI 1)</b> ---                               |             |                              | <b>No of critical MRLs (IESTI 2)</b> ---                               |             |                              | <b>No of critical MRLs (IESTI 1)</b> ---                               |             |                              | <b>No of critical MRLs (IESTI 2)</b> ---                               |             |                              |

|                              |  |                              |                       |  |                       |                              |
|------------------------------|--|------------------------------|-----------------------|--|-----------------------|------------------------------|
| <b>Processed commodities</b> | <b>No of commodities for which ARID/ADI is exceeded:</b> --- |                              |                       | <b>No of commodities for which ARID/ADI is exceeded:</b> --- |                       |                              |
|                              | ***)   | pTMRL/ threshold MRL (mg/kg) | ***)                  | pTMRL/ threshold MRL (mg/kg)                                 | ***)                  | pTMRL/ threshold MRL (mg/kg) |
|                              | Highest % of ARID/ADI  | Processed commodities        | Highest % of ARID/ADI | Processed commodities  | Highest % of ARID/ADI | Processed commodities        |
|                              |  |                              |                       |  |                       |                              |

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

\*\*\*) pTMRL: provisional temporary MRL

\*\*\*) pTMRL: provisional temporary MRL for 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 ARID/ADI was identified for any unprocessed commodity.

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



## Appendix C. EXISTING EU MAXIMUM RESIDUE LEVELS (MRLs)

(Pesticides - Web Version - EU MRLs (File created on 25/04/2013 11:04))

| Code number | Groups and examples of individual products to which the MRLs apply         | Tebuconazole |                                     |                                 |
|-------------|--|--------------|-------------------------------------|---------------------------------|
|             |  | Current MRLs | EFSA recommendations <sup>(a)</sup> | SANCO/10065/2013 <sup>(b)</sup> |
| 100000      | 1. FRUIT FRESH OR FROZEN; NUTS   |              |                                     |                                 |
| 110000      | (i) Citrus fruit   |              |                                     |                                 |
| 110010      | Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids) | 0.9          | 0.90                                | 5                               |
| 110020      | Oranges (Bergamot, bitter orange, chinotto and other hybrids)              | 0.9          | 0.90                                | 0,9                             |
| 110030      | Lemons (Citron, lemon)   | 0.9          | 0.90                                | 5                               |
| 110040      | Limes  | 0.9          | 0.90                                | 5                               |
| 110050      | Mandarins (Clementine, tangerine and other hybrids)                        | 3            | 3.00                                | 5                               |
| 110990      | Others   | 0.9          |                                     | 5                               |
| 120000      | (ii) Tree nuts (shelled or unshelled)                                      | 0.05*        |                                     | 0,05*                           |
| 120010      | Almonds  | 0.05*        | 0.05                                | 0,05*                           |
| 120020      | Brazil nuts  | 0.05*        | 0.05                                | 0,05*                           |
| 120030      | Cashew nuts  | 0.05*        |                                     | 0,05*                           |
| 120040      | Chestnuts  | 0.05*        | 0.05                                | 0,05*                           |
| 120050      | Coconuts   | 0.05*        | 0.05                                | 0,05*                           |
| 120060      | Hazelnuts (Filbert)  | 0.05*        | 0.05                                | 0,05*                           |
| 120070      | Macadamia  | 0.05*        |                                     | 0,05*                           |
| 120080      | Pecans   | 0.05*        | 0.05                                | 0,05*                           |
| 120090      | Pine nuts  | 0.05*        |                                     | 0,05*                           |
| 120100      | Pistachios   | 0.05*        | 0.05                                | 0,05*                           |
| 120110      | Walnuts  | 0.05*        | 0.05                                | 0,05*                           |
| 120990      | Others   | 0.05*        |                                     | 0,05*                           |
| 130000      | (iii) Pome fruit   |              |                                     |                                 |
| 130010      | Apples (Crab apple)  | 1            | 0.30                                | 1                               |
| 130020      | Pears (Oriental pear)  | 1            | 0.30                                | 1                               |
| 130030      | Quinces  | 0.5          | 0.50                                | 0,5                             |
| 130040      | Medlar   | 0.5          | 0.50                                | 0,5                             |
| 130050      | Loquat   | 0.5          | 0.50                                | 0,5                             |
| 130990      | Others   | 0.5          |                                     | 0,5                             |
| 140000      | (iv) Stone fruit   |              |                                     |                                 |
| 140010      | Apricots   | 1            | 0.60                                | 1                               |
| 140020      | Cherries (sweet cherries, sour cherries)                                   | 5            |                                     | 5                               |
| 140030      | Peaches (Nectarines and similar hybrids)                                   | 1            | 0.60                                | 1                               |
| 140040      | Plums (Damson, greengage,  | 0.5          | 0.60                                | 1                               |

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|-------------|---|--------------|-------------------------------------|---------------------------------|
|             |   | Current MRLs | EFSA recommendations <sup>(a)</sup> | SANCO/10065/2013 <sup>(b)</sup> |
|             | mirabelle)  |              |                                     |                                 |
| 140990      | Others  | 0.5          |                                     | 0,5                             |
| 150000      | (v) Berries & small fruit   |              |                                     |                                 |
| 151000      | (a) Table and wine grapes   | 2            |                                     | 2                               |
| 151010      | Table grapes  | 2            | 0.50                                | 2                               |
| 151020      | Wine grapes   | 2            |                                     | 2                               |
| 152000      | (b) Strawberries  | 0.05*        | 0.02*                               | 0,05*                           |
| 153000      | (c) Cane fruit  | 1            |                                     | 1                               |
| 153010      | Blackberries  | 1            | 0.50                                | 1                               |
| 153020      | Dewberries (Loganberries, Boysenberries, and cloudberries)  | 1            |                                     | 1                               |
| 153030      | Raspberries (Wineberries)   | 1            | 0.50                                | 1                               |
| 153990      | Others  | 1            |                                     | 1                               |
| 154000      | (d) Other small fruit & berries   | 2            |                                     | 2                               |
| 154010      | Blueberries (Bilberries cowberries (red bilberries))  | 2            | 1.50                                | 2                               |
| 154020      | Cranberries   | 2            | 1.50                                | 2                               |
| 154030      | Cumants (red, black and white)  | 2            | 1.50                                | 2                               |
| 154040      | Gooseberries (Including hybrids with other ribes species)   | 2            | 1.50                                | 2                               |
| 154050      | Rose hips   | 2            |                                     | 2                               |
| 154060      | Mulberries (arbutus berry)  | 2            |                                     | 2                               |
| 154070      | Azarole (mediterranean medlar)  | 2            |                                     | 2                               |
| 154080      | Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries) | 2            | 1.50                                | 2                               |
| 154990      | Others  | 2            |                                     | 2                               |
| 160000      | (vi) Miscellaneous fruit  |              |                                     |                                 |
| 161000      | (a) Edible peel   | 0.05*        |                                     | 0,05*                           |
| 161010      | Dates   | 0.05*        |                                     | 0,05*                           |
| 161020      | Figs  | 0.05*        |                                     | 0,05*                           |
| 161030      | Table olives  | 0.05*        | 0.05                                | 0,05*                           |
| 161040      | Kumquats (Marumi kumquats, nagami kumquats)   | 0.05*        |                                     | 0,05*                           |
| 161050      | Carambola (Bilimbi)   | 0.05*        |                                     | 0,05*                           |
| 161060      | Persimmon   | 0.05*        |                                     | 0,05*                           |

