Modification of the existing maximum residue levels for tetraconazole in kaki/Japanese persimmon, linseeds and poppy seeds

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Isagro S.p.A submitted a request to the competent national authority in Italy to modify the existing maximum residue levels (MRLs) for the active substance tetraconazole in various crops and animal commodities. The data submitted in support of the request were found to be sufficient to derive MRL proposals for tetraconazole in kaki/Japanese persimmon, linseeds and poppy seeds. Adequate analytical methods for enforcement are available to control MRL compliance for parent compound tetraconazole on the commodities under consideration and in animal products. The proposed use of tetraconazole on crops under assessment will not result in a dietary exposure to residues of parent tetraconazole exceeding the toxicological reference values for tetraconazole. For triazole derivative metabolites (TDMs), only an indicative exposure assessment was performed considering only the crops under assessment; the results showed that the expected exposure to TDMs in the three assessed commodities is well below the toxicological reference values derived for the TDMs. The proposed use of tetraconazole on crops under assessment is therefore unlikely to pose a risk to consumers’ health. TDMs may be generated by several pesticides belonging to the group of triazole fungicides, a comprehensive risk assessment has thus to be performed that covers all existing EU uses and import tolerances for all pesticides belonging to the class of triazole fungicides. EFSA recommended to elaborate together with risk managers a strategy to ensure that the required data are made available to finalise the overall risk assessment for triazole fungicides.

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Keywords: tetraconazole, kaki/Japanese persimmon, linseeds, poppy seeds, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Isagro S.p.A. submitted an application to the competent national authority in Italy (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance tetraconazole in various crops and in animal commodities. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 25 January 2018. To accommodate for the intended uses of tetraconazole, the EMS proposed to raise the existing MRLs for kaki/Japanese persimmons from the limit of quantification (LOQ) to 0.3 mg/kg and for linseeds and poppy seeds from the LOQ to 0.15 mg/kg. In addition, the EMS proposed to lower the existing MRLs in animal commodities except for poultry fat and eggs, where an increase of the existing MRL was considered appropriate.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which needed further clarification, which were requested from the EMS. On September 2018, the EMS submitted a revised evaluation report which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of tetraconazole following foliar application was investigated in crops belonging to the groups of fruit crops, root crops and cereals.

Studies investigating the effect of processing on the nature of tetraconazole (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).

Considering the metabolic pattern identified in metabolism studies, hydrolysis studies and rotational crops and the toxicological significance of metabolites, the following residue definitions derived in previous assessments of EFSA were found appropriate for the current application:

- Residue definition for enforcement: tetraconazole
- Residue definition for risk assessment:
  - Residue definition 1: tetraconazole
  - Residue definition 2: triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity)
  - Residue definition 3: triazole acetic acid (TAA)
  - Residue definitions 4: 1,2,4-triazole.

These residue definitions are applicable to primary crops, rotational crops and processed products.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals for tetraconazole of 0.09 mg/kg for kaki/Japanese persimmon and of 0.15 mg/Kg for linseeds and poppy seeds.

Processing factors (PF) for rapeseeds were derived from previous processing studies provided (EFSA, 2008, 2012); the studies give an indication that tetraconazole residues are accumulating in the oil. Considering the fact that the oil content of linseeds and poppy seeds is different from the oil content of rapeseed, an extrapolation of the processing factor is not recommended.

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

Since the possible occurrence of triazole derivative metabolites (TDMs) in rotational crops cannot be excluded based on the data available, their occurrence in rotational crops has to be further investigated, taking into account not only the uses of tetraconazole but all triazole fungicides. This information is required to perform a comprehensive risk assessment that covers all sources of triazole related metabolites.
As linseed is used as feed product, a potential carry-over into food of animal origin was assessed; the possible occurrence of tetraconazole residues in commodities of animal origin was investigated. Based on studies investigating the nature of residues in livestock, the following residue definitions were derived which are applicable to all animal species:

- Residue definition for enforcement: tetraconazole
- Residue definitions for risk assessment:
  - Residue definition 1: tetraconazole
  - Residue definition 2: triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity)
  - Residue definition 3: triazole acetic acid (TAA)
  - Residue definitions 4: 1,2,4-triazole.

Based on the estimated dietary burdens and the results of livestock feeding studies MRL proposals were derived for products of animal origin which are lower than the existing MRLs established in the EU MRL legislation; except for poultry fat and eggs for which the data suggest an increase of the existing MRL.

The toxicological profile of tetraconazole was assessed in the framework of the peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.004 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.05 mg/kg bw.

The consumer risk assessment was performed for tetraconazole using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure did not exceed the ARfD for the crops assessed in this application. The estimated long-term dietary intake was in the range of 11.3% to 56.8% of the ADI.

EFSA concluded that the proposed use of tetraconazole on kaki/Japanese persimmons, linseeds and poppy seeds will not result in a consumer exposure to residues of parent tetraconazole exceeding the toxicological reference values for tetraconazole and therefore is unlikely to pose a risk to consumers’ health.

An indicative exposure assessment was performed for the TDMs that showed that the expected exposure resulting from the three assessed commodities is well below the toxicological reference values derived for the TDMs. A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed.

EFSA recommended elaborating with risk managers a strategy to ensure that the required data are made available to finalise the overall risk assessment for triazole fungicides that are expected to contribute to the dietary exposure.

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                                                                 |
|---------|--------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0161060 | Kaki/Japanese persimmons       | 0.02*                   | 0.09                    | The MRL proposal was derived by extrapolation from apples, reflecting the intended SEU use. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. The indicative exposure assessment for the triazole derivative metabolites (TDMs) did not identify intake concerns. |
| 0401010 | Linseeds                      | 0.02*                   | 0.15                    | The MRL proposal was derived by extrapolation from oilseed rape, reflecting the intended NEU use. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. The indicative exposure assessment for the TDMs did not identify intake concerns. When granting an authorisation for the use of tetraconazole in linseeds and poppy seeds, the need to define a PHI should be considered by. |
| 0401030 | Poppy seeds                   | 0.02*                   | 0.15                    |                                                                                       |
| Code\(^{(a)}\) | Commodity          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------|--------------------|------------------------|-------------------------|-----------------------|
| 1011010     | Swine: muscle      | 0.05                   | 0.05 or 0.01*           | Based on the updated dietary burden calculation, EFSA concluded that there is no need to increase the existing MRLs. Instead, the data suggest that the existing MRLs could be lowered (further risk management considerations needed). For both options, risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs |
| 1011020     | Swine: fat         | 0.5                    | 0.5 or 0.03             |                       |
| 1011030     | Swine: liver       | 1.0                    | 1.0 or 0.3              |                       |
| 1011040     | Swine: kidney      | 0.2                    | 0.2 or 0.015            |                       |
| 1012010     | Bovine: muscle,    | 0.05                   | 0.05 or 0.01*           |                       |
| 1012020     | Bovine: fat        | 0.5                    | 0.5 or 0.09             |                       |
| 1012030     | Bovine: liver      | 1.0                    | 1.0 or 0.8              |                       |
| 1012040     | Bovine: kidney     | 0.2                    | 0.2 or 0.05             |                       |
| 1013010     | Sheep: muscle      | 0.05                   | 0.05 or 0.01*           |                       |
| 1013020     | Sheep: fat         | 0.5                    | 0.5 or 0.09             |                       |
| 1013030     | Sheep: liver       | 1.0                    | 1.0 or 0.7              |                       |
| 1013040     | Sheep: kidney      | 0.5                    | 0.5 or 0.04             |                       |
| 1014010     | Goat: muscle       | 0.5                    | 0.5 or 0.01*            |                       |
| 1014020     | Goat: fat          | 0.5                    | 0.5 or 0.09             |                       |
| 1014030     | Goat: liver        | 1.0                    | 1.0 or 0.8              |                       |
| 1014040     | Goat: kidney       | 0.5                    | 0.5 or 0.05             |                       |
| 1016010     | Poultry: muscle    | 0.02*                  | 0.01*                   | The MRL proposal is sufficiently supported by data. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs |
| 1016020     | Poultry: fat       | 0.02*                  | 0.2                     |                       |
| 101630      | Poultry: liver     | 1.0                    | 1.0 or 0.04             | Based on the dietary burden calculation, EFSA concluded that there is no need to increase the existing MRLs. Instead, the data suggest that the existing MRLs could be lowered (further risk management considerations needed). For both options, risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs |
| 1020000     | Milk               | 0.05                   | 0.05 or 0.015           | The MRL proposal is sufficiently supported by data. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs |
| 1030000     | Birds eggs         | 0.02*                  | 0.05                    |                       |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; PHI: preharvest interval.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\(^{(F)}\): Fat soluble.
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Assessment

The applicant requested a modification of the existing maximum residue levels (MRLs) for tetraconazole in kaki/Japanese persimmon, linseeds and poppy seeds. The detailed description of the intended uses of tetraconazole, which are the basis for the current MRL application, is reported in Appendix A.

