Modification of the existing maximum residue levels for tebuconazole in olives, rice, herbs and herbal infusions (dried)

European Food Safety Authority (EFSA)
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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants ADAMA Agriculture Espana S.A., Sapec Agro SAU and LSA (Landesanstalt für Landwirtschaft, Forsten und Gartenbau) submitted requests to the competent national authorities in Spain and Germany, to modify the existing maximum residue levels (MRLs) for the active substance tebuconazole in olives, rice, herbs and herbal infusions (dried). The data submitted in support of the requests were found to be sufficient to derive MRL proposals for all the crops under consideration. Adequate analytical methods for enforcement are available to control the residues of tebuconazole on the commodities under consideration at the validated limit of quantification (LOQ) of 0.02 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of tebuconazole according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: tebuconazole, various crops, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture Espana S.A., Sapec Agro SAU and Landesanstalt für Landwirtschaft, Forsten und Gartenbau Sachsen-Anhalt, Dezernat Pflanzenschutz submitted applications to the competent national authorities in Spain and Germany (evaluating Member States (EMSs)) to modify the existing maximum residue levels (MRLs) for the active substance tebuconazole in olives, rice, herbs and herbal infusions (dried). Spain and Germany drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 17 July 2017 (olives), 29 August 2017 (herbal infusions) and 31 October 2017 (rice). To accommodate for the intended uses of tebuconazole, the EMSs proposed to raise the existing MRLs from 0.05 mg/kg to 0.5 mg/kg for olives, to 6 mg/kg for fresh herbs, to 40 mg/kg for herbal infusions and from 1 mg/kg to 4 mg/kg for rice.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMSs. On 12 February 2018, Germany submitted a revised evaluation report (Germany, 2018), which replaced the previously submitted evaluation report and on 27 February 2018, Spain clarified the requested information that the residues trials tested husked rice.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the additional data provided by the EMSs in the framework of these applications, the following conclusions are derived.

The metabolism of tebuconazole in primary corps has been investigated after foliar applications in the groups of fruits, cereals and pulses/oilseeds and after seed treatment in cereals. Studies investigating the effect of processing on the nature of tebuconazole (hydrolysis studies) demonstrated that the active substance is stable. In rotational crops, the major residues identified were the parent compound and triazole derivative metabolites (TDMs).

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

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.02 mg/kg in the crops assessed (limit of quantification (LOQ)).

The available residue trials are sufficient to derive MRL proposals of 0.5 mg/kg for table olives and olives for oil production; 2 mg/kg for the subgroup of herbs and edible flowers; 15 mg/kg for herbal infusions from flowers, leaves and herbs; and 1.5 mg/kg for rice. Risk managers may consider the setting of a MRL for summer savory which is a crop listed in the EU food classification for MRL setting under thyme.

Processing factors (PF) for the crops under assessment were derived from processing studies provided and are recommended to be included in Annex VI of Regulation (EC) No 396/2005 as follows:

- Olives for oil production/cold pressed olive oil: 1.6
- paddy rice/husked rice: 0.17
- paddy rice/polished rice: 0.10
- husked rice/polished rice: 0.57

The occurrence of tebuconazole residues in rotational crops was investigated in the framework of the EU pesticides peer review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

As rice and/or its by-products are used as feed products, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant animal species. However, the contribution of tebuconazole residues in the crops under consideration in this MRL application to the total livestock exposure was insignificant, and therefore, a modification of the existing MRLs for commodities of animal origin was considered unnecessary.
The toxicological profile of tebuconazole was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.03 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO).

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application. The highest international estimated short-term intake (IESTI) was up to 9.7% of the ARfD for rice, 19.1% of the ARfD for celery leaves, 3.5% of the ARfD for table olives and 1.3% of the ARfD for olive oil. Exposure from herbal infusion is negligible.

The estimated long-term dietary intake accounted for up to 16.5% of the ADI for (WHO Cluster diet B). Among the crops under consideration, olives for oil production was the major contributor to the total consumer exposure accounting for a maximum of 0.9% of the ADI for WHO Cluster diet B.

EFSA concluded that the proposed use of tebuconazole on olives, rice, herbs and herbal infusions (dried) will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA emphasises that the above assessment does not yet take into consideration TDMs. As these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

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

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|-------------------------|-------------------------|-----------------------|
| 0161030 | Table olives | 0.05 | 0.5 | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted. |
| 0402010 | Olives for oil production | 0.05 | 0.5 | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted. |
| 0256000 | Herbs and edible flowers | 0.05*–2 | 2 | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. Further risk management considerations required whether the group MRL can be applied for summer savory (0256070-008). An outstandingly high residue observed in one trial exceeded the MRL proposed for the whole subgroup. Data set too small to derive specific MRL. The consumer risk assessment of TDMs has not been conducted. |
| 0631000 | Herbal infusion from flowers, leaves and herbs | 0.05* | 15 | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted. |
| 0632000 | Rice | 1.0 | 1.5 | The submitted data are sufficient to derive a MRL proposal for the SEU use. The MRL proposal relates to husked rice. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted. |

MRL: maximum residue level; SEU: southern Europe; TDM: triazole derivative metabolite; NEU: northern Europe.

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

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

The detailed description of the intended uses of tebuconazole in olives for oil production, table olives, rice, fresh herbs and herbal infusions (dried), which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Tebuconazole is the ISO common name for (RS)-1-\(p\)-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Tebuconazole was evaluated in the framework of Directive 91/414/EEC\(^1\) with Denmark, designated as rapporteur Member State (RMS) for the representative uses as foliar applications on wheat, barley, oat, rye and grape and seed dressing for barley. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2008, 2014). The process of renewal of the first approval has not yet been initiated. Tebuconazole was approved\(^2\) for the use as fungicide on 1 September 2009.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2011) and the proposed modifications have been implemented in the MRL legislation. The European Union (EU) MRLs for tebuconazole are established in Annexes II of Regulation (EC) No 396/2005\(^3\). After completion of the MRL review, EFSA has issued several reasoned opinions on the modification of MRLs for tebuconazole (EFSA, 2012, 2013, 2015a,b, 2017). The proposals from these reasoned opinions have been considered in recent regulations\(^4\) for EU MRL legislation, except the one recently published (EFSA, 2017).

