Modification of the existing maximum residue levels for spirotetramat in small fruits and berries

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landwirtschaftliches Technologiezentrum Augustenberg submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance spirotetramat in crops belonging to the group of other small fruits and berries. The data submitted to support the MRL application were sufficient to derive MRL proposals for the crops concerned. Adequate analytical methods are available to enforce the proposed MRLs. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of spirotetramat according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant (Landwirtschaftliches Technologiezentrum Augustenberg) submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for spirotetramat for the crops group of other small fruits and berries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 24 May 2019. To accommodate for the intended use of spirotetramat, the EMS proposed to raise the existing MRLs from 0.7 to 2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. Upon request of EFSA, the EMS submitted an updated evaluation report on 19 August 2019, in which more detailed information on the residue trials was reported.

Based on the conclusions derived by EFSA in the framework of Commission Regulation (EU) No 188/2011, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of spirotetramat following foliar application was sufficiently elucidated in crops belonging to the group of fruit crops (apples), leafy crops (lettuce), root crops (potatoes) and pulses/oilseeds (cotton). Studies investigating the effect of processing on the nature (hydrolysis studies) of spirotetramat and its -enol, -ketohydroxy, -monohydroxy and -enol-glucoside metabolites demonstrated that spirotetramat-enol and spirotetramat monohydroxy are stable under the standard hydrolysis conditions; parent spirotetramat and two additional metabolites (-ketohydroxy and -enol-glucoside metabolites) were found to degrade to a certain extent depending on the test conditions.

Since the proposed use of spirotetramat is on permanent crops, investigation of residues in rotational crops is not necessary.

Based on the metabolic pattern identified in plant, hydrolysis studies, the toxicological significance of spirotetramat metabolites and the stability of spirotetramat during storage, the residue definition for enforcement proposed during the European Union (EU) pesticides peer review was the ‘sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat’. For the risk assessment the residue definition was proposed as the ‘sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat’. These proposed residue definitions apply to all plant crop groups including processed commodities. The current enforcement residue definition in Regulation (EC) No 396/2005 is set as the ‘sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat’.

Sufficiently validated analytical methods based on LC/HPLC-MS/MS are available to quantify residues in the crops assessed in this application for both the current and the proposed enforcement residue definitions. The methods enable quantification of residues at or above 0.05 mg/kg (current residue definition) and at or above 0.02 mg/kg (proposed residue definition).

The available residue trials in currants are sufficient to derive MRL proposals for both residue definitions (2 mg/kg for the current enforcement residue definition and 1.5 mg/kg for the proposed residue definition). These MRL proposals are extrapolated to all crops belonging to the crop group of other small berries and fruits.

Specific studies investigating the magnitude of spirotetramat residues in processed commodities were not provided and are not required considering the low individual contribution of the processed products prepared from the crops under consideration to the overall dietary consumer exposure.

Residues of spirotetramat in commodities of animal origin were not assessed since the crops under the current MRL application are not fed to livestock.

The toxicological profile of spirotetramat was assessed in the framework of the EU pesticides peer review under Commission Regulation (EU) No 188/2011 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.05 mg/kg body weight (bw) per day and an acute reference dose (ARFD) of 1 mg/kg bw. The toxicological reference values set for spirotetramat are also applicable to the metabolites included in the plant residue definition for risk assessment.

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMO). EFSA concluded that the short-term and long-term intake of residues resulting from the use of spirotetramat in the group of other small fruits and berries according to the intended agricultural practices is unlikely to pose a risk to consumers’ health.
It should be noted that the review of the existing MRL under art 12 of Regulation (EC) No 396/2005 is ongoing; therefore, the outcome of this reasoned opinion might need to be reconsidered when the MRL review is finalised.

EFSA proposes to amend the existing MRL as reported in the summary table below. Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity              | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|------------------------|-------------------------|-------------------------|------------------------------------------------------------|
|         |                        | (Spi + 4) Spi + 4 Spi + enol |                          |                                                            |
| 0154010 | Blueberries           | 0.7                     | 2                       | 1.5 The submitted residue trials in currants are sufficient to derive MRL proposals for the existing and the proposed new enforcement residue definition. These MRL proposals can be extrapolated to all crops belonging to the group of small fruits and berries |
| 0154020 | Cranberries           | 0.7                     | 2                       | 1.5 Risk for consumers unlikely                             |
| 0154030 | Currants              | 0.7                     | 2                       | 1.5 The proposed MRLs cover the intended NEU and indoor uses |
| 0154040 | Gooseberries          | 0.7                     | 2                       | 1.5                                                        |
| 0154050 | Rose hips             | 0.7                     | 2                       | 1.5                                                        |
| 0154060 | Mulberries            | 0.7                     | 2                       | 1.5                                                        |
| 0154070 | Azaroles              | 0.7                     | 2                       | 1.5                                                        |
| 0154080 | Elderberries          | 0.7                     | 2                       | 1.5                                                        |
| 0154990 | Others small fruits and berries | 0.7   | 2                       | 1.5                                                        |

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

The applicant requested the modification of the existing maximum residue levels (MRLs) for spirotetramat in the crops group of other berries and small fruits. The detailed description of the intended use of spirotetramat for these crops, which is the basis for the current MRL application, is reported in Appendix A.

