Modification of the existing maximum residue levels and setting of import tolerances for thiabendazole in various crops

EFSA (European Food Safety Authority), Maria Anastassiadou, Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Miguel Santos, Alessia Pia Scarlato, Anne Theobald, Benedicte Vagenende and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Syngenta España S.A. submitted a request to the competent national authority in Spain to modify the existing maximum residue levels (MRLs) in citrus fruits, bananas and witloofs. Additionally, Syngenta Crop Protection AG submitted two applications to Spain to set import tolerances in mangoes and in sweet potatoes. The data submitted in support of the requests were found to be sufficient to derive MRL proposals for the commodities under evaluation and for commodities of animal origin. Adequate analytical methods for enforcement are available to control the residues of thiabendazole in the commodities under consideration and in animal matrices at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of thiabendazole according to the reported agricultural practices is unlikely to present a risk to consumer health.

Keywords: thiabendazole, import tolerance, pesticide, MRL, consumer risk assessment

Requestor: European Commission

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Correspondence: pesticides.mrl@efsaeuropa.eu
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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta España S.A. submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance thiabendazole in citrus fruits, bananas and witloofs. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 October 2017. To accommodate for the intended uses of thiabendazole, the applicant proposed MRLs at the level of 5 mg/kg in citrus fruits, 6 mg/kg in bananas and 0.15 mg/kg in witloofs. The EMS proposed to lower the existing MRL from 7 mg/kg to 6 mg/kg in citrus fruits, to maintain the existing MRL of 6 mg/kg in bananas and to raise the existing MRL from the limit of quantification (LOQ) of 0.05 to 0.15 mg/kg in witloofs. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 29 April 2020 the EMS submitted a revised evaluation report (Spain, 2017), which replaced the previously submitted evaluation report.

Additionally, in accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Spain to set an import tolerance for the active substance thiabendazole in mangoes. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority EFSA on 26 April 2018. The EMS proposed to establish an MRL for mangoes imported from Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua and Costa Rica at the level of 5 mg/kg, equivalent to the tolerance in force in the exporting countries (Codex MRL, residue definition for enforcement: thiabendazole). EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 7 October 2020 the EMS submitted a revised evaluation report (Spain, 2018a), which replaced the previously submitted evaluation report.

Moreover, a second application was submitted by Syngenta Crop Protection AG to the competent national authority in Spain in order to set an import tolerance for thiabendazole in sweet potatoes. 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 12 December 2018. The EMS initially proposed to establish an MRL for sweet potatoes imported from the United States at the level of 2 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 7 August 2020 the EMS submitted a revised evaluation report (Spain, 2018b), which proposed to establish an MRL for sweet potatoes imported from the United States at the level of 5 mg/kg and replaced the previously submitted evaluation report. The MRL in force in the exporting country is a time-limited tolerance in response to an emergency exemption set at the level of 10 mg/kg determined according to the US residue definition for enforcement: sum of thiabendazole and benzimidazole (free and conjugated), expressed as thiabendazole.

Subsequently, EFSA proceeded merging the assessment of the three applications above. Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of the present applications, the following conclusions are derived.

The metabolism of thiabendazole in primary crops belonging to the crop groups of cereals (wheat), root crops (sugar beet) and pulses/oilseeds (soyabean) upon foliar treatment, and in fruit crops (orange) upon post-harvest application has been investigated. New metabolism studies were not provided. A specific study to cover the treatment of chicory roots prior to witloof forcing was considered not necessary. For the post-harvest use on sweet potatoes, EFSA concluded, on the basis of the available information, that the residue trials data in sweet potatoes provides sufficient evidence to confirm the results of metabolism studies in fruit crops after post-harvest treatments, indicating that benzimidazole is not expected to be formed following the post-harvest treatment of sweet potatoes according to the authorised USA good agricultural practices (GAP).

Studies investigating the effect of processing on the nature of thiabendazole (hydrolysis studies) demonstrated that thiabendazole is hydrolytically stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.
As the proposed and authorised uses of thiabendazole are either for post-harvest application or for the specific use on chicory roots prior to forcing of witloof, which is not normally rotated with other crops, investigations of residues in rotational crops are not required.

The stability of thiabendazole in frozen samples of crops classified as matrices with high water content (spinach), high oil content (soyabeans), dry/high protein content matrices (dry beans), dry/high starch content matrices (barley grain) and high acid content (oranges) commodities was confirmed for at least 24 months. The stability of benzimidazole in frozen samples of crops classified as matrices with dry/high protein content matrices (dry beans), dry/high starch content matrices (barley grain) and high acid content commodities (oranges) for at least 24 months. However, for crops classified as matrices with high water content (spinach leaves), the study demonstrated the stability of benzimidazole in frozen samples of crops stored for only up to 3 months.

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed in the framework of the revision of the MRL review:

- residue definition for enforcement (plant commodities): thiabendazole.
- residue definition for risk assessment:
  - post-harvest treatment crops (relevant to the existing uses on citrus fruits, apples, pears, avocados, mangoes, bananas, papayas and consumption potatoes): thiabendazole.
  - pre-harvest treatment (relevant to the existing uses on seed potatoes and chicory roots prior to forcing of witloof) and rotational crops:
    - thiabendazole.
    - total benzimidazole (tentative, data gap).

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

Taking into account the information provided in the current applications, EFSA concluded that the residue definition for enforcement and for risk assessment for post-harvest treatment (‘thiabendazole’) is appropriate for the intended uses on citrus fruits and bananas, and for the authorised post-harvest uses on mangoes and sweet potatoes. For the intended use on chicory roots prior to forcing of witloof, EFSA concluded that the tentative residue definitions proposed in the revision of the MRL review for pre-harvest treatment are applicable (residue definition for risk assessment: ‘thiabendazole’; ‘total benzimidazole’, tentative, data gap identified).

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues at or above the LOQ of 0.01 mg/kg in crops belonging to the groups of high-water content, high-oil content, acidic and dry commodities.

The available residue trials are sufficient to calculate MRLs for the commodities under evaluation.

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

- Citrus fruits/peeled: 0.047
- Mangoes/pulp: 0.010

As by-products of citrus fruits are used as feed item, a potential carry-over into food of animal origin was assessed. The residue definition for enforcement and risk assessment was defined for all tissues and eggs as: ‘sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole’. In milk, the residue definition for both enforcement and risk assessment was defined as: ‘sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole’. For risk assessment purposes, the revision of the MRL review proposed to also include total benzimidazole in the residue definitions for animal commodities (tentative residue definition, data gap identified).

Methods of analysis for products of animal origin have been assessed by EFSA during the EU pesticides peer review and the revision of the MRL review however validated analytical methods for enforcement of the proposed residue definitions were not available (data gap). In the context of the current assessment the applicant submitted an independent laboratory validation of the QuEChERS multiresidue method. The method is sufficiently validated for the analysis of residues of thiabendazole (thiabendazole and 5-hydroxythiabendazole) in fat, muscle, liver and eggs with an LOQ of 0.01 mg/kg for each analyte. In addition, the applicant submitted a liquid chromatography with tandem mass spectrometry (LC-MS-MS) method for the analysis of residues of thiabendazole (thiabendazole, 5-hydroxythiabendazole and its sulfate conjugates) in milk. The method is sufficiently validated with a
LOQ of 0.01 mg/kg for each analyte. The confirmatory data requirement for information on analytical methods for products of animal origin set by Commission Regulation 2017/1164 has been addressed.

EFSA updated the livestock dietary burden calculation, taking into account the intended and existing uses on citrus fruits, as well as the lower input values supporting the fall-back GAP for seed potatoes which was implemented in the Commission Regulation 2017/1164. The calculated livestock dietary burden exceeds the trigger value of 0.1 mg/kg dry matter (DM) for cattle, sheep and swine; but is significantly lower than the dietary burden calculated in the previous assessment in the context of the revision of the MRL. Considering the intended and existing EU pesticide uses it would be appropriate to lower the MRLs in animal commodities to the LOQ of 0.01 mg/kg. However, considering the veterinary uses, Commission Regulation No 37/2010 set MRLs at the level of 0.1 mg/kg for bovine and goat milk, muscle, fat, liver and kidney, which should be taken into account by risk managers.

The existing EU MRLs for bovine milk, muscle, fat, liver, kidney and other edible offals, and poultry muscle and fat are derived from Codex MRLs which are not sufficiently supported by data. Information to address the confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole in animal matrices has not yet been provided to EFSA.

The toxicological profile of thiabendazole was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.1 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.1 mg/kg bw. The metabolite 5-hydroxythiabendazole and its sulfate conjugate, included in the residue definitions for risk assessment for commodities of animal origin, were expected to share the toxicity potential of the parent thiabendazole, therefore the reference values of the parent are applicable to these metabolites. The toxicity of plant metabolite benzimidazole, which is relevant for the intended use on witloof and potentially in animal commodities, has not been addressed and the lack of this information was set as a data gap after the EU pesticides peer review.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). Lacking information on the magnitude of residues of the metabolite benzimidazole in animal matrices and lacking toxicological reference values for benzimidazole, the risk assessment for consumer exposure to benzimidazole via commodities of animal origin could not be performed for the existing EU MRLs for animal commodities which are derived from Codex MRLs.

EFSA concluded that the proposed uses of thiabendazole on citrus fruits, bananas and witloof, and the authorised uses on mangoes and sweet potatoes in the exporting countries will not result in a consumer exposure exceeding the toxicological reference values for thiabendazole and a risk to consumers’ health was not identified. A risk assessment for the metabolite benzimidazole is not required because residue levels of benzimidazole in witloof, and total residue levels in animal matrices that result from the existing and intended EU pesticide uses (GAPs) and the acceptable Codex MRLs for plant commodities, are expected to be below the LOQ of 0.01 mg/kg. Considering that the existing EU MRLs that are derived from Codex MRLs in animal commodities are associated with residues of benzimidazole higher than the LOQ, a separate risk assessment for benzimidazole would be required. However, since no data is available on the magnitude of benzimidazole in animal commodities and toxicological reference values for benzimidazole are not available, the risk assessment for the residue definition ‘total benzimidazole’ could not be performed.

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 |
|---------|-----------|-------------------------|-------------------------|------------------------|
| 0110000 | Citrus fruits | 7 (ft1) | 7 | The submitted data are sufficient to calculate an MRL of 5 mg/kg for the intended post-harvest EU GAP. The revised livestock dietary burden considering also the more critical uses for citrus fruits supporting the existing MRL (Codex MRL) and the updated input values for other feed commodities as implemented in Commission Regulation 2017/1164 indicate that residues in animal commodities would not occur above the LOQ |

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| Code(a)       | Commodity          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|--------------|--------------------|-------------------------|-------------------------|------------------------|
| 0163020      | Bananas            | 6                       | No change               | The submitted data are sufficient to derive an MRL of 6 mg/kg for the intended post-harvest GAP. The derived MRL is identical to the existing EU MRL. Risk for consumers unlikely. |
| 0163030      | Mangoes            | 0.01*                   | 5 or 7                  | The submitted data are sufficient to derive an import tolerance of 7 mg/kg in support of the authorized post-harvest GAP for dip application (Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua, Costa Rica GAP). The calculated import tolerance is higher than the MRL in force in the exporting countries (Codex MRL: 5 mg/kg). It is noted that the 2019 Extra JMPR estimated a higher Codex MRL of 7 mg/kg for thiabendazole in mangoes that has not yet been adopted by the Codex Alimentarius Commission. Risk for consumers unlikely. |
| 0212020      | Sweet potatoes     | 0.01*                   | 3                       | The submitted data are sufficient to calculate an import tolerance of 3 mg/kg in response to the authorised emergency exemption GAP for post-harvest spray application (USA). Risk for consumers unlikely. The MRL in force in the exporting country is a time-limited tolerance in response to an emergency exemption authorisation at the level of 10 mg/kg determined according to the USA residue definition for enforcement: sum of thiabendazole and benzimidazole (free and conjugated), expressed as thiabendazole. |
| 0255000      | Witloofs/Belgian endives | 0.05* (ft2)          | 0.15                    | The submitted data are sufficient to calculate an MRL of 0.15 mg/kg for the intended indoor GAP (pre-harvest use). The residue definition for risk assessment also includes the metabolite benzimidazole (free and conjugated), however the submitted residue trials demonstrate that benzimidazole is not expected to occur at levels above the LOQ of 0.01 mg/kg. The lack of validation of the analytical method for the determination of conjugates is considered a minor deficiency. The residue trial data are considered fully valid with regard to the storage stability of thiabendazole and were judged to be acceptable with regard to the storage stability of benzimidazole (minor deficiency) and therefore the requirement for confirmatory information on storage stability has been addressed. The requirement for confirmatory information on the magnitude of residues of the metabolite benzimidazole has been superseded by the revised livestock dietary burden calculation. Risk for consumers unlikely. |
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------------|-----------|-------------------------|-------------------------|-----------------------|
| 1011010        | Swine Muscle | 0.05* (ft³)            | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1011020        | Swine Fat    | 0.05* (ft³)            | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1011030        | Swine Liver  | 0.15 (ft³)             | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1011040        | Swine Kidney | 0.3 (ft³)              | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1011050        | Swine Edible offals (other than liver and kidney) | 0.3 (ft³) | **0.01** | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1012010        | Bovine Muscle | 0.1 (ft³)             | **0.1** (ft³)            | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1012020        | Bovine Fat   | 0.1 (ft³)              | **0.1** (ft³)            | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1012030        | Bovine Liver | 0.3 (ft³)              | **0.1 or 0.3** (ft³)     | Further risk management considerations required |
| 1012040        | Bovine Kidney | 1 (ft³)               | **0.1 or 1** (ft³)       | Further risk management considerations required |
| 1012050        | Bovine Edible offals (other than liver and kidney) | 1 (ft³) | **0.1 or 1** (ft³) | Further risk management considerations required |
| 1013010        | Sheep Muscle | 0.05* (ft³)            | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1013020        | Sheep Fat    | 0.05* (ft³)            | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1013030        | Sheep Liver  | 0.15 (ft³)             | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1013040        | Sheep Kidney | 0.3 (ft³)              | **0.01**                 | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| Code(a)  | Commodity                                      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|----------|-----------------------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 1013050  | Sheep Edible offals (other than liver and kidney) | 0.3 (ft³)               | 0.01*                   | requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1014010  | Goat Muscle                                   | 0.1 (ft³)               | 0.1                     | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1014020  | Goat Fat                                      | 0.1 (ft³)               | 0.1                     |                                                                                       |
| 1014030  | Goat Liver                                    | 0.15 (ft³)              | 0.1                     |                                                                                       |
| 1014040  | Goat Kidney                                   | 0.3 (ft³)               | 0.1                     |                                                                                       |
| 1014050  | Goat Edible offals (other than liver and kidney) | 0.3 (ft³)               | 0.1                     | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRLs of 0.1 mg/kg for liver and kidney implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1015010  | Equine Muscle                                 | 0.05* (ft³)             | 0.01*                   | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1015020  | Equine Fat                                    | 0.05* (ft³)             | 0.01*                   |                                                                                       |
| 1015030  | Equine Liver                                  | 0.15 (ft³)              | 0.01*                   |                                                                                       |
| 1015040  | Equine Kidney                                 | 0.3 (ft³)               | 0.01*                   |                                                                                       |
| 1015050  | Equine Edible offals (other than liver and kidney) | 0.3 (ft³)               | 0.01*                   |                                                                                       |
| 1016010  | Poultry Muscle                                | 0.05 (ft³)              | 0.01* or 0.05 (ft)      | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1016020  | Poultry Fat                                   | 0.05 (ft³)              | 0.01* or 0.05 (ft)      | Further risk management required                                                                 |