In accordance with Article 6 of Regulation (EC) No 396/2005, ADAMA Agriculture Espana S.A., Sapec Agro SAU and Landesanstalt für Landwirtschaft, Forsten und Gartenbau Sachsen-Anhalt, Dezernat Pflanzenschutz submitted applications to the competent national authorities in Spain and Germany (evaluating Member States (EMSS)) to modify the existing MRLs for the active substance tebuconazole in olives, rice, herbs and herbal infusions (dried). Spain and Germany drafted evaluation reports in accordance with Article 8 of Regulation (EC) No 396/2005, which were submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 17 July 2017 (olives), 29 August 2017 (herbal infusions) and 31 October 2017 (rice). To accommodate for the intended uses of tebuconazole, the EMSSs proposed to raise the existing MRLs from 0.05 mg/kg to 0.5 mg/kg for olives for oil production and table olives; to 6 mg/kg for fresh herbs, to 40 mg/kg for herbal infusions and from 1 mg/kg to 4 mg/kg for rice.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMSs. On 12 February 2018, Germany submitted a revised evaluation report (Germany, 2018), which replaced the previously submitted evaluation report and on 27 February 2018, Spain clarified the requested information that the residues trials tested husked rice.

EFSA based its assessment on the evaluation reports submitted by the EMSSs (Spain, 2016a,b; Germany, 2018), the DAR and its addenda (Denmark, 2007, 2008, 2012, 2013) prepared under Council Directive 91/414/EEC, the Commission review report on tebuconazole revised in July 2014 (European Commission, 2008, 2014), the conclusions on the peer review of the pesticide risk assessment of the active substance tebuconazole (EFSA, 2008, 2014), the Joint Meeting on Pesticide Residues (JMPR) evaluation reports (FAO, 2011, 2015), as well as the conclusions from previous EFSA opinions on tebuconazole, including Reasoned opinion on the review of the existing MRLs according to Article 12 of Regulation EC) No 396/2005 (MRL review) (EFSA, 2011, 2012, 2013, 2015a,b, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^5\) and the guidance documents applicable at the date of submission of the application to the EMSs are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is

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\(^{1}\) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.

\(^{2}\) Commission Directive 2008/125/EC of 19 December 2008 amending Council Directive 91/414/EEC to include aluminium phosphide, calcium phosphide, cyxomaxan, dodemorph, 2,5-dichlorobenzoic acid methylester, metamitron, sulcotrine, tebuconazole and triadimenol as active substances. OJ L 344, 20.12.2008, p. 78–88.

\(^{3}\) Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.

\(^{4}\) For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/ eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN.

\(^{5}\) Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
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.

The detailed description of the intended uses of tebuconazole in olives, rice, herbs and herbal infusions (dried), which are the basis for the current MRL application, is reported in Appendix A.

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

The evaluation reports submitted by the EMSs (Spain, 2016a,b, Germany, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion. Furthermore, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

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

For the reported uses of tebuconazole under consideration, the metabolic behaviour in primary crops is sufficient addressed. It is noted that the preferential metabolism/degradation of the enantiomers in plants as requested during the peer review was not investigated (EFSA, 2014).

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

Since rice and fresh herbs may be grown in rotation with other plants and since tebuconazole degrades in soil with maximum DT$_{90}$ values exceeding 100 days (EFSA, 2008), the possible occurrence of residues in rotational crops resulting from the use on primary crops was investigated. During the peer review, the metabolism of tebuconazole following soil treatment was assessed in rotational crops belonging to the groups of leafy vegetables (kale), root and tuber vegetables (red beets) and cereals (spring wheat) in three studies (EFSA, 2008). Based on these studies, it was concluded that the metabolism in primary and rotational crops is similar.

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

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

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of tebuconazole residues in plant commodities were assessed during the EU pesticides peer review and the MRL review (EFSA, 2008, 2011, 2014). The multiresidue DFG-S19 was concluded to be sufficiently validated in high water content (tomato, onion, cauliflower), high oil content (rape), acidic (orange) and dry (wheat) commodities at or above the LOQ of 0.02 mg/kg (EFSA, 2014). In addition, the multiresidue Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) method is sufficiently validated at or above the LOQ of 0.01 mg/kg in high water content, acidic and dry commodities (EFSA, 2011). Additional validation data for the QuEChERS method were provided for high oil content commodities (olives and olive oil) supporting the present application; the data demonstrate that a LOQ of 0.01 mg/kg is achievable (Spain, 2016a). These methods quantify residues of tebuconazole as sum of its enantiomers (not stereo-selective).

EFSA concludes that sufficiently validated analytical methods are available for the crops under consideration (i.e. fresh herbs, olives for oil production and table olives and rice) belonging to the high water, high oil content and dry matrix crop groups. None of the above reported methods was specifically validated for herbal infusions. However, considering that QuEChERS methods were
successfully validated in all four major matrices, the physical-chemical properties of tebuconazole and the availability of a method used in residue trials for dry herbs (Germany, 2018) provides sufficient evidence that the MRL in herbal infusions may be enforced by the method DFG-S19 using a gas chromatography with mass spectrometry detector (GC-MSD) at a LOQ of 0.05 mg/kg.

1.1.5. Stability of residues in plants

The storage stability of tebuconazole in high water (apple, cherry, peach), high oil (peanut), high acid (grape) content and dry (wheat grain, straw) plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2011). It was demonstrated that in the crops assessed in the framework of this application, residues were stable for at least 30 months when stored at –20°C.

1.1.6. Proposed residue definitions

Based on the metabolic pattern, the hydrolysis studies, the toxicological significance of metabolites, the capabilities of enforcement analytical methods and that TDMs are not metabolites specific to tebuconazole, but are common to a number of triazole fungicides the peer review and the MRL review proposed parent tebuconazole (sum of enantiomers) as provisional residue definition for enforcement and risk assessment purposes in all plants (EFSA, 2008, 2011, 2014). The residue definitions were set provisionally pending the development of a risk assessment methodology and the outcome of the comprehensive risk assessment for TDMs (EFSA, 2008, 2014).

The current residue definition set in Regulation (EC) No 396/2005 refers to the active substance tebuconazole. EFSA concludes that these residue definitions are applicable to the crops under consideration for the present evaluation and no further information is required. Once the comprehensive risk assessment on TDMs is available, the existing EU MRLs for triazole fungicides, including tebuconazole, may need to be reconsidered.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the application, residue trials on olives, fresh and dry herbs and rice were submitted. Residue data were presented for tebuconazole only, without differentiating the enantiomers. No data were provided regarding the residue levels of TDMs.

According to the assessment of the EMSs, the analytical methods used were sufficiently validated and fit for purpose and samples were taken and stored in compliance with the demonstrated storage conditions (Spain, 2016a,b; Germany, 2018).

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Appendix B.1.2.1.

Table olives and olives for oil production

Eight residue trials compliant with the southern Europe (SEU) outdoor GAP were provided to support the MRL application. The data were sufficient to derive a MRL proposal of 0.5 mg/kg reflecting the SEU GAP.