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| 161070      | Jambolan (java plum) (Java apple (water apple), pomeraç, rose apple, Brazilian cherry (grumichama), Surinam cherry)       | 0.05*        |                                     | 0,05*                           |
| 161990      | Others  | 0.05*        |                                     | 0,05*                           |
| 162000      | (b) Inedible peel, small  |              |                                     |                                 |
| 162010      | Kiwi  | 0.5          |                                     | 0,5                             |
| 162020      | Lychee (Litchi) (Pulasan, rambutan (hairy litchi))  | 0.05*        |                                     | 0,05*                           |
| 162030      | Passion fruit   | 1            | 1.00                                | 1                               |
| 162040      | Prickly pear (cactus fruit)   | 0.05*        |                                     | 0,05*                           |
| 162050      | Star apple  | 0.05*        |                                     | 0,05*                           |
| 162060      | American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mamme sapote) | 0.05*        |                                     | 0,05*                           |
| 162990      | Others  | 0.05*        |                                     | 0,05*                           |
| 163000      | (c) Inedible peel, large  |              |                                     |                                 |
| 163010      | Avocados  | 0.05*        |                                     | 0,05*                           |
| 163020      | Bananas (Dwarf banana, plantain, apple banana)  | 0.05*        | 0.05                                | 0,05*                           |
| 163030      | Mangoes   | 0.1          | 0.10                                | 0,1                             |
| 163040      | Papaya  | 2            | 2.00                                | 2                               |
| 163050      | Pomegranate   | 0.05*        |                                     | 0,05*                           |
| 163060      | Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)                                | 0.05*        |                                     | 0,05*                           |
| 163070      | Guava   | 0.05*        |                                     | 0,05*                           |
| 163080      | Pineapples  | 0.05*        |                                     | 0,05*                           |
| 163090      | Bread fruit (Jackfruit)   | 0.05*        |                                     | 0,05*                           |
| 163100      | Durian  | 0.05*        |                                     | 0,05*                           |
| 163110      | Soursop (guanabana)   | 0.05*        |                                     | 0,05*                           |
| 163990      | Others  | 0.05*        |                                     | 0,05*                           |
| 200000      | 2. VEGETABLES FRESH OR FROZEN   |              |                                     |                                 |
| 210000      | (i) Root and tuber vegetables   |              |                                     |                                 |
| 211000      | (a) Potatoes  | 0.2          |                                     | 0,2                             |
| 212000      | (b) Tropical root and tuber vegetables  | 0.05*        |                                     | 0,05*                           |

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| 212010      | Cassava (Dasheen, eddoe (Japanese taro), tannia)                             | 0.05*        |                                     | 0,05*                           |
| 212020      | Sweet potatoes   | 0.05*        |                                     | 0,05*                           |
| 212030      | Yams (Potato bean (yam bean), Mexican yam bean)                              | 0.05*        |                                     | 0,05*                           |
| 212040      | Arrowroot  | 0.05*        |                                     | 0,05*                           |
| 212990      | Others   | 0.05*        |                                     | 0,05*                           |
| 213000      | (c) Other root and tuber vegetables except sugar beet                        |              |                                     |                                 |
| 213010      | Beetroot   | 0.05*        |                                     | 0,05*                           |
| 213020      | Carrots  | 0.5          | 0.40                                | 0,5                             |
| 213030      | Celeriac   | 0.5          | 0.50                                | 0,5                             |
| 213040      | Horseradish  | 0.4          | 0.40                                | 0,4                             |
| 213050      | Jerusalem artichokes   | 0.05*        |                                     | 0,05*                           |
| 213060      | Parsnips   | 0.5          | 0.40                                | 0,5                             |
| 213070      | Parsley root   | 0.5          | 0.40                                | 0,5                             |
| 213080      | Radishes (Black radish, Japanese radish, small radish and similar varieties) | 0.05*        |                                     | 0,05*                           |
| 213090      | Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))                  | 0.4          |                                     | 0,4                             |
| 213100      | Swedes   | 0.3          | 0.30                                | 0,3                             |
| 213110      | Turnips  | 0.3          | 0.30                                | 0,3                             |
| 213990      | Others   | 0.05*        |                                     | 0,05*                           |
| 220000      | (ii) Bulb vegetables   |              |                                     |                                 |
| 220010      | Garlic   | 0.1          | 0.06                                | 0,1                             |
| 220020      | Onions (Silverskin onions)   | 0.05*        | 0.06                                | 0,1                             |
| 220030      | Shallots   | 0.05*        | 0.05                                | 0,05*                           |
| 220040      | Spring onions (Welsh onion and similar varieties)                            | 0.5          | 0.60                                | 0,5                             |
| 220990      | Others   | 0.05*        |                                     | 0,05*                           |
| 230000      | (iii) Fruiting vegetables  |              |                                     |                                 |
| 231000      | (a) Solanacea  |              |                                     |                                 |
| 231010      | Tomatoes (Cherry tomatoes, )   | 1            | 0.90                                | 1                               |
| 231020      | Peppers (Chilli peppers)   | 0.5          | 0.60                                | 0,5                             |
| 231030      | Aubergines (egg plants) (Pepino)   | 0.5          |                                     | 0,5                             |
| 231040      | Okra, lady's fingers   | 0.05*        |                                     | 0,05*                           |
| 231990      | Others   | 0.05*        |                                     | 0,05*                           |
| 232000      | (b) Cucurbits - edible peel  |              |                                     |                                 |
| 232010      | Cucumbers  | 0.5          | 0.20                                | 0,5                             |
| 232020      | Gherkins   | 0.05*        |                                     | 0,05*                           |
| 232030      | Courgettes (Summer squash, marrow (patisson))                                | 0.2          | 0.20                                | 0,2                             |
| 232990      | Others   | 0.05*        |                                     | 0,05*                           |
| 233000      | (c) Cucurbits-inedible peel  |              |                                     |                                 |
| 233010      | Melons (Kiwano )   | 0.2          |                                     | 0,2                             |