(a) Code numbers are defined in Table A.1 of the EFSA Opinion.
| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------------|------------|------------------------|------------------------|------------------------|
| 1016030         | Poultry Liver | 0.2 (ft³) | **0.01**<sup>*</sup> | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. Risk managers may consider to lower the MRL to the level of the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation 37/2010 or to maintain the existing MRL derived from the Codex MRL which is not sufficiently supported by data and should be re-considered in the framework of confirmatory data assessment. |
| 1016040         | Poultry Kidney | 0.2 (ft³) | **0.01**<sup>*</sup> | Further risk management considerations required |
| 1016050         | Poultry Edible offals (other than liver and kidney) | 0.2 (ft³) | **0.01**<sup>*</sup> | |
| 1017010         | Other farmed terrestrial animals: Muscle | 0.05* (ft³) | **0.01**<sup>*</sup> | |
| 1017020         | Other farmed terrestrial animals: Fat | 0.05* (ft³) | **0.01**<sup>*</sup> | |
| 1017030         | Other farmed terrestrial animals: Liver | 0.15 (ft³) | **0.01**<sup>*</sup> | |
| 1017040         | Other farmed terrestrial animals: Kidney | 0.3 (ft³) | **0.01**<sup>*</sup> | |
| 1017050         | Other farmed terrestrial animals: Edible offals (other than liver and kidney) | 0.3 (ft³) | **0.01**<sup>*</sup> | |

Enforcement residue definition: sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------------|------------|------------------------|------------------------|------------------------|
| 1020010         | Milk Cattle | 0.2 (ft³) | **0.1 or 0.2** (ft³) | Further risk management considerations required |
| 1020020         | Milk Sheep | 0.2 (ft³) | **0.01**<sup>*</sup> | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. Risk managers may consider to lower the MRL to the level of the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation 37/2010 or to maintain the existing MRL derived from the Codex MRL which is not sufficiently supported by data and should be re-considered in the framework of confirmatory data assessment. If risk managers decide to set the MRL at the level of the veterinary MRL the footnote for confirmatory data can be deleted. |
| Code<sup>(a)</sup> | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                                                                                                                                                                                                                 |
|------------------|-----------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1020030          | Milk Goat       | 0.2 (ft³)               | 0.1                     | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1020040          | Milk Horse      | 0.2 (ft³)               | 0.01*                   | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1020990          | Milk Others     | 0.2 (ft³)               | 0.01*                   | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1030000          | Birds eggs      | 2 (ft³)                 | 0.01* or 0.1 (ft)       | Further risk management considerations required                                                                                                                                                                                                                                                                                                                                                         |

**Enforcement residue definition:** sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole

| Code<sup>(a)</sup> | Commodity       | LOD (mg/kg) | Comment/justification                                                                                                                                                                                                                                                                                                                                 |
|-------------------|-----------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1020030           | Milk Goat       | 0.1         | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1020040           | Milk Horse      | 0.01*       | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1020990           | Milk Others     | 0.01*       | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1030000           | Birds eggs      | 0.01* or 0.1 | Further risk management considerations required. The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. Risk managers may consider to lower the MRL to the level of the LOD of 0.01 mg/kg or to lower the MRL to the level of the Codex MRL which is not sufficiently supported by data and should be reconsidered in the framework of confirmatory data assessment. |

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MRL: maximum residue level; GAP: Good Agricultural Practice.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
Modification of MRLs and setting of import tolerances for thiabendazole in various crops

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

(ft1): 0110000 Citrus fruits: The European Food Safety Authority identified some information on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.

(ft2): 0255000 Witloofs/Belgian endives: The European Food Safety Authority identified some information on storage stability and on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.

(ft3): 1000000 Products of Animal Origin -Terrestrial Animals: The European Food Safety Authority identified some information on analytical methods and on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for thiabendazole in citrus fruits, bananas and witloof and two applications to set import tolerances in mangoes and in sweet potatoes. The detailed description of the intended uses on citrus fruits, bananas and in witloof and the existing use of thiabendazole authorised on sweet potatoes in the United States and on mangoes in Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua and Costa Rica, which are the basis for the current MRL applications, is reported in Appendix A.

Thiabendazole is the ISO common name for 2-(1,3-thiazol-4-yl)-1H-benzimidazole (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Thiabendazole was evaluated in the framework of Regulation (EC) No 1107/20091 with Spain designated as rapporteur Member State (RMS) for the representative uses included pre-planting indoor treatment using ultra-low volume (ULV) or spinning disk spray applications to seed potatoes, and post-harvest indoor treatment by dip or drench to apples, pears and citrus fruit. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2014b). The decision on the renewal of approval of the active substance thiabendazole entered into force on 1 April 2017.2

The EU MRLs for thiabendazole are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014a) and, following the lowering of the toxicological reference values for thiabendazole in the renewal of approval process, a revision of the MRL review has been performed in compliance with Article 43 of the Regulation (EFSA, 2016). The proposed modifications from the revision of the MRL review have been implemented in the EU MRL legislation.4

Thiabendazole is approved as a pharmacologically active substance for veterinary use in livestock as an antiparasitic agent/agent against endoparasites in bovine and caprine species. The veterinary MRLs for thiabendazole in foodstuffs of animal origin are established at the level of 0.1 mg/kg in bovine and goat muscle, fat, liver, kidney and milk by Commission Regulation No 37/20105.

In accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta España S.A. submitted an application to the competent national authority in Spain (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance thiabendazole in citrus fruits, bananas and witloof. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 2 October 2017. To accommodate for the intended uses of thiabendazole, the applicant proposed MRLs at the level of 5 mg/kg in citrus fruits, 6 mg/kg in bananas and 0.15 mg/kg in witloofs. The EMS proposed to lower the existing MRL from 7 mg/kg to 6 mg/kg in citrus fruits, to maintain the existing MRL of 6 mg/kg in bananas and to raise the existing MRL from the limit of quantification (LOQ) of 0.05 to 0.15 mg/kg in witloofs. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 29 April 2020 the EMS submitted a revised evaluation report (Spain, 2017), which replaced the previously submitted evaluation report.

Additionally, in accordance with Article 6 of Regulation (EC) No 396/2005, Syngenta Crop Protection AG submitted an application to the competent national authority in Spain to set an import tolerance for the active substance thiabendazole in mangoes. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority EFSA on 26 April 2018. The EMS proposed to

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1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2 Commission Implementing Regulation (EU) 2017/157 of 30 January 2017 renewing the approval of the active substance thiabendazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 25, 31.1.2017, p. 5-9.

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 No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. OJ L 15, 20.1.2010, p. 1–72.
establish an MRL for mangoes imported from Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua and Costa Rica at the level of 5 mg/kg, equivalent to the tolerance in force in the exporting countries (Codex MRL, residue definition for enforcement: thiabendazole). EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 7 October 2020 the EMS submitted a revised evaluation report (Spain, 2018a), which replaced the previously submitted evaluation report.

Moreover, a second application was submitted by Syngenta Crop Protection AG to the competent national authority in Spain in order to set an import tolerance for thiabendazole in sweet potatoes. 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 12 December 2018. The EMS initially proposed to establish an MRL for sweet potatoes imported from the United States at the level of 2 mg/kg. EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data requirements and points which needed further clarification, which were requested from the EMS. On 7 August 2020, the EMS submitted a revised evaluation report (Spain, 2018b), which proposed to establish an MRL for sweet potatoes imported from United States at the level of 5 mg/kg and replaced the previously submitted evaluation report. The MRL in force in the exporting country is a time-limited tolerance in response to an emergency exemption set at the level of 10 mg/kg determined according to the USA residue definition for enforcement: ‘sum of thiabendazole and benzimidazole (free and conjugated), expressed as thiabendazole’.

EFSA based its assessment on the evaluation reports submitted by the EMS (Spain, 2017, 2018a,b), the renewal assessment report (RAR) and its addendum (Spain, 2013, 2014) prepared under Regulation (EC) 1107/2009, the conclusion on the peer review of the pesticide risk assessment of the active substance thiabendazole (EFSA, 2014b), the Commission review report on thiabendazole (European Commission, 2016), as well as the conclusions from the reasoned opinions on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2014a) and the revision of the MRL review in compliance with Article 43 of Regulation No 396/2005 (EFSA, 2016).

For these applications, the data requirements established in Regulation (EU) No 544/20116 and the guidance documents applicable at the date of submission of the applications to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a,b, 2017; 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 546/20117.

A selected list of end points of the studies assessed by EFSA in the framework of these MRL applications including the end points of relevant studies assessed previously, is presented in Appendix B.

The evaluation reports submitted by the EMS (Spain, 2017, 2018a,b) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Mammalian toxicology

The toxicology of thiabendazole was assessed in the pesticides peer review in the framework of the renewal of approval of the active substance (hereafter- EU pesticides peer review) under Regulation (EC) No 1107/2009 (EFSA, 2014b). The toxicological reference values for thiabendazole derived in the EU pesticides peer review (i.e. ADI and ARfD values) were established in the review report (European Commission, 2016) finalised in support of Commission Implementing Regulation (EU) No 2017/1578 concerning the renewal of the approval of the active substance thiabendazole. No new toxicological studies on the parent active substance thiabendazole were submitted in the context of the present MRL and import tolerance applications (Spain, 2017, 2018a,b).

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6 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.

7 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.

8 Commission Implementing Regulation (EU) 2017/157 of 30 January 2017 renewing the approval of the active substance thiabendazole in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.C/2017/0369. OJ L 25, 31.1.2017, p. 5-9.
1.1. Toxicological studies performed on metabolites

The plant metabolite benzimidazole was observed at significant levels in the plant metabolism studies (EFSA, 2014b). For crops having received a treatment prior to their harvest, and for rotational crops, benzimidazole (including its conjugates) may be present in similar amounts compared to the parent compound (EFSA, 2016). Thus, the EU pesticides peer review and subsequently the revision of the MRL review concluded that for crops following pre-harvest treatment and rotational crops, residues of total benzimidazole (i.e. free and conjugated) could be considered for the inclusion in the residue definition for risk assessment, depending on toxicological data (provisional residue definition, data gap identified; EFSA, 2016). In addition, according to livestock metabolism studies, benzimidazole was identified in significant amounts in several livestock tissues and eggs (EFSA, 2016), generated in vivo upon exposure of livestock to residues of thiabendazole via feed items. The magnitude of benzimidazole in animal matrices has not been investigated (data gap was identified; EFSA, 2016).

The available information on the toxicological properties of the plant metabolite benzimidazole was considered in the framework of the EU pesticides peer review in the framework of the renewal of approval of the active substance thiabendazole. In the toxicological studies performed on the active substance thiabendazole, benzimidazole was not found per se in rat metabolism and the available information was insufficient to conclude on the toxicological relevance of the plant metabolite benzimidazole (data gap was identified; EFSA, 2014b).

In the context of the current assessment, EFSA requested additional information to address the toxicological properties for the metabolite benzimidazole, as well as for additional information to address the magnitude of potential residues of benzimidazole in animal commodities considering dietary exposure to benzimidazole residues via feed items and benzimidazole generated in vivo upon exposure of livestock to residues of thiabendazole via feed items. The applicant submitted a review of toxicological information for benzimidazole, which was insufficient to address the toxicity of the benzimidazole. EFSA therefore concluded that the data gap for information to address the toxicological properties for the metabolite benzimidazole has not been addressed (data gap relevant for the intended uses on citrus fruits as their by-product citrus dried pulp is a feed item and witloof (only crop under consideration with pre-harvest treatment)).

2. Residues in plants

2.1. Nature of residues and methods of analysis in plants

2.1.1. Nature of residues in primary crops

The metabolism of thiabendazole in primary crops belonging to the crop groups of cereals (wheat), root crops (sugar beet) and pulses/oilseeds (soyabean) upon foliar treatment, and in fruit crops (orange) upon post-harvest application has been investigated in the framework of the EU pesticides peer review (EFSA, 2014b). In a supplemental study in cereals (maize) upon seed treatment, no identification of residues was attempted as total residues were too low. Results indicate that following post-harvest treatment, thiabendazole is the only relevant compound while following a pre-harvest application, benzimidazole, including its sugar conjugates, may be present at levels similar to the parent compound (EFSA, 2014b).

Since one of the representative uses assessed in the EU pesticides peer review referred to the treatment of seed potatoes for which metabolism studies in primary crop were not available, the EU pesticides peer review assessed a metabolism study in succeeding and rotational crops, which showed a comparable residue pattern as the one in primary crops. The study findings indicated that at a plant back interval of 320 days the proportion and levels at which residues of metabolite benzimidazole (determined as sum of free and conjugated benzimidazole) are present in the crops are increased compared to the shorter plant back intervals.

The EU peer review concluded that the available metabolism studies were considered sufficient to address post-harvest treatments in fruit crops and seed treatments in root crops (EFSA, 2014b). The use of thiabendazole for treatment of chicory roots prior to the forcing of witloof (pre-harvest use) was also assessed in the framework of the revision of the MRL review. Taking into account the overall availability of metabolism data (including rotational crop studies) and the fact that metabolism following early treatment has been sufficiently elucidated, the MRL review considered that a specific study to cover the treatment of chicory roots prior to witloof forcing was not necessary (EFSA, 2016).
EFSA requested additional information on the metabolism of thiabendazole in root crops following post-harvest treatment in order to support the import tolerance application for sweet potatoes. New metabolism studies were not provided. The applicant submitted additional residue trials in sweet potatoes (post-harvest application) which included longer waiting periods and which analysed for the parent compound thiabendazole and the metabolite benzimidazole (see Section 2.2.1). The results indicated that after waiting periods of up to 34 days benzimidazole was either not detected or was detected at levels below the LOQ of 0.01 mg/kg (Spain, 2018b). EFSA noted a minor deficiency that the efficiency of the enzymatic hydrolysis step for the determination of benzimidazole conjugates has not been validated. However, overall, the residue trials data in sweet potatoes provides sufficient evidence to confirm the results of metabolism studies in fruit crops after post-harvest treatments, indicating that benzimidazole is not expected to be formed following the post-harvest treatment of sweet potatoes according to the authorised USA GAP.

EFSA concluded that the metabolic behaviour is sufficiently addressed for the intended post-harvest uses on citrus fruits and bananas, and for the authorised post-harvest uses on mangoes and on sweet potatoes, as well as for the intended pre-harvest use on chicory roots prior to forcing witloof.

2.1.2. Nature of residues in rotational crops

Investigations of residues in rotational crops are not required as the proposed and authorised uses of thiabendazole are either for post-harvest application or for the specific use on chicory roots prior to forcing of witloof, which is not normally rotated with other crops.

2.1.3. Nature of residues in processed commodities

The effect of processing on the nature of thiabendazole was investigated in the framework of the EU pesticides peer review (EFSA, 2014b). These studies showed that thiabendazole is hydrolytically stable under standard processing conditions representative of pasteurisation, cooking, brewing and sterilisation, however a detailed and reproducible evaluation of this study was required to judge the validity of the data (data gap; EFSA, 2016). In the context of the current MRL application for citrus fruits, bananas and witloof, the EMS provided an evaluation and full summary of the hydrolysis study (Spain, 2017). On the basis of the evaluation by the EMS, EFSA concluded that the data gap identified in the EU pesticides peer review for a detailed and reproducible evaluation of the study has been addressed. The hydrolysis study demonstrated that thiabendazole is hydrolytically stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation.

Standard hydrolysis studies regarding the stability of the metabolite benzimidazole under conditions representative for pasteurisation, boiling/cooking and sterilisation are not available and are not triggered for the crops under consideration.

2.1.4. Methods of analysis in plants

Analytical methods for the determination of thiabendazole residues were assessed during the MRL review and the EU pesticides peer review (EFSA, 2014a,b). The methods are sufficiently validated for the determination of residues of thiabendazole in the crops under consideration. The methods allow quantifying residues at or above the LOQ of 0.01 mg/kg in crops belonging to the groups of high-water content, high-oil content, acidic and dry commodities.

2.1.5. Storage stability of residues in plants

The storage stability of thiabendazole and the metabolite benzimidazole in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2014b). It was demonstrated that in crops assessed in the framework of this application, residues of thiabendazole were stable for at least 24 months when stored at −20°C. The metabolite benzimidazole was reported to be stable in high-acid content commodities for at least 24 months when stored at −20°C. However, in high-water content commodities a decline of benzimidazole residues was observed after 9 months (data gap identified in revision of the MRL review pending the final study report) (EFSA, 2016).