Fresh herbs

In total, 15 residue trials compliant with the northern Europe (NEU) outdoor GAP were provided on chervil (2 trials), parsley (8 trials), savory (2 trials) and sage (3 trials). For parsley, two trials were conducted at the same location with only 2 weeks of difference; since these trials were not sufficiently independent the average residue was calculated and was used in the database to derive the MRL proposal (OECD, 2016).

According to the EU guidance document (European Commission, 2017), extrapolation from any representative of the subgroup herbs and edible flowers to the whole subgroup is possible, except from sage, thyme, rosemary or laurel leave. The trials on parsley and chervil are representative commodities of the whole subgroup, they are morphologically similar and therefore the data sets may be combined (OECD, 2016).
Trials with summer savory, which is a non-representative commodity belonging to the category of thyme (Annex I of Regulation (EC) 396/2005; Part B), and trials on sage were not combined with the other trials in line with the extrapolation rules (European Commission, 2017).

Considering the combined data set of parsley and chives a MRL proposal of 2 mg/kg for the whole subgroup of fresh herbs and edible flowers based on the NEU GAP can be derived.

It is noted that the results in sage are comparable with the results in parsley and chives and including sage in the data set used for calculating the MRL proposal would not have had an impact on the outcome. However, the results for summer savory showed residues at 0.18 and 4.4 mg/kg. Thus, the MRL proposal may not be appropriate for summer savory. As no information is available that explains the high residue observed in the given trial, a distinct, higher MRL proposal for summer savory might be more appropriate. However, the limited data set does not allow the derivation of a specific MRL.

Herbal infusions (dry)

Seven trials on herbal infusions (peppermint, lemon balm and St. John’s wort) were provided, but could not be considered, as none of them were GAP compliant. Four of them were overdosed, but since both the number and rate of application is increased scaling could not be applied. However, the EU guidance document (European Commission, 2017) allows extrapolation from any representative of the subgroup of herbs and edible flowers in case an appropriate concentration factor is applied. Although for herbal infusions no restrictions on representative herbs that could be considered is given, the extrapolation was based on the same trials as used to extrapolate to the above subgroup of fresh herbs. The European Spice Association proposed product specific dehydration factors6 for herbs, including 5 for chervil and 6 for parsley, which were applied to the respective trials. The data were sufficient to derive a MRL proposal of 15 mg/kg for the whole subgroup of ‘herbal infusions from leaves and herbs’.

Rice

Eight SEU GAP-compliant residue trials were submitted in support of the application. Tebuconazole residues were measured both in grains and in straw. For the residue trials where information on residues was available only in paddy rice, the processing factor as derived in Section 1.2.3 for husked rice was applied.

In addition, eight residue trials were assessed during the MRL review. It is noted that EFSA received confirmation that in these trials residues in grain were reported for husked rice. In the MRL review, the MRL proposal was only tentative due to potential overestimation of residues as the applications in the trials were carried out at a later growth stage than indicated in the GAP (BBCH 59–69 instead of BBCH 53). However, these residue trials are fully compliant with the GAP assessed in the present application; therefore the two data sets were merged.

The data was sufficient to derive a MRL proposal of 1.5 mg/kg for husked rice based on the SEU GAP.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of tebuconazole residues to crops that are grown in crop rotation has been assessed in the MRL review (EFSA, 2011). The uptake by rotational crops was not expected to lead to tebuconazole residues above the LOQ. In contrast, a significant uptake of TDMs was observed. The residue situation in rotational crops should be reconsidered when a comprehensive approach on TDMs will be available.

Since the application rate of tebuconazole on the crops under consideration is similar or less critical compared with the uses assessed in the framework of the article 12 MRLs review (EFSA, 2011), no significant levels of tebuconazole residues are expected in crops grown in rotation with the crops under consideration, provided that tebuconazole is applied according to the intended GAP.

1.2.3. Magnitude of residues in processed commodities

Four residue trials investigating the effect of processing on the magnitude of residues in (extra) virgin oil produced from olives were submitted (Spain, 2016a). Based on tebuconazole residues measured in unprocessed olives and in respective cold pressed olive oil in accordance with the guidance (OECD, 2008), a median processing factor of 1.6 could be established (see Appendix B.1.2.3).

Four residue trials investigating the effect of processing on the magnitude of residues in grains of husked rice and polished rice obtained following processing of paddy rice. In line with the guidance

6 Published on the website of the European Spice Association: https://www.esa-spices.org/index-esa.html/publications-esa
(OECD, 2008), based on tebuconazole residues measured in paddy rice, in husked rice and in polished rice, a median processing factor of 0.17 and 0.10 could be derived from paddy rice to husked rice and polished rice, respectively, and 0.57 from husked rice to polished rice (see Appendix B.1.2.3).

Considering these studies, EFSA recommends to include the mean processing factors established for cold pressed olive oil, husked and polished rice in Annex VI of Regulation (EC) No 396/2005.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

EFSA concludes that the submitted residue trials are sufficient to derive MRL proposals for all the crops under assessment. Risk managers may need to consider whether the group MRL is relevant to summer savory, a non-representative crop, for which there is indication that this MRL may not be sufficient.

2. Residues in livestock

As rice grain in the form of bran/pollard may be used for feed purposes, the dietary burden calculation for livestock performed in the framework of the MRL review (EFSA, 2011) was updated. It is noted that rice was already considered in the MRL review, using the HR/STMR derived in the framework of the MRL review (EFSA, 2011). The input values for the exposure calculations for livestock are presented in Appendix D.1 and the results of the dietary burden calculation are presented in Appendix B.2. Although exposure for all species exceeded the trigger values defined in the relevant guidance, inclusion of rice did not have a significant impact on the median and maximum animal burden calculation, which is driven by exposure from barley straw and dried citrus pulp (see Appendix B.2). Therefore, EFSA concluded that following the intended use, rice as a feed item does not contribute significantly to the livestock dietary burden and there is no need to modify the existing EU MRLs in products of animal origin listed in Regulation (EU) 2017/6267.

3. Consumer risk assessment

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

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (EFSA, 2007). The complete list of input values is presented in Appendix D.2.

The short-term exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest residue (HR) level as observed in supervised field trials, except for the bulk commodity rice, for which the STMR value was used (Appendix B.1.2.1).

The short-term exposure did not exceed the ARfD for any of the crops assessed in this application (see Appendix C); no risk was identified for the consumers. The highest international estimated short-term intake (IESTI) was up to 9.7% of the ARfD for rice, 19.1% of the ARfD for celery leaves, 3.5% of the ARfD for table olives and 1.3% of the ARfD for olive oil.