Tetraconazole is the ISO common name for the racemic mixture (RS)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl)propyl-1,1,2,2-tetrafluoroethyl ether (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Tetraconazole was evaluated in the framework of Directive 91/414/EEC1 with Italy designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on sugar beet. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2008). Tetraconazole was approved2 for the use as a fungicide on 1 January 2010.

The process of renewal of the first approval is not yet initiated.

The European Union (EU) MRLs for tetraconazole are established in Annexes III of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been initiated. EFSA has issued several reasoned opinions on the modification of MRLs for tetraconazole. The MRL proposals derived in these reasoned opinions have been implemented in the EU MRL legislation4.

In accordance with Article 6 of Regulation (EC) No 396/2005, Isagro S.p.A. submitted an application to the competent national authority in Italy (evaluating Member State (EMS)) to modify the existing MRLs for the active substance tetraconazole in various crops and in animal commodities. 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 25 January 2018. During the detailed assessment, EFSA identified some data gaps which needed further clarifications which were provided by the EMS in an updated evaluation report in September 2018.

EFSA based its assessment on the evaluation report submitted by the EMS (Italy, 2018), the draft assessment report (DAR) (and its addendum) (Italy, 2005, 2007) prepared under Council Directive 91/414/EEC, the Commission review report on tetraconazole (European Commission, 2017a,b), the conclusion on the peer review of the pesticide risk assessment of the active substance tetraconazole (EFSA, 2008), as well as the conclusions from previous EFSA opinions on tetraconazole (EFSA, 2009, 2012, 2013). In addition, the recent assessment of confirmatory data submitted on triazole derivative metabolites (TDMs) has been taken into account (EFSA, 2018).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017a,b; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20116.

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

The evaluation report submitted by the EMS (Italy, 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.

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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 Council Directive 2009/82/EC of 13 July 2009 amending Directive 91/414/EEC to include tetraconazole as an active substance. OJ L 196, 28.7.2009, p. 10–13.
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/ep-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
6 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
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 tetraconazole in primary crops belonging to the group of fruit crops, root crops and cereals has been investigated in the framework of Directive 91/414/EEC (EFSA, 2008).

The parent tetraconazole was the predominant compound of the total residues in the sugar beets, grapes and wheat straw while the TDMs were present in significantly higher amounts in cereal grain (triazole alanine (TA) 50% of total radioactive residue (TRR), triazole acetic acid (TAA) 25% of TRR); triazole lactic acid (TLA) was identified in sugar beet tops. Overall, the metabolic pathway was found to be similar in all crop groups investigated (EFSA, 2008).

For the intended use in kaki/Japanese persimmons and linseeds and poppy seeds, plant metabolism is considered to be sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Linseeds and poppy seeds can be grown in rotation with other crops while kaki/Japanese persimmon is a permanent crop.

According to the soil degradation studies evaluated in the framework of the peer review (EFSA, 2008), tetraconazole is highly persistent in soil with the DT$_{90}$field exceeding 5,000 days. Metabolism studies in rotational crops were assessed in the framework of the peer review (EFSA, 2008). Together with unchanged tetraconazole, the TDMs (TA, TAA and TLA) were found as major components in succeeding crops carrots, lettuce and wheat. The TDMs (TA, TAA and TLA) were present in amounts one order of magnitude higher than tetraconazole.

The metabolism of tetraconazole in rotational crops was considered to be similar to the metabolic pathway depicted in primary crops (EFSA, 2008).

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies simulating processing conditions representative of pasteurisation, boiling and sterilisation were assessed in the peer review (EFSA, 2008). It was concluded that tetraconazole is hydrolytically stable under the representative conditions. Information on the possible degradation of metabolites observed in primary and rotational crop metabolism studies simulating standard processing conditions is not available.

1.1.4. Methods of analysis in plants

An analytical method and its independent laboratory validation (ILV), using liquid chromatography with tandem mass spectrometry (LC–MS/MS), were sufficiently validated at a limit of quantification (LOQ) of 0.01 mg/kg for the determination of tetraconazole in matrices with high water content, high oil content, high acid content and dry/high starch content matrices (EFSA, 2013).

Thus, for kaki/Japanese persimmons, linseeds and poppy seeds sufficiently validated analytical methods are available for enforcing the proposed MRL for tetraconazole.

1.1.5. Stability of residues in plants

Storage stability of tetraconazole under frozen conditions (below –20°C) was demonstrated for at least 3 years in high water-, high oil-, high acid- and dry/high starch content commodities (EFSA, 2008, 2012).

Information on storage stability for metabolites expected in primary and rotational crops has not been provided under the current application.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites, the following residue definitions for enforcement and risk assessment were proposed in the EU peer review (EFSA, 2008):
Residue definition for enforcement:
- tetraconazole.

Residue for risk assessment:
- tetraconazole and
- triazole derivative metabolites (TDMs) (provisionally, pending the definition of a common and harmonised approach for all the active substances of the triazole class).

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

In the recently published conclusion on TDMs EFSA proposed the following residue definitions for risk assessment for active substances belonging to the class of triazole fungicides (EFSA, 2018) which are considered to replace the previously derived provisional residue definition for TDMs:
- Parent compound and any other relevant metabolite exclusively linked to the parent compound;
- Triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity);
- Triazole acetic acid (TAA)
- 1,2,4-triazole.

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

The risk assessment for the crops under consideration has to be performed for parent tetraconazole and should be also performed for the recently derived residue definitions for the metabolites (TA and TLA, TAA and 1,2,4-triazole) (EFSA, 2018). Considering that triazole metabolites are common metabolites that are also formed by other triazole fungicides, a comprehensive risk assessment is required which has to take into account all sources of these metabolites. To ensure that all relevant information is made available, a risk management decision is needed to establish the framework to perform the risk assessment for the residue definitions of these metabolites. In the framework of the current MRL application, the risk assessment was performed for the parent tetraconazole; for the additional residue definitions related to the TDMs, EFSA performed an indicative exposure assessment, considering only the crops under consideration.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the current MRL application, the applicant referred to residue trials in rapeseed and apples which were previously assessed by EFSA (2008, 2012). The samples were analysed for the parent compound tetraconazole. According to the previous assessments the analytical methods used to analyse the residue trials were sufficiently validated for tetraconazole. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Kaki/Japanese persimmon (extrapolated from apples)

In total, eight southern Europe (SEU) residue trials performed in apples (previously submitted in the framework of EU peer review, EFSA, 2008) are available. The trials are compliant with the intended good agricultural practice (GAP) for kaki/Japanese persimmons. The applicant proposed to use these trials to extrapolate to kaki/Japanese persimmons, which is in line with the EU guidance document (European Commission, 2017a,b).

Linseeds and poppy seeds (extrapolated from oilseed rape)

In total, 10 GAP-compliant NEU residue trials performed in oilseed rape (submitted in a previous MRL application, EFSA, 2012) are available. In these trials, tetraconazole was applied between the growth stage of BBCH 69-75 and samples for analysis were collected at day 41 (in 2 trials), 57 (in 2 trials), 60 (in 2 trials) 67 and 77. In one trial, the harvest time was not reported.