In the context of the current assessment, EFSA requested the final study report addressing the full study period finalised in 2014. The applicant Syngenta submitted the study report on the stability of thiabendazole and benzimidazole in frozen samples of crops, which was assessed by the EMS in the context of the import tolerance application on sweet potatoes (Spain, 2018b). The stability of
thiabendazole in frozen samples of crops classified as matrices with high water content (spinach), high oil content (soyabeans), dry/high protein content matrices (dry beans), dry/high starch content matrices (barley grain) and high acid content (oranges) commodities was confirmed for at least 24 months when stored at –20°C (Spain, 2018b). The final study report demonstrated the stability of benzimidazole in frozen samples of crops classified as matrices with dry/high protein content matrices (dry beans), dry/high starch content matrices (barley grain) and high acid content commodities (oranges) for at least 24 months when stored at –20°C. However, for crops classified as matrices with high water content (spinach leaves), the study demonstrated the stability of benzimidazole in frozen samples of crops stored at –20°C for periods of up to 3 months (79% recovery after 3 months and 66% recovery after 9 months in spinach leaves stored at –20°C ± 5°C). The data gap identified in the EU pesticides peer review for the final study report on storage stability data has been addressed.

2.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were proposed in the framework of the revision of the MRL review in compliance with Article 43 of Regulation (EC) No 396/2005 (EFSA, 2016):

- residue definition for enforcement (plant commodities): thiabendazole.
- residue definition for risk assessment:
  - post-harvest treatment crops (relevant to the existing uses on citrus fruits, apples, pears, avocados, mangoes, bananas, papayas and consumption potatoes): thiabendazole.
  - pre-harvest treatment (relevant to the existing uses on seed potatoes and chicory roots prior to forcing of witloof) and rotational crops:
    - thiabendazole.
    - total benzimidazole (tentative, data gap; EFSA, 2016).

The same residue definitions are applicable to processed commodities. The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above-mentioned residue definition for enforcement.

The residue definition for enforcement in the exporting countries in the import tolerance application for mangoes is identical with the above-mentioned residue definition for enforcement. The import tolerance application for sweet potatoes is based on a time-limited tolerance in response to an emergency exemption authorisation in the exporting country (USA) and the US residue definition for tolerance enforcement is the ‘sum of thiabendazole and its metabolite benzimidazole (free and conjugated), expressed as thiabendazole’.

Taking into account the information provided in the current applications, EFSA concluded that the residue definition for enforcement and for risk assessment for post-harvest treatment (‘thiabendazole’) is appropriate for the intended uses on citrus fruits and bananas, and for the authorised post-harvest uses on mangoes and sweet potatoes. For the intended use on chicory roots prior to forcing of witloof, EFSA concluded that the tentative residue definitions proposed in the revision of the MRL review for pre-harvest treatment are applicable (residue for risk assessment: ‘thiabendazole’; ‘total benzimidazole’, tentative, data gap identified, EFSA, 2016). Pending further data on the magnitude of benzimidazole in witloof, an assessment of the toxicity of benzimidazole may be required.

2.2. Magnitude of residues in plants

2.2.1. Magnitude of residues in primary crops

In support of the MRL and import tolerance applications the applicants submitted residue trials performed on oranges and mandarins, bananas, mangoes, sweet potatoes and in witloof. The results of the magnitude of residues studies compliant with the GAPs assessed in the present application are summarised in Appendix B.1.2.1.

Citrus fruit

In support of the MRL application for citrus fruits, 21 residue trials performed by post-harvest application on oranges and mandarins in Spain in 2013 were submitted and were compliant with the intended use GAPs. EFSA requested additional information on the application rates in the residue trials
and the independence of the submitted residues trials and the EMS provided clarification in a revised evaluation report (Spain, 2017).

**Intended use GAP: post-harvest drench/dip application, 1 × 120–200 g a.s./hl (critical GAP, identified on the basis of the submitted residue trials data)**

In support of the intended use GAP, the applicant submitted a total of eight residue trials performed on oranges (four trials) and mandarins (four trials) by post-harvest drench treatment (1 × 200 g a.s./hl) (trial code P1).

**Intended use GAP: post-harvest spray application with wax, 1 × 3.75–5.0 g a.s./tonne crop**

In support of the intended use GAP, the applicant submitted a total of eight residue trials performed on oranges (four trials) and mandarins (four trials) by post-harvest spray application with wax (1 × 500 g a.s./hl wax product, nominal rate 5.0 g a.s./tonne crop) (trial code P2).

**Intended use GAP: post-harvest spray application with water, 1 × 5.6–7.5 g a.s./tonne crop**

In support of the intended use GAP, the applicant submitted a total of eight residue trials performed on oranges (4 trials) and mandarins (4 trials) by post-harvest spray application with water, followed by wax treatment (1 × 500 g a.s./hl, nominal rate 7.5 g a.s./tonne crop) (trial code P4).

In all submitted trials on citrus fruits, the samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated. The samples were separated into peel and pulp and individually analysed for the parent compound thiabendazole in accordance with the residue definition for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Spain, 2017). The data for peel and pulp were used to calculate residues in whole fruit and for the derivation of peeling factors (see Appendix B.1.2.3).

The results of the residues trials demonstrated that the intended use GAP for post-harvest drench/dip application is more critical with regard to residue levels of thiabendazole. The applicant proposed to extrapolate the available residue data on oranges and mandarins to the whole group of citrus fruits. Extrapolation from trials performed on oranges (4 trials) and mandarins (4 trials) to the whole group of citrus fruits is possible (European Commission, 2017). EFSA considered that the number and quality of the trials is sufficient to calculate an MRL of 5 mg/kg for thiabendazole in the whole group of citrus fruits (0110000), on the basis of the proposed GAP for post-harvest drench/dip treatment (critical GAP). The calculated MRL of 5 mg/kg is lower than the existing EU MRL for thiabendazole in citrus fruits (7 mg/kg) that is derived from the existing Codex MRL (EFSA, 2016).

**Bananas**

**Intended use GAP: post-harvest dip application, 1 × 21–45 g a.s./hl, prior to storage**

In support of the MRL application, the applicant submitted three residue decline trials performed by post-harvest dip application on bananas in Guadeloupe, France (1 × 0.044–0.045 kg a.s./hl, PHI 2, 12, 24 days) (Spain, 2017). A pattern of residue decline was not observed in the trials up to PHI 24 days. In addition, the applicant submitted one residue trial performed by post-harvest dip application to bananas in Hawaii, USA (1 × 0.040 kg a.s./hl, PHI 5 days).

The samples were analysed for the parent compound thiabendazole in accordance with the residue definition for enforcement and risk assessment for post-harvest treatment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Spain, 2017). The samples of these trials were stored under conditions for which integrity of the residues has been demonstrated. The mean values were calculated for experimental replicates and the highest value selected from the different experimental conditions (different formulations or PHI) within the same trial. Overall, four trials were available to support the intended use GAP for dip application.

The number and quality of the trials is sufficient to derive an MRL of 6 mg/kg for thiabendazole in bananas (0163020), on the basis of the intended post-harvest GAP for dip application.

The MRL requested by the applicant and proposed by the EMS and EFSA (6 mg/kg) is identical to the existing MRL for thiabendazole in bananas and therefore no modification of the MRL is required.

**Intended use GAP: post-harvest spray application, 45 g a.s./hl, 1 × 7.0 g a.s./tonne crop, prior to storage**

The applicant submitted two residue trials performed by post-harvest spray application to bananas in Honduras (1 × 0.04 kg a.s./hl, PHI 6 days). In accordance with the guidance, a minimum of four
trials are needed to support the post-harvest treatments (European Commission, 2017) and therefore
the number of trials are not sufficient to derive an MRL proposal on the basis of the intended use GAP
for spray application. However, the available residue trials data indicate that the GAP for post-harvest
dip application may be expected to be more critical with regard to residue levels.

**Mangoes**

Authorised use GAP (Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua, Costa Rica): post-harvest dip application, 1 × 97–243 g a.s./hl

In support of the import tolerance application, the applicant submitted four residue trials performed
in Brazil in 2017 by post-harvest dip application on mangoes with sampling at PHI 0 days (Spain,
2018a). EFSA requested additional information to investigate the possible translocation of residues
from peel into pulp in order to support the proposed refinement of the risk assessment to use of
residues in pulp. The applicant submitted four additional residue trials performed in 2020 with waiting
periods for up to 42 days under conditions representative of post-harvest storage. The additional
residue trials demonstrated that levels of thiabendazole in pulp from mangoes after storage for up to
42 days (median 0.04 mg/kg) were comparable with levels in pulp from mangoes in same trials at day
0 (median 0.065 mg/kg), indicating that translocation of residues from peel to pulp did not occur
during storage. In total, eight trials are compliant with the authorised GAP for dip application in
Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua and Costa Rica.

The peel and pulp samples were analysed for the parent compound thiabendazole in accordance
with the residue definition for enforcement and risk assessment for post-harvest treatment. According
to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Spain,
2018a). The samples of these trials were stored under conditions for which integrity of the residues
has been demonstrated. The samples from the four residue-decline trials were also analysed for the
metabolite benzimidazole, which was either not detected, or detected at levels below the LOQ of the
method. Residue values for whole fruit were calculated using exact peel/pulp ratio and stone weights.
The data for whole fruit and pulp were also used for the derivation of peeling factors (see
Appendix B.1.2.3).

The number and quality of the trials is sufficient to calculate an import tolerance MRL of 7 mg/kg
for thiabendazole in mangoes (0163030), on the basis of the authorised GAP for dip application in the
exporting countries (Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua, Costa
Rica). The calculated import tolerance is higher than the MRL in force in the exporting countries
(Codex MRL: 5 mg/kg, enforcement residue definition: thiabendazole) and therefore the MRL may be
set at an equivalent level to the one approved in the exporting country, in accordance with the
guidelines (European Commission, 2018). It is noted that the 2019 Extra JMPR estimated an MRL of
7 mg/kg for thiabendazole in mangoes (FAO, 2019) that has not yet been adopted by the Codex
Alimentarius Commission.

**Sweet potatoes**

Authorised use GAP (USA): post-harvest spray application, 1 × 6.7 g a.s./tonne crop

In support of the import tolerance application, the applicant submitted seven residue trials
performed in the USA in 2016 by post-harvest spray application on sweet potato roots in the USA
(1 × 6.45–6.90 g a.s./tonne roots, PHI 0 days) (Spain, 2018b). The applicant also submitted four
additional GAP compliant residue trials performed in 2019 by post-harvest spray application on sweet
potato roots in the USA with extended waiting periods representative of commercial storage (PHI 0, 7,
13–14, 20–21, 27–28 and 34–35 days) (Spain, 2018b). However, two of the additional trials were
performed by low-volume spray application9 which was considered not representative of commercial
application methods (Spain, 2018b) and resulted in high residue values (outlier). EFSA therefore
excluded these trials from the MRL calculation and overall, nine residue trials were considered
sufficiently compliant with the authorised use GAP.

The samples of sweet potatoes were analysed for the parent compound thiabendazole, in accordance
with the residue definition for enforcement and risk assessment, and for the metabolite
benzimidazole. According to the assessment of the EMS, the analytical method used (GRM040.01A)
has been sufficiently validated for the parent compound thiabendazole and for free benzimidazole

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9 Trials performed by low-volume spray application with 0.39 or 0.53 l water/1,000 kg roots. The US emergency exemption for
post-harvest spray application does not specify a minimum spray volume but states 'sufficient water for complete coverage'.
(Spain, 2018b) but the efficiency of the enzymatic hydrolysis step has not been validated for the determination of conjugates (Spain, 2017). However, since benzimidazole and its conjugates are not included in the residue definitions for sweet potatoes, the lack of validation data does not have an impact on the validity of the studies.

The samples of residue trials were stored frozen at or below -20°C for periods from sampling to analysis of up to 3.5 months (trials performed in 2019) or up to 9 months (trials performed in 2016), which is within the period for which integrity of residues of thiabendazole has been demonstrated, but which for 2016 trials exceeds the storage stability period for the metabolite benzimidazole (demonstrated storage stability of 3 months at -20°C in high water content commodities and 66% recovery after 9 months of storage see Section 2.1.5). The residue trials from 2016 are therefore not considered valid with regard to storage stability of benzimidazole and, in the absence of a specific metabolism study covering post-harvest application to root/tuber crops, these four residue trials demonstrate that benzimidazole was either not formed or was present at levels below the LOQ after waiting periods of up to 34 days.

The number and quality of the trials is sufficient to derive an import tolerance of 3 mg/kg for thiabendazole in sweet potatoes (0212020), in support of the authorised emergency exemption GAP benzimidazole (free and conjugated), expressed as thiabendazole below the LOQ after waiting periods of up to 34 days.

Witloofs/Belgian endives

The intended use GAPs for dip application and drench application are not supported by GAP compliant residue trials and are not assessed in the present reasoned opinion.

**Intended use GAP: spray application to chicory roots prior to forcing of witloof, 1 × 40 g a.s./tonne roots**

In support of the intended use GAP, the applicant submitted four GAP compliant residue trials performed by a spray application to chicory roots (1 × 0.04 kg a.s./kg roots) before being transferred to a commercial facility for forcing witloof (Spain, 2017). The forcing process to develop the chicory lasted for 19 days and samples of witloof chicory chicons were collected at 28 days after application.

All trials were carried out at the same facility in Northern France and applications were performed on the same day. EFSA requested additional information to determine the independence of the residue trials data. The applicant stated that due to the specialised nature of commercial witloof growing, there was only one facility in Northern France that could carry out the trial to good laboratory practice (GLP). The EMS confirmed that different treatments were conducted the same day and at the same facility however each application was made individually and using different varieties and the trials were considering as independent. EFSA accepted the reasoning of the EMS and judged the trials to be sufficiently independent (minor deficiency).

The treatment of chicory roots prior to forcing witloof may be considered an indoor use that is not a typical post-harvest use. The MRL Review proposed to tentatively include total benzimidazole (including its conjugates) in the residue definition for risk assessment relevant to the use on chicory roots prior to forcing witloof, pending information on the toxicological profile of benzimidazole (EFSA, 2016). It is noted that following the revision of the MRL review, Commission Regulation 2017/1164 set a confirmatory data requirement for information on storage stability and on the magnitude of residues of the metabolite benzimidazole to support the existing MRL for thiabendazole in witloofs (ft2).11

In the current MRL application the residue trials samples were analysed for the parent compound thiabendazole and for the metabolite benzimidazole, included in the tentative residue definitions for risk assessment (‘thiabendazole’; ‘total benzimidazole’). According to the assessment of the EMS, the
analytical method used in the residue trials (GRM040.01A) was sufficiently validated for the determination of thiabendazole and free benzimidazole but the method has not been validated for the determination of conjugates of benzimidazole because matrices were fortified with free benzimidazole and the efficiency of the enzymatic hydrolysis step has not been demonstrated (Spain, 2017) (data gap identified in the pesticides peer review; EFSA, 2014b). According to the EMS, the applicant referred to the wheat metabolism study which demonstrated that free benzimidazole is released after glucosidase enzyme hydrolysis, however quantification of the fractions was not reported and the EMS concluded that the efficiency of the hydrolysis step remains a data gap (Spain, 2017).

EFSA concluded that the analytical method was sufficiently validated for the determination of thiabendazole and free benzimidazole only. Assuming that if benzimidazole and its conjugates occur in witloof the analytical method would be capable to identify the presence of the metabolite benzimidazole (free or conjugated); and since benzimidazole residues were not determined at levels above the LOQ of 0.01 mg/kg in all submitted residue trials on witloof, the lack of quantitative validation data for the enzymatic hydrolysis step is considered a minor deficiency.