The long-term exposure assessment was performed taking into account the STMR values derived for the commodities assessed in this application and for the remaining commodities taking into account the STMR values derived in the MRL review and the previous reasoned opinions (EFSA, 2011, 2012, 2013, 2015a,b, 2017). The STMRs as derived by the JMPR were also included, to consider the contribution of Codex maximum residue limits (CXLs) (FAO, 2011, 2015) implemented in the European legislation following the MRL Review.

The estimated long-term dietary intake accounted for up to 16.5% of the ADI for (WHO Cluster diet B). Among the crops under consideration, olives for oil production was the major contributor to the total consumer exposure accounting for a maximum of 0.9% of the ADI for WHO Cluster diet B.

7 Commission Regulation (EU) No 2017/626 of 31 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, cyantraniliprole, cypermethrin, cyprodinil, difenoconazole, ethephon, fluopyram, fluothion, flupyradazol, imazapic, imazapyr, lambda-cyhalothrin, mesotrione, profenofos, propiconazole, pyrimethanil, spirotetramat, tebuconazole, triazophos and trifloxystrobin in or on certain products. OJ L96, 7.4.2017, p. 1-43.
EFSA concludes that the long-term intake of residues of tebuconazole resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Based on these calculations, EFSA concludes that the proposed use of tebuconazole on the crops assessed is unlikely to pose a risk for the consumers. However, the consumer risk assessment has considered the residues of tebuconazole only. The contribution of the TDMs residues in primary crops, rotational crops and products of animal origin resulting from the use of tebuconazole has not been evaluated. In view of this, the consumer risk assessment is considered tentative and may need to be revised when a comprehensive review of the existing uses of several pesticides belonging to the group of triazole fungicides is carried out.

In addition, the above assessment does not consider the possible impact of plant and animal metabolism on the isomer ratio of the active substance and further investigation on this matter would in principle be required. Since guidance is not yet available on the consideration of isomer ratios in the consumer risk assessment, EFSA recommends that this issue is reconsidered when such guidance is available.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive a MRL proposal for table olives, olives for oil production, rice, fresh herbs and herbal infusions (dried).

EFSA concluded that the proposed use of tebuconazole on the crops under consideration will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA emphasises that the above consumer assessment does not yet take into consideration TDMs. As these metabolites may be generated by several pesticides belonging to the group of triazole fungicides, EFSA recommends that a separate risk assessment should be performed for TDMs as soon as the confirmatory data requested for triazole compounds in the framework of Regulation (EC) No 1107/2009 have been evaluated and a general methodology on the risk assessment of triazole compounds and their TDMs is available.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CXL Codex maximum residue limit
DALA days after last application
DAR draft assessment report
DAT days after treatment
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
EW emulsion in water
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-ECD gas chromatography with electron capture detector
GC-MSD gas chromatography with mass spectrometry detector
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
STMR supervised trials median residue
TDM triazole derivative metabolite
TRR total radioactive residue
WHO World Health Organization
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|--------------------------------|---------------|---------|
| Olives for oil production and table olives | SEU F | *Spilocaea olegina* *Gloeosporium olivarum* | SC | 36 g/L | Normal volume/spraying/overall tractor broadcast air assisted | Up to PHI Feb-Oct | 2 | 120 days | 5.4-9 | 500-1,000 | 72 | g/ha | 15 | 150-250 mL/hL (or 0.15–0.25%) with a maximum of 2 L |
| Fresh herbs | NEU F | *Puccinia* spp., *Erysiphe* spp. | EW | 250 g/L | Spray | From the beginning of infestation | 1 | NA | 50–100 | 200–400 | 200 | g/ha | 14 | – |
| Herbal infusions | NEU F | *Puccinia* spp., *Erysiphe* spp. | EW | 250 g/L | Spray | From the beginning of infestation | 1 | NA | 50–100 | 200–400 | 200 | g/ha | 14 | – |
| Rice | SEU F | *Helminthosporium oryzae*, *Pyricularia oryzae* | EW | 250 g/L | Foliar spray | BBCH 30–69 | 2 | 14 | 62.5 | 400 | 250 | g/ha | 35 | – |

NEU: northern European Union; SEU: southern European Union; MS: Member State; NA: not applicable; GAP: good agricultural practice; MRL: maximum residue level; a.s.: active substance; SC: suspension concentrate; EW: emulsion in water.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Grape       | Foliar, 1 × 280 g/ha | 0, 3, 7, 14, 21, 28 DAT | [Phenyl-UL-14C]-tebuconazole Denmark (2008) |
| Cereals/grass                     | Wheat       | Foliar, 1 × 500 g/ha | 0, 7, 14, 21, 28, 50 DAT | [Triazole-3,5-14C]-tebuconazole Denmark (2008) |
| Seed, 11 g/100 kg seed           |             |         | 38, 66 days after planting |                |
| Pulses/oilseeds                  | Peanut      | Foliar, 3 × 250 g/ha, 14 days interval | 49 DALA | [Triazole-3,5-14C]-tebuconazole or [chlorophenyl-UL-14C]-tebuconazole Denmark (2008) |
| Foliar, 3 × 250 g/ha, 14 days interval |          |         | 98 DALA |                |
| Foliar, 7 × 82.6 g/ha, 14 days interval |      |         | 14 DALA |                |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|----------|----------------|
| Root/tuber crops                     | Red beet    | 2 × 500 g/ha or 560 g/ha | 30, 136, 273 | First application (14C-triazole label) on wheat and second on bare soil or one application (14C-phenyl label) on bare soil Denmark (2008) |
| Leafy crops                          | Kale        | 2 × 500 g/ha or 560 g/ha | 30, 136, 273 | First application (14C-triazole label) on wheat and second on bare soil or one application (14C-phenyl label) on bare soil Denmark (2008) |
| Cereal (small grain)                 | Spring wheat| 2 × 500 g/ha or 1 × 560 g/ha | 30, 136, 273 | First application (14C-triazole label) on wheat and second on bare soil or one application (14C-phenyl label) on bare soil Denmark (2008) |
| Wheat                                |             | 2,500 g/ha | 32, 152 | Application (14C-phenyl label) on bare soil Denmark (2008) |
Processed commodities (hydrolysis study)

| Conditions                                | Stable? | Comment/source                                      |
|-------------------------------------------|---------|-----------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4)       | Yes     | [Phenyl-UL-14C]-tebuconazole/Denmark (2008)         |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | [Phenyl-UL-14C]-tebuconazole/Denmark (2008)         |
| Sterilisation (20 min, 120°C, pH 6)       | Yes     | [Phenyl-UL-14C]-tebuconazole/Denmark (2008)         |

DAT: days after treatment; DALA: days after last application; PBI: plant-back interval.