Spirotetramat is the ISO common name for ethyl cis-8-methoxy-2-oxo-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-4-yl carbonate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Spirotetramat was evaluated in the framework of Directive 91/414/EEC¹ to be read in conjunction with Commission Regulation (EU) No 188/2011², with Austria designated as rapporteur Member State (RMS) for the representative uses following foliar application on citrus and lettuces. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013a). Spirotetramat was approved³ for the use as an insecticide on 1 May 2014.

The EU MRLs for spirotetramat are established in Annex III of Regulation (EC) No 396/2005⁴. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) is currently ongoing. EFSA has issued several reasoned opinions on the modification of MRLs for spirotetramat, including a reasoned opinion on other small fruits and berries (EFSA, 2019a). The proposals from these reasoned opinions have been considered in the EU MRL legislation.⁵

In accordance with Article 6 of Regulation (EC) No 396/2005, Landwirtschaftliches Technologiezentrum Augustenberg submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRLs for spirotetramat for the group of other small fruits and berries. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 24 May 2019. An updated ER, with more detailed information on the residue trials, was submitted to EFSA on 19 August 2019.

To accommodate for the intended use of spirotetramat, the EMS proposed to raise the existing group MRL, which covers blueberries, cranberries, currants, gooseberries, rose hips, mulberries, azaroles, elderberries and other small fruits and berries, from 0.7 to 2 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2019), the DAR and its addendum (Austria, 2008, 2013) prepared under Council Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment on spirotetramat (EFSA, 2013a), the Commission review report on spirotetramat (European Commission, 2013) as well as the conclusions from previous EFSA opinions on spirotetramat (EFSA, 2013b, 2014, 2016, 2017, 2019a).

For this application, the data requirements established in Regulation (EU) No 544/2011⁶ and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a-g, 2000, 2010a, 2010b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011⁷.

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review.

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¹ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
² Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51–55.
³ Commission Implementing Regulation (EU) No 1177/2013 of 20 November 2013 approving the active substance spirotetramat, 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 312, 21.11.2013, p. 28–32.
⁴ 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.
⁵ For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
⁶ Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
⁷ Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously are presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

In the framework of the EU pesticides peer review, metabolism of spirotetramat in primary crops was investigated in apples, lettuces, potatoes and cotton following foliar applications (EFSA, 2013a). A similar metabolic pathway was observed in all plant groups. The major part of the residues was composed of spirotetramat, its -enol,-ketohydroxy,-monohydroxy and -enol-glucoside metabolites. It was noted that in the metabolism studies, the possible changes in the stereochmistry of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy were not investigated and a data gap was identified by EFSA (EFSA, 2013a). When the EFSA guidance on the risk assessment for isomers (EFSA, 2019b) will be implemented, this point should be addressed.

For the crops under assessment, which belong to the crop group of fruits, the metabolic behaviour is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Since the proposed use of spirotetramat is on permanent crops, the investigation of residues in rotational crops is not necessary.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of spirotetramat and its four metabolites under standard hydrolytic conditions representing pasteurisation/boiling/baking/sterilisation was investigated in the framework of the EU pesticides peer review (EFSA, 2013a). Spirotetramat and spirotetramat-enol-glucoside remained stable under pasteurisation, degraded partially under cooking/boiling/baking and almost completely under sterilisation conditions into spirotetramat-enol. Spirotetramat-ketohydroxy was stable under pasteurisation and progressively converted to spirotetramat-MA-amide under cooking/boiling/baking and sterilisation conditions. Spirotetramat-enol and spirotetramat-monohydroxy remained stable under all three hydrolysis conditions (EFSA, 2019a).

1.1.4. Methods of analysis in plants

Sufficiently validated analytical methods are available to quantify residues of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside by liquid chromatography with tandem mass spectrometry (HPLC/LC-MS/MS) at the combined limit of quantification (LOQ) of 0.05 mg/kg. Similar analytical methods are available to enforce spirotetramat and spirotetramat-enol at combined LOQ 0.02 mg/kg as proposed in the framework of the peer review (EFSA, 2019a).

EFSA concludes that for the crops under assessment, which are considered matrices with high acid content, analytical methods are available to quantify residues for both the existing and the proposed enforcement residue definitions.

1.1.5. Storage stability of residues in plants

The stability of spirotetramat residues and its -enol, -ketohydroxy, -monohydroxy and -enol-glucoside metabolites was demonstrated under frozen conditions at –18°C in high water, high starch, high oil commodities during the peer review (EFSA, 2013a). Under the previous MRL application, storage stability of residues was evaluated also in kiwi and dry beans (high acid, protein), and it was concluded the residues are stable under frozen condition (EFSA, 2019a).
Overall the residues stability of spirotetramat-ketohydroxy, -monohydroxy and -enol-glucoside was demonstrated for 18 months in high water, high acid, high starch, high oil commodities when stored at 
−18°C.

Spirotetramat showed to be unstable in several matrices with high water content (lettuces, beans with pods) and in certain commodities classified as matrix with high oil content (nut meal) and high starch content (potatoes). However, the sum of spirotetramat and spirotetramat-enol was stable for at least 18 months in high water, high oil and high starch content matrices.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites, and considering that spirotetramat was not stable under frozen storage conditions in several matrices and degraded to spirotetramat-enol, the following residue definitions were proposed in the EU pesticides peer review (EFSA, 2013a):

- Residue definition for risk assessment: sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat
- Residue definition for enforcement: sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat

These residue definitions are appropriate for primary crops, including the crops under consideration, and processed products.

