Evaluation of confirmatory data following the Article 12 MRL review for metalaxyl-M

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Abstract

The applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Belgium to evaluate the confirmatory data that were identified for metalaxyl-M in the framework of the MRL review under Article 43 and Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps new data regarding analytical methods for enforcement (validation data for hops and cocoa beans, ILV for fat) and several residue trials data supporting adjusted GAPs for metalaxyl-M on apples, pears, broccoli, cauliflower, herbs and edible flowers, soya beans and cocoa beans were submitted. Two data gaps concerning analytical methods for enforcement (validation data for hops and cocoa beans, ILV for fat) were considered satisfactorily addressed. However, the data gap on validation of the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock was not addressed. The data gap for residue trials supporting authorisations of metalaxyl-M was partially addressed. The data gap for residue trials supporting authorisations of metalaxyl was not addressed. The new information provided may require a revision of the existing MRLs for several commodities of plant and animal origin. Further risk management considerations are required.

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Keywords: metalaxyl-M, metalaxyl, confirmatory data, pesticide, MRL review, risk assessment

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Question numbers: EFSA-Q-2020-00386
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Declarations of interest: The declarations of interest of all scientific experts active in EFSA’s work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

Acknowledgments: EFSA wishes to thank: Stathis Anagnos, Laszlo Bura, Aija Kazocina, Andrea Mioč, Marta Szot, Aikaterini Vlachou for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Bellisai G, Bernasconi G, Brancato A, Carrasco Cabrera L, Ferreira L, Giner G, Greco L, Jarrah S, Leuschner R, Oriol Magrans J, Miron I, Nave S, Pedersen R, Reich H, Ruocco S, Santos M, Pia Scarlato A, Theobald A, Vagenende B and Verani A, 2021. Reasoned Opinion on the evaluation of confirmatory data following the Article 12 MRL review for metalaxyl-M. EFSA Journal 2021;19(12):6996, 57 pp. https://doi.org/10.2903/j.efsa.2021.6996

ISSN: 1831-4732

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The EFSA Journal is a publication of the European Food Safety Authority, a European agency funded by the European Union.
Summary

In 2015, when the European Food Safety Authority (EFSA) reviewed the existing Maximum Residue Levels (MRLs) for metalaxyl and metalaxyl-M according to Article 43 and Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) Validation of the analytical method for enforcement in complex matrices such as cocoa and hops;
2) Further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock;
3) Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat;
4) Residue trials supporting authorisations of metalaxyl in citrus fruits, apples, table grapes, wine grapes, strawberries, carrots, onions, peppers, melons, watermelons, flowering brassica, globe artichoke and soya beans;
5) Residue trials supporting authorisations of metalaxyl-M in apples, pears, flowering brassica, herbs and cocoa.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) 2017/1164, including footnotes related to data gaps number 1, 2, 3, 4, 5, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRLs by 1 July 2019. For grapefruits, oranges and strawberries, the data gap number 4 has become obsolete as in the meanwhile a new GAP for metalaxyl was reported and assessed under Article 10 of Regulation (EC) No 396/2005. Consequently, the confirmatory data gap footnote set for oranges, grapefruits and strawberries in Commission Regulation (EU) 2017/1164 was removed by Commission Regulation (EU) 2017/171. Similarly, the data gap number 4 for carrots is obsolete and was not implemented in the MRL regulation because the MRL was actually set on the basis of a metalaxyl-M use.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Syngenta Crop Protection AG submitted an application to the competent national authority in Belgium (rapporteur Member State, RMS) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to the EFSA on 14 May 2020. When assessing the evaluation report, EFSA identified points which needed further clarifications. On 21 July 2021, the RMS submitted a revised evaluation report which replaced the previously submitted evaluation report.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------|----------------|--------------|---------------------------|
| 0110030 | Lemons     | 0.5 (ft 1)     | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on citrus fruits is not addressed. No GAP have been reported for metalaxyl-M during the MRL review and confirmatory data processes. Therefore, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ. Further consideration needed. |
| Code<sup>(a)</sup> | Commodity         | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|------------------|-------------------|--------------------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0110040          | Limes             | 0.5 (ft 2)               | (0.4)<sup>(c)</sup> | Further risk management considerations required. The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on citrus fruits is not addressed. However, an alternative MRL of 0.4 mg/kg that is fully supported by data can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.4 mg/kg. Further consideration needed. |
| 0110050          | Mandarins         | 0.5 (ft 2)               | (0.4)<sup>(c)</sup> | Further risk management considerations required. The data gaps identified by EFSA concerning the lack of residue trials to support the SEU GAPs reported for metalaxyl and metalaxyl-M on apples and pears is not addressed. Therefore, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ. Further consideration needed. |
| 0130010          | Apples            | 1 (ft 3)                 | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on apples is not addressed. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.9 mg/kg. Further consideration needed. |
| 0130020          | Pears             | 1 (ft 3)                 | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on pears is not addressed. However, an alternative MRL of 0.9 mg/kg that is fully supported by data can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.9 mg/kg. Further consideration needed. |
| 0151010          | Table grapes      | 2 (ft 4)                 | (0.9)<sup>(c)</sup> | Further risk management considerations required. The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on table and wine grapes is not addressed. However, an alternative MRL of 0.9 mg/kg that is fully supported by data can be derived based on the critical GAPs reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.9 mg/kg. Further consideration needed. |
| 0151020          | Wine grapes       | 1 (ft 4)                 | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on table and wine grapes is not addressed. However, an alternative MRL of 0.9 mg/kg that is fully supported by data can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.9 mg/kg. Further consideration needed. |
| 0220020          | Onions            | 0.5 (ft 4)               | (0.01* or 0.02*)<sup>(c)</sup> | Further risk management considerations required. The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on onions is not addressed. However, an alternative MRL of 0.01* at the enforcement LOQ or at 0.02* mg/kg according to available trials can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.01* or 0.02* mg/kg. Further consideration needed. |
| 0231020          | Sweet peppers/ bell peppers | 0.5 (ft 4) | (0.4)<sup>(c)</sup> | Further risk management considerations required. The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on peppers is not addressed. However, an alternative MRL of 0.4 mg/kg that is fully supported by data can be derived based on the critical indoor GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.4 mg/kg. Further consideration needed. |
| Code<sup>(a)</sup> | Commodity       | Existing MRL<sup>(b)</sup> | Proposed MRL          | Conclusion/recommendation                                                                 |
|-----------------|----------------|-----------------------------|-----------------------|--------------------------------------------------------------------------------------------|
| 0233010         | Melons         | 0.2 (ft 4)                  | (0.15)                | Further risk management considerations required |
|                 |                |                             |                       | The data gap identified by EFSA concerning the lack of residue trials to support the GAPs reported for metalaxyl on melons and watermelons is not addressed. However, an alternative MRL of 0.15 mg/kg that is fully supported by data can be derived based on the critical indoor GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.15 mg/kg. Further consideration needed. |
| 0233030         | Watermelons    | 0.2 (ft 4)                  | (0.15)                | Further risk management considerations required |
| 0241010         | Broccoli       | 0.2 (ft 5)                  | (0.15)                | Further risk management considerations required |
| 0241020         | Cauliflowers   | 0.2 (ft 5)                  |                       | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl-M on flowering cabbages has been addressed, using an adjusted NEU GAP for metalaxyl-M. Based on the adjusted GAP, the existing MRL could be replaced by the updated value of 0.15 mg/kg. An updated consumer risk assessment was carried out; risk for consumers is unlikely. It is noted that the data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on flowering cabbages is not addressed. Further consideration needed. |
| 0256000         | Herbs and edible flowers | 3 (ft 6) | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl-M on herbs and edible flowers has not been addressed. The applicant has indicated that the indoor GAP for which the existing EU MRL was set, is no more authorised in the EU. Alternatively, the applicant reported a more critical indoor GAP, but that was not supported by data. The residue data submitted by the applicant would fully support an indoor GAP with 2 applications at 0.1 kg a.s./kg and a PHI 14 days, but no clear evidence was reported to EFSA that such an indoor GAP was authorised in the EU. Provided that at least one MS confirms such existing authorisation, the existing MRL could be replaced by the updated value of 1.5 mg/kg. Risk for consumers is unlikely. Further consideration needed. |
| 0270050         | Globe artichokes | 0.05 (ft 7) | (0.01* or 0.02*)   | Further risk management considerations required |
|                 |                |                             |                       | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on globe artichokes is not addressed. However, an alternative MRL of 0.01* at the enforcement LOQ or at 0.02* mg/kg according to available residue trials can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Further consideration needed. |
| Code**(a)** | Commodity | Existing MRL**(b)** | Proposed MRL | Conclusion/recommendation |
|------------|-----------|--------------------|--------------|---------------------------|
| 0401070    | Soyabees  | 0.1* (ft 8)       | (0.01* or 0.02*) Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on soya beans is not addressed. The applicant proposed a new SEU GAP for the use of metalaxyl-M on soya beans for which a lower MRL of 0.02* mg/kg is supported by residue data. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL at the enforcement LOQ of 0.01* or at 0.02* mg/kg according to provided residue trials. It is noted that the new GAP is a seed treatment and that a restriction of use was defined during the renewal of the approval of the active substance metalaxyl-M: ‘When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised’. Risk for consumers unlikely. Further consideration needed. |
| 0640000    | Cocoa beans | 0.1 (ft 9)   | 0.05 | The data gap concerning the lack of residue trials to support the GAP reported for metalaxyl-M on cocoa beans and the data gap concerning analytical methods for this matrix have been addressed. Based on an adjusted GAP on metalaxyl-M in Nigeria, the existing MRL could be replaced by the updated value of 0.05 mg/kg. An updated consumer risk assessment was carried out; risk for consumers is unlikely. |
| 0700000    | Hops      | 15 (ft 9)        | 15 | The data gap identified by EFSA concerning analytical methods has been addressed. The MRL is confirmed. The previous consumer risk assessment remains valid. The existing MRL is based on the critical GAP on metalaxyl-M reported during the MRL review. According to RMS and applicant, this critical GAP is not authorised in Germany. However, MRL based on the initial GAP may be maintained as other GAPs might have been authorised since the MRL review. |

**Enforcement residue definition:** Sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl.

| Code**(a)** | Commodity | Existing MRL**(b)** | Proposed MRL | Conclusion/recommendation |
|------------|-----------|--------------------|--------------|---------------------------|
| 1000000    | Products of animal origin-terrestrial animals | (ft 10) | Further risk management consideration required | The general data gap on analytical methods (validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock) is not addressed. |
| 1011010    | Swine muscle | 0.01* (ft 10)   | 0.01* | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| Code<sup>(a)</sup> | Commodity        | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|----------------|------------------|-------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1011020        | Swine fat tissue | 0.01* (ft 10)          | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. The data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1011030        | Swine liver      | 0.05* (ft 10)          | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1011040        | Swine kidney     | 0.2 (ft 10)            | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1011050        | Swine edible offals | 0.2 (ft 10)       | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012010        | Bovine muscle    | 0.01* (ft 10)          | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012020        | Bovine fat tissue | 0.01* (ft 10)         | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. The data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012030        | Bovine liver     | 0.05* (ft 10)          | 0.06         | Livestock dietary burden updated according to the OECD methodology indicates that a higher MRL would be required. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012040        | Bovine kidney    | 0.3 (ft 10)            | 0.4          | Livestock dietary burden updated according to the OECD methodology indicates that a higher MRL would be required. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012050        | Bovine edible offals | 0.3 (ft 10)     | 0.4          | Livestock dietary burden updated according to the OECD methodology indicates that a higher MRL would be required. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1013010        | Sheep muscle     | 0.01* (ft 10)          | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| Code<sup>(a)</sup> | Commodity       | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|------------------|-----------------|---------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1013020          | Sheep fat tissue| 0.01*<br>(ft 10)         | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ.                                                                                                               |
|                  |                 |                           |              | The data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed.                                                   |
|                  |                 |                           |              | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                             |
| 1013030          | Sheep liver     | 0.05*<br>(ft 10)         | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ.                                                                                                               |
|                  |                 |                           |              | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                             |
| 1013040          | Sheep kidney    | 0.3<br>(ft 10)           | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient.                                                                                                     |
| 1013050          | Sheep edible offals | 0.3<br>(ft 10)       | 0.15         | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                              |
| 1014010          | Goat muscle     | 0.01*<br>(ft 10)         | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ.                                                                                                               |
|                  |                 |                           |              | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                             |
| 1014020          | Goat fat tissue | 0.01*<br>(ft 10)         | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ.                                                                                                               |
|                  |                 |                           |              | The data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed.                                                   |
|                  |                 |                           |              | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                             |
| 1014030          | Goat liver      | 0.05*<br>(ft 10)         | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ.                                                                                                               |
|                  |                 |                           |              | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                             |
| 1014040          | Goat kidney     | 0.3<br>(ft 10)           | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient.                                                                                                     |
| 1014050          | Goat edible offals | 0.3<br>(ft 10)       | 0.15         | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                              |
| Code(a)  | Commodity       | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|---------|-----------------|-----------------|--------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1015010 | Equine muscle   | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1015020 | Equine fat tissue | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. The data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1015030 | Equine liver    | 0.05* (ft 10)   | 0.06         | Livestock dietary burden updated according to the OECD methodology indicates that a higher MRL would be required. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1015040 | Equine kidney   | 0.3 (ft 10)     | 0.4          | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                     |
| 1015050 | Equine edible offals | 0.3 (ft 10)     | 0.4          | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                     |
| 1016010 | Poultry muscle  | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1016020 | Poultry fat tissue | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. The data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1016030 | Poultry liver   | 0.05* (ft 10)   | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1016040 | Poultry kidney  | 0.05* (ft 10)   | 0.05*        | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                     |
| 1016050 | Poultry edible offals | 0.05* (ft 10)   | 0.05*        | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                     |
| 1020000 | Milk            | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1030000 | Bird eggs       | 0.01* (ft 10)   | 0.01*        | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                     |
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MRL: maximum residue level; GAP: Good Agricultural Practice; LOQ: limit of quantification; SEU: southern Europe; PHI: pre-harvest interval; RMS: rapporteur Member State.

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gaps No 4).

ft 2: The European Food Safety Authority identified some information on residue trials on metalaxyl 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 (Footnote related to data gap No 4).

ft 3: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gaps No 4 and 5).

ft 4: The European Food Safety Authority identified some information on residue trials on metalaxyl 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 (Footnote related to data gap No 4).

ft 5: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gaps No 4 and 5).

ft 6: The European Food Safety Authority identified some information on residue trials on metalaxyl-M 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 (Footnote related to data gap No 5).

ft 7: The European Food Safety Authority identified some information on residue trials on metalaxyl 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 (Footnote related to data gap No 4).

ft 8: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gaps No 4).

ft 9: The European Food Safety Authority identified some information on residue trials on metalaxyl-M and analytical methods 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 (Footnote related to data gap No 1 for cocoa and hops and to data gap 5 for cocoa).

ft 10: The European Food Safety Authority identified some information on analytical methods 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 (Footnote related to data gap No 2 for all commodities of animal origin and to data gap No 3 for animal fat tissues).
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Assessment

The review of existing MRLs for the active substance metalaxyl-M according to Article 12 of Regulation (EC) No 396/2005\(^1\) (MRL review) was originally performed in 2011 (EFSA, 2011). In 2014, also the review of existing MRLs for the active substance metalaxyl according to Article 12 was performed (EFSA, 2014). The conclusions of these reviews were not legally implemented. Furthermore, metalaxyl-M was evaluated for the renewal of approval in the framework of Regulation (EC) No 1107/2009\(^2\) where new data relevant for the assessment of residues in livestock were identified (EFSA, 2015a).