Can a general residue definition be proposed for primary crops?
- Yes  TDMs were not assessed

Rotational crop and primary crop metabolism similar?
- Yes  TDMs were not assessed

Residue pattern in processed commodities similar to residue pattern in raw commodities?
- Yes  TDMs were not assessed

Plant residue definition for monitoring (RD-Mo; RD-RA)
- Tebuconazole (sum of enantiomers)
  (Provisional, pending outcome of a comprehensive risk assessment on TDMs)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
- Matrices with high water content (tomato, onion, cauliflower), high oil content (rape), high acid (orange) content and dry (wheat) matrices:
  GC-ECD (DFG-S19 method), LOQ 0.02 mg/kg (EFSA, 2014)
- 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, LOQ 0.01 mg/kg (EFSA, 2011)
- High oil (raw oil; olives) content:
  LC–MS/MS (QuEChERS, EN 15662:2009-02), LOQ 0.01 mg/kg (Spain, 2016a) validated.
- Difficult to analyse matrices (herbal infusions, dry):
  GC-MSD (DFG-S19 method), LOQ 0.05 mg/kg (Germany, 2018). Validation report is not included.

TDM: triazole derivative metabolite; GC-ECD: gas chromatography with electron capture detector; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; GC-MSD: gas chromatography with mass spectrometry detector.
## B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category               | Commodity          | T (°C) | Stability period | Value | Unit | Compounds covered | Comment/source |
|-----------------------------------|------------------------|--------------------|--------|------------------|-------|------|-------------------|----------------|
|                                   | High water content     | Apple, cherry, peach, prunes | –20    | 30 Months       |       |      | Tebuconazole      | EFSA (2008)    |
|                                   | High oil content       | Peanut             | –20    | 30 Months       |       |      | Tebuconazole      | EFSA (2008)    |
|                                   | Dry/High starch        | Wheat grain        | –20    | 30 Months       |       |      | Tebuconazole      | EFSA (2008)    |
|                                   | High acid content      | Grape              | –20    | 30 Months       |       |      | Tebuconazole      | EFSA (2008)    |
|                                   | Processed products     | Peanut oil, wheat flour, wheat bran, raisin | –20 | 24 Months |       |      | Tebuconazole      | EFSA (2008)    |
|                                   | Others                 | Wheat straw        | –20    | 30 Months       |       |      | Tebuconazole      | EFSA (2008)    |
|                                   |                        | forage             | –20    | 30 Months       |       |      | Tebuconazole      | EFSA (2008)    |
## B.1.2. Magnitude of residues in plants

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

| Commodity                        | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|----------------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|---------------|-----------------|
| Table olives                     | SEU              | 0.07, 0.09, 0.11, 0.13, 0.14, 0.16, 0.22, 0.31                  | Residue trials on olives compliant with GAP                                    | 0.5                    | 0.31          | 0.14            |
| Olives for oil production        | SEU              | 0.07, 0.09, 0.11, 0.13, 0.14, 0.16, 0.22, 0.31                  | Residue trials on olives compliant with GAP                                    | 0.5                    | 0.31          | 0.14            |
| Fresh herbs                      | NEU              | Chervil: 0.08, 0.36; Parsley: 0.13, 0.41, 0.44, 0.58(d), 0.75, 0.98, 1.00; | Residue trials on chervil and parsley compliant with GAP. Extrapolation to subgroup of fresh herbs possible from chervil and parsley; thus, MRL, HR and STMR values based on pooled residues from these trials. In addition, trials were provided on sage (0.11, 0.37, 0.42) and summer savory (0.18, 4.40) which were not considered for deriving the group MRLs. | 2                      | 1.00          | 0.44            |
| Herbal infusions                 | NEU              | Trials based on fresh herbs: Chervil: 0.39, 1.80 Parsley: 0.78, 2.46, 2.64, 2.94, 3.96, 4.50, 5.88, 6.00 | Residue trials on fresh herbs compliant with GAP and applying a dehydration factor of 6 for trials on parsley and 5 for trials on chervil to extrapolate to dry herbs | 15                     | 6            | 2.64            |
| Rice (grain)                     | SEU              | New trials: Grain (husked): 0.06\textsuperscript{PF}, 2 × 0.21, 2 × 0.21\textsuperscript{PF}, 0.22\textsuperscript{PF}, 0.32, 0.44 Article 12: Grain (husked): 0.11, 0.12, 0.24, 0.26, 0.29, 0.33, 0.53 and 0.97 | Residue trials on rice, both new and in Article 12 compliant with GAP. ‘PF’ indicates that residue levels in husked rice were derived from residues in paddy rice applying a processing factor of 0.17. Data sets merged as all residue trials were GAP compliant | 1.5                    | 0.97          | 0.23            |
| Rice (straw)                     | SEU              | New trials: 0.09, 1.24, 1.7, 2.86, 2.93 4.09, 6.21            | Residue trials on rice compliant with GAP                                      | 1.5                    | 6.21          | 2.86            |

MRL: maximum residue level; GAP: good agricultural practice; PF: processing factor.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe.
(b): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Mean of 2 dependent residue trials.
B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

Yes

In confined rotational crop studies, tebuconazole was found at relevant levels in succeeding crops. In kale, up to 15% of TRR (0.05 mg/kg 4N) or 45% of the TRR (0.048 mg/kg, bare soil 1.125N); in beet roots up to 35% of the TRR (0.017 mg/kg, bare soil; 1.125N); and up to 2.27 mg/kg in wheat straw, forage and chaff (bare soil, 5N)

Studies indicated that also triazole derivative metabolites (TDMs) may be relevant metabolites in succeeding crops

No

Based on the field rotational crop studies, tebuconazole residues are not expected in succeeding crops if used according to the intended GAP

TDMs may be of concern in rotational crops. As these may be generated by several triazole fungicides, a separate assessment is needed when guidance will be available

TRR: total radioactive residue; GAP: good agricultural practice.