The samples of the residue trials were stored frozen at or below –18°C for periods of up to 4 months, which is within the period for which integrity of residues of thiabendazole has been demonstrated, but slightly exceeds the demonstrated storage stability period for benzimidazole (storage stability study: 79% recovery after 3 months and 66% recovery after 9 months in spinach leaves stored at –20°C ± 5°C, Spain, 2018b; see Section 2.1.5). Considering that the recovery at 9-month storage interval is only slightly below the tigger value of 70%, a gradual degradation of benzimidazole seems to occur and EFSA is of the opinion that at 4 months storage interval the degradation rate of benzimidazole will still be within acceptable limits. This, however, needs to be confirmed with additional storage stability studies in witloof or in another high-water content matrix. Overall, the residue trial data are considered fully valid with regard to the storage stability of thiabendazole and were judged to be acceptable with regard to the storage stability of benzimidazole (minor deficiency).

The number and quality of the trials is sufficient to calculate an MRL of 0.15 mg/kg for thiabendazole in witloofs/Belgian endives (0255000), on the basis of the intended use GAP for spray application in the USA.

2.2.2. Magnitude of residues in rotational crops

As the proposed and authorised uses of thiabendazole are for post-harvest application and witloof is not normally rotated with other crops, investigations of the magnitude of residues in rotational crops are not required.

2.2.3. Magnitude of residues in processed commodities

Processing studies for thiabendazole have been conducted and were assessed in the revision of the MRL review, including for peeling of citrus fruits and bananas, and indicative processing studies for orange juice (EFSA, 2016). However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

In the present reasoned opinion, peeling factors for citrus fruits and mangoes were derived from the available residue trials data (see Appendix B.1.2.3). A processing study in sweet potato roots was submitted, which indicated that industrial processing and household preparation in chips, washed and peeled roots, wet peels, washed roots baked with peel, puree, fries and flakes leads to a reduction of the residues in the processed product (Spain, 2018b). However, since only one trial has been submitted for each type of processing, the number of the processing studies is not sufficient to derive robust processing factors.

Processing studies investigating magnitude of benzimidazole in the processed commodities under consideration are not available and the need for such studies will depend on the toxicological profile of this compound as well as the magnitude in raw agricultural commodities.

2.2.4. Proposed MRLs

The available data are considered sufficient to calculate MRLs as well as risk assessment values for the commodities under evaluation (see Appendix B.1.2.1). In Section 4, EFSA assessed whether residues on these crops resulting from the intended and authorised uses are likely to pose a consumer health risk.
3. Residues in livestock

Citrus fruit by-products (citrus pulp) may be used for livestock feed purposes. The existing EU MRL for citrus fruit is set at 7 mg/kg reflecting a Codex MRL for post-harvest use that was derived by the JMPR in 2007 (FAO, 2007). This Codex MRL for citrus fruits is associated with significantly higher risk assessment values derived by the JMPR, but these were not included in the livestock dietary burden calculations performed in the revision of the MRL review. Moreover, confirmatory data requirements for information on the magnitude of residues of the metabolite benzimidazole are applicable to the existing MRL for citrus fruits.12

The residues expected in citrus fruits resulting from the intended use critical GAP assessed in the current MRL application are higher than the residues expected from the existing EU GAP assessed in the revision of the MRL review. The existing EU GAP on citrus fruit assessed in the revision of the MRL review would require an MRL of 3 mg/kg (which was not implemented) (EFSA, 2016). The revision of the MRL review calculated MRLs in livestock matrices on the basis of the dietary burden for this less critical EU GAP on citrus fruit and also included a more critical GAP for consumption potatoes (which was not implemented for potatoes), and the MRLs for products of animal origin were nevertheless implemented by Commission Regulation 2017/1164. Hence, it was necessary to update the previous dietary burden calculation for livestock to estimate whether the intended use of thiabendazole on citrus fruits would have an impact on the residues expected in food of animal origin, and to update the livestock dietary burden calculation using the fall-back GAP for seed potato (EFSA, 2016), in line with the existing EU MRL for potatoes implemented by Commission Regulation 2017/1164.

The input values for the updated exposure calculations for livestock are presented in Appendix D.1. For citrus fruits, EFSA selected the higher risk assessment value (STMR), which was derived by JMPR and supports the existing EU MRL of 7 mg/kg in citrus fruits. The results of the dietary burden calculation (OECD, 2013) are presented in Appendix B.2 and demonstrate that the exposure of cattle, sheep and swine exceed the trigger value. The revised dietary burden is significantly lower than the dietary burden calculated in the previous assessment in the context of the revision of the MRL review (EFSA, 2016) due to the lower input values supporting the fall-back GAP for potatoes which was implemented by Commission Regulation 2017/1164. The highest contributing commodities to the livestock diets are citrus dried pulp (for cattle and swine), apple pomace and potato pulp.

Since the calculated dietary burden is lower than the dietary burden for which the existing EU MRLs in livestock are set, theoretically there is no need to revise the existing EU MRLs in animal matrices on the basis of the new use on citrus fruit. Nevertheless, since the MRL application for citrus fruits is supported on the basis of the significantly lower EU livestock dietary burden calculation which demonstrates that total residue levels, including residues of benzimidazole, will be below the LOQ in animal matrices, EFSA estimated MRLs for commodities of animal origin which are supported by the lower livestock dietary burden (Section 3.2).

The existing MRLs for commodities of animal origin refer only to thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate. Considering the data gap for information to address the magnitude of potential residues of benzimidazole in animal commodities has not been addressed, the existing EU MRLs for commodities of animal origin that are derived from Codex MRLs at levels higher than the LOQ of 0.01 mg/kg are considered on a tentative basis only (EFSA, 2016), and may need to be revised pending the outcome of the assessment of the confirmatory data requirements by Commission Regulation 2017/1164.

3.1. Nature of residues and methods of analysis in livestock

Metabolism studies in livestock (lactating ruminants and poultry) have been assessed previously in the framework of the EU pesticides peer review (EFSA, 2014b). Thiabendazole was rapidly metabolised and identified as a minor component of the residue in animal commodities (generally less than 5% total radioactive residue (TRR), except in eggs up to 10% TRR). In tissues and eggs, the main contributor to the residue was free 5-hydroxythiabendazole (up to 41% TRR), while 5-hydroxythiabendazole O-sulfate conjugate was the most abundant compound in milk (39% TRR). Benzimidazole was also identified in significant amounts (up to 27% TRR) in several tissues and eggs (EFSA, 2014a,b).

12 The data gap refers to information on the magnitude of residues of the metabolite benzimidazole (data gap relevant for commodities of animal origin and for the authorisations on citrus fruits, apples, potatoes and witloof).
The residue definition for enforcement and risk assessment was defined for all tissues and eggs as: ‘sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole’. In milk, the residue for both enforcement and risk assessment was defined as: ‘sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole’. For risk assessment purposes, the revision of the MRL review proposed to also include total benzimidazole in the residue definitions for animal commodities (tentative residue definition, data gap identified; EFSA, 2016). However, since the magnitude of benzimidazole in livestock has not been investigated and, noting that further information regarding the toxicological properties of benzimidazole is still required, this metabolite may require a separate risk assessment compared to the parent compound.

Methods of analysis for products of animal origin have been assessed by EFSA during the EU pesticides peer review and the revision of the MRL review (EFSA, 2014a,b, 2016). However, validated analytical methods for enforcement of the proposed residue definitions were not available and were required (data gap, EFSA, 2016). In the context of the current assessment, EFSA requested additional information on the independent laboratory validation (ILV) of the analytical method for the determination of the sum of thiabendazole and 5-hydroxythiabendazole in animal tissues and eggs, and additional information on a validated analytical method (with its ILV and a confirmatory method) for the determination of the sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugates in milk. The applicant submitted an independent laboratory validation of the QuEChERS multiresidue method. The method is sufficiently validated for the analysis of residues of thiabendazole (thiabendazole and 5-hydroxythiabendazole) in fat, muscle, liver and eggs with a LOQ of 0.01 mg/kg for each analyte (Spain, 2017). In addition, the applicant submitted an LC-MS-MS method for the analysis of residues of thiabendazole (thiabendazole, 5-hydroxythiabendazole and its sulfate conjugates) in milk. The method is sufficiently validated with a LOQ of 0.01 mg/kg for each analyte (Spain, 2017). The confirmatory data requirement for information on analytical methods for products of animal origin set by Commission Regulation 2017/1164 has been addressed.

The storage stability of thiabendazole and 5-hydroxythiabendazole in commodities of animal origin has been investigated in the framework of the EU pesticides peer review (EFSA, 2014b). The storage stability of benzimidazole in commodities of animal origin has not been addressed and may be required if further data on this metabolite are generated in the future (EFSA, 2016).

### 3.2. Magnitude of residues in livestock

Feeding studies with lactating cows and laying hens were assessed during the EU pesticides peer review and the revision of the MRL review (EFSA, 2014a,b). However, residues of benzimidazole were not investigated in the feeding studies and therefore the MRLs derived for commodities of animal origin refer only to thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate (EFSA, 2016). The revision of the MRL review confirmed the data gap for information to address the magnitude of potential residues of benzimidazole in animal commodities (EFSA, 2016). The data gap has been implemented as a confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole to support the MRLs for thiabendazole in citrus fruits (ft1)\(^\text{13}\) by Commission Regulation 2017/1164.

In the context of the current assessment, EFSA requested additional information to address the magnitude of potential residues of benzimidazole in animal commodities, considering livestock dietary exposure to benzimidazole residues via feed items and benzimidazole generated in vivo upon exposure of livestock to residues of thiabendazole via feed items. EFSA also requested additional information on the storage conditions of the samples in the livestock feeding study, as well as information to address the toxicological properties for the metabolite benzimidazole. No new feeding studies or toxicological studies were submitted in the context of the current applications. The applicant provided information on sample storage in the livestock feeding studies, confirming that samples were stored frozen and analyses were carried out within 3 months (Spain, 2017). EFSA concluded that the cow and poultry feeding studies are valid with regard to the storage stability of thiabendazole and 5-hydroxythiabendazole in animal tissues (data gap addressed).

EFSA concluded that, at the updated dietary burden for EU livestock (see Appendix B.2.2.1) total residues of thiabendazole are not expected to be present in animal matrices above the LOQ of

\(^{13}\) 0110000 Citrus fruits: The European Food Safety Authority identified some information on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.
0.01 mg/kg. Consequently, also residues of benzimidazole (formed in vivo from the exposure to thiabendazole via citrus dried pulp and transferred into animal matrices) are expected to be below the LOQ in commodities of animal origin. The estimated MRLs for products of animal origin also support the existing EU MRL of 7 mg/kg in citrus fruits. EFSA proposed MRLs for products of animal origin taking into account the existing Codex MRLs for thiabendazole in animal commodities that have been considered in the context of the revision of the MRL review (EFSA, 2016) and the veterinary MRLs established for thiabendazole in foodstuffs of animal origin by Commission Regulation No 37/2010 (see Appendix B.4).

In Section 4, EFSA assessed whether residues in animal commodities resulting from the intended and authorised uses at EU level and from the existing Codex MRLs and veterinary MRLs are likely to pose a consumer health risk.

4. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The toxicological reference values for thiabendazole used in the risk assessment (i.e. ADI of 0.1 mg/kg bw per day and ARfD value of 0.1 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission, 2016). The metabolite 5-hydroxythiabendazole and its sulfate conjugate, included in the residue definitions for risk assessment for commodities of animal origin, were expected to share the toxicity potential of the parent thiabendazole, therefore the reference values of the parent are applicable to these metabolites (EFSA, 2014b). The toxicity of plant metabolite benzimidazole, which is relevant for the intended use on witloof and potentially in animal commodities, has not been addressed and the lack of this information was set as a data gap after the EU pesticides peer review (EFSA, 2016).

EFSA performed an indicative dietary risk assessment for all plant commodities using the risk assessment residue definition `thiabendazole` only. The available evidence from the submitted residue trials does not exclude the possibility of residues of benzimidazole conjugates in witloof (included in the tentative residue definition for risk assessment for pre-harvest uses) and in sweet potatoes following the authorised post-harvest use. The data gap identified in the EU pesticides peer review for information on the toxicity on the metabolite benzimidazole is relevant for the MRL application for witloof.

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed for the commodities assessed in this application. The calculations were based on the highest residue (HR) values derived from supervised field trials and the complete list of input values can be found in Appendix D.2. The exposure assessment was refined by considering the peeling factor for citrus fruits (0.047) derived from the residue trials data, the previously derived indicative processing factor (PF) for orange juice (0.08), the previously derived peeling factor (PeF) for bananas (EFSA, 2016) and by considering the HR value for the edible portion of mangoes (pulp) as proposed by the EMS (Spain, 2018a).

The short-term exposure estimates for thiabendazole did not exceed the ARfD for any of the crops assessed in this application (see Appendix B.3).

EFSA notes that, if residues of thiabendazole occur in sweet potatoes at the derived MRL value (3 mg/kg), the dietary exposure of certain consumers may exceed the ARfD (151% of the ARfD for sweet potatoes/boiled) under certain conditions (i.e. consumption of a large portion of the product without consideration of washing/peeling/processing which would lead to a reduction of the residues in the product). A single submitted processing study in sweet potatoes indicates that industrial and household processing leads to a reduction of the residues in the processed product, however as only one study is available the information is not sufficient to derive a robust processing factor (Spain, 2018b). Risk managers should decide whether the safety margin of the exposure assessment based on the highest residue and the indicative information from the single available processing study in sweet potato is sufficient, considering that in reality residues in individual units/lot consumed may occur at or above the proposed MRL.
**Long-term (chronic) dietary risk assessment**

In the framework of the revision of the MRL review a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level, the tentative risk assessment values for Codex MRLs assessed in the revision of the MRL review as well as the relevant veterinary MRLs that are established for thiabendazole (EFSA, 2016). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of the current MRL and import tolerance applications. For those commodities where the calculated MRL under current assessment is lower (citrus fruits) or at the same level (bananas) the higher input value was selected to cover the most critical use scenario. Additionally, the consumer exposure assessment was updated using the fall-back GAP for seed potato use (EFSA, 2016) in line with the EU MRL for potatoes implemented by Commission Regulation 2017/1164, and the lower input values calculated for products of animal origin. The input values used in the exposure calculations are summarised in Appendix D.2.

The exposure assessment was refined by considering the peeling factor for citrus fruits derived from the residue trials data and the previously derived peeling factor for bananas (EFSA, 2016) and by considering STMR value for mangoes in the edible portion (pulp), as proposed by the EMS (Spain, 2018a).

The estimated long-term dietary intake for thiabendazole residues accounted for up to 35% of the ADI (NL toddler diet). 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 B.3.

Based on these calculations, EFSA concluded that the long-term intake resulting from the intended uses on citrus fruits, bananas and witloof and the authorised uses of thiabendazole on mangoes and sweet potatoes in the exporting countries are unlikely to present a risk to consumer health with regard to thiabendazole.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

### 5. Conclusion and Recommendations

The data submitted in support of the current MRL and import tolerance applications were found to be sufficient to derive MRL proposals for citrus fruits, bananas and witloof, and import tolerance proposals for mangoes and sweet potatoes.

EFSA updated the livestock dietary burden calculation, taking into account the intended and existing uses on citrus fruits, as well as the implemented MRL reflecting the less critical use pattern on seed potatoes in place of the previous critical use pattern on consumption potatoes, which lead to a significant reduction of the livestock dietary burden. Considering the intended and existing EU uses as a pesticide, it would be appropriate to lower the MRLs in animal commodities to the LOQ of 0.01 mg/kg. However, veterinary use MRLs are set at the level of 0.1 mg/kg for bovine and goat milk, muscle, fat, liver and kidney by Commission Regulation No 37/2010, which should be taken into account by risk managers.

The existing EU MRLs for bovine milk, muscle, fat, liver, kidney and other edible offals, and poultry muscle and fat are derived from Codex MRLs which are not sufficiently supported by data (EFSA, 2016). Information to address the confirmatory data requirements on the magnitude of residues of the metabolite benzimidazole in animal matrices has not yet been provided to EFSA. Lacking information on the magnitude of residues of the metabolite benzimidazole in animal matrices and lacking toxicological reference values for benzimidazole, the risk assessment for consumer exposure to benzimidazole via commodities of animal origin could not be performed for the existing EU MRLs for animal commodities which are derived from Codex MRLs.