It is noted that the residue definition for enforcement currently set under Regulation (EC) No 396/2005 is identical to the residue definition for risk assessment, covering all four major spirotetramat metabolites.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In the support of the MRL application, the applicant submitted a total of 16 residue trials (eight performed in northern Europe (NEU) and eight under indoor conditions) conducted in black and red currants. All the samples were analysed for spirotetramat, its enol, ketohydroxy, monohydroxy and enol-glucoside. The results on the residue levels were reported for the individual components as well as sum, expressed as spirotetramat. Although for nine trials (five from NEU and four indoor) the interval between the applications deviates from the intended good agricultural practice (GAP) (7, 9, 10 and 15 days instead of 14), the deviation from the intended GAP was considered of having a minor impact on the final residue levels in the harvested products. All the submitted trials are supported by storage stability data and validated analytical methods.

Overall, the trials were sufficiently representative for the NEU and indoor uses and allowed to calculate MRL proposals for the existing and the proposed new residue definition. In accordance with the EU guidance document on extrapolation (European Commission, 2017), the MRL proposals can be extrapolated to all crops classified under the crop group of ‘other small fruit and berries’.

1.2.2. Magnitude of residues in rotational crops

Since the proposed use of spirotetramat is on perennial crops, the investigations of residues in rotational crops are not necessary.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the evaluated crops were not provided and are not required considering the low individual contribution of the processed products prepared from the crops under consideration to the overall dietary consumer exposure.

1.2.4. Proposed MRLs

The submitted residue trials on currants were sufficient to derive the MRL proposals for the crop group of other small fruits and berries for the existing and the proposed new enforcement residue definition. In Section 3, EFSA assessed whether residues on these crops are likely to pose a consumer health risk.
2. Residues in livestock

An assessment of residues in livestock is not necessary since the crops under consideration are not fed to livestock.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMo). This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018).

The estimated exposure was compared with the acceptable daily intake (ADI) of 0.05 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 1 mg/kg bw derived for spirotetramat (European Commission, 2013). The toxicological reference values derived for spirotetramat apply also to the metabolites included in the residue definition for risk assessment (EFSA, 2013a).

For the chronic exposure, EFSA used the supervised trial median residues (STMR) derived from the indoor residue trials on currants and the STMRs reported in the most recent EFSA reasoned opinion (EFSA, 2019a). For the remaining commodities of plant and animal origin, the existing MRL values were considered. The short-term exposure was conducted only for crops belonging to the group of small fruits and berries assessed under current MRL application. The input values used in the dietary exposure calculation are summarised in Appendix D.

No long-term consumer intake concern was identified for any of the European diets incorporated in the EFSA PRIMo. The total chronic intake accounted for a maximum of 30% of the ADI (NL toddler diet); the contribution of the residues in the evaluated crops accounted for max. 0.4% of ADI (currants).

The short-term exposure did not exceed the acute reference value for any of the crops assessed (maximum 0.7% ARfD for currants).

As regards the data gap identified during the peer review on the possible stereochemistry changes of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy (EFSA, 2013a), EFSA reiterates the need to address this point when the EFSA guidance on isomers (EFSA, 2019b) will be implemented. For the intended uses assessed in this MRL application, EFSA concluded that according to the exposure calculation, there is a sufficient margin of safety to the toxicological reference values to cover the uncertainty related to this data gap.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were sufficient to derive the MRL proposals for the group of ‘other small fruits and berries’ for both existing and proposed new enforcement residue definition.

EFSA concluded that the proposed use of spirotetramat on small fruits and berries will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
DALA days after last application
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS/MS tandem mass spectrometry detector
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RAC raw agricultural commodity
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
STMR supervised trials median residue
YF yielding factor
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | Preparation | Application | Application rate per treatment | PHI (days) |
|-----------------------|-------------|-------------|-------------------------------|------------|
| **Blueberries, cranberries, currants, gooseberries, rose hips, mulberries, elderberries, other small fruits and berries** | SC | Foliar treatment – broadcast spraying | BBCH 69–85 | 2 | 14 days | 0.011–0.023 | 500–1,000 | 112.5 | g/ha | 14 |
| **Blueberries, cranberries, currants, gooseberries, rose hips, mulberries, elderberries, other small fruits and berries** | SC | Foliar treatment – broadcast spraying | BBCH 69–85 | 2 | 14 days | 0.011–0.023 | 500–1,000 | 112.5 | g/ha | 14 |

NEU: northern European Union; SEU: southern European Union; MS: Member State.

(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 | Crops | Applications | Sampling | Comment/source |
|----------------------------------|-------------|-------|--------------|----------|----------------|
| Fruit crops                      | Apples      | Foliar: 2 x 576 g/ha, BBCH 69, 71 | 63 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |
| Root crops                       | Potatoes    | Foliar: 3 x 96 g/ha, BBCH 75, 85, 93 | 14 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |
| Leafy crops                      | Lettuces    | Foliar: 2 x 72 g/ha, BBCH 41, 45 | 7 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |
| Pulses/ oilseeds                 | Cotton      | Foliar: 2 x (92+172) g/ha BBCH 15, 85 | 19 DAT1, 39 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |