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| 233020      | Pumpkins (Winter squash)   | 0.2          | 0.15                                | 0,2                             |
| 233030      | Watermelons  | 0.2          | 0.15                                | 0,2                             |
| 233990      | Others   | 0.05*        |                                     | 0,05*                           |
| 234000      | (d) Sweet corn   | 0.2          |                                     | 0,6                             |
| 239000      | (e) Other fruiting vegetables  | 0.05*        |                                     | 0,05*                           |
| 240000      | (iv) Brassica vegetables   |              |                                     |                                 |
| 241000      | (a) Flowering brassica   |              |                                     |                                 |
| 241010      | Broccoli (Calabrese, Chinese broccoli, Broccoli raab)  | 1            | 0.15                                | 1                               |
| 241020      | Cauliflower  | 1            | 0.05                                | 1                               |
| 241990      | Others   | 0.05*        |                                     | 0,05*                           |
| 242000      | (b) Head brassica  |              |                                     |                                 |
| 242010      | Brussels sprouts   | 0.5          | 0.70                                | 0,5                             |
| 242020      | Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)   | 1            | 0.70                                | 1                               |
| 242990      | Others   | 0.5          |                                     | 0,5                             |
| 243000      | (c) Leafy brassica   |              |                                     |                                 |
| 243010      | Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage) | 1            |                                     | 1                               |
| 243020      | Kale (Borecole (curly kale), collards)   | 0.05*        |                                     | 0,05*                           |
| 243990      | Others   | 0.05*        |                                     | 0,05*                           |
| 244000      | (d) Kohlrabi   | 0.05*        |                                     | 0,05*                           |
| 250000      | (v) Leaf vegetables & fresh herbs  |              |                                     |                                 |
| 251000      | (a) Lettuce and other salad plants including Brassicacea   | 0.05*        |                                     | 0,5                             |
| 251010      | Lamb's lettuce (Italian consalad)  | 0.05*        |                                     | 0,5                             |
| 251020      | Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)                                    | 0.05*        |                                     | 0,5                             |
| 251030      | Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)                          | 0.05*        |                                     | 0,5                             |
| 251040      | Cress  | 0.05*        |                                     | 0,5                             |
| 251050      | Land cress   | 0.05*        |                                     | 0,5                             |
| 251060      | Rocket, Rucola (Wild rocket)   | 0.05*        |                                     | 0,5                             |
| 251070      | Red mustard  | 0.05*        |                                     | 0,5                             |
| 251080      | Leaves and sprouts of Brassica spp (Mizuna)  | 0.05*        |                                     | 0,5                             |
| 251990      | Others   | 0.05*        |                                     | 0,5                             |
| 252000      | (b) Spinach & similar (leaves)   | 0.05*        |                                     | 0,05*                           |

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| 252010      | Spinach (New Zealand spinach, turnip greens (turnip tops))   | 0.05*        |                                     | 0,05*                           |
| 252020      | Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sornel, glasswort)                              | 0.05*        |                                     | 0,05*                           |
| 252030      | Beet leaves (chard) (Leaves of beetroot)   | 0.05*        |                                     | 0,05*                           |
| 252990      | Others   | 0.05*        |                                     | 0,05*                           |
| 253000      | (c) Vine leaves (grape leaves)   | 0.05*        |                                     | 0,05*                           |
| 254000      | (d) Water cress  | 0.05*        |                                     | 0,05*                           |
| 255000      | (e) Witloof  | 0.05*        | 0.15                                | 0,05*                           |
| 256000      | (f) Herbs  |              |                                     |                                 |
| 256010      | Chervil  | 0.05*        |                                     | 0,05*                           |
| 256020      | Chives   | 0.5          | 0.60                                | 2                               |
| 256030      | Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea) | 0.05*        |                                     | 0,05*                           |
| 256040      | Parsley  | 0.05*        |                                     | 2                               |
| 256050      | Sage (Winter savory, summer savory, )  | 0.05*        |                                     | 0,05*                           |
| 256060      | Rosemary   | 0.05*        |                                     | 0,05*                           |
| 256070      | Thyme ( marjoram, oregano)   | 0.05*        |                                     | 0,05*                           |
| 256080      | Basil (Balm leaves, mint, peppermint)  | 0.05*        |                                     | 0,05*                           |
| 256090      | Bay leaves (laurel)  | 0.05*        |                                     | 0,05*                           |
| 256100      | Tarragon (Hyssop)  | 0.05*        |                                     | 0,05*                           |
| 256990      | Others   | 0.05*        |                                     | 0,05*                           |
| 260000      | (vi) Legume vegetables (fresh)   |              |                                     |                                 |
| 260010      | Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)                   | 2            |                                     | 2                               |
| 260020      | Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)   | 2            |                                     | 2                               |
| 260030      | Peas (with pods) (Mangetout (sugar peas))  | 2            |                                     | 2                               |
| 260040      | Peas (without pods) (Garden pea, green pea, chickpea)  | 0.05*        |                                     | 0,05*                           |
| 260050      | Lentils  | 0.05*        |                                     | 0,05*                           |
| 260990      | Others   | 0.05*        |                                     | 0,05*                           |
| 270000      | (vii) Stem vegetables (fresh)  |              |                                     |                                 |
| 270010      | Asparagus  | 0.05*        | 0.02*                               | 0,05*                           |
| 270020      | Cardoons   | 0.05*        |                                     | 0,05*                           |