7 In the case of tetraconazole, this refers only the parent compound tetraconazole.
The applicant proposed to use these trials to extrapolate to linseeds and poppy seeds, which is in line with the EU guidance document (European Commission, 2017a,b). Considering the sampling time of trials in oilseed rape, EFSA recommends as a minimum a PHI of 41 days for NEU GAP in linseeds and poppy seeds.

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.

1.2.2. Magnitude of residues in rotational crops

In the framework of EU peer review (EFSA, 2008), the magnitude of residues in rotational crops was investigated using two different experimental study designs:

- Direct application of 125, 250, 750 and 1,500 g a.s./ha to bare soil, in three different sites in the UK, followed by planting of succeeding crops.
- Multiple applications to cereals (2, 3 and 4 applications at 125 g a.s./ha) over three consecutive years, in four locations in the UK, followed by planting of succeeding crops.

Under both test conditions, low residues were found in succeeding crops; the peer review concluded that residues of tetraconazole above LOQ are unlikely to occur in usual agricultural crop rotation. For the available field studies some deficiencies were identified (e.g. they did not investigate the uptake of residues of tetraconazole in leafy vegetables grown in crop rotation and the quantity of triazole metabolites) (EFSA, 2008).

Based on the available information, the possible uptake of triazole metabolites cannot be excluded and should be further investigated. This information is required to perform a comprehensive risk assessment that covers all sources of triazole related metabolites.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies on kaki/Japanese persimmon, linseeds and poppy seeds have not been provided. Instead, the applicant referred to processing studies in apples and oilseed rape that have been previously submitted in the framework of EU peer review (EFSA, 2008) and in the context of a previous MRL application (EFSA, 2012).

The studies on apples give an indication that concentration of tetraconazole in processed apple products is lower than in the raw commodity except for dry pomace (EFSA, 2008). The processing study in rapeseed shows that the parent compound is likely to accumulate in the oil. Considering the fact that the oil content of linseeds and poppy seeds is different from the oil content of rapeseed, an extrapolation of the processing factor is not recommended. However, for calculating the dietary burden of livestock, the processing factor for rapeseed meal was used on a provisional basis. Furthermore, information on the occurrence of the relevant metabolites (TA, TAA, TLA and 1,2,3-triazole) in processed products including feed would be required to derive not only processing factors, but also conversion factors for processed products.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals covering the parent compound tetraconazole for the commodity under evaluation (see Appendix B). In Section 3, EFSA assessed whether residues of parent compound tetraconazole on these crops resulting from the intended uses are likely to pose a consumer health risk. Moreover EFSA calculated an indicative exposure for TDMs.

2. Residues in livestock

Since linseed meal is used as feed item, it is necessary to assess whether the intended use of tetraconazole in linseeds would require a modification of the MRLs set for animal commodities. EFSA calculated the dietary burden for parent tetraconazole using the OECD methodology (OECD, 2013) and compared the result with the dietary burden derived previously (EFSA, 2013). The difference however is mainly due to the different calculation methodologies used (the previous dietary burden calculation was performed in accordance with the EU guidance document applicable in 2013 (European Commission,
1996). It should be noted that in the previous assessment (EFSA, 2013), the dietary burden for poultry was not considered, while in the current MRL application, the expected exposure of poultry has been assessed.

The input values for the exposure calculation for livestock are presented in Appendix D.1. The results of the dietary burden calculation are presented in Appendix B.2.

Following the recently published EFSA conclusion on TDMs (EFSA, 2018), the animal dietary burden should be calculated not only for the parent compound, but also for the additional three risk assessment residue definitions derived for plants (see Section 1.1.6). However, EFSA is of the opinion that this assessment goes beyond the scope of the current MRL application for linseeds. A comprehensive assessment, including all uses of triazole fungicides on animal feed, is required and should be performed under a specific mandate implementing a risk management strategy that will allow assessing all triazole fungicides as regards the possible risks related to the common TDMs.

2.1. Nature of residues and methods of analysis in livestock

A metabolism study in lactating goat which was dosed with radiolabelled tetraconazole over five days has been previously assessed in the framework of the peer review (EFSA, 2008). Based on this study, the peer review concluded that the metabolism of tetraconazole in ruminants was comparable with the metabolism in rats and a metabolism study on pigs was not required. The residue definition for monitoring was defined as 'tetraconazole parent compound'. Two separate residue definitions for risk assessment were proposed: (1) tetraconazole; and (2) 1,2,4-triazole (EFSA, 2008).

A new metabolism study in laying hens dosed with radiolabelled tetraconazole for three days has been submitted by the applicant in the current MRL application (Italy, 2018). The major residue in all tissues and eggs was tetraconazole (from 84% to 105% of TRR) and the EMS (Italy, 2018) concluded that the nature of residue was tetraconazole only.

Sufficiently validated analytical methods, including ILV, are available for enforcement of the residue definition of tetraconazole in milk, egg, fat, liver, kidney and muscle and LOQ of 0.01 mg/kg.

In the framework of the peer review, the proposed residue definitions were considered to be fat soluble.

EFSA concluded that the metabolism of tetraconazole in livestock was sufficiently elucidated.

Within the current application, no information on the metabolism of TA, TAA, TLA and 1,2,4-triazole in livestock has been provided.

In the recently published EFSA conclusion on TDMs the available livestock metabolism studies for several triazole fungicides and for TA were re-assessed in view of deriving common risk assessment residue definitions applicable for animal products which would cover all triazole fungicides assessed. In addition, the results of feeding studies carried out with TA and TAA have been taken into account. The following residue definitions have been derived for animal products (EFSA, 2018):

- Residue for enforcement:
  - Parent compound (i.e. tetraconazole)

- Residue definitions for risk assessment:
  - Parent compound and any other relevant metabolite exclusively linked to the parent compound;
  - Triazole alanine (TA) and triazole lactic acid (TLA) (both metabolites were found to share the same toxicity);
  - Triazole acetic acid (TAA)
  - 1,2,4-triazole.

2.2. Magnitude of residues in livestock

A feeding study with lactating dairy cows was assessed previously in the framework of the peer review (EFSA, 2008). Considering the calculated dietary burden for ruminants, the feeding study did not provide evidence that an increase of the existing MRLs for ruminant tissues and milk is needed. Instead, the data suggest the lowering of the existing MRLs for bovine tissues and milk set for the enforcement residue definition tetraconazole which could be further extrapolated to other ruminants.

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8 In the case of tetraconazole, this refers only the parent compound tetraconazole.
A new feeding study with laying hens was submitted in the current MRL application (Italy, 2018). Hens were divided in three treatment groups which were dosed for a minimum of 40 days with 0.0046, 0.0166 and 0.045 mg/kg body weight (bw) per day, respectively. In two additional groups, animals were given a basal diet after day 40 for additional 7 and 14 days respectively in order to investigate the residue depletion. Samples from tissues and eggs were analysed only for tetraconazole since this was found to be the major compound in the metabolism study (from 84% to 105% of TRR).

Residues in eggs were below the LOQ at the lowest dose; at higher dosing levels, quantifiable residues were observed which increased over time/reached the plateau after 15 days. Residues in liver and kidney were mainly observed at the highest dose while residues in fat were observed at all doses. Considering the calculated dietary burden for poultry, the lowering of the current MRL for tetraconazole in all poultry tissues except for fat should be considered by risk managers. For fat and eggs, the existing MRL should be raised to 0.2 and 0.05 mg/kg, respectively.

Based on the feeding studies in laying hens and cows, risk assessment values to be used for the risk assessment residue definition covering only the parent compound were derived. For the other residue definitions suggested in the EFSA conclusion on the TDMs, this information is not available.

3. Consumer risk assessment

EFSA performed a dietary risk assessment for tetraconazole using revision 2 of the EFSA PRIMo. The toxicological reference values for tetraconazole used in the risk assessment (i.e. acceptable daily intake (ADI) and acute reference dose (ARfD) values) were derived in the framework of the EU peer review (EFSA, 2008).