EFSA concluded that the proposed uses of thiabendazole on citrus fruits, bananas and witloof, and the authorised uses on mangoes and sweet potatoes in the exporting countries will not result in a consumer exposure exceeding the toxicological reference values for thiabendazole and a risk to consumers’ health was not identified. A risk assessment for the metabolite benzimidazole is not required because residue levels of benzimidazole in witloof, and total residue levels in animal matrices that result from the existing and intended EU pesticide uses (GAPs) and the acceptable Codex MRLs for plant commodities, are expected to be below the LOQ of 0.01 mg/kg. Considering that the existing EU MRLs that are derived from Codex MRLs in animal commodities are associated with residues of benzimidazole higher than the LOQ, a separate risk assessment for benzimidazole would be required. However, since no data is available on the magnitude of benzimidazole in animal commodities and...
toxicological reference values for benzimidazole are not available, the risk assessment for the residue definition ‘total benzimidazole’ could not be performed.

The MRL recommendations are summarised in Appendix B.4.

References

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**Abbreviations**

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
DM dry matter
DP dustable powder
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-MS gas chromatography with mass spectrometry
GLP Good Laboratory Practice
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS liquid chromatography
LOQ limit of quantification
MRL maximum residue level
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI preharvest interval
\( P_{\text{ow}} \) partition coefficient between n-octanol and water
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
| Acronym | Description |
|---------|-------------|
| RMS     | rapporteur Member State |
| RPF     | relative potency factor |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SEU     | southern Europe |
| STMR    | supervised trials median residue |
| TRR     | total radioactive residue |
| WG      | water-dispersible granule |
| WHO     | World Health Organization |
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F or G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|----------------|------------------------------------|-------------|-----------------|-----------------------------|---------------|---------|
| **Citrus fruits**     | EU                      | I              | Penicillium sp.                     | SC 500 g/L  | Post-harvest drench/dip treatment BBCH 99, prior to storage | 1 n.a. 120-200 n.a. 120-200 g a.s./hL n.a. | n.a.      |
| **Citrus fruits**     | EU                      | I              | Penicillium sp.                     | SC 500 g/L  | Post-harvest spray with wax BBCH 99, prior to storage | 1 n.a. 375-500 1 L wax 3.75-5.0 | n.a.      |
| **Citrus fruits**     | EU                      | I              | Penicillium sp.                     | SC 500 g/L  | Post-harvest spray with water BBCH 99, prior to storage | 1 n.a. 375-500 1.5 5.6-7.5 g a.s./tonne crop | n.a.      |
| **Banana**            | EU (ES, PT)             | I              | Colletotrichum sp., Fusarium spp.   | SC 500 g/L  | Post-harvest dip treatment BBCH 99, prior to storage | 1 n.a. 21-45 n.a. 21-45 g a.s./hL n.a. | n.a.      |
| **Bananas**           | EU (FR)                 | I              | Colletotrichum sp., Fusarium spp.   | SC 500 g/L  | Post-harvest spray BBCH 99, prior to storage | 1 n.a. 45 16 7.0 g a.s./tonne crop | n.a.      |
| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|------------|-----------------------------------|-------------|-------------|--------------------------------|--------------|---------|
| Mangoes               | Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua, Costa Rica | I          | Colletotrichum sp.                | SC          | 485 g/L Dip (post-harvest) | mature 1 – | 97–243 | n.a. | 97–243 | g a.s./hLL min–max | 0 | Mist washed roots on a conveyor line, with tumbling action, before packing with 0.42 US fl oz of Mertect® 340-F to each 2,000 lb of roots in sufficient water for complete coverage. |
| Sweet potatoes        | USA                     | I          | Blackrot                         | SC          | 490 g/L In-line spray (post-harvest) | mature 1 – | n.a. | n.a. | 6.7 | g a.s./tonne crop | 0 | |
| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------------------|------------|-----------------------------------|-------------|-------------|---------------------------------|---------|
|                       |                          |            |                                   | Fungicide  | Method      | Type(b) | Conc. a.s. | Formulation | Range of growth stages & season(c) | Number min–max | Interval between application (min) | g a.s./hL | Water tonne min–max | Rate | Unit | PHI (days)(d) |                         |
| Witloof               | EU (BE, FR, NL)          | I          | Phoma exigua                      | SC         | Root treatment, spray | BBCH 99, prior to storage | 1     | n.a.       | 200          | 20                          | 40              | 28                            | 400 ml product/hL; 20 L of water per tonne roots (8 L of water per pallox of 400 kg roots), spraying on the conveyor belt, chicory roots (conservation) (spray application to chicory roots prior to forcing witloof) |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; a.i.: active ingredient; SC: suspension concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. 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 pre-harvest 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                      | Orange      |         | Post-harvest, 200 g a.s./hl | 0, 56, 112 | Study on oranges and other studies were all performed with phenyl-labelled thiabendazole (EFSA, 2016). |
| Root/tuber crops                 | Sugar beet  |         | Foliar, 5 × 400 g a.s./ha | 0, 56, 90 | |
| Cereals/grass                    | Wheat       |         | Foliar, 1 × 800 g a.s./ha | 0, 7, 37, 63 | Considering the overall availability of metabolism data (including rotational crop studies), a specific study to cover the treatment of chicory roots prior to witloof forcing is not considered necessary (EFSA, 2016). |
|                                  | Maize       |         | Seed, 0.09 mg a.s./seed | 81, 101 | |
| Pulses/oilseeds                  | Soyabean    |         | Foliar, 2 × 340 g a.s./ha | 0, 27, 78 | |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                    | Turnip      |         | Bare soil, 2 × 1.08 or 1 × 2.15 kg a.s./ha | 30, 120, 320 | Study was performed with phenyl-labelled thiabendazole (EFSA, 2016). |
| Leafy crops                         | Lettuce     |         | Bare soil, 2 × 1.08 or 1 × 2.15 kg a.s./ha | 30, 120, 320 | |
| Cereal (small grain)                | Wheat       |         | Bare soil, 2 × 1.08 or 1 × 2.15 kg a.s./ha | 30, 120, 320 | |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|-------------------------------------------|------------|---------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Yes | Thiabendazole is hydrolytically stable under conditions representative of pasteurisation, baking/brewing/boiling and sterilisation (Spain, 2017). |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes | |
|                                          | Other processing conditions | – | – |
Can a general residue definition be proposed for primary crops?

No  EFSA (2016)

Rotational crop and primary crop metabolism similar?

No  EFSA (2016)

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Yes  Spain (2017)

Plant residue definition for monitoring (RD-Mo)

Thiabendazole

Plant residue definition for risk assessment (RD-RA)

Post-harvest treatment:
- thiabendazole

Pre-harvest treatment and rotational crops:
- thiabendazole
- total benzimidazole (tentative, data gap identified) (EFSA, 2016)

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

Acidic, dry, high water content and high oil content:
- QuEChERS method
- HPLC–MS/MS, 0.01 mg/kg (EFSA, 2014a, 2014b)

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity    | T (°C) | Stability period Value | Compounds covered | Comment/ Source |
|-----------------------------------|----------|--------------|--------|------------------------|-------------------|-----------------|
| High water content                | Spinach  | –20          | 24     | Months                 | Thiabendazole     | Spain (2018b)   |
| High oil content                  | Soyabeans | –20          | 3      | Months                 | Thiabendazole     |                 |
| Dry/High protein content          | Dry beans | –20          | 9      | Months                 | Thiabendazole     |                 |
| Dry/High starch                   | Barley grain | –20      | 24     | Months                 | Thiabendazole     |                 |
| High acid content                 | Oranges   | –20          | 24     | Months                 | Thiabendazole     |                 |
| Others                            | –         | –            | –      | –                      | Thiabendazole     |                 |

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.
### 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(d) |
|-----------|------------------|---------------------------------------------------------------|-----------------|------------------------|---------------|----------------|-------|
| **Citrus fruits** (oranges, mandarins, lemons, grapefruits, sour orange)  | Indoor | Trials: post-harvest drench treatment, 1 × 200 g a.s./hl. (trial code: P1)  
**Mo = RA:** 1.27, 1.53, 1.74, 1.89, 2.02, 2.07, 2.41, 3.34 | Residue trials on oranges (4 trials) and mandarins (4 trials) compliant with the GAP for post-harvest drench/dip application (critical GAP). Extrapolation to whole group citrus fruits (0110000) possible. The existing EU MRL is set at the level of 7 mg/kg. | 5(f) | 3.34 | 1.96 | – |
| | Indoor | Trials: post-harvest spray application with wax, 1 × 500 g a.s./hl wax product, nominal rate 5.0 g a.s./tonne crop (trial code: P2)  
**Mo = RA:** 0.28, 0.50, 0.61, 0.72, 0.87, 1.00, 1.07, 1.28 | Residue trials on oranges (4 trials) and mandarins (4 trials) compliant with the GAP for post-harvest spray application with wax. Extrapolation to whole group citrus fruits (0110000) possible. | 3(f) | 1.28 | 0.8 | – |
| | Indoor | Trials: post-harvest spray application with water, 1 × 500 g a.s./hl, nominal rate 7.5 g a.s./tonne crop, followed by wax treatment (trial code: P4)  
**Mo = RA:** 0.12, 0.25, 0.29, 0.33, 0.39, 0.54, 0.71, 0.82 | Residue trials on oranges (4 trials) and mandarins (4 trials) compliant with the GAP for post-harvest spray application with water. Extrapolation to whole group citrus fruits (0110000) possible. | 1.5(f) | 0.82 | 0.36 | – |
| **Bananas**  | Indoor (Guadeloupe, France; Hawaii, USA) | Trials: post-harvest dip application, 1 × 0.040 – 0.045 g a.s./hl, PHI 2, 12, 24 days or PHI 5 days  
**Mo = RA:** 1.72, 2.12(e),(PHI 12d), 2.23(e),(PHI 12d), 3.33 | Residue trials on bananas compliant with the intended use GAP for post-harvest dip application. The existing EU MRL is set at the level of 6 mg/kg. | 6(f) | 3.33 | 2.18 | – |
| | Indoor (Honduras) | Trials: post-harvest spray application, 1 × 0.04 kg a.s./hl, PHI 6 days  
**Mo = RA:** 0.826, 1.00 | Residue trials on bananas compliant with the intended use GAP for post-harvest spray application. The number of trials is not sufficient to derive an MRL proposal or risk assessment values on the basis of the intended use GAP for spray application. | – | – | – | – |
| 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>(d)</sup> |
|---------------|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------|--------------------------|----------------|
| Mangoes       | Indoor (Brazil)             | Trials: post-harvest dip application, 1 × 243-250 g a.s./hl, BBCH 85-89, PHI 0, 7, 14, 21, 28, 35, 42 days  
 Mo = RA (whole fruit): 1.32, 2.4, 2.41<sup>(e)</sup>, (PHI 7d), 2.6, 2.71<sup>(e)</sup>, (PHI 7d), 3.4, 3.55<sup>(e)</sup>, (PHI 7d), 4.5  
 Mo = RA (pulp): 0.08, 0.027, 0.05<sup>(e)</sup>, (PHI 42d), 0.023, 0.16<sup>(e)</sup>, (PHI 42d), 0.010, 0.03<sup>(e)</sup>, (PHI 42d), 0.012 | Residue trials on mangoes compliant with the authorised use GAP for post-harvest dip application (Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua, Costa Rica GAP).  
 The tolerance established in the exporting countries is 5 mg/kg (Codex MRL). | 7<sup>(f)</sup> | Pulp: 0.16  
 Whole fruit: 4.5 | Pulp: 0.03  
 Whole fruit: 2.66 | – |
| Sweet potatoes | Indoor (USA)                | Trials: post-harvest spray application, 1 × 6.45–7.71 g a.s./tonne crop, PHI 0, 7, 13–14, 20–21, 27–28, 34–35 days  
 Mo = RA: 0.210, 0.257, 0.375, 0.457, 0.511, 0.538, 1.196, 1.549<sup>(g)</sup>, (PHI 34d), 1.631<sup>(g)</sup>, (PHI 27d) | Residue trials on sweet potatoes compliant with the authorised emergency exemption GAP for post-harvest spray application (USA).  
 The MRL established in the USA is a time-limited tolerance at the level of 10 mg/kg according to the residue definition for enforcement set as sum of thiabendazole and its metabolite benzimidazole (free and conjugated), expressed thiabendazole.  
 Submitted residue trials data reflect the levels of thiabendazole alone. | 3<sup>(f)</sup> | 1.63 | 0.51 | – |
| Witloof       |                             | Trials: spray application to chicory roots prior to forcing of witloof, 1 × 0.04 g a.s./kg roots, PHI 28 days  
 Mo = 2 × < 0.01, 0.04, 0.06  
 RA (1): 2 × < 0.01, 0.04, 0.06  
 RA (2): 4 × < 0.01 | Residue trials on witloof compliant with the intended use GAP for spray application. | 0.15 | Mo: 0.06  
 RA (1): 0.06  
 RA (2): < 0.01 | Mo: 0.03  
 RA (1): 0.03  
 RA (2): < 0.01 | (g) |

Monitoring residue definition (Mo): thiabendazole  
Risk assessment residue definition (RA):  
- thiabendazole (1)  
- total benzimidazole (2) (tentative residue definition, data gap)

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: risk assessment.

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

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(e): Higher residue value at later PHI selected.

(f): MRL calculation for post-harvest use based on the mean $+ 4 \times$ standard deviation method, due to the lower variability of the residues in post-harvest treatment.

(g): A conversion factor may be considered for pre-harvest uses if it would be demonstrated that the toxicity of benzimidazole is covered by the parent compound (data gap, EFSA, 2016).
B.1.2.2. Residues in rotational crops

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

Yes
Based on the confined rotational crop study (Spain, 1996), significant residues of benzimidazole may be expected in rotational leafy crops, leafy parts of root crops and cereal straw, and of parent thiabendazole in wheat straw, assuming transfer of the applied thiabendazole from the surface of treated seed potatoes into the soil. For authorisations other than seed potatoes, residue behaviour in rotational crops is not considered relevant. (EFSA, 2016)

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

Yes
In an interim report of a rotational field study (Spain, 2013), residues of thiabendazole and benzimidazole were below the limit of quantification of the method (0.01 mg/kg for each analyte as a free compound) in all the succeeding crops at the 30- and 60-day PBI. The submission of the final report is pending. Further data to address longer plant-back intervals and a full validation of data generation method in terms of conjugated residues is still required (data gap identified). (EFSA, 2016)

B.1.2.3. Processing factors

**IMPORTANT NOTE:** The processing factors reported below refer to the parent compound only.

| Processed commodity                  | Number of valid studies(a) | Processing Factor (PF) | Median PF | CF<sub>P</sub> (b) | Comment/Source |
|-------------------------------------|----------------------------|------------------------|-----------|---------------------|----------------|
| **Thiabendazole: robust processing factors (sufficiently supported by data)** |                           |                        |           |                    |                |
| Citrus fruits, peeled               | 48                         | 0.009, 0.014, 0.020, 0.020, 0.021, 0.022, 0.023, 0.025, 0.026, 0.026, 0.028, 0.033, 0.033, 0.034, 0.036, 0.037, 0.037, 0.040, 0.040, 0.040, 0.046, 0.046, 0.046, 0.047, 0.047, 0.048, 0.048, 0.050, 0.055, 0.056, 0.058, 0.061, 0.069, 0.074, 0.076, 0.081, 0.083, 0.083, 0.092, 0.094, 0.099, 0.100, 0.111, 0.143, 0.174, 0.183, 0.233, 0.300 | 0.047 | –                   | Spain (2017) |
| Mangoes, pulp                       | 8                          | 0.003, 0.003, 0.008, 0.009, 0.011, 0.021, 0.059, 0.061 | 0.010    | –                   | Spain (2018a) |
| **Thiabendazole: indicative processing factors (limited data)** |                           |                        |           |                    |                |
| Sweet potato root, baked, washed with peel | 1                          | 0.28                   | n/a       | –                   | The number of the processing studies is not sufficient to derive robust processing factors (Spain, 2018b). |
| Sweet potato root, chips            | 1                          | 0.02                   | n/a       | –                   |                |
### Processed commodity

| Processed commodity            | Number of valid studies | Processing Factor (PF) | Comment/Source |
|-------------------------------|-------------------------|------------------------|----------------|
| Sweet potato root, puree      | 1                       | 0.02                   | n/a            |
| Sweet potato root, fries      | 1                       | 0.12                   | n/a            |
| Sweet potato root, flakes     | 1                       | 0.08                   | n/a            |

**PF**: processing factor.  
(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).  
(b): Conversion factor for risk assessment in the processed commodity; median of the individual conversion factors for each processing residues trial.