European Food Safety Authority (EFSA) therefore received on 4 February 2015, in accordance with Article 43 of Regulation (EC) No 396/2005, a mandate from the European Commission to update the review of the existing MRLs for metalaxyl and metalaxyl-M taking into account the new data that have become available in the framework of the renewal of the approval of metalaxyl-M. During this review, which updates the previous Article 12 MRL reviews both for metalaxyl and metalaxyl-M, the EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data, but for which no risk to consumers was identified (EFSA, 2015b). After the completion of the combined MRL review, EFSA assessed in 2016 an MRL application for the modification of the existing MRLs for metalaxyl in various crops (EFSA, 2016). Following the outcome of this assessment, the data gaps identified by the combined MRL review for grapefruits, oranges and strawberries become obsolete. The list of GAPs assessed in the framework of the MRL review that were not fully supported by data and for which confirmatory data are still requested are listed in Appendix A. Following the combined review of existing MRLs in accordance with Article 43, the legal limits have been modified by Commission Regulation (EU) 2017/1164\(^3\), including footnote(s) for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 1 July 2019.

In accordance with the specific provisions set out in the working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs (European Commission, 2020a), the applicant, Syngenta Crop Protection AG, submitted an application to the competent national authority in Belgium (designated rapporteur Member State, RMS) to evaluate the confirmatory data identified for metalaxyl-M during the MRL review. To address the data gaps identified by EFSA, the applicant provided new data regarding analytical methods for enforcement (validation data for hops and cocoa beans, independent laboratory validation (ILV) for fat) and several residue trials data supporting adjusted GAPs for metalaxyl-M on apples, pears, broccoli, cauliflower, herbs and edible flowers, soya beans and cocoa beans.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 14 May 2020 (Belgium, 2020). It is noted that EFSA initially put the assessment of the present application on hold to clarify first if also confirmatory data for metalaxyl were already submitted to the rapporteur Member State (RMS) Greece or were in the process of being submitted. After a clarification from the RMS and the Commission that such confirmatory data were not available and considering that the deadline for their submission already expired, EFSA resumed the assessment of the current application and the evaluation report, as required by Article 10 of the MRL regulation, on 21 January 2021. When assessing the evaluation report, EFSA identified points which needed further clarifications. On 21 July 2021, the RMS submitted a revised evaluation report which replaced the previously submitted evaluation report (Belgium, 2020).

EFSA based its assessment on the evaluation report submitted by the RMS for metalaxyl-M (Belgium, 2020), the reasoned opinion on the MRL review according to Article 43 (and 12) of Regulation (EC) No 396/2005 and additional assessments of metalaxyl and metalaxyl-M performed after the MRL review (EFSA, 2015c, 2016).

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1. Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
2. 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.
3. Commission Regulation (EU) 2017/1164 of 22 June 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acrinathrin, metalaxyl and thiabendazole in or on certain products. C/2017/4185 OJ L 170, 1.7.2017, p. 3–30.
For this application, the data requirements established in Regulation (EU) No 544/2011\(^4\) and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Commission Regulation (EU) 2017/1164 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\(^5\).

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The peer review for amendment of the approval conditions of the active substance in accordance with Regulation (EC) No 1107/2009 is ongoing, and therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

The evaluation report submitted by the RMS (Belgium, 2020) is considered a supporting document to this reasoned opinion and, thus, is made publicly available as a background document to this reasoned opinion.

1. **Residues in plants**

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

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

Not relevant for the current assessment.

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

Not relevant for the current assessment.

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

Not relevant for the current assessment.

1.1.4. **Methods of analysis in plants**

In the framework of the combined MRL review (EFSA, 2015b), it was concluded that metalaxyl and metalaxyl-M (sum of isomers) can be enforced in food of plant origin with a limit of quantification (LOQ) of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities. However, applicability of this method to complex matrices such as cocoa and hops was not demonstrated and a data gap was identified.

In order to address data gap number 1,\(^6\) the applicant provided new analytical method validation data to demonstrate the reliability of multiresidue QuEChERS method for enforcement of metalaxyl (sum of isomers) in the complex matrices hops and cocoa bean. The data were assessed by the RMS and considered valid (Belgium, 2020).

Details on the analytical method and its validation are presented in Appendix B.1.1.1. The QuEChERS Multiple Residue Method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) has been fully validated according to guidance SANCO/825/00 rev. 8.1, for enforcement of ‘metalaxyl (sum of isomers)’ in hops and cocoa beans. The method is not enantioselective so is valid for the existing residue definition for enforcement (without distinction of isomers). Satisfactory recovery results were found in hops and cocoa beans, for two different mass transitions (m/z 280 → 192 and m/z 280 → 160); therefore, confirmatory methods are not required. Specificity, the absence of interference, linearity and repeatability of the method was also sufficiently demonstrated. The method was validated for an LOQ of 0.01 mg/kg. An independent laboratory validation (ILV) is also available and has been fully validated for hops and cocoa beans (Belgium, 2020).

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\(^4\) 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.

\(^5\) 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.

\(^6\) Data gap number 1: Validation of the analytical method for enforcement in complex matrices such as cocoa and hops.
EFSA concluded that the data gap identified in the framework of the MRL review was addressed. It is noted that in the framework of the renewal of the approval of metalaxyl-M, a data gap regarding the extraction efficiency of the QuEChERS method for plant commodities was identified by the peer review process\(^7\) (EFSA, 2015a). As this issue is out of the scope of the article 12 confirmatory data assessment, new data to address the issue on extraction efficiency were not provided in the current application.

1.1.5. Stability of residues in plants
Not relevant for the current assessment.

1.1.6. Proposed residue definitions
The previously derived residue definitions are still applicable (see Appendix B.1.1.1).

1.2. Magnitude of residues in plants
1.2.1. Magnitude of residues in primary crops

- **Data gaps relevant for metalaxyl-M**

  The data gap number 5 is relevant for those MRLs of ‘metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)’ which were derived from an authorised GAP on metalaxyl-M.\(^8\) Therefore, in order to address data gap number 5, the applicant provided additional residue trials supporting adjusted GAPs for metalaxyl-M for apples, pears, broccoli, cauliflower, herbs and cocoa. In addition, in order to address the existing data gap for metalaxyl/metalaxyl-M, a new GAP with metalaxyl-M and residues trials were also provided to support an MRL on soya beans.

**Apples and pears**

The critical SEU GAP assessed during the MRL review (foliar treatment with two applications at 0.35 kg a.s./unit; PHI 15 days) is not supported by data.

For the confirmatory data assessment, the applicant and the RMS identified adjusted GAPs for use of metalaxyl-M on apples and pears in SEU. The adjusted GAPs consist of soil applications with SL formulation (soil incorporation or drip irrigation) (see Appendix A).

The soil incorporation of metalaxyl-M (2 applications at the single dose rate of 0.93 g a.s./tree; PHI 15 days) in a form of a soluble concentrate (SL) was identified as the critical GAP by the RMS. To support this GAP, four residue trials performed with a soil application using a solid formulation (GR) at higher application rate (i.e. 1–4 g a.s./tree) were reported by the RMS (Belgium, 2020). It is noted that the available trials were conducted with a solid formulation (GR – granule), whereas the adjusted GAPs are for a liquid formulation (SL – soluble concentrate). These formulation types are not equivalent. Granular formulations are applied intact on soil and different uptake is generally observed for granules vs. other types of formulations of the same active ingredient (OECD, 2016). Therefore, the results observed with a soil application using GR formulation might not be representative for a soil application with an SL formulation. The RMS was of the opinion that this deviation in the formulation types was not important because the treatment is made to the soil and residues in overdosed residue trials are below the LOQ (Belgium, 2020). The available trials indeed indicate that residues of metalaxyl-M would be below the LOQ after such soil application with GR formulation. Nevertheless, only four trials are available while eight trials are needed for major crops, as apples and pears. Furthermore, metalaxyl-M is a systemic substance and gradually can be taken up in upper parts of the crops after a soil treatment. Moreover, the active substance in a solution is more readily available for the root uptake than solid granules and therefore is more likely that SL formulation would result in a more critical residue situation than when granules are used. During the combined MRL review (EFSA, 2015b), trials supporting GAPs with soil treatments showed that residue uptake might occur in fruit crops (e.g. peppers, strawberries). Therefore, considering the deviation in the formulation type (GR vs.

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\(^7\) Data gap identified in the peer review of the pesticide risk assessment of the active substance metalaxyl-M (EFSA, 2015a): Extraction efficiency of the QuEChERS method for plants.

\(^8\) Data gap number 5: Residue trials supporting authorisations of metalaxyl-M trials in apples, pears, flowering brassica, herbs and cocoa.
SL) and the uncertainty on the possible residue uptake by the crop after soil application, EFSA is of the opinion that submitted residue trials are not representative of the adjusted GAP and are not adequate to confirm a no-residue situation. Consequently, the reduced data set reported for the confirmatory data assessment is not sufficient to address the data gap.

EFSA concluded that the confirmatory data gap identified in the framework of the MRL review was not addressed for apples and pears.

Broccoli and cauliflower (flowering brassica)

- **NEU:**

  During the combined MRL review (EFSA, 2015b), four trials on broccoli were identified to be missing to support the northern GAP on flowering brassica (2 × 0.08 kg a.s./ha; PHI 14 days; minimum interval between applications 8–14 days). For the confirmatory data assessment, the applicant and the RMS identified an adjusted GAP for use of metalaxyl-M in flowering brassica in the NEU, which is very similar to the initial authorised GAP (2 × 0.075 kg a.s./ha; PHI 14 days; minimum interval between applications 14 days) (see Appendix A).

  For the adjusted GAP, additional trials on broccoli (6 trials) and cauliflower (4 trials) were submitted (Belgium, 2020). The trials were compliant with the adjusted GAP and address the data gap identified during the MRL review. Since the 11 trials on cauliflower which have been assessed by the combined MRL review (EFSA, 2015b; updated in Belgium, 2020) are still considered compliant with the adjusted GAP, a total of 15 trials performed on cauliflower is available.

  Overall, a total of 21 trials (6 on broccoli + 15 on cauliflower) is available. According to the current extrapolation rules, this is sufficient to support the northern GAP on flowering brassica. The residue data indicate that a lower MRL of 0.15 mg/kg than the existing tentative EU MRL of 0.2 mg/kg would be sufficient to support the adjusted GAP of metalaxyl-M on flowering brassica.

- **SEU:**

  During the combined MRL review (EFSA, 2015b), a combined residue data set (one trial on cauliflower and four trials on broccoli) was assessed in support of the authorised SEU GAP on cauliflower and broccoli. Therefore, three trials on cauliflower were identified to be missing to fully support the southern GAP on flowering brassica (3 × 0.1 kg a.s./ha; PHI 21 days).

  Regarding cauliflower, the applicant and the RMS identified two adjusted SEU GAPs for use of metalaxyl-M to be assessed for the confirmatory data assessment. These GAPs are less critical than the initial authorised GAP on cauliflower but should be considered to maintain the metalaxyl-M use on cauliflower (GAP1: 2 × 0.1 kg a.s./ha; PHI 21 days; GAP2: 1 × 0.1 kg a.s./ha; PHI 21 days) (see Appendix A). According to the RMS, the GAP1 is not supported by data while GAP2 is supported by four newly submitted trials on cauliflower (4 × < 0.01 mg/kg). Therefore, the proposal of the RMS was to use GAP2 as an adjusted GAP to address the data gap of the MRL review. This conclusion is acceptable.

  Regarding broccoli, an updated GAP has been reported by the RMS, which is almost the same as the GAP assessed during the combined MRL review (only the PHI differs: 20 days instead of 21 days). The residue trials used in the combined MRL review are still applicable and sufficient to support this GAP (4 × < 0.02 mg/kg; EFSA, 2015b).

  EFSA concluded that the data gap identified in the framework of the MRL review was addressed for flowering brassica. An MRL proposal of 0.15 mg/kg can be derived for flowering brassica on the basis of the northern GAP, which is more critical than the southern GAPs on broccoli and cauliflower.

Herbs and edible flowers

The critical GAP assessed during the MRL review (indoor foliar treatment with three applications at 0.073 kg a.s./ha; PHI 28 days) was not supported by GAP compliant trials. According to the RMS, this GAP is no longer authorised in the EU.

Therefore, for the confirmatory data assessment, the applicant and the RMS have identified a new indoor GAP for use of metalaxyl-M in herbs: Foliar treatment with two to three applications at the rate of 0.1 kg a.s./ha; PHI 14 days (see Appendix A). It is noted that this GAP is more critical than the GAP

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9 It is noted that 10 trials (6 < 0.02; 2 < 0.02; 0.06; 0.11) were selected during the MRL review (EFSA, 2015b). However, in the framework of the confirmatory data, the RMS has updated the data selection based on more detailed summaries of the previous data (Belgium, 2020). It was also noted that the two values (0.06 and 0.11) were replicate trials, therefore, only the max value (0.11) is now retained for the assessment.
reported in the MRL review and in principle should be assessed in the framework of Article 10 of Regulation (EC) No 396/2005.

Several residues trials performed on lettuce have been submitted by the applicant and assessed by the RMS (Belgium, 2020). When considering only the trials performed under indoor conditions, a total of eight trials on open-leaf lettuce varieties is available. However, these trials were all performed according to a GAP with only two applications instead of 3. Therefore, the new GAP reported for the assessment of confirmatory data (with max 3 applications) is not supported by the available trials.

After the request of EFSA for additional data, the applicant informed the RMS and EFSA that a less critical GAP on herbs was authorised in Portugal (two applications at 0.1 kg a.s./ha, PHI 10–14 days); the available eight indoor trials would support this GAP. However, according to the RMS and according to the Portuguese competent authority, the above-mentioned authorisation is for outdoor use in fresh herbs and not for indoor use (Belgium, 2020). Considering that only four outdoor trials were reported in the confirmatory data assessment, this outdoor GAP is also not supported by enough trials.

The GAPs reported by the applicant are not supported by GAP-compliant residue trials. Therefore, EFSA concluded that the data gap identified in the framework of the MRL review was not addressed. However, the RMS noted that nine trials on lettuce (among which eight were performed on open-leaf varieties) are available to support an indoor GAP with maximum two applications at the rate of 0.1 kg a.s./ha (PHI 14 days). Should such a GAP be currently authorised in the EU, this could serve as a basis for risk managers to set an MRL. However, EFSA did not have the confirmation of it during the assessment of the confirmatory data.

**Soybeans**

In the framework of the MRL review (EFSA, 2011, 2015a), no GAP for metalaxyl-M on soya bean was notified. Nevertheless, the footnote associated with the existing EU MRL of 0.1 mg/kg in soya beans in Reg. (EU) 2017/1164 indicated residue trials to be missing for both metalaxyl and for metalaxyl-M.10 Although the original data gap identified during MRL review was linked to the southern GAP for metalaxyl (foliar treatment), the applicant and the RMS have identified a new SEU GAP with metalaxyl-M that is proposed now to be considered by EFSA for confirmatory data assessment. This GAP consists of a seed treatment at the dose of 17 g a.s./ha11 (see Appendix A). This new GAP in principle would need to be assessed in the framework of Article 10 of Regulation (EC) No 396/2005, but, since the MRLs are set for the sum of metalaxyl isomers, no distinction is made for which active substance the MRL is derived and the new use results in a lower MRL proposal, EFSA agreed to assess this GAP in the present framework.