| Rotational crops (available studies) | Crop groups | Crops | Application | PBI (DAT) | Comment/source |
|---------------------------------------|-------------|-------|-------------|-----------|----------------|
| Root/tuber crops                      | Turnips     | Bare soil, 1 x 406 g/ha | 30, 135, 260 | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |
| Leafy crops                           | Swiss chard | Bare soil, 1 x 406 g/ha | 30, 135, 260 | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |
| Cereals (small grain)                 | Spring wheat| Bare soil, 1 x 406 g/ha | 30, 135, 260 | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013a) |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/source |
|------------------------------------------|------------|---------|----------------|
| Spirotetramat, spirotetramat-enol-glucoside | Pasteurisation (20 min, 90°C, pH 4) | Yes | [azaspirodecenyl-3-14C]-spirotetramat; [azaspirodecenyl-3-14C]-spirotetramat-enol-glucoside (EFSA, 2013a) |
|                                            | Baking, brewing and boiling (60 min, 100°C, pH 5) | No |
|                                            | Sterilisation (20 min, 120°C, pH 6) | No |
| Spirotetramat-enol, spirotetramat-monohydroxy | Pasteurisation (20 min, 90°C, pH 4) | Yes | [azaspirodecenyl-3-14C]-spirotetramat-enol [azaspirodecenyl-3-14C]-spirotetramat-monohydroxy (EFSA, 2013a) |
|                                            | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                            | Sterilisation (20 min, 120°C, pH 6) | Yes |
| Spirotetramat-ketohydroxy | Pasteurisation (20 min, 90°C, pH 4) | Yes | [azaspirodecenyl-3-14C]- spirotetramat-ketohydroxy (EFSA, 2013a) |
|                                            | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes |
|                                            | Sterilisation (20 min, 120°C, pH 6) | No |
Can a general residue definition be proposed for primary crops?
Yes EFSA (2013a)

Rotational crop and primary crop metabolism similar?
Metabolism more extensive in rotational crops than in primary crops (EFSA, 2013a)

Residue pattern in processed commodities similar to residue pattern in raw commodities?
Yes EFSA (2013a)

Plant residue definition for monitoring (RD-Mo)

Existing RD-Mo: Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-mono hydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat (Regulation (EC) No 396/2005)

Proposed RD-Mo: Sum of spirotetramat and spirotetramat-enol expressed as spirotetramat (EFSA, 2013a)

Plant residue definition for risk assessment (RD-RA)

Sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat (EFSA, 2013a)

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

Existing RD-Mo (spi + 4)
Matrices with high water content, high oil content, high acid content and dry matrices. HPLC–MS/MS (QuEChERS), individual LOQ 0.01 mg/kg per analyte (combined LOQ 0.05 mg/kg). Confirmatory method available. ILV available (EFSA, 2016)

Proposed RD-Mo (spi + enol)
Matrices with high water content, high oil content, high acid content, hop cone dried: LC–MS/MS, individual LOQ 0.01 mg/kg per analyte (combined LOQ 0.02 mg/kg). Confirmatory method available. ILV available (EFSA, 2013a)

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

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                |          |           |        |                        |                   |               |
|                                   | Lettuces | −18       | 6      | Months                 | spi               | EFSA (2013a)  |
|                                   | Beans with pods | −18       | 1      | Months                 | spi               | EFSA (2016)   |
|                                   | Tomatoes | −18       | 18     | Months                 | spi               | EFSA (2013a)  |
|                                   | Lettuces | −18       | 2      | Months                 | spi-enol          | EFSA (2016)   |
|                                   | Beans with pods | −18       | 1      | Months                 | spi-enol          | EFSA (2016)   |
|                                   | Tomatoes | −18       | 18     | Months                 | spi-enol          | EFSA (2013a)  |
|                                   | Lettuces, beans with pods, tomatoes | −18   | 18  | Months                 | spi + enol        | EFSA (2013a)  |
|                                   | Lettuces, beans with pods | −18   | 18  | Months                 | spi-ketohydroxy, spi-enol-Glc spi-monohydroxy | EFSA (2013a)  |
| High oil content                  | Nut (meal) | −18       | 1      | Months                 | spi               | EFSA (2013a)  |
|                                   | Nut (meal) | −18       | 18     | Months                 | spi-enol          | EFSA (2013a)  |
|                                   | Nut (meal) | −18       | 18     | Months                 | spi + enol        | EFSA (2013a)  |
| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|-----------------------------------|----------|-----------|--------|-----------------|-------------------|---------------|
| Nut (meal)                        | –18      | 18 months |        |                 | spi-ketohydroxy, spi-enol, spi-monohydroxy | EFSA (2013a) |
| High protein content              | Bean (dry) | –18      | 18 months | spi, spi-enol | EFSA (2019a) |
|                                  | Bean (dry) | –18      | 18 months | spi-ketohydroxy, spi-enol, spi-monohydroxy | EFSA (2019a) |
| High starch                       | Potatoes | –18      | 2 months | spi | EFSA (2016) |
|                                  | Potatoes | –18      | 12 months | spi-enol | EFSA (2013a) |
|                                  | Potatoes | –18      | 18 months | spi + enol | EFSA (2013a) |
|                                  | Potatoes | –18      | 18 months | spi-ketohydroxy, spi-enol, spi-monohydroxy | EFSA (2013a) |
| High acid content                 | Kiwi fruit | –18      | 18 months | spi, spi-enol | EFSA (2019a) |
|                                  | Kiwi fruit | –18      | 18 months | spi-ketohydroxy, spi-enol, spi-monohydroxy | EFSA (2019a) |
| Processed products                | Orange juice, prune | –18      | 5 months | spi | EFSA (2013a) |
|                                  | Orange juice, prune | –18      | 5 months | spi-enol | EFSA (2013a) |
|                                  | Orange juice, prune | –18      | 5 months | spi + enol | EFSA (2013a) |
|                                  | Orange juice, prune | –18      | 5 months | spi-ketohydroxy, spi-enol, spi-monohydroxy | EFSA (2013a) |
|                                  | Tomato paste | –18      | 12 months | spi | EFSA (2013a) |
|                                  | Tomato paste | –18      | 3 months | spi-enol | EFSA (2013a) |
|                                  | Tomato paste | –18      | 12 months | spi + enol | EFSA (2013a) |
|                                  | Tomato paste | –18      | 12 months | spi-ketohydroxy, spi-enol, spi-monohydroxy | EFSA (2013a) |