Short-term (acute) dietary risk assessment

The short-term exposure assessment for kaki/Japanese persimmons, linseeds and poppy seeds was performed in accordance with the internationally agreed methodology. The calculation was based on the highest residue (HR) or supervised trials median residue (STMR) derived from supervised field trials submitted in the current application (Appendix D.2). The short-term exposure did not exceed the ARfD for any the crops assessed in this application (for further details see Appendix C).

Long-term (chronic) dietary risk assessment

The long-term exposure assessment for kaki/Japanese persimmons, linseeds and poppy seeds was performed in accordance with the internationally agreed methodology. The calculation was based on the STMR derived from supervised field trials submitted in the current application. In addition, STMR values derived from peer review and previous EFSA opinions (EFSA, 2008, 2009, 2012, 2013) and current MRLs implemented in Regulation (EU) 34/2013 were included in the dietary exposure assessment. The complete list of input values used in the exposure calculations is presented Appendix D.2.

The estimated long-term dietary intake was in the range of 11.3–56.8% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix C.

EFSA concluded that the long-term intake of parent compound tetraconazole resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Indicative exposure assessment of TDMs

An indicative exposure assessment was performed for the additional residue definitions derived in the framework of the conclusion on TDMs (EFSA, 2018), using input values (HR/STMR values) derived from residue trials representative for the intended uses which were submitted in the addendum to the conclusion on TDMs (EFSA, 2018). The indicative short- and long-term exposure calculated for the additional residue definitions covering TDMs was low and did not exceed the corresponding toxicological reference values for the relevant TDMs derived in the EFSA conclusion (EFSA, 2018). More details can be found in Appendix B.3 and Appendix C.

A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed.
4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for kaki/Japanese persimmons, linseeds and poppy seeds.

EFSA concluded that the proposed use of tetraconazole on kaki/Japanese persimmons, linseeds and poppy seeds will not result in a consumer exposure exceeding the toxicological reference values for tetraconazole. A comprehensive risk assessment for the metabolites that are in common with other triazole fungicides has not been performed in the framework of the current application. However, an indicative calculation of the dietary exposure to TDMs was performed considering only the GAPs under assessment; the results of this exposure assessment did not indicate consumer intake concerns.

EFSA is of the opinion that a comprehensive assessment of all uses of triazole fungicides in all commodities for which authorisations exist in the EU or for which import tolerances have been established, would be required. However, this assessment goes beyond the scope of this application because currently the required data on the occurrence of TDMs in crops treated with triazole fungicides or grown in crop rotation after treatment of primary crops with triazole fungicides are not available. Thus, a framework requesting systematically the information on TDMs need to be established to ensure that the required data are made available in due time to finalise the overall risk assessment for triazole fungicides that are expected to contribute to the dietary exposure. For triazole fungicides for which the MRL review has not yet been performed, EFSA will systematically ask for TDM data as confirmatory data. For substances where the MRL review has been already completed, a specific call for data needs to be established.

The MRL recommendations which are proposed to be discussed by risk managers 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
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
DM dry matter
DT90 period required for 90% dissipation (define method of estimation)
EC emulsifiable concentrate
EMS evaluating Member State
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChiKey International Chemical Identifier Key.
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC-MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
ME microemulsion
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 pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
| Acronym | Description |
|---------|-------------|
| SANCO   | Directorate-General for Health and Consumers |
| SE      | suspo-emulsion |
| SEU     | southern Europe |
| SMILES  | simplified molecular-input line-entry system |
| STMR    | supervised trials median residue |
| TA      | triazole alanine |
| TAA     | triazole acetic acid |
| TLA     | triazole lactic acid |
| TAR     | total applied radioactivity |
| TDM     | triazole derivative metabolite |
| TRR     | total radioactive residue |
| YF      | yield factor |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | Preparation | Application | Application rate per treatment |
|-----------------------|-------------|-------------|--------------------------------|
|                       | Type(b) | Conc. a.s. | Method | Range of growth stages & season(c) | Number min– max | Interval between application (min) | g a.s./hl min– max | Water L/ha min– max | Rate | Unit | PHI (days)(d) | Remarks |
| Kaki/ Japanese persimmon | NEU F | ME | EC | ME | 125 g/L | 100 g/L | 40 g/L | Spray | BBCH 57/59-83 | 2–3 | 14 | 2.9–15 | 200–700 | 20–30 | g a.s./ha | 14 |
| Linseed | NEU F | ME | 125 g/L | Spray | BBCH 50-75 | 1 | 42 | 300 | 125 | g a.s./ha | Not defined |
| Poppy seed | NEU F | SE | 62.5 g/L + 250 g/L chlorothalonil | Spray | BBCH 50-75 | 1 | 42 | 300 | 125 | g a.s./ha | Not defined |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; ME: microemulsion; EC: emulsifiable concentrate; SE: suspo-emulsion.

(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                       | Grapes      |         | Topical growth chamber (rate not clearly reported) | 2 h, 3, 7, 10, 14, 28, 0, 1, 4, 8, 14, 20, 32 days | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole (EFSA, 2008) (translocation studies, supportive) |
|                                   |             |         | Foliar: $4 \times 26.5$ mg/L | 0, 14, 28, 42, 102 days after 1st appl. | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole (EFSA, 2008) |
|                                   |             |         | Foliar: $4 \times 22.2$ mg/L |                                      | Radiolabelled active substance: $^{14}$C-phenyl-tetraconazole (EFSA, 2008) |
| Root crops                        | Sugar beet  |         | Topical growth chamber (rate not clearly reported) | 2 h, 3, 7, 14, 21 | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole (EFSA, 2008) (translocation studies, supportive) |
|                                   |             |         | Foliar: $3 \times 100$ g/ha and $3 \times 500$ g/ha | 0, 20, 41, 76 days after 1st appl. | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole (EFSA, 2008) |
| Cereals/grass                     | Wheat       |         | Topical growth chamber (rate not clearly reported) | 0, 4,7, 14, 21, 28 days | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole (EFSA, 2008) (translocation study) |
|                                   |             |         | Foliar: $2 \times 125$ g/ha | Post-1st appl., pre-and post-2nd appl., harvest | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole and $^{14}$C-phenyl-tetraconazole (EFSA, 2008) |
|                                   |             |         | Foliar: $3 \times 120$ g/ha | 44 days (harvest) | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole and $^{14}$C-phenyl-tetraconazole (EFSA, 2008) |
### Rotational crops

| Crop groups     | Crop(s)   | Application(s)         | PBI (DAT)    | Comment/source                                                                 |
|-----------------|-----------|------------------------|--------------|-------------------------------------------------------------------------------|
| Root/tuber crops| Carrots   | Bare soil, 2.5 kg a.s./ha| 30, 120, 365 | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole and $^{14}$C-phenyl-tetraconazole (EFSA, 2008) (wheat sampled also at tillering (forage)) |
| Leafy crops     | Lettuce   | Bare soil, 0.5 kg a.s./ha|              |                                                                                |
| Cereal (small grain) | Wheat, sorghum | Bare soil, 2.5 kg a.s./ha |              |                                                                                |

### Processed commodities

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

Can a general residue definition be proposed for primary crops?  
Rotational crop and primary crop metabolism similar?  
Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Plant residue definition for monitoring (RD-Mo)  
Plant residue definition for risk assessment (RD-RA)

**RD-risk assessment 1:**  
- Tetraconazole (EFSA, 2008)

**RD-risk assessment 2:**  
- Triazole alanine (TA) and triazole lactic acid (TLA) (EFSA, 2018)

**RD-risk assessment 3:**  
- Triazole acetic acid (TAA) (EFSA, 2018)

**RD-risk assessment 4:**  
- 1,2,4-triazole (EFSA, 2018)

The previously derived provisional residue definition for triazole fungicides (i.e. triazole alanine, triazole acetic acid and provisionally triazole hydroxypropionic acid, EFSA, 2008) has been replaced by the abovementioned residue definitions.