The new GAP (seed treatment) is adequately supported by eight trials performed on sunflower seeds (4 SEU + 4 NEU) at a higher dose rate of 61–83 g a.s./100 kg seed. These trials have been evaluated in the framework of the renewal of metalaxyl-M approval (Belgium, 2013,2014). They have not been re-evaluated in the framework of this application but summaries are available in the evaluation of the RMS (Belgium, 2020). These trials are valid and sufficient to confirm that residues remain below the LOQ (< 0.02 mg/kg) in sunflower seeds after seed treatment. Therefore, a reduced data set is considered sufficient to support the GAP. The residue data extrapolation from sunflower seed to soya beans is acceptable, according to EU guidance document (European Commission, 2017). An MRL of 0.01 mg/kg is thus derived for soya beans in support of the new SEU use.

EFSA concluded that the data gap identified in the framework of the MRL review was addressed for soya beans, noting that the use of metalaxyl on soya beans initially notified during the MRL review is not supported by data. Furthermore, it should be noted that the following restriction of use was defined by Commission Implementing Regulation (EU) 2020/61712 renewing the approval of the active substance metalaxyl-M: ‘When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised’.

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10 Footnote: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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.

11 50 mL of APRON XL (339 g/L) per 100 kg seed.

12 Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, 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 143, 6.5.2020, p. 6–10.
Cocoa beans

The critical GAP assessed during the MRL review (foliar treatment with four applications at 0.09 kg a.s./ha; PHI 30 days) was not supported by a sufficient number of trials. According to the applicant, this GAP is no longer authorised in the exporting country (Ivory Coast). Therefore, for the confirmatory data assessment, the applicant and the RMS have identified an adjusted non-EU GAP (Nigeria) for use of metalaxyl-M in cocoa (foliar treatment with six applications at 0.072 kg a.s./ha; PHI 14 days; minimum interval between applications 14 days) (see Appendix A); according to the applicant, this is currently the critical GAP for this crop.

In support of this GAP, the applicant submitted eight decline residue trials performed in Ivory Coast and Ghana. These trials are compliant with the adjusted GAP (authorised in Nigeria). Cocoa is a major crop according to the EU crop classification (European Commission, 2017). Therefore, the available eight trials are sufficient to support the GAP and to derive an MRL of 0.05 mg/kg, which is lower than the existing tentative EU MRL of 0.1 mg/kg.

It was noted that the portions analysed in the trials consisted of fermented, dry cocoa beans still including shells while according to Annex I of Reg. (EC) No 396/2005 (amended by Commission Regulation (EU) 2018/6213), the portion to be analysed for MRL enforcement consists of ‘beans fermented or dried, after removal of shells’. Considering the low MRL being proposed (0.05 mg/kg) and noting that this can only result in a worst-case scenario for the consumer risk assessment, this minor deviation is deemed acceptable.

EFSA concluded that the data gap identified in the framework of the MRL review was addressed for cocoa beans.

- Data gaps relevant for metalaxyl

The data gap number 414 is relevant for those MRLs on ‘Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))’ which were derived from a GAP on metalaxyl. So far, no confirmatory data for metalaxyl have submitted by the authorisation holders. Therefore, EFSA concluded that the data gap 4 identified in the framework of the MRL review (EFSA, 2015b) was not addressed.

Nevertheless, for all crops concerned by this data gap (citrus fruits, apples, table grapes, wine grapes, strawberries, carrots, onions, peppers, melons, watermelons, flowering brassica, globe artichoke and soya beans), EFSA checked whether another MRL could be derived from a GAP currently authorised on metalaxyl-M and fully supported by data. To do this screening, EFSA considered the list of GAPs and residue trials available in the previous opinion on the combined MRL review (EFSA, 2015b) and in the present opinion.

Citrus fruits

During the MRL review, there were no trials available to support the metalaxyl SEU GAP on grapefruits, oranges, lemons, lime and mandarins. Therefore, a data gap was identified for all citrus fruits. In the meantime, an MRL modification for grapefruits and oranges based on a metalaxyl GAP fully supported by data (EFSA, 2016) was implemented in the Regulation (Reg. (EU) 2017/171).15 Therefore, the data gap identified during the MRL review is now only applicable to lemons, lime and mandarins according to the most recent MRL Regulation (Reg. (EU) 2017/1164). This data gap has not been addressed.

- For limes and mandarins, an MRL of 0.4 mg/kg could be derived from a GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the current tentative MRL of 0.5 mg/kg (for which the data gap is not addressed) can be lowered to 0.4 mg/kg, without footnote.
- For lemons, no GAPs have been reported on metalaxyl-M during the MRL review and no adjusted GAP has been reported as part of the present confirmatory data assessment. Therefore, MRL might be lowered to the enforcement LOQ.

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13 Commission Regulation (EU) 2018/62 of 17 January 2018 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council. OJ L 18, 23.1.2018, p. 1–73.
14 Data gap number 4: Residue trials supporting authorisations of metalaxyl in citrus fruits, apples, table grapes, wine grapes, strawberries, carrots, onions, peppers, melons, watermelons, flowering brassica, globe artichoke and soya beans.
15 For grapefruits and oranges, the current MRL is 0.7 mg/kg and is fully supported by data.
Apples

During the MRL review, there were no trials available to support the metalaxyl SEU GAP on apples. Therefore, a data gap was identified for this crop. This data gap has not been addressed.

Furthermore, the SEU GAP authorised for metalaxyl-M on apples was also not supported by data and the adjusted GAP for metalaxyl-M submitted in the present assessment (see metalaxyl-M assessment above) was not deemed supported by data either. Therefore, the tentative MRL cannot be confirmed and might be lowered to the enforcement LOQ.

Table and wine grapes:

During the MRL review, there were not enough trials available to support the metalaxyl NEU and SEU GAPs on table and wine grapes. Therefore, a data gap was identified for these crops. This data gap has not been addressed.

However, an MRL of 0.9 mg/kg could be derived from a GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the current tentative MRLs of 2 mg/kg in table grapes and 1 mg/kg in wine grapes (for which the data gap is not addressed) can be lowered to 0.9 mg/kg, without footnote.

Strawberries

During the MRL review, there were no trials available to support the metalaxyl indoor GAP on strawberries. Therefore, a data gap was identified for this crop. In the meantime, an MRL modification for strawberries based on a metalaxyl GAP fully supported by data (EFSA, 2016) was implemented in the Regulation (Reg. (EU) 2017/171)\textsuperscript{16}. Therefore, the data gap identified during the MRL review for strawberries is obsolete.

Carrots

During the MRL review, there were no trials available to support the metalaxyl SEU GAP on carrots. Therefore, a data gap was identified for this crop. However, this data gap was not reported in the Regulation because an MRL of 0.1 mg/kg was set based on a GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the data gap identified during the MRL review for carrots is obsolete.

Onions

During the MRL review, there were no trials available to support the metalaxyl GAP on onions (NEU, SEU, Indoor). Therefore, a data gap was identified for this crop. This data gap has not been addressed.

However, an MRL of 0.02* mg/kg could be derived from a GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the current tentative MRL of 0.5 mg/kg (for which the data gap is not addressed) can be lowered to 0.02* mg/kg, without footnote.

Peppers

During the MRL review, there were no trials available to support the indoor metalaxyl GAP on peppers. Therefore, a data gap was identified for this crop. This data gap has not been addressed.

However, an MRL of 0.4 mg/kg could be derived from indoor GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the current tentative MRL of 0.5 mg/kg (for which the data gap is not addressed) can be modified to 0.4 mg/kg, without footnote.

Melons, watermelons

During the MRL review, there were no trials available to support the metalaxyl GAPs on melons and watermelons (SEU and Indoor). Therefore, a data gap was identified for these crops. This data gap has not been addressed.

However, an MRL of 0.15 mg/kg could be derived from an indoor GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the current tentative MRLs of 0.2 mg/kg (for which the data gap is not addressed) can be modified to 0.15 mg/kg, without footnote.

\textsuperscript{16} For strawberries, the current MRL is 0.6 mg/kg and is fully supported by data.
Flowering brassica

During the MRL review, there were no trials available to support the metalaxyl GAPs on flowering brassica (NEU and Indoor). Therefore, a data gap was identified for these crops. This data gap has not been addressed.

The GAP authorised for metalaxyl-M was also not fully supported by data (EFSA, 2015b), but the adjusted GAPs for metalaxyl-M and the new data submitted in the present assessment allow to derive an MRL of 0.15 mg/kg (NEU GAP) fully supported by data (see metalaxyl-M assessment above). Therefore, the current tentative MRL of 0.2 mg/kg (for which the data gap is not addressed) can be modified to 0.15 mg/kg, without footnote.

Globe artichokes

During the MRL review, there were no trials available to support the metalaxyl SEU GAP on globe artichoke. Therefore, a data gap was identified for this crop. This data gap has not been addressed.

However, an MRL of 0.02* mg/kg could be derived from a GAP on metalaxyl-M, which was fully supported by data (EFSA, 2015b). Therefore, the current tentative MRL of 0.05 mg/kg (for which the data gap is not addressed) can be modified to 0.02* mg/kg, without footnote.

Soyabeans

During the MRL review, there were no trials available to support the metalaxyl SEU GAP on soya beans. Therefore, a data gap was identified for this crop. This data gap has not been addressed.

In the framework of the MRL review, no GAP for metalaxyl-M on soya bean was notified. However, a new GAP for metalaxyl-M and the data submitted in the present assessment allow to derive an MRL of 0.02* mg/kg fully supported by data (see metalaxyl-M assessment above). Therefore, the current tentative MRL of 0.1* mg/kg (for which the data gap is not addressed) can be modified to 0.02* mg/kg, without footnote.

1.2.2. Magnitude of residues in processed commodities

No data gaps were identified during the MRL review for this section (EFSA, 2015b). Nevertheless, a new study investigating the magnitude of residues in processed commodities was submitted in the present application (Belgium, 2020).

The newly submitted study investigates the levels of metalaxyl-M residues (measured as metalaxyl, sum of isomers) in commodities derived from the industrial processing of the raw agricultural commodity (RAC) cocoa beans. Fermented dry cocoa beans samples were taken from the field residue trials submitted in this application to address data gap 5 (Belgium, 2020). Two different processing trials have been performed. In each trial, a complete process has been tested, which included roasting of cocoa nibs, milling, cocoa liquor production, cocoa powder extraction, cocoa butter extractions and chocolate production. Residues have been measured in four relevant processed items (roasted nibs, cocoa powder, cocoa butter and chocolate) to derive processing factors (PF).

Samples were stored frozen (≤ –18°C) for a maximum of 10 months until extraction. Considering that metalaxyl-M residues (measured as metalaxyl, sum of isomers) have been demonstrated to be stable for a period of 24 months in the four main plant matrices, this is deemed acceptable. Furthermore, the stability in the sample extracts was proven by the corresponding procedural recovery samples, which were stored under the same conditions together with the sample extracts (Belgium, 2020).

The analytical method used to analyse samples for residues of metalaxyl-M (measured as metalaxyl, sum of isomers) based on liquid chromatography with tandem mass spectrometry (LC-MS/MS) and was successfully validated for the different processed fractions of cocoa beans (Belgium, 2020).

The calculated processing factors indicate that there is concentration of the residues in all processed fractions. Median processing factors derived from this study range between 1.1 (cocoa powder) and 2.0 (cocoa butter). Detailed results and PFs are reported in Appendix B.1.2.3. It is noted that the median PFs derived by the RMS (Belgium, 2020) slightly differ from the values reported in this reasoned opinion because the RMS has calculated the PF ratios based on average of the individual residues values while EFSA first derived single PF and then calculated the median of the PFs.
EFSA acknowledges that according to the data requirements applicable for the assessment of this MRL application, at least one additional trial would be required. However, the submitted studies are fully valid and compliant with the data requirements of Commission Regulation (EU) No 283/2013. Therefore, the lack of additional trial is considered a minor data gap and the available processing studies are deemed sufficient to derive robust processing factors which can be recommended for inclusion in Annex VI of Regulation (EC) No 396/2005.

2. Residues in livestock

In the framework of the combined MRL review of metalaxyl-M and metalaxyl (EFSA, 2015b), an estimation of the livestock dietary burden was performed according to the former European methodology (European Commission, 1996).

In the framework of the present assessment of the confirmatory data, the livestock exposure was recalculated according to the OECD methodology (OECD, 2013), considering all authorised uses of metalaxyl-M and metalaxyl supported by data. This update also includes the MRL application for metalaxyl on citrus fruits (EFSA, 2016) which was assessed after the combined MRL review. In addition, the new trials received in the present confirmatory data assessment allowed to derive updated input values for soya bean and soya bean by-products, which were considered in the calculation. The input values used to perform the calculation are reported in Appendix D.1 and the outcome of the calculations is reported in Appendix B.2.

For cattle (dairy and beef) and for swine, the calculated dietary burdens exceed the trigger value and a significant increase of the dietary burden is observed compared to the calculations performed in the combined MRL review of metalaxyl-M and metalaxyl. This increase can be attributed to the use of the Dietary burden calculator according to the Organisation for Economic Co-operation and Development (OECD) (OECD, 2013), which was not used at the time of the MRL review and to the consideration of new feed items which were not considered in previous assessments. For poultry, however, a slight decrease is observed (from 0.12 mg/kg DM to 0.09 mg/kg DM), noting that this is now below the trigger value used under the data requirements established in Regulation (EU) No 544/2011.

2.1. Nature of residues

Not relevant for the current assessment.

The previously derived residue definition is still applicable (see Appendix B.2.1.1).

2.2. Methods of analysis in livestock

In the framework of the combined MRL review (EFSA, 2015b), it was concluded that metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety could be enforced in food of animal origin with an LOQ of 0.01 mg/kg in muscle, fat, milk and eggs, and with an LOQ of 0.05 mg/kg in liver and kidney. This conclusion refers to a common moiety method using LC-MS/MS. However, data gaps were identified for further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps of the above-mentioned analytical method (data gap number 2) and for an ILV for fat (data gap number 3).

Regarding data gap number 2, no further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps were provided by the applicant. It is noted that this uncertainty was also identified by the RMS in the framework of the renewal of the approval of metalaxyl-M (Belgium, 2013, 2014). It is uncertain whether all metabolites of metalaxyl-M that contain the 2,6-dimethylaniline moiety and are possibly present in animal commodities are effectively and sufficiently covered by the common moiety analytical method (Belgium, 2020). Hence, EFSA concluded that data gap number 2 was not addressed.

17 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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. OJ L 93, 3.4.2013, p. 1–84.
18 Data gap number 2: Further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock.
19 Data gap number 3: Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat.
In order to address data gap number 3, the applicant provided an independent laboratory validation (ILV) of the common moiety analytical method for the matrix animal fat, which was assessed by the RMS according to guidance SANCO/825/00 rev. 8.1. The provided validation data confirm that the analytical method is suitable for the enforcement of residues of 2,6-dimethylaniline, expressed as metalaxyl-M, in animal fat with an LOQ of 0.01 mg/kg. EFSA concluded that the data gap 3 identified in the framework of the MRL review was addressed.

Details on the available analytical methods for animal matrices and their validation data are presented in Appendix B.2.1.1.