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| 270030      | Celery  | 0.3          |                                     | 0,3                             |
| 270040      | Fennel  | 0.05*        |                                     | 0,05*                           |
| 270050      | Globe artichokes  | 0.5          | 0.60                                | <b>0,6</b>                      |
| 270060      | Leek  | 1            | 0.60                                | 1                               |
| 270070      | Rhubarb   | 0.05*        |                                     | 0,05*                           |
| 270080      | Bamboo shoots   | 0.05*        |                                     | 0,05*                           |
| 270090      | Palm hearts   | 0.05*        |                                     | 0,05*                           |
| 270990      | Others  | 0.05*        |                                     | 0,05*                           |
| 280000      | (viii) Fungi  | 0.05*        |                                     | 0,05*                           |
| 280010      | Cultivated (Common mushroom, Oyster mushroom, Shi-take)                                   | 0.05*        |                                     | 0,05*                           |
| 280020      | Wild (Chanterelle, Truffle, Morel...)   | 0.05*        |                                     | 0,05*                           |
| 280990      | Others  | 0.05*        |                                     | 0,05*                           |
| 290000      | (ix) Sea weeds  | 0.05*        |                                     | 0,05*                           |
| 300000      | 3. PULSES, DRY  |              |                                     |                                 |
| 300010      | Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas) | 0.2          | 0.20                                | <b>0,3</b>                      |
| 300020      | Lentils   | 0.05*        | 0.20                                | <b>0,2</b>                      |
| 300030      | Peas (Chickpeas, field peas, chickling vetch)   | 0.05*        | 0.20                                | <b>0,2</b>                      |
| 300040      | Lupins  | 0.2          | 0.20                                | 0,2                             |
| 300990      | Others  | 0.05*        |                                     | <b>0,2</b>                      |
| 400000      | 4. OILSEEDS AND OILFRUITS   |              |                                     |                                 |
| 401000      | (i) Oilseeds  |              |                                     |                                 |
| 401010      | Linseed   | 0.05*        | 0.60                                | 0,05*                           |
| 401020      | Peanuts   | 0.05*        |                                     | <b>0,15</b>                     |
| 401030      | Poppy seed  | 0.05*        | 0.05                                | 0,05*                           |
| 401040      | Sesame seed   | 0.05*        |                                     | 0,05*                           |
| 401050      | Sunflower seed  | 0.05*        |                                     | 0,05*                           |
| 401060      | Rape seed (Bird rapeseed, turnip rape)  | 0.5          | 0.50                                | 0,5                             |
| 401070      | Soya bean   | 0.1          | 0.07                                | <b>0,15</b>                     |
| 401080      | Mustard seed  | 0.2          | 0.30                                | 0,2                             |
| 401090      | Cotton seed   | 0.05*        |                                     | <b>2</b>                        |
| 401100      | Pumpkin seeds   | 0.05*        |                                     | 0,05*                           |
| 401110      | Safflower   | 0.05*        |                                     | 0,05*                           |
| 401120      | Borage  | 0.05*        |                                     | 0,05*                           |
| 401130      | Gold of pleasure  | 0.05*        | 0.30                                | 0,05*                           |
| 401140      | Hempseed  | 0.05*        |                                     | 0,05*                           |
| 401150      | Castor bean   | 0.05*        |                                     | 0,05*                           |
| 401990      | Others  | 0.05*        |                                     | 0,05*                           |
| 402000      | (ii) Oilfruits  | 0.05*        |                                     | 0,05*                           |

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| 402010      | Olives for oil production  | 0.05*        | 0.05                                | 0,05*                           |
| 402020      | Palm nuts (palmoil kernels)  | 0.05*        |                                     | 0,05*                           |
| 402030      | Palmfruit  | 0.05*        |                                     | 0,05*                           |
| 402040      | Kapok  | 0.05*        |                                     | 0,05*                           |
| 402990      | Others   | 0.05*        |                                     | 0,05*                           |
| 500000      | 5. CEREALS   |              |                                     |                                 |
| 500010      | Barley   | 2            | 2                                   | 2                               |
| 500020      | Buckwheat  | 0.2          |                                     | 0,2                             |
| 500030      | Maize  | 0.2          |                                     | 0,2                             |
| 500040      | Millet (Foxtail millet, teff)  | 0.2          |                                     | 0,2                             |
| 500050      | Oats   | 2            | 2                                   | 2                               |
| 500060      | Rice   | 2            |                                     | 2                               |
| 500070      | Rye  | 0.2          | 0.1                                 | 0,2                             |
| 500080      | Sorghum  | 0.2          |                                     | 0,2                             |
| 500090      | Wheat (Spelt Triticale)  | 0.2          | 0.1                                 | 0,2                             |
| 500990      | Others   | 0.2          |                                     | 0,2                             |
| 600000      | 6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA   |              |                                     |                                 |
| 610000      | (i) Tea (dried leaves and stalks, fermented or otherwise of <i>Camellia sinensis</i> ) | 0.05*        |                                     | 0,05*                           |
| 620000      | (ii) Coffee beans  | 0.1          | 0.1                                 | 0,1                             |
| 630000      | (iii) Herbal infusions (dried)   | 50           |                                     | 50                              |
| 631000      | (a) Flowers  | 50           |                                     | 50                              |
| 631010      | Camomille flowers  | 50           |                                     | 50                              |
| 631020      | Hybiscus flowers   | 50           |                                     | 50                              |
| 631030      | Rose petals  | 50           |                                     | 50                              |
| 631040      | Jasmine flowers  | 50           |                                     | 50                              |
| 631050      | Lime (linden)  | 50           |                                     | 50                              |
| 631990      | Others   | 50           |                                     | 50                              |
| 632000      | (b) Leaves   | 50           |                                     | 50                              |
| 632010      | Strawberry leaves  | 50           |                                     | 50                              |
| 632020      | Rooibos leaves   | 50           |                                     | 50                              |
| 632030      | Maté   | 50           |                                     | 50                              |
| 632990      | Others   | 50           |                                     | 50                              |
| 633000      | (c) Roots  | 50           |                                     | 50                              |
| 633010      | Valerian root  | 50           |                                     | 50                              |
| 633020      | Ginseng root   | 50           |                                     | 50                              |
| 633990      | Others   | 50           |                                     | 50                              |
| 639000      | (d) Other herbal infusions   | 50           |                                     | 50                              |
| 640000      | (iv) Cocoa (fermented beans)   | 0.05*        |                                     | 0,05*                           |
| 650000      | (v) Carob (st.johns bread)   | 0.05*        |                                     | 0,05*                           |
| 700000      | 7. HOPS (dried), including hop pellets and unconcentrated powder                       | 30           |                                     | <b>40</b>                       |
| 800000      | 8. SPICES  |              |                                     |                                 |