B.1.2.3. Processing factors

| Processed commodity                  | Number of valid studies | Processing Factor (PF)         | Comment/Source                           |
|--------------------------------------|-------------------------|--------------------------------|------------------------------------------|
|                                       | Individual values       | Median PF                      |                                          |
| Olives/(extra) virgin oil            | 4                       | 0.5, 1.6, 1.7, 2.1              | Based on tebuconazole only Spain (2016a) |
| Paddy rice/Husked rice               | 4                       | 0.18, 0.17, 0.24, 0.13          | Based on tebuconazole only Spain (2016b) |
| Paddy rice/Polished rice             | 4                       | 0.10, 0.10, 0.14, 0.08          | Based on tebuconazole only Spain (2016b) |
| Husked rice/Polished rice            | 4                       | 0.57, 0.62, 0.56, 0.57          | Based on tebuconazole only Spain (2016b) |
B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|----------------------------|-----------------------------|---------------------------|---------------------------|-----------------------|
|                            | mg/kg bw per day mg/kg DM | Median Maximum            | Median Maximum            |                       |
| Cattle (all)               | 0.203 0.356 5.28 9.26      | Dairy cattle              | Barley straw              | Yes                   |
| Cattle (dairy only)        | 0.203 0.356 5.28 9.26      | Dairy cattle              | Barley straw              | Yes                   |
| Sheep (all)                | 0.204 0.529 4.80 12.45     | Lamb                      | Barley straw              | Yes                   |
| Sheep (ewe only)           | 0.160 0.415 4.80 12.45     | Ram/Ewe                   | Barley straw              | Yes                   |
| Swine (all)                | 0.069 0.085 2.97 3.67      | Swine (breeding)          | Citrus dried pulp         | Yes                   |
| Poultry (all)              | 0.087 0.137 1.27 2.00      | Poultry layer             | Barley straw              | Yes                   |
| Poultry (layer only)       | 0.087 0.137 1.27 2.00      | Poultry layer             | Barley straw              | Yes                   |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

B.3. Consumer risk assessment

ARfD 0.03 mg/kg bw (European Commission, 2008)

Highest IESTI, according to EFSA PRIMo
- Rice: 9.7% of ARfD
- Table olives: 3.5% of ARfD
- Olives for oil production: 1.3% of ARfD
- Fresh herbs: up to 19.1% of ARfD (celery leaves)
- Herbal infusion: negligible contribution

Assumptions made for the calculations
- The calculation is based on the highest residue levels expected in raw agricultural commodities assuming no change in residues isomer ratio (1:1), except for rice where the STMR was applied
- TDMs were not assessed

ADI 0.03 mg/kg bw per day (European Commission, 2008)

Highest IEDI, according to EFSA PRIMo
- 16.5% ADI (WHO Cluster diet B)
- Contribution of crops assessed:
  - Rice: 0.6% of ADI
  - Table olives: 0.04% of ADI
  - Olives for oil production: 0.9% of ADI
  - Fresh herbs: up to 0.07% (parsley)
  - Herbal infusion: no contribution

Assumptions made for the calculations
- The calculation is based on the median residue levels of tebuconazole derived for raw agricultural commodities (or tentative MRL when median value was not available) assuming no change in residues isomer ratio (1:1). Peeling factor for citrus and passion fruits were applied (EFSA, 2011, 2012).
- TDMs were not assessed.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; TDM: triazole derivative metabolite; ADI: acceptable daily intake; IEDI: international estimated daily intake; WHO: World Health Organization.
### B.4. Recommended MRLs

| Code(a) | Commodity                          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                                                                                                                                                                                                                 |
|---------|------------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0161030 | Table olives                       | 0.05                    | 0.5                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted                                                                                                                                                                                                 |
| 0402010 | Olives for oil production          | 0.05                    | 0.5                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted                                                                                                                                                                                                 |
| 0256000 | Herbs and edible flowers           | 2 (chives, parsley) 0.05* (others) | 2                       | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. Further risk management considerations required whether the group MRL can be applied for summer savory (0256070-008). An outstandingly high residue observed in one trial exceeded the MRL proposed for the whole subgroup. Data set too small to derive specific MRL. The consumer risk assessment of TDMs has not been conducted |
| 0631000 | Herbal infusion from flowers leaves and herbs | 0.05* | 15                      | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted                                                                                                                                                                                                 |
| 0632000 | Rice                               | 1.0                     | 1.5                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. The MRL proposal relates to husked rice. Risk for consumers unlikely. The consumer risk assessment of TDMs has not been conducted                                                                                                                                                                                                 |

MRL: maximum residue level; SEU: southern Europe; TDM: triazole derivative metabolite; NEU: northern Europe.

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

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

### Tebuconazole

**Status of the active substance:**
- Code no. 40783
- LOQ (mg/kg bw): 0.03

**Toxicological end points**
- ADI (mg/kg bw per 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

### Chronic risk assessment - refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI minimum - maximum |
|--------------------------------|-------------------------------------------|
| Milk and cream                 | 17.7 17.5                                 |
| Barley                         | 15.2 14.7                                 |
| Wine grapes                    | 14.5 14.3                                 |
| Tomatoes                       | 13.1 12.5                                 |
| Oats                           | 12.3 11.7                                 |
| Beans with pods                | 11.9 10.9                                 |
| Wheat                          | 10.9 10.2                                 |
| Apples                         | 10.1 9.7                                  |
| Carrots                        | 9.1  8.4                                  |
| Beans without pods             | 8.8  8.2                                  |
| Peas (with pods)               | 8.4  7.7                                  |
| Wheat grapes                   | 7.7  7.0                                  |
| Carrots                        | 7.3  6.5                                  |
| Wheat                          | 6.9  6.4                                  |
| Tomatoes                       | 6.5  6.0                                  |
| Barley                         | 6.1  5.7                                  |
| Wheat grapes                   | 5.9  5.4                                  |
| Wine grapes                    | 5.4  4.9                                  |
| Tomatoes                       | 4.8  4.4                                  |
| Apples                         | 4.5  4.1                                  |
| Oats                           | 4.2  3.8                                  |
| Rice                           | 4.0  3.6                                  |
| Meat                           | 3.9  3.5                                  |
| Tomato juice                   | 3.8  3.4                                  |
| Apples                         | 3.7  3.3                                  |
| Oats                           | 3.5  3.1                                  |
| Tomatoes                       | 3.4  3.0                                  |
| Wheat                          | 3.2  2.8                                  |
| Barley                         | 3.1  2.7                                  |
| Wine grapes                    | 2.9  2.5                                  |
| Milk and cream                 | 2.7  2.3                                  |
| Carrots                        | 2.4  2.0                                  |
| Beans with pods                | 2.2  1.8                                  |
| Wheat                          | 2.1  1.7                                  |
| Apples                         | 2.0  1.6                                  |
| Oats                           | 1.9  1.5                                  |
| Beans without pods             | 1.8  1.4                                  |
| Peas (with pods)               | 1.6  1.2                                  |
| Wheat grapes                   | 1.4  1.0                                  |
| Carrots                        | 1.0  0.7                                  |
| Wheat                          | 0.8  0.5                                  |
| Tomato juice                   | 0.4  0.1                                  |
| Rice                           | 0.3  0.1                                  |
| Meat                           | 0.1  0.1                                  |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Tebuconazole is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculation, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

#### Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)

| ARfD/ADI | Processed commodities |
|-----------------|-----------------------|
| Celery leaves 1/- | 19.1 |
| Rice 0.23/- | 9.7 |
| Chervil 1/- | 4.3 |
| Table olives 0.31/- | 3.5 |
| Parsley 1/- | 2.5 |

#### No of critical MRLs (IESTI 1): ---

#### No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---

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

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

Conclusion:

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

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

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

**) pTMRL: provisional temporary MRL.

***) pTMRL: provisional temporary MRL for unprocessed commodity.

No of commodities for which ARfD/ADI is exceeded: ---

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---

No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---

---

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

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

---

No of commodities for which ARfD/ADI is exceeded: ---

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---

No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---

---

No of commodities for which ARfD/ADI is exceeded: ---

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---

No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---

---

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

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

---

No of critical MRLs: ---

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No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
### Appendix D – Input values for the exposure calculations

#### D.1. Livestock dietary burden calculations

| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
|                                       | Input value (mg/kg)   | Comment                | Input value (mg/kg) | Comment                |
| Rice bran/pollard                     | 0.23                  | STMR (current)         | 0.23                | STMR (current)         |
| Rice straw                            | 2.86                  | STMR (current)         | 6.21                | HR (current)           |
| Cabbage                               | 0.05                  | STMR (EFSA, 2011)      | 0.56                | HR (EFSA, 2011)        |
| Apple pomace                          | 0.65                  | STMR × 5 (EFSA, 2011)  | 0.65                | STMR × 5 (EFSA, 2011)  |
| Triticale grain                       | 0.05                  | STMR (EFSA, 2011)      | 0.05                | STMR (EFSA, 2011)      |
| Wheat, rye grain                      | 0.03                  | STMR (EFSA, 2015b)     | 0.03                | STMR (EFSA, 2015b)     |
| Barley, oat grain                     | 0.68                  | STMR (EFSA, 2011)      | 0.68                | STMR (EFSA, 2011)      |
| Triticale straw                       | 2.50                  | STMR (EFSA, 2011)      | 6.00                | HR (EFSA, 2011)        |
| Wheat, rye straw                      | 1.25                  | STMR (EFSA, 2015b)     | 2.30                | HR (EFSA, 2011)        |
| Barley, oat straw                     | 5.80                  | STMR (EFSA, 2011)      | 17.00               | HR (EFSA, 2011)        |
| Carrot culls                          | 0.15                  | STMR (EFSA, 2011)      | 0.22                | HR (EFSA, 2011)        |
| Turnips, swedes roots                 | 0.12                  | STMR (EFSA, 2011)      | 0.22                | HR (EFSA, 2011)        |
| Linseed meal                          | 0.28                  | STMR × 2 (EFSA, 2011)  | 0.28                | STMR × 2 (EFSA, 2011)  |
| Soya bean seed                        | 0.15                  | STMR (FAO, 2011)       | 0.15                | STMR (FAO, 2011)       |
| Soya bean meal                        | 0.2                   | STMR × 1.3 (FAO, 2011) | 0.2                 | STMR × 1.3 (FAO, 2011) |
| Bean seed (dry)                       | 0.05                  | STMR (FAO, 2011)       | 0.05                | STMR (FAO, 2011)       |
| Pea seed, cowpea seed, lupin seed (dry)| 0.07                 | STMR (EFSA, 2011)      | 0.07                | STMR (EFSA, 2011)      |
| Soybean hulls                         | 0.34                  | STMR × 13 (EFSA, 2011) | 0.34                | STMR × 13 (EFSA, 2011) |
| Brewer's grain, dried                 | 2.24                  | STMR × 3.3 (EFSA, 2011) | 2.24                | STMR × 3.3 (EFSA, 2011) |
| Canola (rape seed) meal               | 0.08                  | STMR × 0.8 (FAO, 2011) | 0.08                | STMR × 0.8 (FAO, 2011) |
| Citrus, dried pulp                    | 1.3                   | STMR for mandarin × 10 (EFSA, 2012) | 1.3 | STMR for mandarin × 10 (EFSA, 2011) |
| Distiller's grain, dried              | 0.17                  | STMR × 3.3 (EFSA, 2011) | 0.17                | STMR × 3.3 (EFSA, 2011) |
| Lupin seed meal                       | 0.07                  | STMR (EFSA, 2011)      | 0.07                | STMR (EFSA, 2011)      |
| Wheat gluten meal                     | 0.05                  | STMR × 1.8 (EFSA, 2015b) | 0.05                | STMR × 1.8 (EFSA, 2015b) |
| Wheat milled by-products              | 0.21                  | STMR × 7 (EFSA, 2015b)  | 0.21                | STMR × 7 (EFSA, 2015b)  |

**Risk assessment residue definition:** sum of tebuconazole, hydroxy-tebuconazole and their conjugates expressed as tebuconazole.

STMR: supervised trials median residue; HR: highest residue.
### D.2. Consumer risk assessment