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

Validated analytical LC–MS/MS method to control residues of parent compound tetraconazole in high water, high acid, high oil content matrices and in dry commodities allow quantifying residues at the LOQ of 0.01 mg/kg. ILV method available (EFSA, 2013)

DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### 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, sugar beet root     | –20    | 3                      | Years | Tetraconazole     | EFSA (2008)    |
|                                   | High oil content              | Rape seed                  | –20    | 3                      | Years | Tetraconazole     | EFSA (2012)    |
|                                   | High protein content          |                            | –      | –                      | –     | –                 | –              |
|                                   | Dry/High starch content       | Cereal grains              | –20    | 3                      | Years | Tetraconazole     | EFSA (2008)    |
|                                   | High acid content             | Wine grape                 | –20    | 3                      | Years | Tetraconazole     | EFSA (2008)    |
|                                   | Processed products            |                            | –      | –                      | –     | –                 | –              |
|                                   | Others                        |                            | –      | –                      | –     | –                 | –              |
## 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) | CF(e) |
|----------------------------|-------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Kaki/Japanese persimmons   | SEU               | Apple:                                                          | Residue trials on apple compliant with the intended GAP. Extrapolation to kaki/Japanese persimmons possible | 0.09                   | 0.06         | 0.02           |       |
|                            |                   | RD enf. and RD RA1:                                             |                                                                                  |                        |              |                |       |
|                            |                   | < 0.01, 0.014, 0.021, 0.021, 0.025, 0.035, 0.035, 0.057           |                                                                                  |                        |              |                |       |
|                            |                   | Apple:                                                          |                                                                                  |                        |              |                |       |
|                            |                   | RD-RA 2:                                                        |                                                                                  |                        |              |                |       |
|                            |                   | TA: 0.349, 0.198, 0.039, 0.030, 0.015, 0.038                      | Sum of TA and TLA for calculation of HR and STMR:                                |                        |              |                |       |
|                            |                   | TLA: 0.040, 0.024, 0.028, 0.026, 0.030, 0.030                    | 0.389, 0.222, 0.067, 0.056, 0.045, 0.068                                        |                        |              |                |       |
|                            |                   | Apple:                                                          | Residue trials submitted in the addendum of the peer review of pesticides risk assessment for TDMs (EFSA, 2018) are considered representative for the GAP assessed and sufficient to derive indicative risk assessment values for the TDMs. In each trial, the four TDMs were measured separately. It is noted that residues of TDMs were always found in control samples within the same range of treated samples or even higher in some cases |                        |              |                |       |
|                            |                   | RD-RA 3:                                                        |                                                                                  |                        |              |                |       |
|                            |                   | TAA: < 0.005, < 0.005, 0.018, 0.020, < 0.005, 0.013              |                                                                                  |                        |              |                |       |
|                            |                   | Apple:                                                          |                                                                                  |                        |              |                |       |
|                            |                   | RD-RA 4:                                                        |                                                                                  |                        |              |                |       |
|                            |                   | 1,2,4-triazole: 2 × < 0.005, 4 × < 0.005                       |                                                                                  |                        |              |                |       |
| Commodity                | Region/indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(e)</sup> |
|-------------------------|-------------------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|----------------|
| Linseed and poppy seed  | NEU                           | Oilseed rape:                                                   | Residue trials on oilseed rape compliant with the intended GAP; samples analysed between 41 and 77 days after the last treatment. Extrapolation to linseed and poppy seed possible | 0.15                   | 0.08                     | 0.03                      |                |
|                         |                               | RD enf. and RD RA1:                                             |                                                                                            |                        |                          |                           |                |
|                         |                               | 0.01, 0.018, 0.019, 0.020, 0.026, 0.027, 0.036, 0.042, 0.061, 0.082 |                                                                                            |                        |                          |                           |                |
|                         |                               | Oilseed rape:                                                   | Residue trials submitted in the addendum of the peer review of pesticides risk assessment for TDMs (EFSA, 2018) are considered representative for the GAP assessed and sufficient to derive indicative risk assessment values for the TDMs. In each trial, the four TDMs were measured separately. It is noted that residues of TDMs were always found in control samples within the same range of treated samples or even higher in some cases |                        | 1.95                     | 1.05                      |                |
|                         |                               | RD-RA 2:                                                        |                                                                                            |                        |                          |                           |                |
|                         |                               | TA: 0.988, 1.015, 0.621, 1.890, 1.033, 0.259                    |                                                                                            |                        |                          |                           |                |
|                         |                               | TLA: 0.059, 0.043, 0.015, 0.064, 0.030, 0.024                  |                                                                                            |                        |                          |                           |                |
|                         |                               | Sum of TA and TLA for calculation of HR and STMR: 1.047, 1.058, 0.636, 1.954, 1.063, 0.283 |                                                                                            |                        |                          |                           |                |
|                         |                               | Oilseed rape:                                                   |                                                                                            |                        | 1.95                     | 1.05                      |                |
|                         |                               | RD-RA 3:                                                        |                                                                                            |                        |                          |                           |                |
|                         |                               | TAA: 0.032, 0.043, 0.015, 0.064, 0.024, 0.021                  |                                                                                            |                        | 0.06                     | 0.03                      |                |
|                         |                               | Oilseed rape:                                                   |                                                                                            |                        |                          |                           |                |
|                         |                               | RD-RA 4:                                                        |                                                                                            |                        |                          |                           |                |
|                         |                               | 1,2,4-triazole: 6 × < 0.005                                     |                                                                                            |                        |                          |                           |                |

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; TDM: triazole derivative metabolites.

*: Indicates that the MRL is proposed at the limit of quantification.

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

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

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

| Yes | EFSA (2008) |
|-----|-------------|
| Residues in rotational and succeeding crops expected based on confined rotational crop study? |

| No | EFSA (2008) |
|----|-------------|
| Residues in rotational and succeeding crops expected based on field rotational crop study? |

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing factor (PF) | Comment/source |
|---------------------|---------------------------|------------------------|----------------|
|                     |                           | Individual values      | Median PF      |                |
| **Enforcement residue definition:** tetraconazole |
| Rape seeds, cake    | 4                         | 0.41, 0.7, 1.06, 1.78  | 0.88           | EFSA (2012)    |
| Rape seed, crude oil| 4                         | 1.32, 1.7, 2.55, 4.89  | 2.31           | EFSA (2012)    |
| Rape seed, refined oil | 3                     | 1.27, 1.9, 5.67       | 1.9            | EFSA (2012)    |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------|---------------------------|------------------------|
|                             | Median | Maximum | Median | Maximum |              |                          |                          |
| Cattle (all)                | 0.036  | 0.064   | 0.93  | 1.65    | Dairy cattle | Beet sugar tops | Y                        |
| Cattle (dairy only)         | 0.036  | 0.064   | 0.93  | 1.65    | Dairy cattle | Beet sugar tops | Y                        |
| Sheep (all)                 | 0.028  | 0.058   | 0.66  | 1.36    | Lamb         | Wheat straw      | Y                        |
| Sheep (ewe only)            | 0.020  | 0.045   | 0.60  | 1.36    | Ram/Ewe      | Wheat straw      | Y                        |
| Swine (all)                 | 0.008  | 0.013   | 0.34  | 0.58    | Swine (breeding) | Beet sugar tops | Y                        |
| Poultry (all)               | 0.011  | 0.023   | 0.17  | 0.34    | Poultry layer | Wheat straw      | Y                        |
| Poultry (layer only)        | 0.011  | 0.023   | 0.17  | 0.34    | Poultry layer | Wheat straw      | Y                        |

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

### B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal                  | Dose (mg/kg bw per day) | Duration (days) | Comment/source                                                                 |
|-------------------------------|-------------------------|-------------------------|-----------------|-------------------------------------------------------------------------------|
|                               | Laying hen              | 1.3–1.4                 | 3               | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole and $^{14}$C-phenyl-tetraconazole (Italy, 2018) |
|                               | Lactating ruminants     | 0.45                    | 5               | Radiolabelled active substance: $^{14}$C-triazole-tetraconazole and $^{14}$C-phenyl-tetraconazole (EFSA, 2008) |

**Time needed to reach a plateau concentration in milk and eggs (days)**

- **Milk**: 3 days  
  EFSA (2008)
- **Eggs**: 15 days  
  Italy (2018)