Spi: spirotetramat; spi-enol: spirotetramat-enol; spi + enol: spirotetramat plus spirotetramat-enol; spi-ketohydroxy: spirotetramat-ketohydroxy; spi-monohydroxy: spirotetramat-monohydroxy; spi-enol-Glc: spirotetramat-enol glucoside.
B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-----------|--------------------------|---------------------------------------------------------------|-----------------|------------------------|-----------------|------------------|---------|
| Currants  | NEU                      | **existing RD Mo = RD RA:** 0.081, 0.10, 0.11, 0.12, 0.16, 0.21, 0.27, 0.44 | Extrapolation to the group of other small fruits and berries classified under crop code 0154000 is possible | 0.7 mg/kg (existing RD Mo) | RA: 0.44 | RA: 0.14 | – |
|           |                          | **proposed RD Mo** (EFSA, 2013a): 0.03, 0.04, 0.06, 0.08, 0.06, 0.12, 0.21, 0.39 | | 0.6 mg/kg (proposed RD Mo) | | | 1.6 |
|           | Indoor                   | **existing RD Mo = RD RA:** 0.27, 0.29; 0.37, 0.51, 0.60, 0.62, 0.71, 0.95 | | | | | |
|           |                          | **proposed RD Mo** (EFSA, 2013a): 0.24, 0.25, 0.34, 0.48, 0.53, 0.56, 0.59, 0.91 | Extrapolation to the group of other small fruits and berries classified under crop code 0154000 is possible | 2 mg/kg (existing RD Mo) | RA: 0.95 | RA: 0.56 | – |
|           |                          | **RD RA:** 0.27, 0.29; 0.37, 0.51, 0.60, 0.62, 0.71, 0.95 | | 1.5 mg/kg (proposed RD Mo) | | | 1.6 |

\*: Indicates that the MRL is proposed at the limit of quantification. The bold indicates the proposed MRLs and the input values used for in the consumer risk assessment.

(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 (residue definition for RA).

(c): Supervised trials median residue (residue definition for RA).

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

The crops under consideration are perennial; therefore, the assessment on the succeeding crops is not relevant under this MRL application.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

The crops under consideration are not fed to livestock; thus, an assessment of residues in livestock is not necessary.

B.3. Consumer risk assessment

| ARfD | 1 mg/kg bw (European Commission, 2013) |
|------|---------------------------------------|
|      | RAC:                                  |
|      | Currants: 0.7% of ARfD                |
|      | Gooseberries: 0.6% of ARfD            |
|      | Blueberries: 0.4% of ARfD             |
|      | Cranberries: 0.2% of ARfD             |
|      | Azarole: 0.09% of ARfD                |
|      | Processed products:                   |
|      | Currants (red, black and white) / juice: 1.6% of ARfD |
|      | Elderberries / juice 0.9% of ARfD     |
|      | Cranberries / juice 0.3% of ARfD      |
|      | Blueberries / juice 0.3% of ARfD      |
|      | Azarole (mediteranean medlar) / juice: 0.3% of ARfD |
|      | Rose hips / jam 0.2% of ARfD          |

| Assumptions made for the calculations | The calculation is based on the highest residue levels expected in raw agricultural commodities |
|--------------------------------------|-----------------------------------------------------------------------------------------------|
|                                      | The calculations were performed with PRIMo rev. 3 (EFSA, 2018)                                      |

| ADI | 0.05 mg/kg bw per day (European Commission, 2013) |
|-----|---------------------------------------------------|
|     | RAC:                                              |
|     | Currants: 0.4% of ADI                             |
|     | Rose hips: 0.2% of ADI                            |
|     | Gooseberries: 0.05% of ADI                        |
|     | Blueberries: 0.03% of ADI                         |
|     | Cranberries: 0.02% of ADI                         |
|     | Mulberries: 0.01% of ADI                          |
|     | Azarole: 0.01% of ADI                             |
|     | Other small fruit and berries: 0.2% of ADI        |