| Code number | Groups and examples of individual products to which the MRLs apply | Tebuconazole |                                     |                                 |
|-------------|--|--------------|-------------------------------------|---------------------------------|
|             |  | Current MRLs | EFSA recommendations <sup>(6)</sup> | SANCO/10065/2013 <sup>(b)</sup> |
| 810000      | (i) Seeds  |              |                                     |                                 |
| 810010      | Anise  | 2            |                                     | 2                               |
| 810020      | Black caraway  | 2            |                                     | 2                               |
| 810030      | Celery seed (Lovage seed)  | 1            |                                     | 1                               |
| 810040      | Coriander seed   | 2            |                                     | 2                               |
| 810050      | Cumin seed   | 1            |                                     | 1                               |
| 810060      | Dill seed  | 1            |                                     | 1                               |
| 810070      | Fennel seed  | 2            |                                     | 2                               |
| 810080      | Fenugreek  | 1            |                                     | 1                               |
| 810090      | Nutmeg   | 1            |                                     | 1                               |
| 810990      | Others   | 1            |                                     | 1                               |
| 820000      | (ii) Fruits and berries  | 1            |                                     | 1                               |
| 820010      | Allspice   | 1            |                                     | 1                               |
| 820020      | Anise pepper (Japan pepper)  | 1            |                                     | 1                               |
| 820030      | Caraway  | 1            |                                     | 1                               |
| 820040      | Cardamom   | 1            |                                     | 1                               |
| 820050      | Juniper berries  | 1            |                                     | 1                               |
| 820060      | Pepper, black and white (Long pepper, pink pepper)                 | 1            |                                     | 1                               |
| 820070      | Vanilla pods   | 1            |                                     | 1                               |
| 820080      | Tamarind   | 1            |                                     | 1                               |
| 820990      | Others   | 1            |                                     | 1                               |
| 830000      | (iii) Bark   | 1            |                                     | 1                               |
| 830010      | Cinnamon (Cassia)  | 1            |                                     | 1                               |
| 830990      | Others   | 1            |                                     | 1                               |
| 840000      | (iv) Roots or rhizome  | 1            |                                     | 1                               |
| 840010      | Liquorice  | 1            |                                     | 1                               |
| 840020      | Ginger   | 1            |                                     | 1                               |
| 840030      | Turmeric (Curcuma)   | 1            |                                     | 1                               |
| 840040      | Horseradish  | 1            |                                     | 1                               |
| 840990      | Others   | 1            |                                     | 1                               |
| 850000      | (v) Buds   | 1            |                                     | 1                               |
| 850010      | Cloves   | 1            |                                     | 1                               |
| 850020      | Capers   | 1            |                                     | 1                               |
| 850990      | Others   | 1            |                                     | 1                               |
| 860000      | (vi) Flower stigma   | 1            |                                     | 1                               |
| 860010      | Saffron  | 1            |                                     | 1                               |
| 860990      | Others   | 1            |                                     | 1                               |
| 870000      | (vii) Aril   | 1            |                                     | 1                               |
| 870010      | Mace   | 1            |                                     | 1                               |
| 870990      | Others   | 1            |                                     | 1                               |
| 900000      | 9. SUGAR PLANTS  | 0.05*        |                                     | 0,05*                           |
| 900010      | Sugar beet (root)  | 0.05*        |                                     | 0,05*                           |
| 900020      | Sugar cane   | 0.05*        |                                     | 0,05*                           |
| 900030      | Chicory roots  | 0.05*        |                                     | 0,05*                           |

| Code number | Groups and examples of individual products to which the MRLs apply   | Tebuconazole |                                     |                                 |
|-------------|--|--------------|-------------------------------------|---------------------------------|
|             |  | Current MRLs | EFSA recommendations <sup>(a)</sup> | SANCO/10065/2013 <sup>(b)</sup> |
| 900990      | Others   | 0.05*        |                                     | 0,05*                           |
| 1000000     | 10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS   |              |                                     |                                 |
| 1010000     | (i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these | 0.1          |                                     |                                 |
| 1011000     | (a) Swine  | 0.1          |                                     |                                 |
| 1011010     | Meat   | 0.1          | 0.1*                                | 0,1                             |
| 1011020     | Fat free of lean meat  | 0.1          | 0.1*                                | 0,1                             |
| 1011030     | Liver  | 0.1          | 0.1*                                | <b>0,2</b>                      |
| 1011040     | Kidney   | 0.1          | 0.1*                                | <b>0,2</b>                      |
| 1011050     | Edible offal   | 0.1          |                                     | <b>0,2</b>                      |
| 1011990     | Others   | 0.1          |                                     | 0,1                             |
| 1012000     | (b) Bovine   | 0.1          |                                     |                                 |
| 1012010     | Meat   | 0.1          | 0.1*                                | 0,1                             |
| 1012020     | Fat  | 0.1          | 0.1*                                | 0,1                             |
| 1012030     | Liver  | 0.1          | 0.20                                | <b>0,2</b>                      |
| 1012040     | Kidney   | 0.1          | 0.1*                                | <b>0,2</b>                      |
| 1012050     | Edible offal   | 0.1          |                                     | <b>0,2</b>                      |
| 1012990     | Others   | 0.1          |                                     | 0,1                             |
| 1013000     | (c) Sheep  | 0.1          |                                     |                                 |
| 1013010     | Meat   | 0.1          | 0.1*                                | 0,1                             |
| 1013020     | Fat  | 0.1          | 0.1*                                | 0,1                             |
| 1013030     | Liver  | 0.1          | 0.2                                 | <b>0,2</b>                      |
| 1013040     | Kidney   | 0.1          | 0.1*                                | <b>0,2</b>                      |
| 1013050     | Edible offal   | 0.1          |                                     | <b>0,2</b>                      |
| 1013990     | Others   | 0.1          |                                     | 0,1                             |
| 1014000     | (d) Goat   | 0.1          |                                     |                                 |
| 1014010     | Meat   | 0.1          | 0.1*                                | 0,1                             |
| 1014020     | Fat  | 0.1          | 0.1*                                | 0,1                             |