Out of the scope of the confirmatory data assessment, it is noted that the above-mentioned method is a common moiety method based on hydrolysis of the residues and subsequent determination of the 2,6-dimethylaniline (DMA) formed. Therefore, it may not be specific for metalaxyl/metalaxyl-M and their metabolites as the method can also detect DMA-moiety from other compounds.

Therefore, in case a simplified residue definition would be proposed in the future, the RMS assessed the applicability of QuEChERS analytical method for monitoring only metalaxyl (sum of isomers) in animal products. Based on new validation data, the RMS concluded that QuEChERS method has been fully validated for the determination of metalaxyl (sum of isomers) in animal matrices (milk, eggs, meat, fat, liver and kidney) with an LOQ of 0.01 mg/kg. However, it should be noted that extraction efficiency has not been addressed (Belgium, 2020).

2.3. Magnitude of residues in livestock

The current MRL values for animal commodities were derived on the basis of a former methodology and the calculated dietary burden was found to be different from the one assessed in the combined MRL review. Therefore, an update of the MRL calculations for all livestock commodities was performed.

The cow feeding study assessed in the framework of the EU pesticides peer review of the renewal of the approval of metalaxyl-M (EFSA, 2015a) and considered under the combined MRL review (EFSA, 2015b) is still relevant. Cows were dosed with metalaxyl at 0.07, 0.36 and 0.68 mg/kg bw. Samples were analysed using a common moiety method taking into account metalaxyl and metabolites containing the 2,6-dimethylaniline moiety, in line with the existing residue definition for enforcement and risk assessment. In the framework of the renewal of metalaxyl-M approval, detailed values of this feeding study were reported by the RMS (Belgium, 2013, 2014). These updated figures were considered in the calculation.

In addition, a new feeding study performed on laying hens (3 dose levels: 10, 30, 100 mg/kg DM) was also assessed in the framework of the renewal of metalaxyl-M approval (Belgium, 2013, 2014). In this study, the samples were analysed according to the common moiety method for metalaxyl and metabolites containing the 2,6-dimethylaniline moiety. This study was also considered in the present assessment for sake of completeness.

The results of the updated calculations are presented in Section B.2.2. A specific comparison between existing EU MRLs (derived from the combined MRL review and implemented in Reg. (EU) 2017/1164) and the updated values derived in the present opinion is reported in the same table.

- For cattle, the updated calculation shows that MRLs in muscle, fat and milk are still expected to remain below the LOQ. However, a slight increase compared to current MRL is observed for liver (from 0.05* to 0.06 mg/kg) and kidney (from 0.3 to 0.4 mg/kg).
- For sheep, the updated calculation shows that MRLs in muscle, fat, liver and milk are still expected to remain below the enforcement LOQs. Furthermore, a slight decrease compared to the current MRL is observed for kidney (from 0.3 to 0.15 mg/kg), probably due to the assessment of a specific dietary burden for sheep under the new methodology compared to the previous methodology.
- For swine, the updated calculation shows that MRLs in muscle, fat and liver are still expected to remain below the enforcement LOQs. Furthermore, a slight decrease compared to current MRL is observed for kidney (from 0.2 to 0.15 mg/kg).
- For poultry, the updated calculation does not indicate any modifications of the MRLs, all remaining below the LOQ.

It is concluded that the current MRL values are still valid except the MRLs on cattle liver, cattle kidney that need to be increased and the MRLs on sheep kidney and swine kidney that could be decreased. The modification of those MRL values, justified by most recent data and method of calculation, may be considered by risk managers, noting that the general data gap for further data
demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock is still not addressed (see Section 2.2).

3. Consumer risk assessment

An updated consumer risk assessment was performed considering:

- All input values previously considered for the consumer risk assessment of metalaxyl and metalaxyl-M (combined MRL review: EFSA, 2015b).
- Reasoned opinions on the MRL applications for metalaxyl-M (EFSA, 2015c) and metalaxyl (EFSA, 2016) assessed after the combined MRL review (for the risk assessment values for oranges, grapefruits, strawberries, gooseberries, Brussels sprouts, spinach and chards/beet leaves).
- The new risk assessment values (STMR and HR) for broccoli, cauliflower, soya beans and cocoa beans calculated in the present opinion.
- Updated risk assessment values for livestock commodities calculated in the present opinion.
- The revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

As the CXLs for metalaxyl and metalaxyl-M are not implemented in the EU legislation, they are not considered in the EU consumer risk assessment.

For apples, pears and herbs, it was concluded that the data gap for metalaxyl-M uses identified in the MRL review was not addressed and risk management decisions are needed. Meanwhile, for these commodities, the current MRLs and risk assessment values used in the MRL review were still considered for a conservative scenario.

For the other crops considered in the present assessment (lemons, limes, mandarins, table and wine grapes, onions, peppers, melons, watermelons, globe artichoke), the authorised GAPs for metalaxyl were not supported by data. Therefore, lower MRLs were proposed on the basis of authorised metalaxyl-M uses. Nevertheless, the existing MRLs were used as input values for a conservative scenario.

The toxicological profile of metalaxyl-M assessed in the framework of the EU pesticides peer review and the data were sufficient to derive an acceptable daily intake (ADI) of 0.08 mg/kg bw per day and acute reference dose (ARfD) of 0.5 mg/kg bw (EFSA, 2015a; European Commission, 2020b).

The input values used to perform this calculation are reported in Annex D.2.

Short-term (acute) dietary risk assessment

The short-term exposure did not exceed the ARfD of metalaxyl-M for any of the crops assessed in this application and in the previous MRL review (see Appendix B.3).

Long-term (chronic) dietary risk assessment

The estimated chronic exposures were compared with the ADI of metalaxyl-M. The highest calculated chronic intake accounted for 25% of the ADI (NL toddler).

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

It is noted that apples and pears were found to be some of the main drivers of the chronic exposure (max 15.6% of ADI and 5.4% of ADI, respectively) and acute exposure (22 and 28% of ARfD, respectively). For these commodities, it should be highlighted that the existing MRL (1 mg/kg), which was used as a worst-case assumption, is not supported by data (see Section 1.2.1). Therefore, risk managers may decide to lower those MRLs to the enforcement LOQ and the dietary exposures (chronic and acute) are therefore expected to significantly decrease further.

For the crops for which a potential lowering of the MRL is proposed under the present assessment, the input values used for the risk assessment were either the existing EU MRLs or the tentative risk assessment values derived in the MRL review. Pending on future risk management decision on lowering those MRLs, the actual consumer exposure to metalaxyl residues is expected to be lower. Therefore, EFSA notes that the calculated consumer exposure reflects the worst-case scenario.
4. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2015b), new data regarding analytical methods for enforcement (validation data for hops and cocoa beans, ILV for fat) and several residue trials data supporting adjusted GAPs for metalaxyl-M on apples, pears, broccoli, cauliflower, herbs and edible flowers, soya beans and cocoa beans were submitted by the applicant.

Data gap 1 (validation of the analytical method for enforcement in complex matrices such as cocoa and hops) and data gap 3 (independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) were sufficiently addressed.

Data gap 2 (further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock) was not addressed.

Data gap 5 (residue trials supporting authorisations of metalaxyl-M trials in apples, pears, flowering brassica, herbs and cocoa) was partially addressed. EFSA concluded that the lack of trials for flowering brassica and cocoa was addressed. However, this is not the case for apples, pears and herbs for which risk management decisions need to be taken.

Data gap 4 (Residue trials supporting authorisations of metalaxyl in lemons, limes, mandarins, apples, table grapes, wine grapes, onions, peppers, melons, watermelons, flowering brassica, globe artichoke and soya beans) was relevant for those MRLs on ‘metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers)’ which were derived from a GAP on metalaxyl. Since confirmatory data for metalaxyl were not submitted by the authorisation holders, EFSA concluded that the data gap 4 identified in the framework of the MRL review was not addressed. However, for all crops concerned by this data gap, EFSA checked whether another MRL fully supported by data could be derived from a GAP currently authorised on metalaxyl-M.

The existing EU MRLs for animal commodities were reassessed using the OECD methodology for calculating the livestock dietary burden. The results confirm the existing EU MRL for all commodities, except for cattle liver and kidney and sheep and swine kidney.

The consumer exposure as calculated in the MRL review was updated, considering the uses assessed after the MRL review and considering the data provided under the present assessment. No consumer intake concerns were identified for the existing and adjusted uses of metalaxyl/metalaxyl-M.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
Bw body weight
CAS Chemical Abstract Service
CS capsule suspension
CV coefficient of variation (relative standard deviation)
DAT days after treatment
DM dry matter
dS powder for dry seed treatment
DT₉₀ period required for 90 % dissipation (define method of estimation)
EC emulsifiable concentrate
Eq residue expressed as a.s. equivalent
EURL EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC gas chromatography
GC-ECD gas chromatography with electron capture detector
GC-MS gas chromatography with mass spectrometry
### Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

| Crop and/or situation | NEU, SEU, MS or country (or) F, G or T<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|----------------------|--------------------------------------------------|-----------------------------------|-------------|----------------|-------------------------------|---------|
|                      |                                                  |                                    | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages and season<sup>(c)</sup> | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)<sup>(d)</sup> |          |
| **Authorised northern GAPs for metalaxyl-M (MRL review, EFSA, 2015b)** | | | | | | | | | | | | | | |
| Broccoli DE F | Peronospora parasitica, Albugo candida | WG | Foliar spray | 2 | 8 | 0.08 | kg a.s./ha | 14 | No longer registered in the EU (Belgium, 2020) |
| Cauliflower DE F | Peronospora parasitica, Albugo candida | WG | Foliar spray | 2 | 8 | 0.08 | kg a.s./ha | 14 | No longer registered in the EU (Belgium, 2020) |
| Hops DE F | Pseudoperonospora humuli | Foliar treatment | 6 | n.r. | 0.30 | kg a.s./ha | 10 | No longer registered in the EU (Belgium, 2020) |
| **Adjusted northern GAPs for metalaxyl-M (Belgium, 2020)** | | | | | | | | | | | | | | |
| Broccoli NEU (UK) F | Albugo candida | SL | 465 g/L | Foliar spray | 1-2 | 14 | 200 | kg a.s./ha | 14 | Authorisation for use will expire on 31/12/2022. |
| Cauliflower NEU (UK, IE, BE) F | Albugo candida, Alternaria sp, Peronospora parasitica, Mycosphaerella brassicicola | SC | Foliar spray | 1-2 | 14 | 200 | kg a.s./ha | 14 | – |
### Evaluation of confirmatory data following the Article 12 MRL review for metalaxyl-M

| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|------------------------------------|-------------|-------------|--------------------------------|---------|
|                       |                         |                                    | Type(b)     | Conc. a.s.  | Method kind                    | g a.s./ha  | Water L/ha | Rate | Unit | PHI (days)(d) |               |          |
| Hops (FR)             | F                       | *Pseudoperonospora humuli*        | WG          | Foliar spray | 1 –                             | 1200–2200 | 0.194 kg a.s./ha | 14   | –    |               | Authorised southern GAPs for metalaxyl-M (MRL review, EFSA, 2015b) |
| Apples (ES)           | F                       | *Phytophthora spp.*               | Foliar      | 2           | n.r.                            | 0.35 g a.s./unit | 15   | Same remark. |
| Pears (ES)            | F                       | *Phytophthora spp.*               | Foliar      | 2           | n.r.                            | 0.35 g a.s./unit | 15   | Same remark. |
| Broccoli (SEU)        | F                       |                                    | Foliar      | 3           | n.r.                            | 0.1 kg a.s./ha | 21   | No longer registered in the EU (Belgium, 2020) |
| Cauliflower (SEU)     | F                       |                                    | Foliar      | 3           | n.r.                            | 0.1 kg a.s./ha | 21   | No longer registered in the EU (Belgium, 2020) |

**Adjusted southern GAPs for metalaxyl-M (Belgium, 2020)**

| Apples Pears | SEU (ES) | F | *Phytophthora sp.* | SL | Soil incorporation | 1–2 | 0.93 g a.s./tree | 15 | 2 mL product/tree |
|--------------|----------|---|-------------------|----|-------------------|-----|-----------------|----|-----------------|
| Crop and/or situation | NEU, SEU, MS or country | F, G or T | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|--------------------------|-----------|------------------------------------|-------------|----------------|-------------------------------|------------|--------|
|                       |                          |           |                                    | Type(b) | Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit | |
| Apples Pears          | SEU (ES, PT)             | F         | Phytophthora sp.                   | SL        | Drip irrigation | BBCH 11–49 | 1-2 | 0.576 | 15 | – |
| Broccoli              | SEU (CY, EL, IT)         | F         | Alternaria sp., Bremia sp., Peronospora sp. | WG      | Foliar spray | BBCH 11–49 | 2-3 | 10   | 1000 | 0.1 | kg a.s./ha | 20 | – |
| Cauliflower           | SEU (PT)                 | F         | Alternaria brassicae, Peronospora parasitica | WG      | Foliar spray | BBCH 11–49 | 2  | 10   | 0.1 | kg a.s./ha | 21 | GAP 1 Not supported by data |
| Cauliflower           | SEU (HR)                 | F         | Peronospora parasitica            | WG      | Foliar spray | BBCH 11–49 | 1  | -    | 1000 | 0.1 | kg a.s./ha | 21 | GAP2 Used to derive MRL |
| New southern GAP for metalaxyl-M (Belgium, 2020) |                        |           |                                    |           |             |                             |              |                     |              |                   |       |      | |
| Soyabean              | SEU (IT)                 | F         | Peronosclerospora Peronospora sp., Phytophthora sp., Phytophthora sp. | ES       | Seed treatment | ES 339 g/L | 00  | 1    | –   | 17 | g a.s./100 kg seed | n.a | 50 mL pdct/100 kg seed |
| Authorised indoor GAP for metalaxyl-M (MRL review, EFSA, 2015b) |                        |           |                                    |           |             |                             |              |                     |              |                   |       |      | |
| Herbs and edible flowers | NL                      | I         | Bremia                            | EC        | Foliar treatment | EC 36.6 g/L | 1-3 | 7    | 0.073 | kg a.s./ha | 28 | No longer registered in the EU (Belgium, 2020) |
| Adjusted indoor GAP for metalaxyl-M (Belgium, 2020) |                        |           |                                    |           |             |                             |              |                     |              |                   |       |      | |
| Herbs and edible flowers | FR                      | I         | Alternaria sp., Peronospora sp., Bremia sp. | WG      | Foliar spray | BBCH 11–49 | 2-3 | 10   | 1000 | 0.1 | kg a.s./ha | 14 | – |
| Authorised indoor GAP for metalaxyl-M (MRL review, EFSA, 2015b) |                        |           |                                    |           |             |                             |              |                     |              |                   |       |      | |
| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Method kind | Range of growth stages and season | Number min–max | Interval between application (min) | Application rate per treatment | PHI (days) |Remarks |
|-----------------------|--------------------------|------------------------------------|-------------|-------------|---------------------------------|----------------|-------------------------------|--------------------------------|------------|--------|
| Cocoa beans | CI | F | Foliar treatment | 4 | n.r. | 0.09 kg a.s./ ha | 30 | |
| **Adjusted indoor GAP for metalaxyl-M (Belgium, 2020)** | | | | | | | | |
| Cocoa beans | Nigeria | F | Black pod disease (*Phytophthora spp.*) | WG | Foliar spray | 6 | 14 | 0.072 kg a.s./ ha | 14 | Also authorised in Cameroon with an interval between applications of 21 days. |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; WG: water-dispersible granule; n.r.: not reported; SL: soluble concentrate; SC: suspension concentrate; ES: emulsion for seed treatment; n.a.: not applicable; EC: emulsifiable concentrate.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|---------------|---------------|
| Fruit crops                       | Tomato      | Foliar: | 3 × 160 g/ha   | 3, 14         | Radiolabelled active substance: phenyl-UL-14C-metalaxyl-M (EFSA, 2015a) |
| Leafy crops                       | Lettuce     | Foliar: | 3 × 200 g/ha   | 21            | Radiolabelled active substance: phenyl-UL-14C-metalaxyl and phenyl-UL-14C-metalaxyl-M (EFSA, 2011, 2014) |
| Cereals                           | Wheat       | Seed treatment: 19.3 g/100 kg seeds | 83, 127 | Radiolabelled active substance: phenyl-UL-14C-metalaxyl-M (EFSA, 2015a) |
|                                   |             | Seed treatment: 157 g/100 kg seeds | 83, 127 | |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                     | Carrot      | Bare soil, 616–628 g/ha | 30, 120, 270 | EFSA (2015a) |
| Leafy crops                          | Lettuce     | Bare soil, 616–628 g/ha | 30, 120, 270 | EFSA (2015a) |
| Cereal (small grain)                 | Wheat       | Bare soil, 616–628 g/ha | 30, 120, 270 | EFSA (2015a) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|---------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Yes | EFSA (2015a) |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | EFSA (2015a) |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes | EFSA (2015a) |
|                                          | Other processing conditions | – | – |
Can a general residue definition be proposed for primary crops?