### B.2. Residues in livestock

Dietary burden calculation according to OECD, 2013.

**IMPORTANT NOTE:** The livestock dietary burden calculations reported below refer to the parent compound only (EFSA, 2016).

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) 0.10 mg/kg DM | Previous assessment(c) |
|----------------------------|---------------------------------------------|---------------------------|----------------------------|----------------------------------------|------------------------|
|                            | Median | Maximum | Median | Maximum |                                      |                         |
| Cattle (all diets)         | 0.131  | 0.131   | 3.40   | 3.41    | Dairy cattle                          | Citrus dried pulp      | Yes                     | 117                     |
| Cattle (dairy only)        | 0.131  | 0.131   | 3.40   | 3.41    | Dairy cattle                          | Citrus dried pulp      | Yes                     | 92                      |
| Sheep (all diets)          | 0.018  | 0.018   | 0.42   | 0.44    | Lamb                                   | Apple pomace, wet      | Yes                     | 117                     |
| Sheep (ewe only)           | 0.014  | 0.015   | 0.42   | 0.44    | Ram/Ewe                               | Apple pomace, wet      | Yes                     | 117                     |
| Swine (all diets)          | 0.059  | 0.060   | 2.56   | 2.59    | Swine (breeding)                      | Citrus dried pulp      | Yes                     | 80                      |
| Poultry (all diets)        | 0.006  | 0.007   | 0.09   | 0.10    | Poultry broiler                       | Potato dried pulp      | No                      | 53                      |
| Poultry (layer only)       | 0.005  | 0.005   | 0.07   | 0.07    | Poultry layer                         | Potato dried pulp      | No                      | 41                      |
| Fish                       | –      | –       | –      | –       | –                                      | –                       | –                       | –                       |

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’.  
(c): Previous assessment considering the GAP for post-harvest use on consumption potatoes (supporting a tentative MRL of 20 mg/kg) and the existing EU GAP for citrus fruit (supporting tentative MRL of 3 mg/kg) (EFSA, 2016). Neither of these MRLs were implemented in the EU legislation and therefore the current livestock dietary burden calculation considers the fall-back GAP for use on seed potatoes assessed in the MRL review supporting the existing EU MRL for potatoes (0.04 mg/kg), and the GAP for citrus fruits assessed by JMPR supporting the existing EU MRL for citrus fruits (7 mg/kg), as implemented in Commission Regulation 2017/1164.
### 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/d) | Duration (days) | Comment/Source                                                                                                                                 |
|-------------------------------|-----------------|-------------------|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
|                               | Laying hen      | 1.6–3.2           | 7               | 0.56–0.76 N for cattle (all diets) 0.56–0.76 N for cattle (dairy) 0.51–0.69 N for sheep (all diets) 0.51–0.69 N for sheep (ewe) Studies performed with phenyl-labelled thiabendazole (Spain, 1996). |
|                               | Lactating goats | 2.0–2.7           | 10              | 0.43–0.86 N for poultry (all diets) 0.57–1.14 N for poultry (layer) Studies performed with phenyl-labelled thiabendazole (Spain, 1996).         |

- **Time needed to reach a plateau concentration in milk and eggs (days):**
  - Milk: 2 days (EFSA, 2016)
  - Eggs: Not reported (minor deficiency) (EFSA, 2016)

- **Metabolism in rat and ruminant similar:** Yes (EFSA, 2016)

- **Can a general residue definition be proposed for animals?** No (EFSA, 2016)

- **Animal residue definition for monitoring (RD-Mo):**
  - **Milk:** Sum of thiabendazole, 5-OH-thiabendazole and its sulfate conjugate, expressed as thiabendazole (EFSA, 2016)
  - **Other animal commodities:** Sum of thiabendazole and 5-OH-thiabendazole, expressed as thiabendazole (EFSA, 2016)

- **Animal residue definition for risk assessment (RD-RA):**
  - **Milk:** Sum of thiabendazole, 5-OH-thiabendazole and its sulfate conjugate, expressed as thiabendazole
    - Total benzimidazole (tentative, data gap identified) (EFSA, 2016)
  - **Other animal commodities:** Sum of thiabendazole and 5-OH-thiabendazole, expressed as thiabendazole
    - Total benzimidazole (tentative, data gap identified) (EFSA, 2016)

- **Fat soluble residues:** No

- **Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs):** QuEChERS multiresidue method for the analysis of residues of thiabendazole (thiabendazole and 5-hydroxythiabendazole) in fat, muscle, liver, and eggs, with a LOQ of 0.01 mg/kg for each analyte. ILV available. (Spain, 2017)
LC–MS/MS method for the analysis of residues of thiabendazole (thiabendazole, 5-hydroxythiabendazole and its sulfate conjugates) in milk, with a LOQ of 0.01 mg/kg for each analyte. ILV available. (Spain, 2017)

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 |
|-------------------------------------|--------|-----------|--------|------------------|-------|------|------------------|----------------|
|                                     | Bovine | Muscle    | –18    | 3 Months         | 3     | Months | Thiabendazole    | Storage stability was demonstrated for thiabendazole and 5-OH-thiabendazole (Spain, 2013). Available data are considered sufficient to address storage stability in all livestock commodities, including conjugates in milk. |
|                                     | Bovine | Liver     | –18    | 3 Months         | 3     | Months | Thiabendazole    | |
|                                     | Bovine | Milk      | –18    | 3 Months         | 3     | Months | Thiabendazole    | |
|                                     | Poultry| Egg       | –18    | 3 Months         | 3     | Months | Thiabendazole    | |

B.2.2. Magnitude of residues in livestock

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

IMPORTANT NOTE: Feeding studies with thiabendazole. The livestock feeding data reported below refer to the sum of thiabendazole and 5-OH-thiabendazole, also including the sulfate conjugate of 5-OH-thiabendazole in milk.

Feeding studies with benzimidazole not available, toxicity of benzimidazole unknown.

Calculations performed with Animal model 2017.14

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|-----------------------------------------------|-----------------------|----------------------|
|                  | Mean Highest STMR(a) (mg/kg) HR(b) (mg/kg)    |                       |                      |
| Cattle (all diets) | (0.96 mg/kg bw; 7.3 N; Dairy cattle (highest diet))(c) |                       |                      |
| Muscle           | n.r. 0.05 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Fat              | n.r. 0.05 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Liver            | n.r. 0.05 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Kidney           | n.r. 0.06 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Cattle (dairy only) | (0.96 mg/kg bw; 7.3 N)(c) |                       |                      |
| Milk(d)          | 0.05 n.a. 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Sheep (all diets)(e) | (0.96 mg/kg bw; 52.6 N; Lamb (highest diet))(c) |                       |                      |
| Muscle           | n.r. 0.05 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Fat              | n.r. 0.05 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Liver            | n.r. 0.05 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |
| Kidney           | n.r. 0.06 0.01(f) 0.01(f) 0.01(f) 0.01(f)     | 0.01*                 |

14 https://ec.europa.eu/food/plant/pesticides/max_residue_levels/guidelines_en
| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) |
|------------------|---------------------------------------------|-----------------------|---------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) |
| Sheep (dairy only)<sup>(e)</sup> |                   |                      |                      |                      |
| Closest feeding level (0.96 mg/kg bw; 65.5 N)<sup>(c)</sup> |                   |                      |                      |                      |
| Milk<sup>(d)</sup> | 0.05 | n.a. | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Swine<sup>(e)</sup> |                   |                      |                      |                      |
| Closest feeding level (0.96 mg/kg bw; 16.1 N; Breeding (highest diet))<sup>(c)</sup> |                   |                      |                      |                      |
| Muscle | n.r. | 0.05 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Fat | n.r. | 0.05 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Liver | n.r. | 0.05 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Kidney | n.r. | 0.06 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Poultry (all diets) |                   |                      |                      |                      |
| Closest feeding level (0.14 mg/kg bw; 20.6 N; Broiler (highest diet))<sup>(c)</sup> |                   |                      |                      |                      |
| Muscle | n.r. | 0.02 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Fat | n.r. | 0.03 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Liver | n.r. | 0.04 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |
| Poultry (layer only) |                   |                      |                      |                      |
| Closest feeding level (0.14 mg/kg bw; 27.4 N)<sup>(c)</sup> |                   |                      |                      |                      |
| Eggs | n.r. | 0.05 | 0.01<sup>(f)</sup> | 0.01<sup>(f)</sup> | 0.01* |

bw: body weight; STMR: supervised trials median residue; HR: highest residue; n.a.: not applicable; n.r.: not reported.

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

(a): As the mean residue levels were not reported for tissues and eggs (minor deficiency), the mean residue level for milk and the highest residue levels for eggs and tissues were recalculated at the 1 N rate for the median dietary burden.

(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1N rate for the maximum dietary burden.

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

(d): Highest residue level from day 1 to day 28 (daily mean of 3 cows).

(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.

(f): Risk assessment value at the LOQ monitoring (0.01 mg/kg) based on expert judgment.

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B.3. Consumer risk assessment

| ARfD  | Thiabendazole: 0.10 mg/kg bw (European Commission, 2016) |
|-------|--------------------------------------------------------|
| Highest IESTI, according to EFSA PRiMo | Sweet potatoes/boiled: 82% of ARfD (children)  
Sweet potatoes: 34% of ARfD (adults)  
Oranges: 32% of ARfD (children) (refined with PF)  
Grapefruits/ juice: 29% of ARfD (adults)  
Sweet potatoes: 9% of ARfD (children)  
Mangoes: 13% of ARfD (children)  
Grapefruits: 19% of ARfD (children)  
Mandarins: 14% of ARfD (children)  
Oranges/juice: 11% of ARfD (children)  
Bananas: 7% of ARfD (children)  
Lemons/jam: 8% of ARfD (children)  
Lemons: 8% of ARfD (children)  
Witloofs/boiled: 5% of ARfD (children)  
Limes: 5% of ARfD  
Witloofs: 2% of ARfD |
| Assumptions made for the calculations | The toxicity of benzimidazole currently being unknown (data gap identified), the exposure calculations were performed for the parent compound only. The exposure assessment to benzimidazole residues is relevant only for the pre-harvest uses (witloof) and, potentially, for residues in livestock commodities.  
The calculation is based on the highest residue levels expected in raw agricultural commodities, except for citrus fruits and bananas where the derived peeling factors were applied, and for mangoes where the highest residue level in the edible portion (pulp) was used.  
For the processed commodity oranges/juice, EFSA applied the indicative processing factor reported in the revision of the MRL review but for which the individual trials in citrus fruits were not reported to EFSA (2016).  
EFSA notes that, if residues of thiabendazole occur in sweet potatoes at the derived MRL value (3 mg/kg), the dietary exposure of certain consumers may exceed the ARfD under certain conditions (151% of the ARfD for sweet potatoes/boiled). Robust processing factors are not available for the processed commodity sweet potatoes/boiled.  
For animal commodities, the risk assessment was performed taking into account the existing and intended uses at EU level and the tentative risk assessment values for Codex MRLs assessed in the revision of the MRL review (EFSA, 2016). For goat muscle, fat, liver, kidney and milk, where the veterinary MRL is higher than the EU MRL proposal or Codex MRL, the highest residue levels were replaced by the veterinary MRL.  
For commodities not included in the present MRL application, the short-term exposure assessment was performed using the risk assessment values derived in previous EFSA reasoned opinions (HR values), which indicated exceedance of the ARfD for papayas due to differences in the revised version PRiMo exposure |
Further refinement of the exposure estimate for papayas may be possible, such as by the use of a peeling factor. For apples and pears EFSA replaced the default variability factor of 7 with the derived variability factor of 1.6 for the post-harvest treatment of pome fruits (EFSA, 2016).

Calculations performed with PRIMo revision 3.1

**ARfD**

Benzimidazole: toxicological reference values not available (data gap, EFSA, 2014b)

**Highest IESTI, according to EFSA PRIMo**

Not relevant for the crops/GAPs under consideration. Not assessed for commodities of animal origin.

**Assumptions made for the calculations**

Not relevant for residues in fruit crops following post-harvest treatment and for the authorised post-harvest use on sweet potatoes in the USA. For the intended use on witloof, residues of benzimidazole (free and conjugated) were not quantified at levels above the LOQ of 0.01 mg/kg and therefore an exposure assessment for benzimidazole was not required.

For animal commodities, the intended use on citrus fruits is not expected to contribute significantly to residues in animal matrices (levels above the LOQ of 0.01 mg/kg). However, information on the magnitude of residues of the metabolite benzimidazole in animal matrices is not available (data gap) and therefore a short-term consumer exposure assessment to benzimidazole could not be performed with regard to the existing EU MRLs for bovine and goat milk, muscle, fat, liver, kidney and other edible offals, and poultry muscle, fat and eggs.

**ADI**

Thiabendazole: 0.1 mg/kg bw per day (European Commission, 2016)

**Highest IEDI, according to EFSA PRIMo**

35% ADI (NL toddler)

Highest contributor among the crops under assessment:
- Sweet potatoes: 1.8% of ADI (IE adult)
- Oranges: 0.51% of ADI (DE child)
- Bananas: 0.27% of ADI (NL toddler)
- Mandarins: 0.10% of ADI (FR toddler)
- Grapefruits: 0.09% of ADI (IE adult)
- Lemons: 0.05% of ADI (GEMS/Food G11)
- Witloofs/Belgian endives: 0.01% of ADI (NL toddler)
- Mangoes: 0.01% of ADI (IE adult)
- Limes: <0.01% of ADI (all diets)
- Other citrus fruit: <0.01% of ADI (all diets)

**Assumptions made for the calculations**

The toxicity of benzimidazole currently being unknown the exposure calculations were performed for the parent compound only (plant commodities) or for the relevant animal residue definition in animal commodities.
The exposure assessment to benzimidazole residues is relevant only for the pre-harvest uses (witloof) and, potentially, for residues in livestock commodities.

The calculation is based on the median residue levels derived for raw agricultural commodities derived in the revision of MRL review or under the present assessment. For citrus fruits, avocados and banana the derived peeling factors were applied and for mangoes the median residue level in the edible portion (pulp) was used.

For animal commodities, the risk assessment was performed taking into account the existing and intended uses at EU level and the tentative risk assessment values for Codex MRLs assessed in the revision of the MRL review (EFSA, 2016). For goat muscle, fat, liver, kidney and milk, where the veterinary MRL is higher than the EU MRL proposal or Codex MRL, the median residue levels were replaced by the veterinary MRL.