| Code number | Groups and examples of individual products to which the MRLs apply   | Tebuconazole |                                     |                                 |
|-------------|--|--------------|-------------------------------------|---------------------------------|
|             |  | Current MRLs | EFSA recommendations <sup>(a)</sup> | SANCO/10065/2013 <sup>(b)</sup> |
| 1014030     | Liver  | 0.1          | 0.2                                 | <b>0,2</b>                      |
| 1014040     | Kidney   | 0.1          | 0.1*                                | <b>0,2</b>                      |
| 1014050     | Edible offal   | 0.1          |                                     | <b>0,2</b>                      |
| 1014990     | Others   | 0.1          |                                     | 0,1                             |
| 1015000     | (e) Horses, asses, mules or hinnies  | 0.1          |                                     |                                 |
| 1015010     | Meat   | 0.1          |                                     | 0,1                             |
| 1015020     | Fat  | 0.1          |                                     | 0,1                             |
| 1015030     | Liver  | 0.1          |                                     | <b>0,2</b>                      |
| 1015040     | Kidney   | 0.1          |                                     | <b>0,2</b>                      |
| 1015050     | Edible offal   | 0.1          |                                     | <b>0,2</b>                      |
| 1015990     | Others   | 0.1          |                                     | 0,1                             |
| 1016000     | (f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon  | 0.1          |                                     | 0,1                             |
| 1016010     | Meat   | 0.1          | 0.1*                                | 0,1                             |
| 1016020     | Fat  | 0.1          | 0.1*                                | 0,1                             |
| 1016030     | Liver  | 0.1          | 0.1*                                | 0,1                             |
| 1016040     | Kidney   | 0.1          |                                     | 0,1                             |
| 1016050     | Edible offal   | 0.1          |                                     | 0,1                             |
| 1016990     | Others   | 0.1          |                                     | 0,1                             |
| 1017000     | (g) Other farm animals (Rabbit, Kangaroo)  | 0.1          |                                     |                                 |
| 1017010     | Meat   | 0.1          |                                     | 0,1                             |
| 1017020     | Fat  | 0.1          |                                     | 0,1                             |
| 1017030     | Liver  | 0.1          |                                     | <b>0,2</b>                      |
| 1017040     | Kidney   | 0.1          |                                     | <b>0,2</b>                      |
| 1017050     | Edible offal   | 0.1          |                                     | <b>0,2</b>                      |
| 1017990     | Others   | 0.1          |                                     | 0,1                             |
| 1020000     | (ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd | 0.05*        |                                     | 0,05*                           |
| 1020010     | Cattle   | 0.05*        | 0.02*                               | 0,05*                           |

| Code number | Groups and examples of individual products to which the MRLs apply  | Tebuconazole |                                     |                                 |
|-------------|---|--------------|-------------------------------------|---------------------------------|
|             |   | Current MRLs | EFSA recommendations <sup>(a)</sup> | SANCO/10065/2013 <sup>(b)</sup> |
| 1020020     | Sheep   | 0.05*        | 0.02*                               | 0,05*                           |
| 1020030     | Goat  | 0.05*        | 0.02*                               | 0,05*                           |
| 1020040     | Horse   | 0.05*        |                                     | 0,05*                           |
| 1020990     | Others  | 0.05*        |                                     | 0,05*                           |
| 1030000     | (iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter | 0.1          | 0.1*                                | 0,1                             |
| 1030010     | Chicken   | 0.1          |                                     | 0,1                             |
| 1030020     | Duck  | 0.1          |                                     | 0,1                             |
| 1030030     | Goose   | 0.1          |                                     | 0,1                             |
| 1030040     | Quail   | 0.1          |                                     | 0,1                             |
| 1030990     | Others  | 0.1          |                                     | 0,1                             |
| 1040000     | (iv) Honey (Royal jelly, pollen)  | 0.05*        |                                     | 0,05*                           |
| 1050000     | (v) Amphibians and reptiles (Frog legs, crocodiles)   | 0.05*        |                                     | 0,05*                           |
| 1060000     | (vi) Snails   | 0.05*        |                                     | 0,05*                           |
| 1070000     | (vii) Other terrestrial animal products   | 0.1          |                                     | 0,1                             |

(\* ) Indicates lower limit of analytical determination.

<sup>(a)</sup> The MRLs recommended by EFSA in its reasoned opinion on the review of the existing maximum residue levels for tebuconazole (EFSA, 2011a) and not yet voted by the SCFCAH. For details on the derived MRLs see the table footnotes of the reasoned opinion.

<sup>(b)</sup> MRLs voted in February 2012, not yet published, taking into account MRL proposals derived in response to MRL applications (EFSA, 2012) and acceptable Codex CXLs adopted in 2011.