Yes EFSA (2015a)

Rotational crop and primary crop metabolism similar?

Yes EFSA (2015a)

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

Yes EFSA (2015a)

Plant residue definition for monitoring (RD-Mo)

Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))

Plant residue definition for risk assessment (RD-RA)

Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))

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

Matrices with high water content, high oil content, high acid content and dry matrices (EFSA, 2015a,b; Belgium, 2013, 2014): QuEChERS method in combination with HPLC–MS/MS, LOQ 0.01 mg/kg, non enantioselective method: validated for enforcement of metalaxyl and metalaxyl-M (sum of isomers)

Complex matrices (hops and cocoa beans) (Belgium, 2020): QuEChERS method in combination with HPLC–MS/MS, LOQ 0.01 mg/kg, non enantioselective method: validated for enforcement of metalaxyl and metalaxyl-M (sum of isomers). Confirmatory method not required (validation for two different mass transitions (m/z 280-192 and m/z 280-160)). ILV available.

DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.

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                | Tomato fruit | –20 | 24 Months | Metalaxyl-M | The ratio of the R- and S-enantiomers is constant over the storage period (EFSA, 2015a). |
|                                   | Potato tuber  | –20 | 24 Months | Metalaxyl-M | The ratio of the R- and S-enantiomers is constant over the storage period (EFSA, 2015a). |
| High oil content                  | Rapeseed | –20 | 24 Months | Metalaxyl-M | The ratio of the R- and S-enantiomers is constant over the storage period (EFSA, 2015a). |
| Plant products (available studies) | Category               | Commodity    | T (°C) | Stability period | Compounds covered | Comment/Source                                                                 |
|-----------------------------------|------------------------|--------------|--------|------------------|-------------------|--------------------------------------------------------------------------------|
| Dry/High starch                   | Wheat grain            | -20          | 24     | Months           | Metalaxyl-M       | The ratio of the R- and S-enantiomers is constant over the storage period (EFSA, 2015a). |
| High acid content                 | Orange fruit           | -20          | 24     | months           | Metalaxyl-M       | The ratio of the R- and S-enantiomers is constant over the storage period (EFSA, 2015a). |
### B.2.1. Magnitude of residues in plants

#### B.2.1.1. 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) |
|----------------------|------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------|--------------|
| Apples Pears         | SEU              | 4 × < 0.02                                                   | Residue trials performed on apples with soil incorporation at rates equivalent to 1-4 g a.s./tree (higher than the adjusted GAP on metalaxyl-M: 0.93 g a.s./tree) (Belgium, 2020). However, trials were performed with GR formulation and that is not deemed appropriate to support the adjusted GAP which refers to SL formulation. | –                      | –            | –            |
| Broccoli Cauliflower | NEU              | Broccoli: 0.01; 3 × < 0.02; 0.02; 0.045 Cauliflower: 2 × < 0.01; 0.01; 8 × < 0.02; 3 × 0.02; 0.11 | A combined residue data set on broccoli (6 new trials) and cauliflower (4 new trials and 11 trials from the MRL review) compliant with the northern adjusted GAP for broccoli and cauliflower addressing data gap of the MRL review (Belgium, 2020). MRL
OECD = 0.15                                                                                           | 0.15                   | 0.11         | < 0.02       |
| Broccoli             | SEU              | 4 × < 0.02                                                   | 4 trials on broccoli compliant with the southern adjusted GAP for broccoli (3 × 0.1 kg a.s./ha; PHI 21 days) (EFSA, 2015b).                                                                                                                                                                                                                                                            | 0.02*                  | < 0.02       | < 0.02       |
| Cauliflower          | SEU              | 4 × < 0.01                                                   | 4 new trials on cauliflower compliant with the southern adjusted GAP for cauliflower (1 × 0.1 kg a.s./ha; PHI 21 days) addressing data gap of the MRL review (Belgium, 2020).                                                                                                                                                                                                                                     | 0.01*                  | < 0.01       | < 0.01       |
| Herbs and edible flowers | Indoor         | 3 × < 0.01; 2 × 0.06; 0.07; 0.66; 0.7                          | 8 new trials on open-leaf varieties of lettuce performed according to a use pattern reflecting 2 × 0.1 kg a.s./ha (± 25%); PHI 14 days (Belgium, 2020). The new indoor GAP under assessment (with maximum 3 applications at 0.1 kg/ha; 14 days) is not supported by data. MRL
OECD = 1.5                                                                                               | 1.5                    | 0.7          | 0.06          |
| 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) |
|-----------------|--------------------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------|------------------|------------------|
| Soyabeans       | SEU                      | SEU: 4 × < 0.02                                               | Trials previously assessed in peer review framework (EFSA, 2015a) and resubmitted for the confirmatory data assessment (Belgium, 2020), performed on sunflower at an exaggerated treatment rate (61–83 g a.s./100 kg seed) compared with the notified new (SEU) GAP (17 g a.s./100 kg seed). 4 trials performed in NEU (4 × < 0.02) are also available (Belgium, 2020). Reduced data set is acceptable due to residues < LOQ, confirming a no-residues situation. Therefore, MRL can be set at the enforcement LOQ of 0.01 mg/kg. Extrapolation from sunflower seeds to soya beans is possible for seed treatments. | 0.02\(^*\)             | < 0.01           | < 0.01           |
| Cocoa beans     | Nigeria                  | < 0.01; 3 × 0.01; 4 × 0.02                                     | New residue trials on cocoa compliant with GAP (Belgium, 2020). \(MRL_{OECD} = 0.05\)                                                                                                                      | 0.05                  | 0.02             | 0.015            |

MRL: maximum residue level; a.s.: active substance; GR: granule; SL: soluble concentrate; GAP: Good Agricultural Practice; PHI: preharvest interval.

\(^*\): Indicates that the MRL is proposed at the limit of quantification.

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

\(^{(b)}\): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

\(^{(d)}\): Supervised trials median residue according to the residue definition for monitoring.
B.1.2.2. Residues in rotational crops

| Inconclusive | - |
|--------------|---|
| Significant residues are not expected in rotational crops provided that metalaxyl and metalaxyl-M are applied in compliance with the authorised GAPs reported during the MRL review (EFSA, 2015b).|

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

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | Comment/Source |
|---------------------|-----------------------------|------------------------|----------------|
|                     |                             | Individual values      | Median PF      |                |
| Cocoa, roasted nib  | 2                           | 1.30; 1.33             | 1.3            | Belgium (2020) |
| Cocoa, powder       | 2                           | 0.97; 1.14             | 1.1            | Belgium (2020) |
| Cocoa, butter       | 2                           | 1.96; 2.05             | 2.0            | Belgium (2020) |
| Cocoa, chocolate    | 2                           | 1.38; 1.58             | 1.5            | Belgium (2020) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
### B.2. Residues in livestock

| Relevant groups (sub groups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup *(a)* | Most critical commodity *(b)* | Trigger exceeded *(Y/N)* | Previous assessment (maximum dietary burden in mg/kg DM, calculated in the MRL review - EFSA, 2015b) *(c)* |
|-----------------------------|---------------------------------------------|-----------------------------|-------------------------------|--------------------------|--------------------------------------------------------------------------------------------------|
|                             | Median | Maximum | Median | Maximum | Dairy cattle | Citrus, dried pulp | Y | 0.61 |
| Cattle (all)                | 0.023  | 0.033   | 0.59   | 0.86    | Dairy cattle | Citrus, dried pulp | Y | 0.59 |
| Cattle (dairy only)         | 0.023  | 0.033   | 0.59   | 0.86    | Dairy cattle | Citrus, dried pulp | Y | 0.59 |
| Sheep (all)                 | 0.005  | 0.013   | 0.15   | 0.33    | Lamb         | Kale (leaves)    | Y | Not relevant *(c)* |
| Sheep (ewe only)            | 0.005  | 0.011   | 0.15   | 0.33    | Ram/Ewe      | Kale (leaves)    | Y | Not relevant *(c)* |
| Swine (all)                 | 0.010  | 0.015   | 0.45   | 0.66    | Swine (breeding) | Citrus, dried pulp | Y | 0.32 |
| Poultry (all)               | 0.003  | 0.006   | 0.05   | 0.09    | Poultry layer | Carrot culls    | N | 0.12 |
| Poultry (layer only)        | 0.003  | 0.006   | 0.05   | 0.09    | Poultry layer | Carrot culls    | N | 0.12 |
| Fish                        | N/A    | –       | –      | –       | –            | –                    | – | – |

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)*: During the MRL review, former recommendations and calculators were used to assess the dietary burden (JMPR recommendations from FAO, 2009) in which no specific calculations were made for sheep.
### 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                    | Laying hen      | 6                 | 4               | Study performed with phenyl labelled metalaxyl (EFSA, 2015a)                   |
| Lactating ruminants           | Lactating goat  | 3.9               | 4               | Study performed on lactating goat with phenyl labelled metalaxyl (EFSA, 2015a) |
|                               | Lactating goat  | 0.14              | 10              | Study performed on lactating goat with phenyl labelled metalaxyl (EFSA, 2015a) |

- **Time needed to reach a plateau concentration in milk and eggs (days)**
  - Milk: immediately (EFSA, 2015a)
  - Eggs: not reached (possible that plateau had not been reached (residues continuously increasing along 4 days of dosing) (EFSA, 2015a))

- **Metabolism in rat and ruminant similar**: Yes (EFSA, 2015a)

- **Can a general residue definition be proposed for animals?**: Yes (Residue definition was proposed in MRL review (EFSA, 2015b))

- **Animal residue definition for monitoring (RD-Mo)**: Sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl

- **Animal residue definition for risk assessment (RD-RA)**: Sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl

- **Fat soluble residues**: No (EFSA, 2015a)

- **Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs)**: Common method for enforcement of metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety validated in Milk, Eggs, Muscle, Fat, Liver and Kidney: HPLC–MS/MS (EFSA, 2015b).
  - Milk, Eggs, Muscle, Fat: LOQ 0.01 mg/kg
  - Liver, Kidney: LOQ 0.05 mg/kg

General data gap for further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps still not addressed.

ILV for fat matrix was assessed in the framework of article 12 confirmatory data assessment and considered valid (Belgium, 2020).

bw: body weight; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
B.2.1.2. Stability of residues in livestock

| Animal product (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|--------|-----------|--------|-----------------|-------------------|----------------|
|                                   | Beef   | Muscle    | -20    | 21 Months       | Total residues determined as 2,6-dimethylaniline(\(a\)) | EFSA (2015a) |
|                                   | –      | Fat       | -20    | 21 Months       | Total residues determined as 2,6-dimethylaniline(\(a\)) | Extrapolation to fat (EFSA, 2015a) |
|                                   | Beef   | Liver     | -20    | 21 Months       | Total residues determined as 2,6-dimethylaniline(\(a\)) | EFSA (2015a) |
|                                   | –      | Kidney    | -20    | 21 Months       | Total residues determined as 2,6-dimethylaniline(\(a\)) | Extrapolation to kidney (EFSA, 2015a) |
|                                   | Cow    | Milk      | -20    | 21 Months       | Total residues determined as 2,6-dimethylaniline(\(a\)) | EFSA (2015a) |
|                                   | Laying hen | Eggs   | -20    | 21 Months       | Total residues determined as 2,6-dimethylaniline(\(a\)) | EFSA (2015a) |
|                                   | Beef   | Muscle    | -20    | 21 Months       | CGA62826 | EFSA (2015a) |
|                                   | –      | Fat       | -20    | 21 Months       | CGA62826 | Extrapolation to fat (EFSA, 2015a) |
|                                   | Beef   | Liver     | -20    | 21 Months       | CGA62826 | EFSA (2015a) |
|                                   | –      | Kidney    | -20    | 21 Months       | CGA62826 | Extrapolation to kidney (EFSA, 2015a) |
|                                   | Cow    | Milk      | -20    | 21 Months       | CGA62826 | EFSA (2015a) |
|                                   | Laying hen | Eggs   | -20    | 21 Months       | CGA62826 | EFSA (2015a) |

(a): Residues determined with a non-specific analytical method (common moiety method determining 2,6-dimethylaniline) in accordance with the residue definition for enforcement and risk assessment.