**Metabolism in rat and ruminant similar**

Yes  
EFSA (2008)

**Can a general residue definition be proposed for animals?**

Yes  
EFSA (2008); Italy (2018)

**Animal residue definition for monitoring (RD-Mo)**

Tetraconazole (EFSA, 2008)

**Animal residue definition for risk assessment (RD-RA)**

RD-risk assessment 1:  
Tetraconazole (EFSA, 2008)

RD-risk assessment 2:  
Triazole alanine (TA) and triazole lactic acid (TLA) (these compounds share the same toxicity) (EFSA, 2018)

RD-risk assessment 3:  
Triazole acetic acid (TAA) (EFSA, 2018)

RD-risk assessment 4:  
1,2,4-Triazole (EFSA, 2018)

**Fat soluble residues**

Yes  
EFSA (2008)

**Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)**

Validated analytical LC–MS/MS method is available to enforce tetraconazole in milk, eggs, bovine muscle, fat, kidney and liver with an LOQ of 0.01 mg/kg. ILV available (EFSA, 2013)

bw: body weight; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity          | T (°C) | Stability period Value Unit | Compounds covered | Comment/source |
|-------------------------------------|--------|--------------------|--------|-----------------------------|-------------------|---------------|
|                                     | Ruminant | Tissues, milk     | –20    | 42 Days                     | Tetraconazole     | No data on stability (EFSA, 2008) |
|                                     | Hen     | Muscle, fat, liver, kidney | –20    | 42 Days                     | Tetraconazole     | Italy (2018)  |
|                                     |         | Eggs               | –20    | 39 Days                     | tetraconazole     | Italy (2018)  |
## B.2.2. Magnitude of residues in livestock

### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | CF(c) |
|------------------|---------------------------------------------|------------------------------------------|-------|
|                  | Mean | Highest | STMR(a) (mg/kg) | HR(b) (mg/kg) | |
| **Risk assessment residue definition:** tetraconazole |
| Cattle (all)     |      |         |                |               |       |
| Closest feeding level (0.036 mg/kg bw; 0.6 N rate)(d) |
| Muscle           | 0.01 | 0.01    | 0.01           | 0.01          | 0.01* |
| Fat              | 0.05 | 0.05    | 0.05           | 0.09          | 0.09  |
| Liver            | 0.38 | 0.38    | 0.45           | 0.74          | 0.8   |
| Kidney           | 0.02 | 0.02    | 0.02           | 0.04          | 0.05  |
| Cattle (dairy only) |     |          |                |               |       |
| Closest feeding level (0.036 mg/kg bw; 0.6 N rate)(d) |
| Milk(d)          | 0.01 | 0.01    | 0.01           | 0.01          | 0.015 |
| **Sheep (all)(e)** |      |         |                |               |       |
| Closest feeding level (0.036 mg/kg bw; 0.6 N rate)(d) |
| Muscle           | 0.01 | 0.01    | 0.01           | 0.01          | 0.01* |
| Fat              | 0.05 | 0.05    | 0.04           | 0.08          | 0.09  |
| Liver            | 0.38 | 0.38    | 0.37           | 0.68          | 0.7   |
| Kidney           | 0.02 | 0.02    | 0.02           | 0.04          | 0.04  |
| **Sheep (ewe only)(e)** |     |          |                |               |       |
| Closest feeding level (0.036 mg/kg bw; 0.8 N rate)(d) |
| Milk(d)          | 0.01 | 0.01    | 0.01           | 0.01          | 0.015 |
| **Swine (all)(e)** |      |         |                |               |       |
| Closest feeding level (0.012 mg/kg bw; 0.9 N rate)(d) |
| Muscle           | 0.01 | 0.01    | 0.01           | 0.01          | 0.01* |
| Fat              | 0.02 | 0.02    | 0.01           | 0.02          | 0.03  |
| Liver            | 0.27 | 0.27    | 0.17           | 0.30          | 0.3   |
| kidney           | 0.01 | 0.01    | 0.01           | 0.01          | 0.015 |
| **Poultry (all)** |      |         |                |               |       |
| Closest feeding level (0.0166 mg/kg bw; 0.7 N rate)(d) |
| Muscle           | 0.12 | 0.12    | 0.09           | 0.19          | 0.2   |
| Fat              | 0.02 | 0.02    | 0.02           | 0.04          | 0.04  |
| Liver            |      |         |                |               |       |
| **Poultry (layer only)** |     |          |                |               |       |
| Closest feeding level (0.0166 mg/kg bw; 0.7 N rate)(d) |
| Eggs             | 0.03 | 0.03    | 0.02           | 0.05          | 0.05  |

MRL: maximum residue level; bw: body weight; n.a.: not applicable; n.r.: not reported.

*: Indicates that the MRL is proposed at the limit of quantification.

(a): Mean residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

(d): Closest feeding level and N dose rate related to the maximum dietary burden.

(e): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
### Risk assessment residue definition 2, 3 and 4:
Triazole alanine (TA) and triazole lactic acid (TLA)
Triazole acetic acid (TAA)
1,2,4-triazole

No data available, a comprehensive risk assessment has to be performed for all triazole fungicides

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition.

### B.3. Consumer risk assessment

| Residue Level | Tetraconazole: | 0.05 mg/kg bw (EFSA, 2008) |
|---------------|----------------|---------------------------|
| ARfD          | Residue definitions for Triazole Derivative Metabolites (TDM): |
|               | Triazole alanine: | 0.3 mg/kg bw (EFSA, 2018) |
|               | Triazole lactic acid: | 0.3 mg/kg bw (EFSA, 2018) |
|               | Triazole acetic acid: | 1 mg/kg bw (EFSA, 2018) |
|               | 1,2,4-triazole: | 0.1 mg/kg bw (EFSA, 2018) |

| Highest IESTI, according to EFSA PRIMo |
|----------------------------------------|
| Tetraconazole: |
| Kaki/Japanese persimmon: | 4.8% of ARfD |
| Linseeds: | 0.1% of ARfD |
| Poppy seeds: | 0.1% of ARfD |
| TDMs: |
| Sum of triazole alanine and triazole lactic acid: |
| Kaki/Japanese persimmon: | 5.2% of ARfD |
| Linseeds: | 0.1% of ARfD |
| Poppy seeds: | 0.1% of ARfD |
| Triazole acetic acid: |
| Kaki/Japanese persimmon: | 0.1% of ARfD |
| Linseeds: | <0.01% of ARfD |
| Poppy seeds: | <0.01% of ARfD |
| 1,2,4-triazole: |
| Kaki/Japanese persimmon: | no residues |
| Linseeds: | no residues |
| Poppy seeds: | no residues |

| Assumptions made for the calculations |
|---------------------------------------|
| Tetraconazole: The calculation is based on the highest residue levels of parent compound tetraconazole expected in raw agricultural commodities (kaki/Japanese persimmons, linseeds and poppy seeds) based on the GAP-compliant supervised residue trials submitted in support of this MRL application |
| TDMs: |
| Indicative exposure assessment for the triazole derivative metabolites (TDMs) has been performed considering only the residue concentrations for the crops under assessment which were derived from the trials submitted in the addendum to the peer review of the pesticide risk assessment of triazole derivative metabolites in light of confirmatory data (EFSA, 2018). A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed |
ADI Tetraconazole: 0.004 mg/kg bw per day (EFSA, 2008)

Residue definitions for Triazole Derivative Metabolites (TDM):
Triazole alanine: 0.3 mg/kg bw (EFSA, 2018)
Triazole lactic acid: 0.3 mg/kg bw (EFSA, 2018)
Triazole acetic acid: 1 mg/kg bw (EFSA, 2018)
1,2,4-triazole: 0.023 mg/kg bw (EFSA, 2018)

Highest IEDI, according to EFSA PRIMo Tetraconazole: 56.8% ADI (DE child)

Contribution of crops assessed:
- Kaki/Japanese persimmon: 0.01% of the ADI
- Linseeds: 0.11% of the ADI
- Poppy seeds: 0.03% of the ADI