| Assumptions made for the calculations | The calculation is based on the median residue levels derived from the indoor trials on currants and the STMRs reported in the most recent EFSA reasoned opinion (EFSA, 2019a). For the remaining commodities of plant and animal origin, the existing MRL values were considered. |
|--------------------------------------|-----------------------------------------------------------------------------------------------|
|                                      | The calculations were performed with PRIMo rev. 3 (EFSA, 2018)                                      |
### B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity                | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|--------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
|                   |                          | (Spi + 4)               | Spi + 4                 | Spi + enol                                                                            |
| **Enforcement residue definition (existing):** Spirotetramat and its four metabolites BYI08330-enol, BYI08330-ketoxyhydroxy, BYI08330-monohydroxy and BYI08330 enol-glucoside, expressed as spirotetramat (Spi + 4)<sup>(R)</sup> | |  | | |
| 0154010           | Blueberries              | 0.7                     | 2                       | 1.5                                                                                   |
| 0154020           | Cranberries              | 0.7                     | 2                       | 1.5                                                                                   |
| 0154030           | Currants                 | 0.7                     | 2                       | 1.5                                                                                   |
| 0154040           | Gooseberries             | 0.7                     | 2                       | 1.5                                                                                   |
| 0154050           | Rose hips                | 0.7                     | 2                       | 1.5                                                                                   |
| 0154060           | Mulberries               | 0.7                     | 2                       | 1.5                                                                                   |
| 0154070           | Azaroles                 | 0.7                     | 2                       | 1.5                                                                                   |
| 0154080           | Elderberries             | 0.7                     | 2                       | 1.5                                                                                   |
| 0154990           | Others small fruits and berries | 0.7                 | 2                       | 1.5                                                                                   |
| **Enforcement residue definition (proposed):** Sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat (Spi + enol) | | | | |

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

### LOQs (mg/kg)

- Range from: 0.005 to: 0.10

### ADI (mg/kg bw per day)
- 0.05

### ARfD (mg/kg bw)
- 1

#### Source of ADI
- European Commission

#### Source of ARfD
- European Commission

### EFSA PRIMo revision 3.0; 2017/12/11

#### Year of evaluation
- 2013

### Calculated exposure (% of ADI)

| Commodity/group of commodities | No of diets exceeding the ADI | MS Diet Exposure (% of ADI) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|-------------------------------|------------------------------|-----------------------------|-------------------------------------------|----------------------------------------|----------------------------------------|
| Escaroles/broad-leaved endives | --- 0                        | 30%                         | 14.82                                     | 5%                                     | 4%                                      |
| Spinaches                     |                             | 20%                         | 9.95                                      | 4%                                     | 2%                                      |
| Soyabeans                     |                             | 17%                         | 8.64                                      | 3%                                     | 1%                                      |
| Sugar beet roots              |                             | 17%                         | 8.36                                      | 2%                                     | 2%                                      |
| Tomatoes                      |                             | 16%                         | 8.18                                      | 3%                                     | 2%                                      |
| Tomatoes                      |                             | 15%                         | 7.46                                      | 3%                                     | 0.9%                                    |
| Olives for oil production     |                             | 15%                         | 7.41                                      | 2%                                     | 1%                                      |
| Tomatoes                      |                             | 14%                         | 7.04                                      | 3%                                     | 0.9%                                    |
| Tomatoes                      |                             | 14%                         | 6.84                                      | 2%                                     | 2%                                      |
| Tomatoes                      |                             | 13%                         | 6.50                                      | 2%                                     | 1%                                      |
| Tomatoes                      |                             | 12%                         | 6.21                                      | 3%                                     | 1%                                      |
| Other lettuce and other salad plants |                | 12%                         | 6.05                                      | 3%                                     | 1%                                      |
| Olives for oil production     |                             | 11%                         | 5.58                                      | 1%                                     | 0.9%                                    |
| Peaches                       |                             | 11%                         | 5.49                                      | 4%                                     | 0.7%                                    |
| Peaches                       |                             | 10%                         | 5.27                                      | 1%                                     | 1%                                      |
| Tomatoes                      |                             | 9%                          | 4.83                                      | 2%                                     | 1%                                      |
| Tomato                        |                             | 7%                          | 3.87                                      | 1%                                     | 0.9%                                    |
| Tomato                        |                             | 7%                          | 3.68                                      | 0.9%                                   | 0.9%                                    |
| Wheat                         |                             | 7%                          | 3.36                                      | 1%                                     | 0.8%                                    |
| Wheat                         |                             | 6%                          | 3.13                                      | 1%                                     | 0.5%                                    |
| Spinaches                     |                             | 5%                          | 2.73                                      | 0.7%                                   | 0.8%                                    |
| Tomatoes                      |                             | 5%                          | 2.44                                      | 0.8%                                   | 0.7%                                    |
| Tomatoes                      |                             | 4%                          | 2.22                                      | 1%                                     | 0.6%                                    |
| Tomatoes                      |                             | 4%                          | 2.07                                      | 0.5%                                   | 0.6%                                    |
| Lettuce/other salad plants    |                             | 3%                          | 1.94                                      | 0.5%                                   | 0.5%                                    |
| Lettuce/other salad plants    |                             | 3%                          | 1.87                                      | 0.8%                                   | 0.6%                                    |
| Lettuce/other salad plants    |                             | 2%                          | 1.63                                      | 0.8%                                   | 0.5%                                    |
| Peaches                       |                             | 2%                          | 1.39                                      | 0.8%                                   | 0.8%                                    |
| Peaches                       |                             | 2%                          | 1.27                                      | 1%                                     | 0.8%                                    |
| Peaches                       |                             | 1%                          | 1.14                                      | 1%                                     | 0.5%                                    |
| Peaches                       |                             | 1%                          | 1.02                                      | 0.5%                                   | 0.5%                                    |

### Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Spirotetramat is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

The calculation is based on the large portion of the most critical consumer group.