B.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) (confirmatory data assessment) | MRL proposal (mg/kg) (confirmatory data assessment) | Current EU MRL (mg/kg) (Reg. (EU) 2017/1164) |
|------------------|-----------------------------------------------|-------------------------------------------------|-------------------------------------------------|---------------------------------------------|
|                  | Mean Highest STMR(\(a\)) (mg/kg) HR(\(b\)) (mg/kg) | | | |
| Cattle (all) – Closest feeding level (0.07 mg/kg bw; 2.1 N rate)\(^{(c)}\) | | | | |
| Muscle           | < 0.05 < 0.05 < 0.01 < 0.01 | 0.01*(\(j,h\)) | 0.01* |
| Fat              | < 0.05 < 0.05 < 0.01 < 0.01 | 0.01*(\(j,h\)) | 0.01* |
| Liver            | 0.10 0.11 0.03 0.05 | 0.06(\(i\)) | 0.05* |
| Kidney           | 0.36 0.70 0.12 0.33 | 0.4(\(i\)) | 0.3 |
| Cattle (dairy only) – Closest feeding level (0.07 mg/kg bw; 2.1 N rate)\(^{(c)}\) | | | | |
| Milk(\(d\))     | < 0.01 n.a. < 0.01 < 0.01 | 0.01*(\(j\)) | 0.01* |
| Sheep (all)\(^{(e)}\) – Closest feeding level (0.07 mg/kg bw; 5.5 N rate)\(^{(c)}\) | | | | |
| Muscle           | < 0.05 < 0.05 < 0.01 < 0.01 | 0.01*(\(j,h\)) | 0.01* |
| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N (mg/kg) | MRL proposal (mg/kg) (confirmatory data assessment) | Current EU MRL (mg/kg) (Reg. (EU) 2017/1164) |
|------------------|-----------------------------------------------|-------------------------------|------------------------------------------------|----------------------------------|
|                  | Mean | Highest | STMR<sup>(a)</sup> | HR<sup>(b)</sup> |                              |                                |
| Fat              | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01<sup>*(b),*(i)</sup> | 0.01<sup>*(g)</sup> |
| Liver            | 0.10 | 0.11 | 0.01 | 0.02 | 0.05<sup>*(i)</sup> | 0.05<sup>*(g)</sup> |
| Kidney           | 0.36 | 0.70 | 0.03 | 0.13 | 0.15<sup>(i)</sup> | 0.3<sup>(g)</sup> |

**Sheep (ewe only)**<sup>(e)</sup> – Closest feeding level (0.07 mg/kg bw; 6.4 N rate)<sup>(c)</sup>

| Milk<sup>(d)</sup> | < 0.01 | n.a. | < 0.01 | < 0.01 | 0.01<sup>*(i)</sup> | 0.01<sup>*(g)</sup> |

**Swine (all)**<sup>(e)</sup> – Closest feeding level (0.07 mg/kg bw; 4.6 N rate)<sup>(c)</sup>

| Muscle | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01<sup>*(b),*(i)</sup> | 0.01* |
| Fat    | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01<sup>*(b),*(i)</sup> | 0.01* |
| Liver  | 0.10 | 0.11 | 0.02 | 0.02 | 0.05<sup>*(i)</sup> | 0.05* |
| Kidney | 0.36 | 0.70 | 0.05 | 0.15 | 0.15<sup>(i)</sup> | 0.2 |

**Poultry (all)** – Closest feeding level (10 mg/kg DM; 109 N rate)<sup>(c)</sup>

| Muscle | 0.05 | 0.06 | < 0.01 | < 0.01 | 0.01<sup>*(i)</sup> | 0.01* |
| Fat    | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01<sup>*(b),*(i)</sup> | 0.01* |
| Liver  | 0.08 | 0.18 | < 0.01 | < 0.01 | 0.05<sup>*(i)</sup> | 0.05* |

**Poultry (layer only)** – Closest feeding level (10 mg/kg DM; 109 N rate)<sup>(c)</sup>

| Eggs<sup>(f)</sup> | < 0.05 | < 0.05 | < 0.01 | < 0.01 | 0.01<sup>*(b),*(i)</sup> | 0.01* |

bw: body weight; n.a.: not applicable.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Median residues recalculated at the 1N rate for the median dietary burden.
(b): Highest residues 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): Milk samples were collected at 7, 14, 21 and 28 days for all dose levels with an additional sampling at 40 days for the middle dose level (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): Egg samples were collected from day 1 to 28 days.
(g): During the MRL review (EFSA, 2015b), former recommendations and calculators were used to assess the dietary burden and MRLs (JMPR recommendations from FAO, 2009), in which no specific calculations were made for sheep products.
(h): MRLs, STMR and HR proposed at 0.01 mg/kg, since all residues < 0.05 mg/kg at the highest feeding levels.
(i): MRL proposal is tentative because data gap number 2 (Further validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock) has not been addressed.
### B.3. Consumer risk assessment

| ARfD | 0.5 mg/kg bw (European Commission, 2020b) |
|------|----------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Highest IESTI (overall): |
|      | Table grapes: 29% of ARfD |
|      | Highest IESTI for crops assessed with confirmatory data for metalaxyl-M: |
|      | Apples: 22% of ARfD |
|      | Pears: 28% of ARfD |
|      | Broccoli: 0.9% of ARfD |
|      | Cauliflower: 1.3% of ARfD |
|      | Herbs and edible flowers: 0.5% of ARfD (chervil) |
|      | Soyabeans: <0.01% of ARfD |
|      | Cocoa beans: <0.01% of ARfD |

#### Assumptions made for the calculations

A common exposure assessment is performed for metalaxyl and metalaxyl-M as these two substances share the same residue definitions for enforcement and risk assessment. The consumer exposure was performed for those commodities for which the existing uses were reported in the combined MRL review (EFSA, 2015b) and in the MRL applications received afterwards (EFSA, 2015c, 2016).

The input values were selected as follows:

- HR values for broccoli, cauliflower and cocoa beans as derived in framework of the present opinion;
- STMR value for soyabeans as derived in framework of the present opinion;
- HR values for livestock commodities (STMR for milk) as derived in the framework of the present opinion following most recent recommendations;
- for apples, pears and herbs, it was concluded that the data gap for metalaxyl-M uses identified in the MRL review was not addressed and risk management decisions are needed. The current MRLs (apples, pears) and HR value (herbs) derived in the MRL review were considered as input values for these crops;
- for lemons, limes, mandarins, table and wine grapes, onions, peppers, melons, watermelons and globe artichoke, for which the data gaps identified for metalaxyl uses were not addressed, the current MRLs were used as input values;
- for remaining commodities for which the authorized use has been reported in the MRL review or afterwards in an Article 10 reasoned opinion, the input value was the highest residue.
- for oranges and grapefruits, highest residue levels found in pulp were used for a refined calculation (EFSA, 2016).

EFSA notes that the consumer exposure reflects the worst case scenario, since for the crops for which a potential lowering of the MRL is proposed under the present assessment and is awaiting a risk management decision, the input values were the existing EU MRLs and therefore the actual consumer exposure to metalaxyl/metalaxyl-M residues is expected to be lower.
ADI 0.08 mg/kg bw per day (European Commission, 2020b)

Highest IEDI, according to EFSA PRIMo

25% ADI (NL toddler)

Contribution of crops assessed (with confirmatory data for metalaxyl-M):
- Apples: 15.6% of ADI (DE child)
- Pears: 5.4% of ADI (NL toddler)
- Broccoli: 0.01% of ADI (NL toddler)
- Cauliflower: 0.02% of ADI (NL toddler)
- Herbs: 0.06% of ADI (Parsley/ GEMS Food G10)
- Soyabeans: 0.09% of ADI (GEMS Food G11)
- Cocoa beans: 0.01% of ADI (ES child)

Assumptions made for the calculations

A common exposure assessment is performed for metalaxyl and metalaxyl-M as these two substances share the same residue definitions for enforcement and risk assessment. The consumer exposure was performed for those commodities for which the existing uses were reported in the combined MRL review (EFSA, 2015b) and in the MRL applications received afterwards (EFSA, 2015c, 2016).

The input values were selected as follows:
- STMR values for broccoli, cauliflower, soyabeans and cocoa beans as derived in framework of the present opinion;
- STMR values for livestock commodities as derived in framework of the present opinion;
- for apples, pears and herbs, it was concluded that the data gap for metalaxyl-M uses identified in the MRL review was not addressed and risk management decisions are needed. The current MRLs (apples, pears) and STMR value (herbs) were considered as input values for these crops;
- for lemons, limes, mandarins, table and wine grapes, onions, peppers, melons, watermelons and globe artichoke, for which the data gaps identified for metalaxyl uses were not addressed, the current MRLs were used as input values;
- for remaining commodities for which the authorized use has been reported in the MRL review or afterwards in an Article 10 reasoned opinion, the input value was the median residue.
- for oranges and grapefruits, median residue levels found in pulp were used for a refined calculation (EFSA, 2016).

The contributions of commodities where no GAP was reported in the framework of the MRL reviews or in subsequent MRL applications of metalaxyl or metalaxyl-M were not included in the calculation.

EFSA notes that the consumer exposure reflects the worst case scenario, since for the crops for which a potential lowering of the MRL is proposed under the present assessment and is awaiting a risk management decision, the input values were the existing EU MRLs and therefore the actual consumer exposure to metalaxyl/metalaxyl-M residues is expected to be lower.

ARFD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; HR: highest residue; STMR: supervised trials median residue; ADI: acceptable daily intake; IEDI: international estimated daily intake.
## B.4. Recommended MRLs

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|----------------------------|
| 0110030 | Lemons    | 0.5 (ft 1)     | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on citrus fruits is not addressed. No GAP have been reported for metalaxyl-M during the MRL review and confirmatory data processes. Therefore, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ. Further consideration needed. |
| 0110040 | Limes     | 0.5 (ft 2)     | (0.4)        | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on citrus fruits is not addressed. However, an alternative MRL of 0.4 mg/kg that is fully supported by data can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.4 mg/kg. Further consideration needed. |
| 0110050 | Mandarins | 0.5 (ft 2)     | (0.4)        | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on citrus fruits is not addressed. However, an alternative MRL of 0.4 mg/kg that is fully supported by data can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.4 mg/kg. Further consideration needed. |
| 0130010 | Apples    | 1 (ft 3)       | Further risk management considerations required | The data gaps identified by EFSA concerning the lack of residue trials to support the SEU GAPs reported for metalaxyl and metalaxyl-M on apples and pears is not addressed. Therefore, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ. Further consideration needed. |
| 0130020 | Pears     | 1 (ft 3)       | Further risk management considerations required | The data gaps identified by EFSA concerning the lack of residue trials to support the SEU GAPs reported for metalaxyl and metalaxyl-M on apples and pears is not addressed. Therefore, risk managers may consider the deletion of the existing MRL, replacing it with the LOQ. Further consideration needed. |
| 0151010 | Table grapes | 2 (ft 4) | (0.9)        | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on table and wine grapes is not addressed. However, an alternative MRL of 0.9 mg/kg that is fully supported by data can be derived based on the critical GAPs reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.9 mg/kg. Further consideration needed. |
| 0151020 | Wine grapes | 1 (ft 4) | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on table and wine grapes is not addressed. However, an alternative MRL of 0.9 mg/kg that is fully supported by data can be derived based on the critical GAPs reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.9 mg/kg. Further consideration needed. |
| 0220020 | Onions    | 0.5 (ft 4)     | (0.01* or 0.02*) Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on onions is not addressed. However, an alternative MRL of 0.01* at the enforcement LOQ or at 0.02* mg/kg according to available trials can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.01* or 0.02* mg/kg. Further consideration needed. |
| 0231020 | Sweet peppers/bell peppers | 0.5 (ft 4) | (0.4)        | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on peppers is not addressed. However, an alternative MRL of 0.4 mg/kg that is fully supported by data can be derived based on the critical indoor GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.4 mg/kg. Further consideration needed. |

### Enforcement residue definition:
Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers))
| Code<sup>(a)</sup> | Commodity               | Existing MRL<sup>(b)</sup> | Proposed MRL                | Conclusion/recommendation                                                                                                                                                                                                                                                                                                                                 |
|-----------------|-------------------------|-----------------------------|-----------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0233010         | Melons                  | 0.2 (ft 4)                  | (0.15) Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAPs reported for metalaxyl on melons and watermelons is not addressed. However, an alternative MRL of 0.15 mg/kg that is fully supported by data can be derived based on the critical indoor GAP reported for metalaxyl-M during the MRL review. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL of 0.15 mg/kg. Further consideration needed. |
| 0233030         | Watermelons             | 0.2 (ft 4)                  | (0.15) Further risk management considerations required |                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0241010         | Broccoli                | 0.2 (ft 5)                  | (0.15) Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl-M on flowering cabbages has been addressed, using an adjusted NEU GAP for metalaxyl-M. Based on the adjusted GAP, the existing MRL could be replaced by the updated value of 0.15 mg/kg. An updated consumer risk assessment was carried out; risk for consumers is unlikely. It is noted that the data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on flowering cabbages is not addressed. Further consideration needed. |
| 0241020         | Cauliflowers            | 0.2 (ft 5)                  | Further risk management considerations required |                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0256000         | Herbs and edible flowers| 3 (ft 6)                    | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl-M on herbs and edible flowers has not been addressed. The applicant has indicated that the indoor GAP for which the existing EU MRL was set, is no more authorised in the EU. Alternatively, the applicant reported a more critical indoor GAP, but that was not supported by data. The residue data submitted by the applicant would fully support an indoor GAP with 2 applications at 0.1 kg a.s./kg and a PHI 14 days, but no clear evidence was reported to EFSA that such an indoor GAP was authorised in the EU. Provided that at least one MS confirms such existing authorisation, the existing MRL could be replaced by the updated value of 1.5 mg/kg. Risk for consumers is unlikely. |
| 0270050         | Globe artichokes        | 0.05 (ft 7)                 | (0.01* or 0.02*) Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on globe artichokes is not addressed. However, an alternative MRL of 0.01* at the enforcement LOQ or at 0.02* mg/kg according to available residue trials can be derived based on the critical GAP reported for metalaxyl-M during the MRL review. Further consideration needed. |
| Code\(^{(a)}\) | Commodity | Existing MRL\(^{(b)}\) | Proposed MRL | Conclusion/recommendation |
|----------------|-----------|----------------|--------------|---------------------------|
| 0401070 | Soyabeans | 0.1* (ft 8) | (0.01* or 0.02*) | Further risk management considerations required | The data gap identified by EFSA concerning the lack of residue trials to support the GAP reported for metalaxyl on soya beans is not addressed. The applicant proposed a new SEU GAP for the use of metalaxyl-M on soya beans for which a lower MRL of 0.02* mg/kg is supported by residue data. Risk managers may consider the deletion of the existing MRL, replacing it with the alternative MRL at the enforcement LOQ of 0.01* or at 0.02* mg/kg according to provided residue trials. It is noted that the new GAP is a seed treatment and that a restriction of use was defined during the renewal if the approval of the active substance metalaxyl-M: ‘When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised’. Risk for consumers unlikely. |
| 0640000 | Cocoa beans | 0.1 (ft 9) | 0.05 | The data gap concerning the lack of residue trials to support the GAP reported for metalaxyl-M on cocoa beans and the data gap concerning analytical methods for this matrix have been addressed. Based on an adjusted GAP on metalaxyl-M in Nigeria, the existing MRL could be replaced by the updated value of 0.05 mg/kg. An updated consumer risk assessment was carried out; risk for consumers is unlikely. |
| 0700000 | Hops | 15 (ft 9) | 15 | The data gap identified by EFSA concerning analytical methods has been addressed. The MRL is confirmed. The previous consumer risk assessment remains valid. The existing MRL is based on the critical GAP on metalaxyl-M reported during the MRL review. According to RMS and applicant, this critical GAP is not authorised in Germany. However, MRL based on the initial GAP may be maintained as other GAPs might have been authorised since the MRL review. |