## Appendix D. INPUT VALUES USED FOR CHRONIC CONSUMER RISK ASSESSMENT

The input values were derived in the framework of the MRL review (EFSA, 2011)

| Commodity   | Chronic risk assessment |   |
|---|-------------------------|---|
|   | Input value (mg/kg)     | Comment                                   |
| <b>Risk assessment residue definition: tebuconazole</b> |                         |   |
| Grapefruit  | 0.05                    | Median x PF <sup>(1)</sup>                |
| Oranges   | 0.05                    | Median x PF <sup>(1)</sup>                |
| Lemons  | 0.05                    | Median x PF <sup>(1)</sup>                |
| Limes   | 0.05                    | Median x PF <sup>(1)</sup>                |
| Mandarins   | 0.18                    | Median x PF <sup>(1)</sup>                |
| Almonds   | 0.05                    | Median residue <sup>(1)</sup>             |
| Brazil nuts   | 0.05                    | Median residue <sup>(1)</sup>             |
| Chestnuts   | 0.05                    | Median residue <sup>(1)</sup>             |
| Coconuts  | 0.05                    | Median residue <sup>(1)</sup>             |
| Hazelnuts   | 0.05                    | Median residue <sup>(1)</sup>             |
| Pecans  | 0.05                    | Median residue <sup>(1)</sup>             |
| Pistachios  | 0.05                    | Median residue <sup>(1)</sup>             |
| Walnuts   | 0.05                    | Median residue <sup>(1)</sup>             |
| Apples  | 0.13                    | Median residue <sup>(1)</sup>             |
| Pears   | 0.13                    | Median residue <sup>(1)</sup>             |
| Quinces   | 0.13                    | Median residue <sup>(1)</sup>             |
| Apricots  | 0.16                    | Median residue <sup>(1)</sup>             |
| Cherries  | 0.37                    | Median residue (tentative) <sup>(2)</sup> |
| Peaches   | 0.16                    | Median residue <sup>(1)</sup>             |
| Plums   | 0.11                    | Median residue <sup>(1)</sup>             |
| Table grapes  | 0.17                    | Median residue <sup>(1)</sup>             |
| Wine grapes   | 0.37                    | Median residue (tentative) <sup>(2)</sup> |
| Strawberries  | 0.02                    | MRL(=LOQ) <sup>(1)</sup>                  |
| Blackberries  | 0.10                    | Median residue <sup>(1)</sup>             |
| Raspberries   | 0.10                    | Median residue <sup>(1)</sup>             |
| Dewberries  | 0.10                    | Median residue (tentative) <sup>(2)</sup> |
| Blueberries   | 0.52                    | Median residue <sup>(1)</sup>             |
| Cranberries   | 0.52                    | Median residue <sup>(1)</sup>             |
| Currants (red, black and white)                         | 0.52                    | Median residue <sup>(1)</sup>             |
| Gooseberries  | 0.52                    | Median residue <sup>(1)</sup>             |
| Elderberries  | 0.35                    | Median residue <sup>(1)</sup>             |
| Table olives  | 0.05                    | Median residue <sup>(1)</sup>             |
| Passion fruit   | 0.03                    | Median x PF <sup>(1)</sup>                |

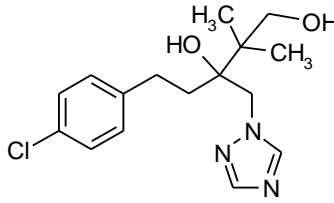
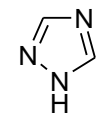
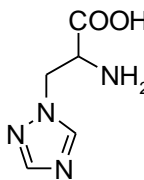
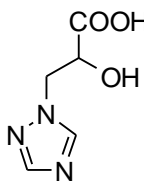
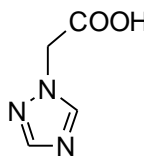
| Commodity                   | Chronic risk assessment |   |
|-----------------------------|-------------------------|---|
|                             | Input value (mg/kg)     | Comment                                   |
| Mangoes                     | 0.05                    | Median residue <sup>(1)</sup>             |
| Papaya                      | 0.36                    | Median residue <sup>(1)</sup>             |
| Carrots                     | 0.15                    | Median residue <sup>(1)</sup>             |
| Celeriac                    | 0.08                    | Median residue <sup>(1)</sup>             |
| Horseradish                 | 0.15                    | Median residue <sup>(1)</sup>             |
| Parsnips                    | 0.15                    | Median residue <sup>(1)</sup>             |
| Parsley root                | 0.15                    | Median residue <sup>(1)</sup>             |
| Salsify                     | 0.15                    | Median residue (tentative) <sup>(2)</sup> |
| Swedes                      | 0.12                    | Median residue <sup>(1)</sup>             |
| Turnips                     | 0.12                    | Median residue <sup>(1)</sup>             |
| Garlic                      | 0.04                    | Median residue <sup>(1)</sup>             |
| Onions                      | 0.04                    | Median residue <sup>(1)</sup>             |
| Shallots                    | 0.04                    | Median residue <sup>(1)</sup>             |
| Spring onions               | 0.11                    | Median residue <sup>(1)</sup>             |
| Tomatoes                    | 0.23                    | Median residue <sup>(1)</sup>             |
| Peppers                     | 0.26                    | Median residue <sup>(1)</sup>             |
| Aubergines (egg plants)     | 0.11                    | Median residue (tentative) <sup>(2)</sup> |
| Cucumbers                   | 0.08                    | Median residue <sup>(1)</sup>             |
| Courgettes                  | 0.08                    | Median residue <sup>(1)</sup>             |
| Melons                      | 0.09                    | Median residue (tentative) <sup>(2)</sup> |
| Pumpkins                    | 0.04                    | Median residue <sup>(1)</sup>             |
| Watermelons                 | 0.04                    | Median residue <sup>(1)</sup>             |
| Broccoli                    | 0.04                    | Median residue <sup>(1)</sup>             |
| Cauliflower                 | 0.05                    | Median residue <sup>(1)</sup>             |
| Brussels sprouts            | 0.06                    | Median residue <sup>(1)</sup>             |
| Head cabbage                | 0.05                    | Median residue <sup>(1)</sup>             |
| Chinese cabbage             | 0.46                    | Median residue <sup>(1)</sup>             |
| Kohlrabi                    | 0.05                    | EU MRL <sup>(3)</sup>                     |
| Witloof                     | 0.05                    | Median residue <sup>(1)</sup>             |
| Chives                      | 0.11                    | Median residue <sup>(1)</sup>             |
| Beans (fresh, with pods)    | 2.00                    | EU MRL <sup>(3)</sup>                     |
| Beans (fresh, without pods) | 2.00                    | EU MRL <sup>(3)</sup>                     |
| Asparagus                   | 0.02                    | MRL(=LOQ) <sup>(1)</sup>                  |
| Celery                      | 0.19                    | Median residue (tentative) <sup>(2)</sup> |