### Unprocessed commodities

| IESTI |  |  |
|---|---|---|
| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
| 0.7% | Currants (red, black and white) | 2.05 | 7.5 | 0.9% | Blueberries | 20.95 | 8.7 |
| 0.6% | Gooseberries (green, red) | 20.95 | 6.6 | 0.6% | Currants (red, black and white) | 20.95 | 6.3 |
| 0.4% | Blueberries | 20.95 | 3.8 | 0.4% | Gooseberries (green, red) | 20.95 | 4.3 |
| 0.2% | Cranberries | 20.95 | 2.5 | 0.2% | Rose hips | 20.95 | 2.1 |
| 0.09% | Azarole/Mediterranean | 20.95 | 0.86 | 0.00% | 0.00 |

### Processed commodities

| IESTI |  |  |
|---|---|---|
| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
| 2% | Currants (red, black and white) | 20.56 | 16 | 0.7% | Currants (red, black and white) | 20.56 | 7.1 |
| 0.9% | Elderberries/juice | 20.56 | 8.9 | 0.5% | Elderberries/juice | 20.56 | 5.1 |
| 0.3% | Cranberries/juice | 20.56 | 3.2 | 0.5% | Elderberries/juice | 20.56 | 5.1 |
| 0.3% | Blueberries/processed (not s) | 20.56 | 3.2 | 0.5% | Elderberries/juice | 20.56 | 5.1 |
| 0.3% | Blueberries/processed (med) | 20.56 | 3.1 | 0.5% | Elderberries/juice | 20.56 | 5.1 |
| 0.2% | Rose hips/jam | 20.56 | 1.7 | 0.1% | Rose hips/jam | 20.56 | 0.70 |
| 0.0% | 0.00 | 0.00 | 0.00% | 0.00 |
| 0.0% | 0.00 | 0.00 | 0.00% | 0.00 |
| 0.0% | 0.00 | 0.00 | 0.00% | 0.00 |
| 0.0% | 0.00 | 0.00 | 0.00% | 0.00 |
| 0.0% | 0.00 | 0.00 | 0.00% | 0.00 |
| 0.0% | 0.00 | 0.00 | 0.00% | 0.00 |

**Conclusion:** No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short term intake of residues of Spirotetramat is unlikely to pose a risk for processed commodities, no exceedance of the ARfD/ADI was identified.

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**

Not applicable to the current assessment.

**D.2. Consumer risk assessment**

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               |
| Citrus fruits                    | 0.22 STMR x CF x PF (EFSA, 2016) |                        |
| Tree nuts                        | 0.084 STMR (EFSA, 2016) |                       |
| Pome fruits                      | 0.17 STMR (EFSA, 2016)  |                       |
| Stone fruits                     | 1.60 STMR (EFSA, 2016)  |                       |
| Table grapes                     | 0.41 STMR (EFSA, 2016)  |                       |
| Wine grapes                      | 0.17 STMR x CF x PF x YF (EFSA, 2016) |         |
| Strawberries                     | 0.08 STMR (EFSA, 2016)  |                       |
| Other small fruits and berries   | 0.56 STMR               | 0.95 HR               |
| Table olives                     | 0.72 STMR (EFSA, 2016)  |                       |
| Kaki/Japanese persimmons         | 0.14 STMR (EFSA, 2016)  |                       |
| Kiwi fruits                      | 0.41 STMR (EFSA, 2019a) |                       |
| Litchis/lychees                  | 1.60 STMR (EFSA, 2016)  |                       |
| Avocados                         | 0.22 STMR (EFSA, 2016)  |                       |
| Bananas                          | 0.08 STMR (EFSA, 2016)  |                       |
| Mangoes                          | 0.16 STMR (EFSA, 2016)  |                       |
| Papayas                          | 0.17 STMR (EFSA, 2016)  |                       |
| Granate apples/Pomegranates      | 0.20 STMR (EFSA, 2017)  |                       |
| Guavas                           | 0.55 STMR (EFSA, 2017)  |                       |
| Pineapples                       | 0.07 STMR (EFSA, 2016)  |                       |
| Potatoes                         | 0.12 STMR (EFSA, 2016)  |                       |
| Other root & tuber vegetables, except sugar beets | 0.05 STMR (EFSA, 2017) |                       |
| Garlic                           | 0.10 STMR (EFSA, 2019a) |                       |
| Onions                           | 0.11 STMR (EFSA, 2016)  |                       |
| Shallots                         | 0.10 STMR (EFSA, 2016)  |                       |
| Solanaceae, except peeper        | 0.44 STMR (EFSA, 2016)  |                       |
| Peppers                          | 0.95 STMR (EFSA, 2016)  |                       |
| Cucurbits                        | 0.057 STMR (EFSA, 2016) |                       |
| Sweet corns                      | 0.31 STMR (EFSA, 2017)  |                       |
| Flowering Brassica               | 0.50 STMR (EFSA, 2016)  |                       |
| Brussels sprouts                 | 0.11 STMR (EFSA, 2016)  |                       |
| Head cabbages                    | 0.23 STMR (EFSA, 2016)  |                       |
| Leafy brassica                   | 3.70 STMR (EFSA, 2016)  |                       |
| Kohlrabies                       | 0.35 STMR (EFSA, 2016)  |                       |
| Lettuces & salad plants          | 3.70 STMR (EFSA, 2016)  |                       |
|Spinaches & similar leaves | 3.70 STMR (EFSA, 2016) |                       |
| Water cresses                    | 3.70 STMR (EFSA, 2016)  |                       |
| Herbs & edible flowers           | 1.23 STMR (EFSA, 2016)  |                       |
| Legume vegetables                | 0.505 STMR (EFSA, 2016) |                       |
| Commodity                        | Input value (mg/kg) | Comment                     | Input value (mg/kg) | Comment                     |
|---------------------------------|--------------------|-----------------------------|--------------------|-----------------------------|
| Celeries                        | 0.58               | STMR (EFSA, 2016)           |                    |                             |
| Florence fennels                | 0.68               | STMR (EFSA, 2019a)          |                    |                             |
| Globe artichokes                | 0.41               | STMR (EFSA, 2016)           |                    |                             |
| Rhubarbs                        | 0.68               | STMR (EFSA, 2019a)          |                    |                             |
| Pulses                          | 0.21               | STMR (EFSA, 2016)           |                    |                             |
| Soya beans                      | 0.45               | STMR (EFSA, 2016)           |                    |                             |
| Cotton seeds                    | 0.095              | STMR (EFSA, 2016)           |                    |                             |
| Olives for oil productions      | 0.72               | STMR (EFSA, 2016)           |                    |                             |
| Hops                            | 5.20               | STMR (FAO, 2008)            |                    |                             |
| Chicory roots                   | 0.05               | STMR (EFSA, 2017)           |                    |                             |
| Muscle<sup>(a)</sup>            | 0.007              | STMR (EFSA, 2016)           |                    |                             |
| Fat tissue<sup>(a)</sup>        | 0.012              | STMR (EFSA, 2016)           |                    |                             |
| Liver<sup>(a)</sup>             | 0.166              | STMR (EFSA, 2016)           |                    |                             |
| Kidney<sup>(a)</sup>            | 0.024              | STMR (EFSA, 2016)           |                    |                             |
| Edible offal<sup>(a)</sup>      | 0.166              | STMR (EFSA, 2016)           |                    |                             |
| Poultry tissues<sup>(a)</sup>   | 0.022              | STMR (EFSA, 2016)           |                    |                             |
| Milks<sup>(a)</sup>             | 0.003              | STMR (EFSA, 2016)           |                    |                             |
| Bird eggs<sup>(a)</sup>         | 0.022              | STMR (EFSA, 2016)           |                    |                             |