**Enforcement residue definition:** Sum of metalaxyl (sum of isomers) and its metabolites containing the 2,6-dimethylaniline moiety, expressed as metalaxyl

| 1000000 | Products of animal origin-terrestrial animals | (ft 10) | Further risk management consideration required | The general data gap on analytical methods (validation data demonstrating the efficiency of the extraction, hydrolysis and derivatisation steps included in the proposed analytical method for enforcement of residues in livestock) is not addressed. |
| 1011010 | Swine muscle | 0.01* (ft 10) | 0.01* | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| Code(a) | Commodity     | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|--------|---------------|-----------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1011020 | Swine fat tissue | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. A data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1011030 | Swine liver    | 0.05* (ft 10)   | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1011040 | Swine kidney   | 0.2 (ft 10)     | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1011050 | Swine edible offals | 0.2 (ft 10)   | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012010 | Bovine muscle  | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012020 | Bovine fat tissue | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. A data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012030 | Bovine liver   | 0.05* (ft 10)   | 0.06         | Livestock dietary burden updated according to the OECD methodology indicates that a higher MRL would be required. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1012040 | Bovine kidney  | 0.3 (ft 10)     | 0.4          | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                 |
| 1012050 | Bovine edible offals | 0.3 (ft 10) | 0.4          | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                 |
| 1013010 | Sheep muscle   | 0.01* (ft 10)   | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| Code<sup>(a)</sup> | Commodity       | Existing MRL<sup>(b)</sup> | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|------------------|-----------------|---------------------------|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1013020          | Sheep fat tissue | 0.01* (ft 10)            | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. A data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1013030          | Sheep liver     | 0.05* (ft 10)            | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1013040          | Sheep kidney    | 0.3 (ft 10)              | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1013050          | Sheep edible offals | 0.3 (ft 10)            | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1014010          | Goat muscle     | 0.01* (ft 10)            | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1014020          | Goat fat tissue | 0.01* (ft 10)            | 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. A data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1014030          | Goat liver      | 0.05* (ft 10)            | 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1014040          | Goat kidney     | 0.3 (ft 10)              | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1014050          | Goat edible offals | 0.3 (ft 10)            | 0.15         | Livestock dietary burden updated according to the OECD methodology indicates that a lower MRL would be sufficient. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| Code   | Commodity       | Existing MRL | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                 |
|--------|-----------------|--------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1015010| Equine muscle   | 0.01* (ft 10)| 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1015020| Equine fat tissue | 0.01* (ft 10)| 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. A data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1015030| Equine liver    | 0.05* (ft 10)| 0.06         | Livestock dietary burden updated according to the OECD methodology indicates that a higher MRL would be required. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1015040| Equine kidney   | 0.3 (ft 10)  | 0.4          | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                                   |
| 1015050| Equine edible offals | 0.3 (ft 10)  | 0.4          | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                                   |
| 1016010| Poultry muscle  | 0.01* (ft 10)| 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1016020| Poultry fat tissue | 0.01* (ft 10)| 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. A data gap on analytical methods (Independent laboratory validation (ILV) of the proposed analytical method for enforcement of residues in fat) has been addressed. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1016030| Poultry liver   | 0.05* (ft 10)| 0.05*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1016040| Poultry kidney  | 0.05* (ft 10)| 0.05*        | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                                   |
| 1016050| Poultry edible offals | 0.05* (ft 10)| 0.05*        | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                                   |
| 1020000| Milk            | 0.01* (ft 10)| 0.01*        | Livestock dietary burden updated according to the OECD methodology confirms the existing EU MRL at the LOQ. Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed. |
| 1030000| Bird eggs       | 0.01* (ft 10)| 0.01*        | Further risk management consideration is needed considering that the general data gap for the analytical enforcement method in livestock is not addressed.                                                                                                   |
MRL: maximum residue level; GAP: Good Agricultural Practice; LOQ: limit of quantification; SEU: southern Europe; PHI: preharvest interval; RMS: rapporteur Member State.

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

(b): Existing EU MRL and corresponding footnote on confirmatory data.

ft 1: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gaps No 4).

ft 2: The European Food Safety Authority identified some information on residue trials on metalaxyl 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 (Footnote related to data gap No 4).

ft 3: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gap No 4).

ft 4: The European Food Safety Authority identified some information on residue trials on metalaxyl 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 (Footnote related to data gap No 4).

ft 5: The European Food Safety Authority identified some information on residue trials on metalaxyl and metalaxyl-M 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 (Footnote related to data gaps No 4 and 5).

ft 6: The European Food Safety Authority identified some information on residue trials on metalaxyl-M 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 (Footnote related to data gap No 4).

ft 7: The European Food Safety Authority identified some information on residue trials on metalaxyl-M 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 (Footnote related to data gap No 4).

ft 8: The European Food Safety Authority identified some information on residue trials on metalaxyl-M and analytical methods 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 (Footnote related to data gap No 4).

ft 9: The European Food Safety Authority identified some information on residue trials on metalaxyl-M and analytical methods 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 (Footnote related to data gap No 4).

ft 10: The European Food Safety Authority identified some information on analytical methods 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 (Footnote related to data gap No 2 for all commodities of animal origin and to data gap No 3 for animal fat tissues).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Diazinon

| Commodity/group of commodities | Source of ADI | Source of ARfD |
|-------------------------------|--------------|----------------|
| Pears                         | EFSA         | EFSA           |

### Metalaxyl/Metalaxyl-M

#### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

**Conclusion:**
- IT toddler
- UK vegetarian
- UK adult
- NL toddler
- NL child
- PT general
- GEMS/Food G06
- DE women 14-50 yr
- FR adult
- NL general
- PL general
- UK toddler
- DK adult
- SE general
- ES child
- ES adult
- UK infant
- FI 3 yr
- IT adult
- FR infant
- LT adult
- RO general
- GEMS/Food G11
- DE general
- GEMS/Food G08
- FI adult
- IE child
- IE adult

**The estimated long-term dietary intake (TMDI/IEDI/NEDI) was below the ADI.**
**The long-term intake of residues of Metalaxyl/Metalaxyl-M 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.

### Metalaxyl-M

#### Calculated exposure (% of ADI)

| Commodity/group of commodities | Commodity/group of commodities |
|--------------------------------|--------------------------------|
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |

#### Exposure resulting from

| Commodity/group of commodities | Commodity/group of commodities |
|--------------------------------|--------------------------------|
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
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| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
| Apples                         | Apples                         |
| Pears                          | Pears                          |
| Wine grapes                    | Wine grapes                    |
| Table grapes                   | Table grapes                   |
### Results for all crops

#### Unprocessed commodities

| Commodity                        | RA Value (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI |
|----------------------------------|------------------|---------------------|---------------|
| Table grapes                     | 0.02             | 169                 | 28%           |
| Pears                            | 0.02             | 138                 | 28%           |
| Apples                           | 0.02             | 108                 | 22%           |
| Escaroles/broad-leaved endives    | 0.02             | 72                  | 14%           |
| Lettuces                         | 0.02             | 69                  | 14%           |
| Cabbage                          | 0.02             | 69                  | 6%            |
| Sweet peppers/bell peppers       | 0.02             | 30                  | 6%            |
| Mandarins                        | 0.02             | 30                  | 6%            |
| Watermelons                      | 0.02             | 24                  | 5%            |
| Lemons                           | 0.02             | 17                  | 3%            |
| Spinaches                        | 0.02             | 17                  | 2%            |
| Cucumbers                        | 0.02             | 17                  | 2%            |
| Chard leaves/boiled              | 0.02             | 12                  | 2%            |
| Spinaches/frozen; boiled          | 0.02             | 10                  | 2%            |

#### Processed commodities

| Commodity                        | RA Value (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI |
|----------------------------------|------------------|---------------------|---------------|
| Escaroles/broad-leaved endives    | 0.02             | 119                 | 24%           |
| Apples                           | 0.02             | 54                  | 11%           |
| Wine grapes/raisins               | 0.02             | 39                  | 8%            |
| Wine grapes/raisins               | 0.02             | 39                  | 8%            |
| Pears                            | 0.02             | 33                  | 7%            |
| Pears/juice                       | 0.02             | 33                  | 7%            |
| Wine grapes/raisins               | 0.02             | 33                  | 7%            |
| Wine grapes/raisins               | 0.02             | 33                  | 7%            |
| Table grapes/raisins              | 0.02             | 19                  | 4%            |
| Table grapes/raisins              | 0.02             | 19                  | 4%            |
| Spinaches/boiled                  | 0.02             | 15                  | 2%            |
| Spinaches/boiled                  | 0.02             | 15                  | 2%            |
| Cauliflower/boiled                | 0.02             | 7.7                 | 2%            |
| Cauliflower/boiled                | 0.02             | 7.7                 | 2%            |
| Kale                              | 0.02             | 5.8                 | 1%            |
| Kale                              | 0.02             | 5.8                 | 1%            |
| Parsnip/potato                    | 0.02             | 3.5                 | 0.7%          |
| Parsnip/potato                    | 0.02             | 3.5                 | 0.7%          |
| Potatoes/potato                   | 0.02             | 1.5                 | 0.3%          |
| Potatoes/potato                   | 0.02             | 1.5                 | 0.3%          |
| Potatoes/potato                   | 0.02             | 1.5                 | 0.3%          |
| Potatoes/fried                     | 0.02             | 1.5                 | 0.3%          |
| Potatoes/fried                     | 0.02             | 1.5                 | 0.3%          |
| Potatoes/fried                     | 0.02             | 1.5                 | 0.3%          |
| Leek                              | 0.02             | 0.099               | 0.2%          |
| Leek                              | 0.02             | 0.099               | 0.2%          |

## Conclusion

- No exceedance of the toxicological reference value was identified for any unprocessed commodity.
- A short-term intake of residues of Metalaxyl/Metalaxyl-M is unlikely to present a public health risk.
- For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

## D.1. Livestock dietary burden calculations

| Feed commodity                  | Median dietary burden | Maximum dietary burden |
|---------------------------------|-----------------------|------------------------|
|                                 | Input value (mg/kg)   | Comment                |
|                                 |                       |                        |
| Risk assessment residue definition: Metalaxyl and metalaxyl-M (metalaxyl including other mixtures of constituent isomers including metalaxyl-M (sum of isomers) |
| Cabbage, heads leaves           | 0.02                  | STMR (EFSA, 2015b)     | 0.04                  | HR (EFSA, 2015b) |
| Kale, leaves (forage)           | 0.05                  | STMR (EFSA, 2015b)     | 0.21                  | HR (EFSA, 2015b) |
| Rape, forage                    | 0.04                  | STMR (EFSA, 2015b)     | 0.04                  | HR (EFSA, 2015b) |
| Carrot, culls                   | 0.02                  | STMR (EFSA, 2015b)     | 0.07                  | HR (EFSA, 2015b) |
| Potato, culls                   | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Bean, seed (dry)                | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Corn, field (Maize) grain       | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Corn, pop grain                 | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Cowpea, seed                    | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Lupin, seed                     | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Pea, (Field pea) seed (dry)     | 0.02*                 | STMR (EFSA, 2015b)     | 0.02*                 | STMR (EFSA, 2015b) |
| Soybean, seed                   | 0.02*                 | STMR (confirmatory data metalaxyl-M) | 0.02* | STMR (confirmatory data metalaxyl-M) |
| Canola (Rape seed), meal        | 0.04                  | STMR \times default PF (2)\textsuperscript{(c)} (EFSA, 2015b) | 0.04                  | STMR \times default PF (2)\textsuperscript{(c)} (EFSA, 2015b) |
| Citrus, dried pulp              | 2.2                   | STMR \times default PF (10)\textsuperscript{(c)} (EFSA, 2016) | 2.2                   | STMR \times default PF (10)\textsuperscript{(c)} (EFSA, 2016) |
| Corn, field milled by-pdts      | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) |
| Corn, field hominy meal         | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) |
| Corn, field gluten feed         | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) |
| Corn, field gluten, meal        | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) |
| Distiller’s grain dried         | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(d)} (EFSA, 2015b) |
| Flaxseed/Linseed, meal          | 0.04                  | STMR \times default PF (2)\textsuperscript{(d)} (EFSA, 2015b) | 0.04                  | STMR \times default PF (2)\textsuperscript{(d)} (EFSA, 2015b) |
| Lupin seed, meal                | 0.02*                 | STMR \times default PF (1.1)\textsuperscript{(d)} (EFSA, 2015b) | 0.02*                 | STMR \times default PF (1.1)\textsuperscript{(d)} (EFSA, 2015b) |
| Potato, process waste           | 0.02*                 | STMR\textsuperscript{(c)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(c)} (EFSA, 2015b) |
| Potato, dried pulp              | 0.02*                 | STMR\textsuperscript{(c)} (EFSA, 2015b) | 0.02*                 | STMR\textsuperscript{(c)} (EFSA, 2015b) |
| Rape, meal                      | 0.04                  | STMR \times default PF (2)\textsuperscript{(c)} (EFSA, 2015b) | 0.04                  | STMR \times default PF (2)\textsuperscript{(c)} (EFSA, 2015b) |
| Soybean, meal                   | 0.02*                 | STMR\textsuperscript{(d)} (confirmatory data metalaxyl-M) | 0.02*                 | STMR\textsuperscript{(d)} (confirmatory data metalaxyl-M) |
| Soybean, hulls                  | 0.02*                 | STMR\textsuperscript{(d)} (confirmatory data metalaxyl-M) | 0.02*                 | STMR\textsuperscript{(d)} (confirmatory data metalaxyl-M) |
| Sunflower, meal                 | 0.04                  | STMR \times default PF (2)\textsuperscript{(c)} (EFSA, 2015b) | 0.04                  | STMR \times default PF (2)\textsuperscript{(c)} (EFSA, 2015b) |

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

(a): The input from carrot culls was not taken in the combined MRL review (EFSA 2015b) because it was not considered under the former European methodology reported (EU guideline 7031/VI/95 rev. 4).

(b): MRL and risk assessment values were derived in the present opinion based on data submitted in the framework of confirmatory data assessment of metalaxyl-M.

(c): For citrus pomace, meals of oilseeds with 50% oil content and lupins seed meal, in the absence of processing factors supported by data, default processing factors of 2.5, 2 and 1.1 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