| Commodity                                           | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------------|-------------------------|-----------------------|
|                                                     | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| **Risk assessment residue definition (plant commodities):** Tebuconazole (sum of enantiomers) |
| Olives for oil production                           | 0.14 STMR × PF (current)| 0.31 HR (current)     |
| Table olives                                        | 0.14 STMR (current)     | 0.31 HR (current)     |
| Fresh herbs (chervil, chives, celery leaves, parsley, sage, rosemary, thyme, basil, bay leaves (laurel), tarragon, other herbs) | 0.44 STMR (current)     | 1.0 HR (current)     |
| Herbal infusion (commodities within dried flowers and leaves) | 2.64 STMR from fresh herbs × dehydration factor (current) | 6 HR from fresh herbs × dehydration factor (current) |
| Rice                                                | 0.23 STMR (current)     |                       | 0.23 STMR (current) |                       |
| Beans with pods                                     | 0.32 STMR (EFSA, 2017)  |                       |                      |                       |
| Citrus (except orange)                              | 0.24 STMR-peel F (EFSA, 2012) |               |                      |                       |
| Oranges                                             | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Tree nuts                                           | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Pome fruits (except apple, pear)                    | 0.19 STMR (EFSA, 2011)  |                       |                      |                       |
| Apples, pears                                       | 0.13 STMR (EFSA, 2011)  |                       |                      |                       |
| Apricots, peaches                                   | 0.16 STMR (EFSA, 2011)  |                       |                      |                       |
| Cherries                                            | 0.34 STMR (EFSA, 2011)  |                       |                      |                       |
| Plums                                               | 0.11 STMR (EFSA, 2011)  |                       |                      |                       |
| Table grapes                                        | 0.17 STMR (EFSA, 2011)  |                       |                      |                       |
| Wine grapes                                         | 0.37 STMR (EFSA, 2011)  |                       |                      |                       |
| Strawberries                                        | 0.02 STMR (EFSA, 2011)  |                       |                      |                       |
| Cane fruits                                         | 0.11 STMR (EFSA, 2011)  |                       |                      |                       |
| Other small fruits and berries                      | 0.52 STMR (EFSA, 2011)  |                       |                      |                       |
| Passion fruits                                       | 0.03 STMR-peel F (EFSA, 2011) |              |                      |                       |
| Banana                                              | 0.07 STMR (FAO, 2015)   |                       |                      |                       |
| Mango                                               | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Papaya                                              | 0.36 STMR (EFSA, 2011)  |                       |                      |                       |
| Carrots, Horseradish                                | 0.15 STMR (EFSA, 2011)  |                       |                      |                       |
| Celeriac                                            | 0.08 STMR (EFSA, 2011)  |                       |                      |                       |
| Parsnips, parley root, salsify                      | 0.15 STMR (EFSA, 2011)  |                       |                      |                       |
| Swedes, turnips                                     | 0.12 STMR (EFSA, 2011)  |                       |                      |                       |
| Garlic                                              | 0.04 STMR (EFSA, 2011)  |                       |                      |                       |
| Onion, shallot                                      | 0.06 STMR (FAO, 2015)   |                       |                      |                       |
| Spring onion                                        | 0.10 STMR (FAO, 2015)   |                       |                      |                       |
| Tomatoes                                            | 0.23 STMR (EFSA, 2011)  |                       |                      |                       |
| Peppers                                             | 0.26 STMR (EFSA, 2011)  |                       |                      |                       |
| Aubergines                                          | 0.11 STMR (EFSA, 2011)  |                       |                      |                       |
| Cucumbers, courgette                                | 0.08 STMR (EFSA, 2015a) |                       |                      |                       |
| Melons                                              | 0.09 STMR (EFSA, 2011)  |                       |                      |                       |
### Commodity

| Commodity                                           | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------------|-------------------------|-----------------------|
|                                                     | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Pumpkins, watermelons                               | 0.04 STMR (EFSA, 2011)  |                       |                      |                       |
| Sweet corn                                          | 0.06 STMR (FAO, 2011)   |                       |                      |                       |
| Broccoli                                            | 0.04 STMR (EFSA, 2011)  |                       |                      |                       |
| Cauliflowers                                        | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Brussels sprout                                     | 0.06 STMR (EFSA, 2011)  |                       |                      |                       |
| Head cabbage                                        | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Lettuce and other salad plants including Brassicaceae| 0.05 STMR (EFSA, 2012)  |                       |                      |                       |
| Witloof                                             | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Beans without pods                                  | 2.00 MRL (EFSA, 2011)   |                       |                      |                       |
| Peas with pods                                      | 2.00 MRL (EFSA, 2011)   |                       |                      |                       |
| Asparagus                                           | 0.02 STMR (EFSA, 2011)  |                       |                      |                       |
| Celery                                              | 0.19 STMR (EFSA, 2011)  |                       |                      |                       |
| Globe artichokes                                    | 0.15 STMR (EFSA, 2011)  |                       |                      |                       |
| Leek                                                | 0.21 STMR (EFSA, 2011)  |                       |                      |                       |
| Pulses (expect lentils, beans)                      | 0.07 STMR (EFSA, 2011)  |                       |                      |                       |
| Beans                                               | 0.05 STMR (FAO, 2011)   |                       |                      |                       |
| Lentils                                             | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Linseeds                                            | 0.14 STMR (EFSA, 2011)  |                       |                      |                       |
| Peanuts                                             | 0.04 STMR (FAO, 2011)   |                       |                      |                       |
| Poppy seeds                                         | 0.04 STMR (EFSA, 2013)  |                       |                      |                       |
| Rape seeds                                          | 0.09 STMR (FAO, 2011)   |                       |                      |                       |
| Soya beans                                          | 0.15 STMR (FAO, 2011)   |                       |                      |                       |
| Mustard seeds                                       | 0.05 STMR (EFSA, 2011)  |                       |                      |                       |
| Cotton seeds                                        | 0.05 STMR (FAO, 2011)   |                       |                      |                       |
| Gold of pleasure                                    | 0.10 STMR (EFSA, 2011)  |                       |                      |                       |
| Barley, oats                                        | 0.68 STMR (EFSA, 2011)  |                       |                      |                       |
| Wheat, Rye                                          | 0.03 STMR (EFSA, 2015b) |                       |                      |                       |
| Coffee beans                                        | 0.04 STMR (FAO, 2011)   |                       |                      |                       |
| Ginseng root                                        | 0.05 STMR (FAO, 2015)   |                       |                      |                       |
| Hops                                                | 9.65 STMR (EFSA, 2011)  |                       |                      |                       |
| Spices (seeds)                                      | 0.40 STMR (EFSA, 2011)  |                       |                      |                       |
| Caraway                                             | 0.40 STMR (EFSA, 2011)  |                       |                      |                       |
| Products of animal origin                           | MRLs listed for the commodities under Regulation (EC) No 2017/626 | | | |

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

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|-------------------------------------------------|----------------------------------|
| Tebuconazole     | (RS)-1-p-chlorophenyl-4,4-dimethyl-3-(1H-1,2,4-triazol-1-ylmethyl)pentan-3-ol OC(Cn1cnc1)(CCc2ccc(Cl)cc2)C(C)(C)C PXMNMQRDXWABCY-UHFFFAOYSA-N | ![Structural formula](image) |
| Triazole alanine | 3-(1H-1,2,4-triazol-1-yl)-D,L-alanine NC(Cn1cnc1)C(=O)O XVWFTOJHOHJIMQ-UHFFFAOYSA-N | ![Structural formula](image) |
| Triazole lactic acid Triazole hydroxy propionic acid | (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid OC(Cn1cnc1)C(=O)O KJRGHGWTVMENC-UHFFFAOYSA-N | ![Structural formula](image) |
| 1,2,4 triazole   | 1H-1,2,4-triazole c1ncn1 NSPMIYGKQJPBQR-UHFFFAOYSA-N | ![Structural formula](image) |
| Triazole acetic acid | (1H-1,2,4-triazol-1-yl)acetic acid O=C(O)Cn1cnc1 RXDBSQXFIWBJSR-UHFFFAOYSA-N | ![Structural formula](image) |

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

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

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