| Commodity   | Chronic risk assessment |   |
|---|-------------------------|---|
|   | Input value (mg/kg)     | Comment                                   |
| Globe artichokes  | 0.15                    | Median residue <sup>(1)</sup>             |
| Leek  | 0.21                    | Median residue <sup>(1)</sup>             |
| Beans (dry)   | 0.07                    | Median residue <sup>(1)</sup>             |
| Lentils   | 0.05                    | Median residue <sup>(1)</sup>             |
| Peas (dry)  | 0.07                    | Median residue <sup>(1)</sup>             |
| Lupins (dry)  | 0.07                    | Median residue <sup>(1)</sup>             |
| Linseed   | 0.14                    | Median residue <sup>(1)</sup>             |
| Peanuts   | 0.05                    | EU MRL <sup>(3)</sup>                     |
| Poppy seed  | 0.05                    | Median residue <sup>(1)</sup>             |
| Sunflower seed  | 0.05                    | EU MRL <sup>(3)</sup>                     |
| Rape seed   | 0.10                    | Median residue <sup>(1)</sup>             |
| Soya bean   | 0.02                    | Median residue <sup>(1)</sup>             |
| Mustard seed  | 0.05                    | Median residue <sup>(1)</sup>             |
| Gold of pleasure  | 0.10                    | Median residue <sup>(1)</sup>             |
| Olives for oil production   | 0.05                    | Median residue <sup>(1)</sup>             |
| Barley grain  | 0.68                    | Median residue <sup>(1)</sup>             |
| Oats grain  | 0.68                    | Median residue <sup>(1)</sup>             |
| Rice grain  | 0.28                    | Median residue (tentative) <sup>(2)</sup> |
| Rye grain   | 0.05                    | Median residue <sup>(1)</sup>             |
| Wheat grain   | 0.05                    | Median residue <sup>(1)</sup>             |
| Hops (dried)  | 9.65                    | Median residue (tentative) <sup>(2)</sup> |
| Spices (seeds)  | 0.40                    | Median residue (tentative) <sup>(2)</sup> |
| Sugar beet (root)   | 0.05                    | EU MRL <sup>(3)</sup>                     |
| <b>Risk assessment residue definition: sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole</b> |                         |   |
| Swine meat  | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Swine fat (free of lean meat)   | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Ruminant meat   | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Ruminant fat  | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Poultry meat  | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Poultry fat   | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Poultry liver   | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Cattle milk   | 0.02                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Sheep milk  | 0.02                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Goat milk   | 0.02                    | MRL (=LOQ) <sup>(4)</sup>                 |
| Birds' eggs   | 0.10                    | MRL (=LOQ) <sup>(4)</sup>                 |

(1): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.

- (2): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
- (3): Use reported by the RMS is not fully supported by data; the existing EU MRL is used for indicative exposure calculations.
- (4): Livestock dietary burden resulting from the GAPs reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.

**Appendix E. LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA**

| Common name          | IUPAC name  | Structural formula   |
|----------------------|---|--|
| Hydroxy-tebuconazole | 5-(4-chlorophenyl)-2,2-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentane-1,3-diol |    |
| 1,2,4-triazole       | 1H-[1,2,4]triazole  |   |
| triazole alanine     | 2-amino-3-[1,2,4]triazol-1-yl-propionic acid                                    |    |
| triazole lactic acid | [1,2,4]triazol-1-yl-lactic acid   |   |
| triazole acetic acid | [1,2,4]triazol-1-yl-acetic acid   |  |



## ABBREVIATIONS

|       |  |
|-------|--|
| ADI   | acceptable daily intake  |
| ARfD  | acute reference dose   |
| a.s.  | active substance   |
| BBCH  | growth stages of mono- and dicotyledonous plants   |
| bw    | body weight  |
| CAC   | Codex Alimentarius Commission  |
| CEN   | European Committee for Standardisation (Comité Européen de Normalisation, <i>French</i> )  |
| CF    | conversion factor for enforcement residue definition to risk assessment residue definition |
| CIPAC | Collaborative International Pesticide Analytical Council                                   |
| CXL   | Codex Maximum Residue Limit (Codex MRL)  |
| d     | day  |
| DAR   | Draft Assessment Report  |
| EC    | emulsifiable concentrate   |
| EC    | European Community   |
| EFSA  | European Food Safety Authority   |
| EMS   | evaluating Member State  |
| EU    | European Union   |
| FAO   | Food and Agriculture Organisation of the United Nations                                    |
| GAP   | good agricultural practice   |
| GC    | gas chromatography   |
| GS    | growth stage   |
| ha    | hectare  |
| hL    | hectolitre   |
| HPLC  | high performance liquid chromatography   |
| HR    | highest residue  |
| i.e.  | that is (id est, <i>Latin</i> )  |
| ILV   | independent laboratory validation  |
| IPCS  | International Programme of Chemical Safety   |
| ISO   | International Organisation for Standardisation   |
| IUPAC | International Union of Pure and Applied Chemistry  |
| JMPR  | Joint FAO/WHO Meeting on Pesticide Residues  |
| kg    | kilogram   |
| L     | litre  |

|           |   |
|-----------|---|
| LOAEL     | lowest observed adverse effect level                                |
| LOQ       | limit of quantification   |
| MRL       | maximum residue level   |
| MS        | Member States   |
| MS/MS     | tandem mass spectrometry  |
| NEU       | northern European Union   |
| NOAEL     | no observed adverse effect level                                    |
| MW        | molecular weight  |
| OECD      | Organisation for Economic Co-operation and Development              |
| PF        | processing factor   |
| PHI       | pre-harvest interval  |
| PRIMo     | (EFSA) Pesticide Residues Intake Model                              |
| QuEChERS  | Quick, Easy, Cheap, Effective, Rugged, and Safe (method)            |
| $R_{ber}$ | statistical calculation of the MRL by using a non-parametric method |
| $R_{max}$ | statistical calculation of the MRL by using a parametric method     |
| RAC       | raw agricultural commodity  |
| RD        | residue definition  |
| RMS       | rapporteur Member State   |
| SANCO     | Directorate-General for Health and Consumers                        |
| SCFCAH    | Standing Committee on the Food Chain and Animal Health              |
| SEU       | Southern European Union   |
| WHO       | World Health Organisation   |