(d): For processed commodities of maize, potatoes and soybeans, no default processing factor was applied because residues are expected to be below the LOQ. Concentration of residues in these commodities is therefore not expected.
### D.2. Consumer risk assessment

| Commodity | Existing/proposed MRL (mg/kg) | Source | Chronic risk assessment | Acute risk assessment |
|-----------|--------------------------------|--------|-------------------------|-----------------------|
| Grapefruits | 0.7 | Existing EU MRL (EFSA, 2016) | 0.01 STMR-pulp | 0.02 HR-pulp |
| Oranges | 0.7 | Existing EU MRL (EFSA, 2016) | 0.01 STMR-pulp | 0.02 HR-pulp |
| Lemons | 0.5 | Existing EU MRL (EFSA, 2015b) | 0.5 MRL\(^{(c)}\) | 0.5 MRL\(^{(c)}\) |
| Limes | 0.5 | Existing EU MRL (EFSA, 2015b) | 0.5 MRL\(^{(c)}\) | 0.5 MRL\(^{(c)}\) |
| Mandarins | 0.5 | Existing EU MRL (EFSA, 2015b) | 0.5 MRL\(^{(c)}\) | 0.5 MRL\(^{(c)}\) |
| Apples | 1 | Existing EU MRL (EFSA, 2015b) | 1 MRL\(^{(d)}\) | 1 MRL\(^{(c)}\) |
| Pears | 1 | Existing EU MRL (EFSA, 2015b) | 1 MRL\(^{(d)}\) | 1 MRL\(^{(c)}\) |
| Table grapes | 2 | Existing EU MRL (EFSA, 2015b) | 2 MRL\(^{(c)}\) | 2 MRL\(^{(c)}\) |
| Wine grapes | 1 | Existing EU MRL (EFSA, 2015b) | 1 MRL\(^{(c)}\) | 1 MRL\(^{(c)}\) |
| Strawberries | 0.6 | Existing EU MRL (EFSA, 2016) | 0.17 STMR-RAC | 0.3 HR-RAC |
| Blackberries | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Dewberries | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Raspberries (red and yellow) | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Currants (red, black and white) | 0.4 | Existing EU MRL (EFSA, 2015b) | 0.02 STMR-RAC | 0.17 HR-RAC |
| Gooseberries (green, red and yellow) | 0.3 | Existing EU MRL (EFSA, 2015c) | 0.02 STMR-RAC | 0.17 HR-RAC |
| Kiwi fruits (green, red, yellow) | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Potatoes | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Beetroots | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Carrots | 0.1 | Existing EU MRL (EFSA, 2015b) | 0.02 STMR-RAC | 0.07 HR-RAC |
| Horseradishes | 0.1 | Existing EU MRL (EFSA, 2015b) | 0.02 STMR-RAC | 0.07 HR-RAC |
| Parsnips | 0.1 | Existing EU MRL (EFSA, 2015b) | 0.02 STMR-RAC | 0.07 HR-RAC |
| Radishes | 0.06 | Existing EU MRL (EFSA, 2015b) | 0.02 STMR-RAC | 0.04 HR-RAC |
| Salsifies | 0.02* | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC | 0.02* HR-RAC |
| Commodity                                      | Existing/proposed MRL (mg/kg) | Source                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------------|---------------------------------------------|-------------------------|----------------------|
|                                               |                               |                                             | Input value (mg/kg)     | Comment              |
|                                               |                               |                                             | Comment                 | Input value (mg/kg)  |
|                                               |                               |                                             |                         | Comment              |
| Garlic                                        | 0.02*                         | Existing EU MRL (EFSA, 2015b)              | 0.02*                   | STMR-RAC             |
|                                               |                               |                                             |                         | 0.02*                |
|                                               |                               |                                             |                         | HR-RAC               |
| Onions                                        | 0.5                           | Existing EU MRL (EFSA, 2015b)              | 0.5                     | MRL(c)               |
|                                               |                               |                                             |                         | 0.5                  |
|                                               |                               |                                             |                         | MRL(c)               |
| Shallots                                      | 0.02*                         | Existing EU MRL (EFSA, 2015b)              | 0.02*                   | STMR-RAC             |
|                                               |                               |                                             |                         | 0.02*                |
|                                               |                               |                                             |                         | HR-RAC               |
| Spring onions/green onions and Welsh onions  | 0.3                           | Existing EU MRL (EFSA, 2015b)              | 0.02                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.17                 |
|                                               |                               |                                             |                         | HR-RAC               |
| Tomatoes                                      | 0.3                           | Existing EU MRL (EFSA, 2015b)              | 0.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.18                 |
|                                               |                               |                                             |                         | HR-RAC               |
| Sweet peppers/bell peppers                   | 0.5                           | Existing EU MRL (EFSA, 2015b)              | 0.5                     | MRL(c)               |
|                                               |                               |                                             |                         | 0.5                  |
|                                               |                               |                                             |                         | MRL(c)               |
| Cucumbers                                     | 0.5                           | Existing EU MRL (EFSA, 2015b)              | 0.15                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.255                |
|                                               |                               |                                             |                         | HR-RAC               |
| Melons                                        | 0.2                           | Existing EU MRL (EFSA, 2015b)              | 0.2                     | MRL(c)               |
|                                               |                               |                                             |                         | 0.2                  |
|                                               |                               |                                             |                         | MRL(c)               |
| Watermelons                                   | 0.2                           | Existing EU MRL (EFSA, 2015b)              | 0.2                     | MRL(c)               |
|                                               |                               |                                             |                         | 0.2                  |
|                                               |                               |                                             |                         | MRL(c)               |
| Sweet corn                                    | 0.05*                         | Existing EU MRL (EFSA, 2015b)              | 0.04                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.05                 |
|                                               |                               |                                             |                         | HR-RAC               |
| Broccoli                                      | 0.15                          | Proposed MRL(a)                             | 0.02                    | STMR-RAC(a)          |
|                                               |                               |                                             |                         | 0.11                 |
|                                               |                               |                                             |                         | HR-RAC(a)            |
| Cauliflower                                  | 0.15                          | Proposed MRL(a)                             | 0.02                    | STMR-RAC(a)          |
|                                               |                               |                                             |                         | 0.11                 |
|                                               |                               |                                             |                         | HR-RAC(a)            |
| Brussels sprouts                              | 0.15                          | Existing EU MRL (EFSA, 2016)               | 0.04                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.07                 |
|                                               |                               |                                             |                         | HR-RAC               |
| Head cabbages                                 | 0.06                          | Existing EU MRL (EFSA, 2015b)              | 0.02                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.04                 |
|                                               |                               |                                             |                         | HR-RAC               |
| Chinese cabbages/pe-tsai                      | 0.02*                         | Existing EU MRL (EFSA, 2015b)              | 0.02*                   | STMR-RAC             |
|                                               |                               |                                             |                         | 0.02*                |
|                                               |                               |                                             |                         | HR-RAC               |
| Kales                                         | 0.3                           | Existing EU MRL (EFSA, 2015b)              | 0.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 0.21                 |
|                                               |                               |                                             |                         | HR-RAC               |
| Kohlrabies                                    | 0.02*                         | Existing EU MRL (EFSA, 2015b)              | 0.02*                   | STMR-RAC             |
|                                               |                               |                                             |                         | 0.02*                |
|                                               |                               |                                             |                         | HR-RAC               |
| Lamb’s lettuce/corn salads                    | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Lettuces                                      | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Escaroles/broad-leaved endives                | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Cress and other sprouts and shoots            | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Land cress                                    | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Roman rocket/rucola                           | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Red mustards                                  | 3                             | Existing EU MRL (EFSA, 2015b)              | 1.05                    | STMR-RAC             |
|                                               |                               |                                             |                         | 1.8                  |
|                                               |                               |                                             |                         | HR-RAC               |
| Commodity                                  | Existing/ proposed MRL (mg/kg) | Source                         | Chronic risk assessment | Acute risk assessment |
|-------------------------------------------|-------------------------------|--------------------------------|-------------------------|-----------------------|
|                                           |                               |                                | Input value (mg/kg)     | Comment               | Input value (mg/kg)   | Comment               |
| Baby leaf crops (including brassica species) | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC              | 1.8                  | HR-RAC                |
| Spinaches                                 | 1.5                           | Existing EU MRL (EFSA, 2016)   | 0.16                    | STMR-RAC              | 0.74                 | HR-RAC                |
| Chards/beet leaves                        | 1.5                           | Existing EU MRL (EFSA, 2016)   | 0.16                    | STMR-RAC              | 0.74                 | HR-RAC                |
| Witloofs/Belgian endives                  | 0.4                           | Existing EU MRL (EFSA, 2015b)  | 0.125                   | STMR-RAC              | 0.21                 | HR-RAC                |
| Chervil                                   | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Chives                                    | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Celery leaves                             | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Parsley                                   | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Sage                                      | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Rosemary                                  | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Thyme                                     | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Basil and edible flowers                  | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Laurel/bay leaves                         | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Tarrgon                                   | 3                             | Existing EU MRL (EFSA, 2015b)  | 1.05                    | STMR-RAC(e)           | 1.8                  | HR-RAC(e)             |
| Beans (with pods)                         | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | HR-RAC                |
| Beans (without pods)                      | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | HR-RAC                |
| Peas (with pods)                          | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | HR-RAC                |
| Peas (without pods)                       | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | HR-RAC                |
| Asparagus                                 | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | HR-RAC                |
| Globe artichokes                          | 0.05                          | Existing EU MRL (EFSA, 2015b)  | 0.05                    | MRL(c)                | 0.05                 | MRL(c)                |
| Leeks                                     | 0.03                          | Existing EU MRL (EFSA, 2015b)  | 0.02                    | STMR-RAC              | 0.02                 | HR-RAC                |
| Beans                                     | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | STMR-RAC              |
| Peas                                      | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | STMR-RAC              |
| Lupins/lupini beans                       | 0.02*                         | Existing EU MRL (EFSA, 2015b)  | 0.02*                   | STMR-RAC              | 0.02*                | STMR-RAC              |
| Commodity                     | Existing/proposed MRL (mg/kg) | Source                        | Chronic risk assessment | Acute risk assessment |
|------------------------------|-------------------------------|-------------------------------|-------------------------|-----------------------|
|                              |                               |                               | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Linseeds                     | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Poppy seeds                  | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Sunflower seeds              | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Rapeseeds/Canola seeds       | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Soyabean                     | 0.02*                         | Proposed MRL<sup>(a)</sup>     | 0.02* STMR-RAC<sup>(a)</sup> | STMR-RAC<sup>(a)</sup> |
| Mustard seeds                | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Gold of pleasure seeds       | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Maize/corn                   | 0.02*                         | Existing EU MRL (EFSA, 2015b) | 0.02* STMR-RAC          | STMR-RAC              |
| Cocoa beans                  | 0.05                          | Proposed MRL<sup>(a)</sup>     | 0.015 STMR-RAC<sup>(a)</sup> | HR-RAC<sup>(b)</sup>  |
| Hops (dried)                 | 15                            | Existing EU MRL (EFSA, 2015b) | 2.6 STMR-RAC            | 6 HR-RAC             |
| Swine: Muscle/meat           | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Swine: Fat tissue            | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Swine: Liver                 | 0.05*                         | Proposed MRL<sup>(b)</sup>     | 0.05* STMR-RAC          | HR-RAC                |
| Swine: Kidney                | 0.15                          | Proposed MRL<sup>(b)</sup>     | 0.05 STMR-RAC           | HR-RAC                |
| Swine: Edible offals (other than liver and kidney) | 0.15 | Proposed MRL<sup>(b)</sup> | 0.05 STMR-RAC | HR-RAC |
| Bovine: Muscle/meat          | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Bovine: Fat tissue           | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Bovine: Liver                | 0.06                          | Proposed MRL<sup>(b)</sup>     | 0.05* STMR-RAC          | HR-RAC                |
| Bovine: Kidney               | 0.4                           | Proposed MRL<sup>(b)</sup>     | 0.12 STMR-RAC           | HR-RAC                |
| Bovine: Edible offals (other than liver and kidney) | 0.4 | Proposed MRL<sup>(b)</sup> | 0.12 STMR-RAC | HR-RAC |
| Sheep: Muscle/meat           | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Sheep: Fat tissue            | 0.01*                         | Proposed MRLv                    | 0.01* STMR-RAC          | HR-RAC                |
| Sheep: Liver                 | 0.05*                         | Proposed MRL<sup>(b)</sup>     | 0.05* STMR-RAC          | HR-RAC                |
| Sheep: Kidney                | 0.15                          | Proposed MRL<sup>(b)</sup>     | 0.03 STMR-RAC           | HR-RAC                |
| Sheep: Edible offals (other than liver and kidney) | 0.15 | Proposed MRL<sup>(b)</sup> | 0.03 STMR-RAC | HR-RAC |
| Goat: Muscle/meat            | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Goat: Fat tissue             | 0.01*                         | Proposed MRL<sup>(b)</sup>     | 0.01* STMR-RAC          | HR-RAC                |
| Goat: Liver                  | 0.05*                         | Proposed MRL<sup>(b)</sup>     | 0.05* STMR-RAC          | HR-RAC                |
| Goat: Kidney                 | 0.15                          | Proposed MRL<sup>(b)</sup>     | 0.03 STMR-RAC           | HR-RAC                |
| Commodity                                      | Existing/ proposed MRL (mg/kg) | Source                          | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|--------------------------------|--------------------------------|-------------------------|-----------------------|
|                                               |                                |                                |                         |                       |
| Goat: Edible offals (other than liver and kidney) | 0.15                           | Proposed MRL\(^{(b)}\)         | 0.03 STMR-RAC           | 0.13 HR-RAC           |
| Equine: Muscle/meat                           | 0.01*                          | Proposed MRL\(^{(b)}\)         | 0.01* STMR-RAC          | 0.01* HR-RAC          |
| Equine: Fat tissue                            | 0.01*                          | Proposed MRL\(^{(b)}\)         | 0.01* STMR-RAC          | 0.01* HR-RAC          |
| Equine: Liver                                 | 0.4                            | Proposed MRL\(^{(b)}\)         | 0.12 STMR-RAC           | 0.33 HR-RAC           |
| Equine: Edible offals (other than liver and kidney) | 0.4                            | Proposed MRL\(^{(b)}\)         | 0.12 STMR-RAC           | 0.33 HR-RAC           |
| Poultry: Muscle/meat                          | 0.01*                          | Proposed MRL\(^{(b)}\)         | 0.01* STMR-RAC          | 0.01* HR-RAC          |
| Poultry: Fat tissue                           | 0.01*                          | Proposed MRL\(^{(b)}\)         | 0.01* STMR-RAC          | 0.01* HR-RAC          |
| Poultry: Liver                                | 0.05*                          | Proposed MRL\(^{(b)}\)         | 0.05* STMR-RAC          | 0.05* HR-RAC          |
| Poultry: Edible offals (other than liver and kidney) | 0.05*                          | Proposed MRL\(^{(b)}\)         | 0.05* STMR-RAC          | 0.05* HR-RAC          |
| Milks                                         | 0.01*                          | Proposed MRL\(^{(b)}\)         | 0.01* STMR              | 0.01* STMR            |
| Eggs                                          | 0.01*                          | Proposed MRL\(^{(b)}\)         | 0.01* STMR              | 0.01* HR              |

MRL: maximum residue level; STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity.

(a): MRL and risk assessment values were derived in the present opinion based on data submitted in the framework of confirmatory data assessment of metalaxyl-M.

(b): MRL and risk assessment values for livestock commodities were updated in the framework of the present opinion based on updated dietary burden calculations.

(c): The existing MRL comes from a use on metalaxyl, which was not supported by data (EFSA, 2015b). In the absence of confirmatory data for this use, this MRL might need to be lowered (either at the enforcement LOQ or using a fall-back MRL based on metalaxyl-M uses). In the meanwhile, the current MRL is still used for a conservative risk assessment.

(d): For apples and pears, it was concluded in the present opinion that the fall-back GAPs reported in the framework of confirmatory data assessment of metalaxyl-M were not supported by data. The MRL might be lowered at the enforcement LOQ. In the meanwhile, the current MRL is still used for a conservative risk assessment.

(e): For herbs and edible flowers, it was concluded in the present opinion that a risk management decision needs to be taken to which level the MRL might need to be lowered. In the meanwhile, the risk assessment values derived in the combined MRL review (EFSA, 2015b) are still used for a conservative risk assessment.
### Appendix E – Used compound codes

| Code/Trivial name<sup>(a)</sup> | Chemical name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|--------------------------------|-----------------------------------------------------|---------------------------------|
| Metalaxyl                      | methyl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-DL-alaninate | ![Metalaxyl Structural Formula](image) |
| (R, S enantiomers racemic)     | ZQEIXNjIjKjNjTD-UHFFFAOYSA-N                         |                                 |
|                                | CC(N(C(=O)COC)c1c(C)cccc1C)(C(=O)OC)                  |                                 |
| Metalaxyl-M                    | methyl N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-D-alaninate | ![Metalaxyl-M Structural Formula](image) |
| (R-enantiomer)                 | ZQEIXNjIjKjNjTD-GFCCVEGCSA-N                         |                                 |
|                                | C[C@@H]N(C(=O)COC)c1c(C)cccc1C)(C(=O)OC)              |                                 |
| CGA62826                       | N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine       | ![CGA62826 Structural Formula](image) |
|                                | ZRIKZVLHMGYCIR-UHFFFAOYSA-N                          |                                 |
|                                | CC(N(C(=O)COC)c1c(C)cccc1C)(C(=O)O)                   |                                 |

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

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

<sup>(b)</sup> ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

<sup>(c)</sup> ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).