The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

Calculations performed with PRImo revision 3.1

| ADI | Benzimidazole: toxicological reference values not available (data gap, EFSA, 2014b) |
|-----|---------------------------------------------------------------------------------|
| Highest IEDI, according to EFSA PRImo | Not relevant for the crops/GAPs under consideration. Not assessed for commodities of animal origin. |
| Assumptions made for the calculations | Not relevant for residues in fruit crops following post-harvest treatment and for the authorised post-harvest use on sweet potatoes in the USA. For the intended use on witloof, residues of benzimidazole (free and conjugated) were not quantified at levels above the LOQ of 0.01 mg/kg and therefore an exposure assessment for benzimidazole was not required. For animal commodities, the intended use on citrus fruits is not expected to contribute significantly to residues in animal matrices (levels above the LOQ of 0.01 mg/kg). However, information on the magnitude of residues of the metabolite benzimidazole in animal matrices is not available (data gap) and therefore a long-term consumer exposure assessment to benzimidazole could not be performed with regard to the existing EU MRLs for bovine and goat milk, muscle, fat, liver, kidney and other edible offals, and poultry muscle, fat and eggs. |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRImo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue; LOQ: limit of quantification; GAP: Good Agricultural Practice
## B.4. Recommended MRLs

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                                                                                                                                 |
|---------|-------------------|-------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0110000 | Citrus fruits     | 7 (ft1)                 | 7                       | The submitted data are sufficient to calculate an MRL of 5 mg/kg for the intended post-harvest EU GAP. The revised livestock dietary burden considering also the more critical uses for citrus fruits supporting the existing MRL (Codex MRL) and the updated input values for other feed commodities as implemented in Commission Regulation 2017/1164 indicate that residues in animal commodities would not occur above the LOQ of 0.01 mg/kg. Therefore, the levels of benzimidazole in animal matrices that result from pesticide uses would be insignificant. The requirement for confirmatory information on the magnitude of residues of the metabolite benzimidazole has been superseded by the revised livestock dietary burden calculation. The MRL proposal reflects the existing EU MRL derived from the Codex MRL (7 mg/kg). Risk for consumers unlikely. |
| 0163020 | Bananas           | 6                       | No change               | The submitted data are sufficient to derive an MRL of 6 mg/kg for the intended post-harvest GAP. The derived MRL is identical to the existing EU MRL. Risk for consumers unlikely. |
| 0163030 | Mangoes           | 0.01*                   | 5 or 7                  | The submitted data are sufficient to derive an import tolerance of 7 mg/kg in support of the authorised post-harvest GAP for dip application (Guatemala, Belize, Honduras, Panama, Dominican Republic, Nicaragua, Costa Rica GAP). The calculated import tolerance is higher than the MRL in force in the exporting countries (Codex MRL: 5 mg/kg). It is noted that the 2019 Extra JMPR estimated a higher Codex MRL of 7 mg/kg for thiabendazole in mangoes that has not yet been adopted by the Codex Alimentarius Commission. Risk for consumers unlikely. |
| 0212020 | Sweet potatoes    | 0.01*                   | 3                       | The submitted data are sufficient to calculate an import tolerance of 3 mg/kg in response to the authorised emergency exemption GAP for post-harvest spray application (USA). Risk for consumers unlikely. The MRL in force in the exporting country is a time-limited tolerance in response to an emergency exemption authorisation at the level of 10 mg/kg determined according to the USA residue definition for enforcement: sum of thiabendazole and benzimidazole (free and conjugated), expressed as thiabendazole. |
| 0255000 | Witloofs/Belgian endives | 0.05* (ft2)             | 0.15                    | The submitted data are sufficient to calculate an MRL of 0.15 mg/kg for the intended indoor GAP (pre-harvest use). The residue definition for risk assessment also includes the metabolite benzimidazole (free and conjugated), however the... |
| Code<sup>a</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-----------------|-----------|------------------------|-------------------------|-----------------------|
| 1011010         | Swine Muscle | **0.05** (ft<sup>3</sup>) | **0.01** | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1011020         | Swine Fat   | **0.05** (ft<sup>3</sup>) | **0.01** | |
| 1011030         | Swine Liver | **0.15** (ft<sup>3</sup>) | **0.01** | |
| 1011040         | Swine Kidney | **0.3** (ft<sup>3</sup>) | **0.01** | |
| 1011050         | Swine Edible offals (other than liver and kidney) | **0.3** (ft<sup>3</sup>) | **0.01** | |
| 1012010         | Bovine Muscle | **0.1** (ft<sup>3</sup>) | **0.1** | |
| 1012020         | Bovine Fat   | **0.1** (ft<sup>3</sup>) | **0.1** | |
| 1012030         | Bovine Liver | **0.3** (ft<sup>3</sup>) | **0.1** or **0.3** (ft<sup>3</sup>) | Further risk management considerations required |
| 1012040         | Bovine Kidney | **1** (ft<sup>3</sup>) | **0.1** or **1** (ft<sup>3</sup>) | Further risk management |

Enforcement residue definition: sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole

- **1011010** Swine Muscle | **0.05** (ft<sup>3</sup>) | **0.01** | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
- **1011020** Swine Fat | **0.05** (ft<sup>3</sup>) | **0.01** | |
- **1011030** Swine Liver | **0.15** (ft<sup>3</sup>) | **0.01** | |
- **1011040** Swine Kidney | **0.3** (ft<sup>3</sup>) | **0.01** | |
- **1011050** Swine Edible offals (other than liver and kidney) | **0.3** (ft<sup>3</sup>) | **0.01** | |
- **1012010** Bovine Muscle | **0.1** (ft<sup>3</sup>) | **0.1** | |
- **1012020** Bovine Fat | **0.1** (ft<sup>3</sup>) | **0.1** | |
- **1012030** Bovine Liver | **0.3** (ft<sup>3</sup>) | **0.1** or **0.3** (ft<sup>3</sup>) | Further risk management considerations required |
- **1012040** Bovine Kidney | **1** (ft<sup>3</sup>) | **0.1** or **1** (ft<sup>3</sup>) | Further risk management |
| Code(a) | Commodity                                      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|--------|-----------------------------------------------|-------------------------|-------------------------|----------------------------------------------------------------------------------------|
| 1012050| Bovine Edible offals (other than liver and kidney) | 1 (ft³) | 0.1 or 1 (ft³) Further risk management considerations required | residues of the metabolite benzimidazole has not been addressed. Risk managers may consider to lower the MRL to the level of the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation 37/2010 or to maintain the existing EU MRLs derived from Codex MRLs which are not sufficiently supported by data and should be re-considered in the framework of confirmatory data assessment. If risk managers decide to set the MRL at the level of the veterinary MRL the footnote for confirmatory data can be deleted. |
| 1013010| Sheep Muscle                                  | 0.05* (ft³) | 0.01* | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1013020| Sheep Fat                                     | 0.05* (ft³) | 0.01* | |
| 1013030| Sheep Liver                                   | 0.15 (ft³) | 0.01* | |
| 1013040| Sheep Kidney                                  | 0.3 (ft³) | 0.01* | |
| 1013050| Sheep Edible offals (other than liver and kidney) | 0.3 (ft³) | 0.01* | |
| 1014010| Goat Muscle                                   | 0.1 (ft³) | 0.1 | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1014020| Goat Fat                                      | 0.1 (ft³) | 0.1 | |
| 1014030| Goat Liver                                    | 0.15 (ft³) | 0.1 | |
| 1014040| Goat Kidney                                   | 0.3 (ft³) | 0.1 | |
| 1014050| Goat Edible offals (other than liver and kidney) | 0.3 (ft³) | 0.1 | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRLs of 0.1 mg/kg for liver and kidney implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1015010| Equine Muscle                                 | 0.05* (ft³) | 0.01* | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data |
| Code(a)          | Commodity                              | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-----------------|----------------------------------------|------------------------|------------------------|---------------------------------------------------------------------------------------|
| 1015050         | Equine Edible offals (other than liver and kidney) | 0.3 (ft3)              | **0.01**                | requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1016010         | Poultry Muscle                         | 0.05 (ft3)             | **0.01** or **0.05** (ft) | Further risk management considerations required                                                                                           |
|                 |                                        |                        |                        | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. Risk managers may consider to lower the MRL to the level of the LOQ of 0.01 mg/kg or to maintain the existing MRLs derived from Codex MRLs which are not sufficiently supported by data and should be re-considered in the framework of confirmatory data assessment. |
| 1016020         | Poultry Fat                            | 0.05 (ft3)             | **0.01** or **0.05** (ft) | Further risk management considerations required                                                                                           |
|                 |                                        |                        |                        | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. Risk managers may consider to lower the MRL to the level of the LOQ of 0.01 mg/kg or to maintain the existing MRLs derived from Codex MRLs which are not sufficiently supported by data and should be re-considered in the framework of confirmatory data assessment. |
| 1016030         | Poultry Liver                          | 0.2 (ft3)              | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1016040         | Poultry Kidney                         | 0.2 (ft3)              | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1016050         | Poultry Edible offals (other than liver and kidney) | 0.2 (ft3)              | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1017010         | Other farmed terrestrial animals: Muscle | 0.05* (ft3)            | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1017020         | Other farmed terrestrial animals: Fat   | 0.05* (ft3)            | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1017030         | Other farmed terrestrial animals: Liver | 0.15 (ft3)             | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1017040         | Other farmed terrestrial animals: Kidney | 0.3 (ft3)              | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1017050         | Other farmed terrestrial animals: Edible offals (other than liver and kidney) | 0.3 (ft3)              | **0.01**                | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |

**Enforcement residue definition**: sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole
| Code\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                                                                                 |
|-----------|----------------|-------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1020020   | Milk Sheep     | 0.2 (ft³)               | 0.01*                   | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1020030   | Milk Goat      | 0.2 (ft³)               | 0.1                     | The available information is sufficient to derive an MRL at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed. The MRL proposal reflects the veterinary MRL of 0.1 mg/kg implemented by Commission Regulation No 37/2010. EFSA proposed to remove the footnote since for the veterinary MRL no confirmatory data are required. |
| 1020040   | Milk Horse     | 0.2 (ft³)               | 0.01*                   | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| 1020990   | Milk Others    | 0.2 (ft³)               | 0.01*                   | The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. |
| Code\(^{(a)}\) | Commodity                        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-----------|----------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 1030000   | Birds eggs                       | 2 (ft3)                 | \(0.01^{*}\) or \(0.1\) (ft) | Further risk management considerations required  
The available data are sufficient to derive an MRL proposal at the LOQ of 0.01 mg/kg on the basis of the updated EU livestock dietary burden, which is supported by the available data and for which the risk for consumers is unlikely. The confirmatory data requirement for information on analytical methods has been addressed. The confirmatory data requirement for information on the magnitude of residues of the metabolite benzimidazole has not been addressed but has been superseded by the revised livestock dietary burden calculation where the MRL is proposed at the LOQ of 0.01 mg/kg. Risk managers may consider to lower the MRL to the level of the LOQ of 0.01 mg/kg or to lower the MRL to the level of the Codex MRL which is not sufficiently supported by data and should be reconsidered in the framework of confirmatory data assessment. |

MRL: maximum residue level; GAP: Good Agricultural Practice.  
\(^{*}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ).  
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.  
\(^{(ft1)}\): 0110000 Citrus fruits: The European Food Safety Authority identified some information on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.  
\(^{(ft2)}\): 0255000 Witloofs/Belgian endives: The European Food Safety Authority identified some information on storage stability and on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.  
\(^{(ft3)}\): 1000000 Products of Animal Origin -Terrestrial Animals: The European Food Safety Authority identified some information on analytical methods and on the magnitude of residues of the metabolite benzimidazole as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2019, or, if that information is not submitted by that date, the lack of it.
Thiabendazole

### LOQs (mg/kg)

| Source of ADI | ADI (mg/kg bw per day) | Source of ARfD | ARfD (mg/kg bw) | Year of evaluation |
|---------------|------------------------|----------------|-----------------|-------------------|
| European Commission | 0.1                     | European Commission | 0.1             | 2016              |

### Source of ADI: European Commission

### No of diets exceeding the ADI:

| Commodity/group of commodities | Calculated exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|-------------------------------|----------------------------------------|----------------------------------------|----------------------------------------|----------------------------------------|
| Milk: Cattle                  | 39.93                                  | 10%                                    | 2%                                    | Milk: Cattle                           |
|                            | 27%                                    |                                        |                                        |                                        |
|                             | DL child                               | 39.94                                  | 22%                                    | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 18%                                    |                                        |                                        |                                        |
|                             | NL child                               | 16.14                                  | 10%                                    | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 10%                                    |                                        |                                        |                                        |
|                             | FR tanker 2-3 yr                        | 10.42                                  | 6%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 9%                                     |                                        |                                        |                                        |
|                             | UK infant                              | 6.06                                   | 5%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 7%                                     |                                        |                                        |                                        |
|                             | DL child                               | 7.32                                   | 4%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 7%                                     |                                        |                                        |                                        |
|                             | FR child 2-15 yr                        | 7.10                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 7%                                     |                                        |                                        |                                        |
|                             | DE women 14-60 yr                       | 6.63                                   | 5%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 7%                                     |                                        |                                        |                                        |
|                             | UK bitholder                           | 6.53                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 6%                                     |                                        |                                        |                                        |
|                             | DE general                             | 6.46                                   | 4%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 6%                                     |                                        |                                        |                                        |
|                             | FR infant                              | 5.54                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 5%                                     |                                        |                                        |                                        |
|                             | GEMS/Food G11                          | 5.29                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 5%                                     |                                        |                                        |                                        |
|                             | ES child                               | 5.11                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 5%                                     |                                        |                                        |                                        |
|                             | IE adult                               | 5.03                                   | 2%                                     | Sweet potatoes                        |
|                             |                                        |                                        |                                        |                                        |
|                             | 5%                                     |                                        |                                        |                                        |
|                             | SE general                             | 5.00                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | RO general                             | 4.46                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | NL general                             | 4.32                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | LT adult                               | 4.26                                   | 3%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | PL general                             | 4.24                                   | 4%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | GEMS/Food G28                          | 3.72                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | GEMS/Food G7                            | 3.66                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 4%                                     |                                        |                                        |                                        |
|                             | GEMS/Food G15                          | 3.67                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 3%                                     |                                        |                                        |                                        |
|                             | DL adult                               | 3.16                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 3%                                     |                                        |                                        |                                        |
|                             | GEMS/Food G10                          | 3.04                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 3%                                     |                                        |                                        |                                        |
|                             | ES adult                               | 2.90                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 3%                                     |                                        |                                        |                                        |
|                             | GEMS/Food G6                           | 2.70                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 3%                                     |                                        |                                        |                                        |
|                             | PT general                             | 2.74                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | FR adult                               | 2.47                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | IT toddler                             | 2.20                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | F1 3yr                                 | 2.20                                   | 2%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | IT adult                               | 1.94                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | UK vegetable                           | 1.81                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | F1 6yr                                 | 1.73                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 2%                                     |                                        |                                        |                                        |
|                             | NL adult                               | 1.46                                   | 0.7%                                   | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 1%                                     |                                        |                                        |                                        |
|                             | F1 adult                               | 1.34                                   | 1%                                     | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 1%                                     |                                        |                                        |                                        |
|                             | IE child                               | 1.13                                   | 0.6%                                   | Milk: Cattle                           |
|                             |                                        |                                        |                                        |                                        |
|                             | 1%                                     |                                        |                                        |                                        |

### Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of Thiabendazole is unlikely to present a public health concern.