Indicative calculation for TDMs:
Triazole alanine and triazole lactic acid: 0.1% of ADI
Triazole acetic acid: <0.01% of ADI
1,2,4-triazole: no contribution

Assumptions made for the calculations
Tetraconazole: The chronic calculation is based on the median residue levels (STMR) of parent compound tetraconazole derived for raw agricultural commodities based on supervised residue trials submitted in support of this MRL application. Furthermore, all available median residue levels for the crops assessed in previous reasoned opinions were considered together with the MRL established for tetraconazole in Regulation (EC) 34/2013
TDMs:
Indicative exposure assessment for the triazole derivative metabolites (TDMs) has been performed considering only the residue concentrations for the crops under assessment which were derived from the trials submitted in the addendum to the peer review of the pesticide risk assessment of triazole derivative metabolites in light of confirmatory data (EFSA, 2018). A comprehensive risk assessment, including all crops and all pesticides belonging to the class of triazole fungicides has not yet been performed

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

B.4. Recommended MRLs

| Code(a) | Commodity                        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|--------|----------------------------------|-------------------------|-------------------------|-----------------------|
| 0161060 | Kaki/Japanese persimmons         | 0.02*                   | 0.09                    | The MRL proposal was derived by extrapolation from apples, reflecting the intended SEU use. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. The indicative exposure assessment for the triazole derivative metabolites (TDMs) did not identify intake concerns. |
| Code(a) | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|---------|---------------|--------------------------|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0401010 | Linseeds      | 0.02*                    | 0.15                    | The MRL proposal was derived by extrapolation from oilseed rape, reflecting the intended NEU use. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. The indicative exposure assessment for the TDMs did not identify intake concerns. When granting an authorisation for the use of tetraconazole in linseeds and poppy seeds, the need to define a PHI should be considered by national competent authorities, to ensure that residues occurring in the harvested crop do not exceed the MRL proposal derived from residue trials in rapeseed where samples were taken between 41 and 77 days after the last treatment. |
| 0401030 | Poppy seeds   | 0.02*                    | 0.15                    |                                                                                                                                                      |
| 1011010 | Swine: muscle | 0.05                     | 0.05 or 0.01*           | Based on the updated dietary burden calculation, EFSA concluded that there is no need to increase the existing MRLs. Instead, the data suggest that the existing MRLs could be lowered (further risk management considerations needed). For both options, risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs. |
| 1011020 | Swine: fat    | 0.5                      | 0.5 or 0.03             |                                                                                                                                                      |
| 1011030 | Swine: liver  | 1.0                      | 1.0 or 0.3              |                                                                                                                                                      |
| 1011040 | Swine: kidney | 0.2                      | 0.2 or 0.015            |                                                                                                                                                      |
| 1012010 | Bovine: muscle, | 0.05                     | 0.05 or 0.01*           |                                                                                                                                                      |
| 1012020 | Bovine: fat   | 0.5                      | 0.5 or 0.09             |                                                                                                                                                      |
| 1012030 | Bovine: liver | 1.0                      | 1.0 or 0.8              |                                                                                                                                                      |
| 1012040 | Bovine: kidney | 0.2                     | 0.2 or 0.05             |                                                                                                                                                      |
| 1013010 | Sheep: muscle | 0.05                     | 0.05 or 0.01*           |                                                                                                                                                      |
| 1013020 | Sheep: fat    | 0.5                      | 0.5 or 0.09             |                                                                                                                                                      |
| 1013030 | Sheep: liver  | 1.0                      | 1.0 or 0.7              |                                                                                                                                                      |
| 1013040 | Sheep: kidney | 0.5                      | 0.5 or 0.04             |                                                                                                                                                      |
| 1014010 | Goat: muscle  | 0.5                      | 0.5 or 0.01*            |                                                                                                                                                      |
| 1014020 | Goat: fat     | 0.5                      | 0.5 or 0.09             |                                                                                                                                                      |
| 1014030 | Goat: liver   | 1.0                      | 1.0 or 0.8              |                                                                                                                                                      |
| 1014040 | Goat: kidney  | 0.5                      | 0.5 or 0.05             |                                                                                                                                                      |
| 1016010 | Poultry: muscle | 0.02*                  | 0.01*                  | The MRL proposal is sufficiently supported by data. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs. |
| 1016020 | Poultry: fat  | 0.02*                    | 0.2                    |                                                                                                                                                      |
| 101630  | Poultry: liver | 1.0                     | 1.0 or 0.04             | Based on the dietary burden calculation, EFSA concluded that there is no need to increase the existing MRLs. Instead, the data suggest that the existing MRLs could be lowered (further risk management considerations needed). For both options, risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs. |
| 1020000 | Milk          | 0.05                     | 0.05 or 0.015           |                                                                                                                                                      |
**Modification of existing MRLs for tetraconazole in various commodities**

| Code\(^{(a)}\) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|------------|-------------------------|-------------------------|-----------------------|
| 1030000        | Birds eggs | 0.02\(^{*}\)           | 0.05                    | The MRL proposal is sufficiently supported by data. Risk for consumers regarding residues of parent compound tetraconazole is unlikely. However, the assessment does not cover TDMs |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; PHI: preharvest interval.

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

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

\(^{(F)}\): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Tetraconazole

| Status of the active substance: | Code no. |
|--------------------------------|----------|
| LOQ (mg/kg bw): | Proposed LOQ |

Toxicological end points

| ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
|------------------------|------------------|
| Source of ADI: | Source of ARfD: |
| Year of evaluation: | Year of evaluation: |

| Year of evaluation: | 2009 |
|---------------------|------|

| No of diets exceeding ADI: | --- |
|---------------------------|------|

Highest calculated TMDI values in % of ADI

| Commodity/ group of commodities | MS Diet |
|---------------------------------|---------|

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment – refined calculations

| Commodity/ group of commodities | pTMRLs at LOQ (in % of ADI) |
|---------------------------------|-----------------------------|

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

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The acute risk assessment is based on the ARfD.

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

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

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

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

| Unprocessed commodities | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------|---------------------------------------------------------------|---------------------------------------------------------------|
|                         | IESTI 1 (*) | IESTI 2 (*) | IESTI 1 (***) | IESTI 2 (***) | IESTI 1 (***) | IESTI 2 (***) |
| Highest % of ARfD/ADI   | 4.8 Persimmon 0.06/- | 4.4 Persimmon 0.06/- | 1.7 Persimmon 0.06/- | 1.2 Persimmon 0.06/- |
|                        | 0.1 Linseed 0.03/- | 0.1 Linseed 0.03/- | 0.0 Linseed 0.03/- | 0.0 Linseed 0.03/- |
|                        | 0.1 Poppy seed 0.03/- | 0.1 Poppy seed 0.03/- | 0.0 Poppy seed 0.03/- | 0.0 Poppy seed 0.03/- |

| Processed commodities | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|-----------------------|---------------------------------------------------|---------------------------------------------------|
|                       | IESTI 1 (***) | IESTI 2 (***) | IESTI 1 (***) | IESTI 2 (***) |
| Highest % of ARfD/ADI  | Processed commodities | pTMRL/ threshold MRL (mg/kg) | Processed commodities | pTMRL/ threshold MRL (mg/kg) |