<sup>(a)</sup>: Median residue (STMR) according to the residue definition for risk assessment in products of animal origin as the sum of spirotetramat-enol and spirotetramat-enol-GA, expressed as spirotetramat (EFSA, 2013a).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|--------------------------------------------------|----------------------------------|
| Spirotetramat (BYI 08330)     | ethyl cis-8-methoxy-2-oxo-3-(2,5-xylyl)-1-azaspiro[4.5]dec-3-en-4-yl carbonate | ![Structural formula](image1) |
|                               | O=C(OCC)OC1=C(C(-O)[N[C@@]21CC[C@H](CC2)OC]1cc(C)c1cc1C) CLSVJBIHYWPQY-GGYDESQDSA-N |                                  |
| Spirotetramat-enol            | (S<sub>s</sub>,S<sub>s</sub>)--3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one | ![Structural formula](image2) |
|                               | Cc1cc(C=C(-O)[N[C@@]3(CC[C@H](CC3)OC)C2]-20)c(C)cc1 XOCVOLJZHNLHA-GESSKKQQA-N |                                  |
| Spirotetramat-ketohydroxy     | (S<sub>s</sub>,S<sub>s</sub>)--3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione | ![Structural formula](image3) |
|                               | Unstated stereochemistry Cc1cc(c(C)cc1)C1(O)C(-O)[N[C@@]2(CC[C@H](CC2)OC)C1]=O HPQGJNTUXNUJDL-RMVSHPHEA-N |                                  |
| Spirotetramat-monohydroxy     | (S<sub>s</sub>,S<sub>s</sub>)--3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one | ![Structural formula](image4) |
|                               | Unstated stereochemistry Cc1cc(C2C(-O)[N[C@@]3(CC[C@H](CC3)OC)C2O])c(C)cc1 HPQGJNTUXNUJDL-RMVSHPHEA-N |                                  |
| Spirotetramat-enol-glucoside  | (S<sub>s</sub>,S<sub>r</sub>)--3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl [β-D-glucopyranoside | ![Structural formula](image5) |
| spirotetramat-enol-Glc        | Cc1cc(c(C)cc1)C1=C(O[C@H]20[C@H](DO)[C@H][O][C@H][O][C@H]20[C@H]2(CC[C@H](CC2)NC1)=O UZUGTDHNHPYHPX-UHFFFAOYSA-N |                                  |
| Spirotetramat-MA-amide        | cis-1-[2-(2,5-dimethylphenyl)(hydroxy)acetamido]-4-methoxycyclohexanecarboxylic acid | ![Structural formula](image6) |
|                               | unstated stereochemistry CO[C@H]1CC[C@]2(NC(-O)C(O)c2cc(C)c2cc2C)(CC1)C(-O)O BQMSZLYWPQFG-ZSNGYVYCVSA-N |                                  |
| Code/trivial name | IUPAC name/SMILES notation/InChIKey | Structural formula |
|------------------|--------------------------------------|--------------------|
| Spirotetramat-enol-GA | (5s,8S)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl D-glucopyranosiduronic acid | ![Structural formula](image) |

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 Dec 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 Dec 2014).