### DISCLAIMER:
Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.
### Results for children

| Commodity                | ARfD/ADI MRL (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity                | ARfD/ADI MRL (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|--------------------------|----------------------|---------------------|-----------------------|--------------------------|----------------------|---------------------|-----------------------|
| Papayas                  | 10/5.1               | 216                 | 71%                   | Papayas                  | 10/5.1               | 71                  | 71%                   |
| Pears                    | 4/3                  | 95                  | 41%                   | Pears                    | 4/3                  | 41                  | 41%                   |
| Apples                   | 4/3                  | 88                  | 35%                   | Apples                   | 4/3                  | 35                  | 35%                   |
| Avocados                 | 20/1.47              | 74                  | 34%                   | Sweet potatoes           | 5/1.63               | 34                  | 34%                   |
| Quinces                  | 3/2                  | 49                  | 30%                   | Quinces                  | 3/2                  | 30                  | 30%                   |
| Oranges                  | 7/0.24               | 32                  | 22%                   | Avocados                 | 20/1.47              | 22                  | 22%                   |
| Medlar                   | 3/2                  | 28                  | 14%                   | Medlar                   | 3/2                  | 14                  | 14%                   |
| Grapefruits              | 7/0.24               | 19                  | 7%                    | Oranges                  | 7/0.24               | 7.5                 | 7%                    |
| Milk: Cattle             | 0.2/0.12             | 15                  | 5%                    | Milk: Cattle             | 0.2/0.12             | 4.6                 | 5%                    |
| Mandarins                | 7/0.24               | 14                  | 5%                    | Mandarins                | 7/0.24               | 4.4                 | 4%                    |
| Mangoes                  | 5/1.63               | 13                  | 4%                    | Grapefruits              | 7/0.24               | 4.4                 | 4%                    |
| Kumquats                 | 7/5.2                | 9.3                 | 4%                    | Mangos                   | 5/0.16               | 4.1                 | 4%                    |
| Sweet potatoes           | 5/1.63               | 8.6                 | 2%                    | Lemons                   | 7/0.24               | 2.2                 | 2%                    |
| Lemons                   | 7/0.24               | 8.4                 | 2%                    | Bovine: Edible offals (other) | 10/6.6        | 2.0                 | 2%                    |
| Bananas                  | 6/0.08               | 7.4                 | 2%                    | Milk: Goat               | 0.1/0.1             | 1.8                 | 2%                    |

### Results for adults

| Commodity                | ARfD/ADI MRL (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity                | ARfD/ADI MRL (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|--------------------------|----------------------|---------------------|-----------------------|--------------------------|----------------------|---------------------|-----------------------|
| Apples/juice             | 4/1.8                | 97                  | 60%                   | Apples/juice             | 4/1.8                | 60                  | 60%                   |
| Sweet potatoes/boiled    | 5/1.63               | 82                  | 29%                   | Sweet potatoes/boiled    | 5/1.63               | 29                  | 29%                   |
| Oranges/juice            | 7/0.22               | 11                  | 5%                    | Oranges/juice            | 7/0.22               | 5.1                 | 5%                    |
| Lemons/jam               | 7/2.7                | 8.2                 | 3%                    | Oranges/boiled           | 7/0.22               | 3.3                 | 3%                    |
| Quinces/boiled           | 0.15/0.06            | 5.3                 | 2%                    | Quinces/boiled           | 3/1.7                | 2.1                 | 2%                    |
| Wildboots/boiled         | 3/1.7                | 5.1                 | 1%                    | Wildboots/boiled         | 0.15/0.06            | 1.1                 | 1%                    |
| Potatoes/fried           | 0.04/0.02            | 1.9                 | 0.08%                 | Potatoes/fried           | 0.04/0.02            | 0.08                | 0.08%                 |
| Potatoes/dried (flakes)  | 0.04/0.05            | 0.59                | 0.06%                 | Potatoes/dried (flakes)  | 0.04/0.05            | 0.06                | 0.06%                 |
| Limes/juice              | 7/2.7                | 0.25                | #NUM!                 | #NUM!                     |                     |                     |                       |
| #NUM!                    | #NUM!                | #NUM!               | #NUM!                 | #NUM!                     |                     |                     |                       |
| #NUM!                    | #NUM!                | #NUM!               | #NUM!                 | #NUM!                     |                     |                     |                       |
| #NUM!                    | #NUM!                | #NUM!               | #NUM!                 | #NUM!                     |                     |                     |                       |

### Conclusion:

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 1 commodities. 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          | Input value (mg/kg) | Comment                              | Input value (mg/kg) | Comment                              |
|-------------------------|--------------------|--------------------------------------|--------------------|--------------------------------------|
| Potato culls            | 0.01               | STMR seed potato use, tentative (EFSA, 2016) | 0.02               | HR seed potato use, tentative (EFSA, 2016) |
| Apple pomace, wet       | 1.64               | STMR × PF (0.9) (indicative processing factor) (EFSA, 2016) | 1.64               | STMR × PF (0.9) (indicative processing factor) (EFSA, 2016) |
| Citrus dried pulp       | 15.39              | STMR (CXL, 2.7) (FAO, 2007) × PF (5.7) (indicative processing factor; EFSA, 2016) | 15.39              | STMR (CXL, 2.7) (FAO, 2007) × PF (5.7) (indicative processing factor; EFSA, 2016) |
| Potato process waste    | 0.06               | STMR seed potato use, tentative × PF (5.5) (EFSA, 2016) | 0.06               | STMR seed potato use, tentative × PF (5.5) (EFSA, 2016) |
| Potato dried pulp       | 0.38               | STMR seed potato use, tentative × default PF (38)(a) (EFSA, 2016) | 0.38               | STMR seed potato use, tentative × default PF (38)(a) (EFSA, 2016) |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For potato dried pulp, in the absence of processing factors supported by data, default processing factor of 38 was included in the calculation to consider the potential concentration of residues in these commodities.

D.2. Consumer risk assessment

| Commodity                  | Exiting/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|---------------------------|------------------------------|--------------------|-------------------------|-----------------------|
|                           |                              |                    | Input value (mg/kg)     | Comment               |
|                           |                              |                    |                        | Input value (mg/kg)   | Comment(a)              |
| Grapefruits               | 7                            | Existing MRL       | 0.127                  | STMR-RAC (CXL, 2.7) (FAO, 2007) × PeF (0.047) (EFSA, 2016) | 0.244                  | HR-RAC (CXL, 5.2) (FAO, 2007) × PeF (0.047) (EFSA, 2016) |
| Oranges                   | 7                            | Existing MRL       | 0.127                  | STMR-RAC (CXL, 2.7) (FAO, 2007) × PeF (0.047) (EFSA, 2016) | 0.244                  | HR-RAC (CXL, 5.2) (FAO, 2007) × PeF (0.047) (EFSA, 2016) |
| Oranges/juice             | –                            | –                  | –                      | –                     | 0.216                  | STMR-RAC (CXL, 2.7) (FAO, 2007) × PF (0.08) (indicative, EFSA, 2016) |
| Lemons                    | 7                            | Existing MRL       | 0.127                  | STMR-RAC (CXL, 2.7) (FAO, 2007) × PeF (0.047) (EFSA, 2016) | 0.244                  | HR-RAC (CXL, 5.2) (FAO, 2007) × PeF (0.047) (EFSA, 2016) |
| Limes                     | 7                            | Existing MRL       | 0.127                  | STMR-RAC (CXL, 2.7) (FAO, 2007) × PeF (0.047) (EFSA, 2016) | 0.244                  | HR-RAC (CXL, 5.2) (FAO, 2007) × PeF (0.047) (EFSA, 2016) |
| Mandarins                 | 7                            | Existing MRL       | 0.127                  | STMR-RAC (CXL, 2.7) (FAO, 2007) × PeF (0.047) (EFSA, 2016) | 0.244                  | HR-RAC (CXL, 5.2) (FAO, 2007) × PeF (0.047) (EFSA, 2016) |

Risk assessment residue definition: thiabendazole

Source: EFSA, 2016; FAO, 2007; PeF = processing factor; STMR = supervised trials median residue.
| Commodity | Exiting/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment | Comment |
|-----------|----------------------------|-------------------|-------------------------|----------------------|---------|
| Other citrus fruit | 7 | Existing MRL | 0.127 | STMR-RAC (CXL, 2.7) (FAO, 2007) × PeF (0.047) (EFSA, 2016) | – | – |
| Apples | 4 | EFSA (2016) | 1.8 | STMR-RAC (tentative) | 3 | HR-RAC (tentative)VF: 1.6 |
| Pears | 4 | EFSA (2016) | 1.8 | STMR-RAC (tentative) | 3 | HR-RAC (tentative)VF: 1.6 |
| Quinces | 3 | EFSA (2016) | 1.7 | STMR-RAC (CXL, tentative) | 2 | HR-RAC (CXL, tentative) |
| Medlar | 3 | EFSA (2016) | 1.7 | STMR-RAC (CXL, tentative) | 2 | HR-RAC (CXL, tentative) |
| Loquats/Japanese medlars | 3 | EFSA (2016) | 1.7 | STMR-RAC (CXL, tentative) | 2 | HR-RAC (CXL, tentative) |
| Kumquats | 7 | EFSA (2016) | 2.7 | STMR-RAC (CXL, tentative) | 5.2 | HR-RAC (CXL, tentative) |
| Avocados | 20 | EFSA (2016) | 0.945 | STMR-RAC × tentative PeF (0.15) (tentative) | 1.47 | HR-RAC × tentative PeF (0.15) (tentative) |
| Bananas | 6 | Intended MRL | 0.050 | STMR-RAC × PeF (0.023) (EFSA, 2016) | 0.077 | HR-RAC × PeF (0.023) (EFSA, 2016) |
| Mangoes | 5 | Intended import tolerance | 0.03 | STMR-pulp | 0.16 | HR-pulp |
| Papayas | 10 | EFSA (2016) | 3.8 | STMR-RAC (tentative) | 5.1 | HR-RAC (tentative) |
| Potatoes | 0.04 | EFSA (2016) | 0.01 | STMR-RAC (tentative) | 0.02 | HR-RAC (tentative) |
| Sweet potatoes | 5 | Intended import tolerance | 0.51 | STMR-RAC | 1.63 | HR-RAC |

**Risk assessment residue definition:**
- thiabendazole
- total benzimidazole (tentative residue definition, data gap)

**Risk assessment residue definition: sum of thiabendazole and 5-hydroxythiabendazole, expressed as thiabendazole**

| Commodity | Exiting/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment | Comment |
|-----------|----------------------------|-------------------|-------------------------|----------------------|---------|
| Swine: Muscle/meat | 0.01* | Intended | 0.01 | STMR-RAC | 0.01 | HR-RAC |
| Swine: Fat tissue | 0.01* | Intended | 0.01 | STMR-RAC | 0.01 | HR-RAC |
| Swine: Liver | 0.01* | Intended | 0.01 | STMR-RAC | 0.01 | HR-RAC |
| Swine: Kidney | 0.01* | Intended | 0.01 | STMR-RAC | 0.01 | HR-RAC |
| Commodity                                                                 | Exiting/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|-------------------------------------------------------------------------|------------------------------|--------------------|------------------------|-----------------------|
|                                                                        |                              |                    | Comment                | comment<sup>a</sup>   |
|                                                                        |                              |                    | Input value (mg/kg)    | Input value (mg/kg)   |
|                                                                        |                              |                    | Comment                | comment               |
| Swine: Edible offals (other than liver and kidney)                      | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Bovine: Muscle/meat                                                     | 0.1                          | EFSA (2016)        | 0.1                    | STMR-RAC (CXL, tentative) | 0.1                  | HR-RAC (CXL, tentative) |
| Bovine: Fat tissue                                                      | 0.1                          | EFSA (2016)        | 0.1                    | STMR-RAC (CXL, tentative) | 0.1                  | HR-RAC (CXL, tentative) |
| Bovine: Liver                                                           | 0.3                          | EFSA (2016)        | 0.2                    | STMR-RAC (CXL, tentative) | 0.21                 | HR-RAC (CXL, tentative) |
| Bovine: Kidney                                                          | 1                            | EFSA (2016)        | 0.5                    | STMR-RAC (CXL, tentative) | 0.6                  | HR-RAC (CXL, tentative) |
| Bovine: Edible offals (other than liver and kidney)                     | 1                            | EFSA (2016)        | 0.5                    | STMR-RAC (CXL, tentative) | 0.6                  | HR-RAC (CXL, tentative) |
| Sheep: Muscle/meat                                                      | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Sheep: Fat tissue                                                       | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Sheep: Liver                                                            | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Sheep: Kidney                                                           | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Sheep: Edible offals (other than liver and kidney)                      | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Goat: Muscle/meat                                                       | 0.1                          | Commission Regulation No 37/2010 | 0.1                  | Veterinary MRL      | 0.1                  | Veterinary MRL        |
| Goat: Fat tissue                                                       | 0.1                          | Commission Regulation No 37/2010 | 0.1                  | Veterinary MRL      | 0.1                  | Veterinary MRL        |
| Goat: Liver                                                             | 0.1                          | Commission Regulation No 37/2010 | 0.1                  | Veterinary MRL      | 0.1                  | Veterinary MRL        |
| Goat: Kidney                                                            | 0.1                          | Commission Regulation No 37/2010 | 0.1                  | Veterinary MRL      | 0.1                  | Veterinary MRL        |
| Goat: Edible offals (other than liver and kidney)                       | 0.1                          | Commission Regulation No 37/2010 | 0.1                  | Veterinary MRL liver, kidney | 0.1              | Veterinary MRL liver, kidney |
| Equine: Muscle/meat                                                     | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Equine: Fat tissue                                                      | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Equine: Liver                                                           | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Equine: Kidney                                                          | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Equine: Edible offals (other than liver and kidney)                     | 0.01*                        | Intended           | 0.01                   | STMR-RAC              | 0.01                  | HR-RAC                |
| Poultry: Muscle/meat                                                    | 0.05                         | EFSA (2016)        | 0.05                   | STMR-RAC (CXL, tentative) (FAO, 1997) | 0.05              | HR-RAC (CXL, tentative) (FAO, 1997) |
| Poultry: Fat tissue                                                     | 0.05                         | EFSA (2016)        | 0.05                   | STMR-RAC (CXL, tentative) (FAO, 1997) | 0.05              | HR-RAC (CXL, tentative) (FAO, 1997) |
| Commodity | Exiting/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|-----------|-----------------------------|-------------------|------------------------|----------------------|
| Poultry: Liver | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Poultry: Kidney | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Poultry: Edible offals (other than liver and kidney) | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Other farmed terrestrial animals: Muscle | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Other farmed terrestrial animals: Fat | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Other farmed terrestrial animals: Liver | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Other farmed terrestrial animals: Kidney | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Other farmed terrestrial animals: Edible offals (other than liver and kidney) | 0.01* | Intended | 0.01 STMR-RAC | 0.01 HR-RAC |
| Milk: Cattle | 0.2 EFSA (2016) | 0.12 | STMR-RAC (CXL, tentative) (FAO, 2000) | 0.12 STMR-RAC (CXL, tentative) (FAO, 2000) |
| Milk: Sheep | 0.01* | Intended | 0.01 STMR-RAC | 0.01 STMR-RAC |
| Milk: Goat | 0.1 Commission Regulation No 37/2010 | 0.1 Veterinary MRL | 0.1 Veterinary MRL |
| Milk: Horse | 0.01* | Intended | 0.01 STMR-RAC | 0.01 STMR-RAC |
| Eggs: Chicken | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Duck | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Goose | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Quail | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Others | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | – |
| Other crops/commodities | – | – | – | – |

Risk assessment residue definition: sum of thiabendazole, 5-hydroxythiabendazole and its sulfate conjugate, expressed as thiabendazole

| Commodity | Exiting/Proposed MRL (mg/kg) | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|-----------|-----------------------------|-------------------|------------------------|----------------------|
| Eggs: Chicken | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Duck | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Goose | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Quail | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | 0.1 HR-RAC (CXL, tentative) |
| Eggs: Others | 0.1 FAO, 1997 | 0.1 | STMR-RAC (CXL, tentative) | – |
| Other crops/commodities | – | – | – | – |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor; VF: variability factor; CXL: Codex maximum residue limit.
(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| thiabendazole        | 2-(1,3-thiazol-4-yl)-1H-benzimidazole  | ![Structural formula](image) |
| MK 360               | [NH]1c2cccc2nc1c1scn1                  |                       |
| CGA 28020            | WJCNZQLVWNLKYO-UHFFFAOYSA-N            |                       |
| 5-hydroxythiabendazole | 2-(1,3-thiazol-4-yl)-1H-benzimidazol-5-ol | ![Structural formula](image) |
| NOA 415696           | Oc1cc2nc([NH]c2cc1)c1csn1              |                       |
| VNENJHUOPQAPAT-UHFFFAOYSA-N |                        |                       |
| 5-hydroxythiabendazole O-sulfate conjugate | 2-(1,3-thiazol-4-yl)-1H-benzimidazol-5-y1 hydrogen sulfate | ![Structural formula](image) |
|                       | O=S(-O)(O)Oc1cc2nc([NH]c2cc1)c1csn1  |                       |
| FYTJWBDCONMFDZ-UHFFFAOYSA-N |                        |                       |
| benzimidazole         | 1H-benzimidazole                      | ![Structural formula](image) |
| CGA 18306            | c1ccccc2[NH]cnc12                     |                       |
| HYZICKYKOHLV3F-UHFFFAOYSA-N |                        |                       |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version NOSE41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C0SH41, Build 111302, 27 August 2019).