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

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

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

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

For processed commodities, no exceedance of the ARfD/ADI was identified.
### 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 |
| **Risk assessment residue definition number 1: Tetraconazole**       |                       |                        |
| Sugar beet tops        | 0.65                  | EFSA (2008)            | 1.20                 | EFSA (2008) |
| Wheat straw            | 1.20                  | EFSA (2013)            | 2.80                 | EFSA (2013) |
| Triticale grain        | 0.02                  | EFSA (2013)            | 0.02                 | EFSA (2013) |
| Wheat grain            | 0.02                  | EFSA (2013)            | 0.02                 | EFSA (2013) |
| Apple pomace wet       | 0.03                  | STMR 0.043*PF 0.77 (EFSA, 2008) | 0.03 | STMR 0.043*PF 0.77 (EFSA, 2008) |
| Beet sugar dried pulp  | 0.18                  | STMR 0.01*PF 18 (EFSA, 2008) | 0.18 | STMR 0.01*PF 18 (EFSA, 2008) |
| Beet sugar ensiled pulp| 0.03                  | STMR 0.01*PF 3 (EFSA, 2008) | 0.03 | STMR 0.01*PF 3 (EFSA, 2008) |
| Beet sugar molasses    | 0.28                  | STMR 0.01*PF 0.28 (EFSA, 2008) | 0.28 | STMR 0.01*PF 0.28 (EFSA, 2008) |
| Rape seed meal         | 0.03                  | STMR 0.03*PF 0.88 (EFSA, 2012) | 0.03 | STMR 0.03*PF 0.88 (EFSA, 2012) |
| Distiller’s grain dried| 0.07                  | STMR 0.02*PF 3.3 (EFSA, 2013) | 0.07 | STMR 0.02*PF 3.3 (EFSA, 2013) |
| Flaxseed/Linseed meal  | 0.03                  | STMR 0.03*PF 0.88 (current application) | 0.03 | STMR 0.03*PF 0.88 (current application; Italy, 2018) |
| Rape meal              | 0.03                  | STMR 0.03*PF 0.88 (EFSA, 2012) | 0.03 | STMR 0.03*PF 0.88 (EFSA, 2012) |
| Wheat gluten meal      | 0.04                  | STMR 0.02*PF 1.8 (EFSA, 2013) | 0.04 | STMR 0.02*PF 1.8 (EFSA, 2013) |
| Wheat milled-by-products | 0.02                | STMR 0.02*PF 1.1 (EFSA, 2013) | 0.02 | STMR 0.02*PF 1.1 (EFSA, 2013) |

**Risk assessment residue definition 2, 3 and 4:**
- Triazole alanine (TA) and triazole lactic acid (TLA)
- Triazole acetic acid (TAA)
- 1,2,4-triazole

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**STMR:** supervised trials median residue; **HR:** highest residue; **PF:** processing factor.

#### 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 1: Tetraconazole**       |                       |                        |
| Kaki/Japanese persimmon | 0.02                  | STMR (current application; Italy, 2018) | 0.06 | HR (current application; Italy, 2018) |
| Linseed               | 0.03                  | STMR (current application; Italy, 2018) | 0.03 | STMR (current application; Italy, 2018) |
| Commodity       | Chronic risk assessment | Acute risk assessment |
|-----------------|-------------------------|-----------------------|
|                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment                           |
| Poppy seed      | 0.03                    | STMR (current application; Italy, 2018) | 0.03 | STMR (current application; Italy, 2018) |
| Apple           | 0.043                   | STMR (EFSA, 2013)     |                  |                                   |
| Table grape     | 0.016                   | STMR (EFSA, 2013)     |                  |                                   |
| Wine grape      | 0.003                   | STMR 0.016*PF 0.26 (EFSA, 2008)*YF 0.7 |                  |                                   |
| Wheat           | 0.02                    | STMR (EFSA, 2013)     |                  |                                   |
| Rape seed       | 0.03                    | STMR (EFSA, 2012)     |                  |                                   |
| Apricot         | 0.04                    | STMR (EFSA, 2009)     |                  |                                   |
| Sugar beet (root)| 0.01                   | STMR (EFSA, 2008)     |                  |                                   |
| Swine meat      | 0.01                    | STMR (current application; Italy, 2018) |                  |                                   |
| Swine fat       | 0.01                    |                         |                  |                                   |
| Swine liver     | 0.17                    |                         |                  |                                   |
| Swine kidney    | 0.01                    |                         |                  |                                   |
| Bovine meat     | 0.01                    |                         |                  |                                   |
| Bovine fat      | 0.05                    |                         |                  |                                   |
| Bovine liver    | 0.45                    |                         |                  |                                   |
| Bovine kidney   | 0.02                    |                         |                  |                                   |
| Sheep meat      | 0.01                    |                         |                  |                                   |
| Sheep fat       | 0.04                    |                         |                  |                                   |
| Sheep liver     | 0.37                    |                         |                  |                                   |
| Sheep kidney    | 0.02                    |                         |                  |                                   |
| Goat meat       | 0.01                    |                         |                  |                                   |
| Goat fat        | 0.05                    |                         |                  |                                   |
| Goat liver      | 0.45                    |                         |                  |                                   |
| Goat kidney     | 0.02                    |                         |                  |                                   |
| Poultry meat    | 0.00                    |                         |                  |                                   |
| Poultry fat     | 0.09                    |                         |                  |                                   |
| Poultry liver   | 0.02                    |                         |                  |                                   |
| Milk            | 0.01                    |                         |                  |                                   |
| Egg             | 0.02                    |                         |                  |                                   |
| Other commodities of plant origin | MRL | Commission Regulation (EC) 34/2013 |

**Risk assessment residue definition 2**: Triazole alanine (TA) and triazole lactic acid (TLA)

| Commodity       | Input value (mg/kg) | Comment                                                                 | Input value (mg/kg) | Comment                                                                 |
|-----------------|--------------------|-------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------|
| Kaki/Japanese persimmon | 0.07             | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) | 0.39               | HR (calculated from trials submitted to addendum of EFSA conclusion 2018) |
| Linseed         | 1.05               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) | 1.05               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) |
| Poppy seed      | 1.05               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) | 1.05               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) |

**Risk assessment residue definition 3**: Triazole acetic acid (TAA)

| Commodity       | Input value (mg/kg) | Comment                                                                 | Input value (mg/kg) | Comment                                                                 |
|-----------------|--------------------|-------------------------------------------------------------------------|--------------------|-------------------------------------------------------------------------|
| Kaki/Japanese persimmon | 0.01             | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) | 0.02               | HR (calculated from trials submitted to addendum of EFSA conclusion 2018) |
| Linseed         | 0.03               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) | 0.03               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) |
| Poppy seed      | 0.03               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) | 0.03               | STMR (calculated from trials submitted to addendum of EFSA conclusion 2018) |
### Risk assessment residue definition 4: 1,2,4-triazole

No residues detected

Comprehensive risk assessment to be performed for all triazole fungicides

| Commodity | Chronic risk assessment | Acute risk assessment |
|-----------|-------------------------|-----------------------|
|           | Input value (mg/kg)     | Comment               |
|           |                         |                       |
|           | Input value (mg/kg)     | Comment               |
|           |                         |                       |
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-------------------------------------------------|---------------------------------|
| Tetraconazole                | (RS)-2-(2,4-dichlorophenyl)-3-(1H-1,2,4-triazol-1-yl) propyl-1,1,2,2-tetrafluoroethyl ether  
FC(F)C(F)(F)OCC(Cn1cnnc1)c1ccc(C)c1Cl  
LQDARGUHUSPFNLUHFFFAOYSA-N | ![Structural formula](image1) |
| **Triazole derivative metabolites** | | |
| 1,2,4-triazole                | 1H-1,2,4-triazole  
c1ncnn1  
NSPMIYGKQJPBQR-UHFFFAOYSA-N | ![Structural formula](image2) |
| **1,2,4-T**                   | | |
| Triazole alanine              | 3-(1H-1,2,4-triazol-1-yl)-D,L-alanine  
NC(Cn1cnnc1)C(=O)O  
XVWFTOJHOHJIMQ-UHFFFAOYSA-N | ![Structural formula](image3) |
| **TA**                       | | |
| Triazole acetic acid          | 1H-1,2,4-triazol-1-ylactic acid  
O=C(Cn1cnnc1)  
RXDBSQXFIWBJR-UHFFFAOYSA-N | ![Structural formula](image4) |
| **TAA**                      | | |
| Triazole lactic acid or Triazole hydroxy propionic acid | (2RS)-2-hydroxy-3-(1H-1,2,4-triazol-1-yl)propanoic acid  
OC(Cn1cnnc1)C(=O)O  
KJRGGHWETVMMN-UHFFFAOYSA-N | ![Structural formula](image5) |
| **TLA** | | |

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

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

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

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