Modification of the existing maximum residue levels for spirotetramat in various crops

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the competent national authority in Belgium prepared a request to modify the existing maximum residue levels (MRLs) for the active substance spirotetramat in Florence fennels and rhubarbs. Furthermore, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer SAS submitted a request to the competent national authority in Austria to modify the existing MRLs for spirotetramat in the group of other small fruits and berries, kiwi fruits and garlic. The data submitted in support to both requests were found to be sufficient to derive MRL proposals for all the crops under consideration. 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 intended 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 competent national authority in Belgium (evaluating Member State, EMS-BE) prepared a request to modify the existing maximum residue levels (MRL) for the active substance spirotetramat in Florence fennels and rhubarbs. The EMS-BE 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 31 July 2018. To accommodate for the intended uses of spirotetramat, the EMS-BE proposed to raise the existing MRLs from the limit of quantification (LOQ) to 4 mg/kg for Florence fennels and rhubarbs.

Furthermore, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer SAS, CropScience division, submitted a request to the competent national authority in Austria (EMS-AT) to modify the MRLs for spirotetramat in the group of other small fruits and berries, kiwi fruits and garlic. The EMS-AT drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 4 October 2018. To accommodate for the intended uses of spirotetramat, the EMS-AT proposed to raise the existing MRLs to 0.6 mg/kg for the small fruits and berries, 4 mg/kg for kiwi fruits and 0.4 mg/kg for garlic.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS-AT. On 14 November 2018, the EMS-AT submitted a revised evaluation report, which replaced the previously submitted evaluation report.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by both EMS in the framework of the corresponding applications, the following conclusions are derived.

The metabolism of spirotetramat in primary crops was investigated in four crop groups following foliar applications and in rotational crops, root/tuber crops, leafy crops and cereals, during the European Union (EU) pesticides peer review. Studies investigating the effect of processing on the nature of spirotetramat and its four main metabolites (hydrolysis studies) demonstrated that only spirotetramat-enol and spirotetramat-monohydroxy were stable under standard hydrolysis conditions.

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 and degraded to spirotetramat-enol, the EU pesticides peer review proposed the residue definition for enforcement as ‘sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat’. For risk assessment, the residue definition was concluded as the ‘sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat’. The residue definition for enforcement currently set under Regulation (EC) No 396/2005 includes the four spirotetramat metabolites. Therefore, it is equivalent to the residue definition for risk assessment. The residue definitions are applicable to primary crops, including the crops under consideration, and processed products.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed according to both the existing and the proposed enforcement residue definition. The methods enable quantification of residues at or above 0.05 mg/kg (existing residue definition) or 0.02 mg/kg (proposed residue definition). In the framework of one of the two applications, the results of storage stability on kiwi fruits under frozen conditions were provided to support the reliability of residues of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside quantified in the residue trials on crops belonging to the high acid content group.

The available residue trials are sufficient to derive MRL proposals for Florence fennels, rhubarbs, other small fruits and berries, kiwi fruits and garlic. Anticipating that the residue definition for enforcement may be changed in accordance with the recommendation of the EU pesticides peer review, EFSA also derived MRL proposals for the residue definition proposed during the EU pesticides peer review.

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.

Among the crops under consideration, only Florence fennel and garlic may be grown in crop rotation. Based on the available information on the nature and magnitude of residues, EFSA concluded that significant residue levels are unlikely to occur in rotational crops provided that the active
substance is used on Florence fennels and garlic according to the intended good agricultural practice (GAP). Residues of spirotetramat in commodities of animal origin were not assessed since none of the crops under consideration is normally used as feed item for livestock.

The toxicological profile of spirotetramat was assessed in the framework of the EU pesticides peer review 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 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 on Florence fennels, rhubarbs, other small fruits and berries, kiwi fruits and garlic according to the intended agricultural practices is unlikely to present a risk to consumer health.

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 should be taken as provisional and might need to be reconsidered in the light of the outcome the MRL review.

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

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

| Code(a) | Commodity                              | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|---------|----------------------------------------|-------------------------|-------------------------|-----------------------------------------------------------|
|         |                                        | (Spi + 4)               | (Spi + 4)               | (Spi + enol)                                              |
| 0154010 | Blueberries                            | 0.1*                    | 0.7                     | 0.5            | The submitted data are sufficient to derive, by extrapolation from data on currants and grapes, a MRL proposal for the NEU use. Risk for consumers unlikely |
| 0154020 | Cranberries                            | 0.2                     | 0.7                     | 0.5            |                                                                 |
| 0154030 | Currants (black, red and white)        | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0154040 | Gooseberries (green, red and yellow)   | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0154050 | Rose hips                              | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0154060 | Mulberries (black and white)           | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0154070 | Azaroles/ Mediterranean medlars         | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0154080 | Elderberries                           | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0154990 | Others small fruits and berries        | 0.1*                    | 0.7                     | 0.5            |                                                                 |
| 0162010 | Kiwi fruits (green, red, yellow)       | 0.3                     | 4                       | 3              | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 0220010 | Garlic                                 | 0.1*                    | 0.4                     | 0.3            | The submitted data are sufficient to derive, by extrapolation from data on onions, a MRL proposal for the NEU and SEU use. Risk for consumers unlikely |

Enforcement residue definition (existing): Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat (Spi + 4)

Enforcement residue definition (proposed): Sum of spirotetramat, spirotetramat-enol, expressed as spirotetramat (Spi + enol)
| Code\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------|-----------------|-------------------------|-------------------------|------------------------|
| 0270040  | Florence fennels | 0.1*                    | 4                       | 4                      |
| 0270070  | Rhubarbs        | 0.1*                    | 4                       | 4                      |

The submitted data are sufficient to derive, by extrapolation from data on celeries, a MRL proposal for the indoor use. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
BYI08330: code for spirotetramat (spi); (enol): spirotetramat-enol.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The European Food Safety Authority (EFSA) was asked to assess the application to modify the existing maximum residue levels (MRLs) for spirotetramat in a number of crops. The detailed description of the intended uses of spirotetramat in Florence fennels, rhubarbs, crops belonging to the group other small fruits and berries, kiwi fruits and garlic which are the basis for the current MRL applications, is reported in Appendix A.

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

Spirotetramat was evaluated in the framework of Regulation (EC) No 1107/2009 with Austria designated as rapporteur Member State (RMS) for the representative uses as a foliar application on citrus and lettuces. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2013). Spirotetramat was approved for the use as an insecticide on 1 May 2014.

The European Union (EU) MRLs for spirotetramat are established in Annex III of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for spirotetramat. In 2016, EFSA already assessed the intended use on crops belonging to the group of small fruits and berries and kiwi fruits (EFSA, 2016). Since the data were found to be incomplete, the MRLs for these crops have not been modified. The other proposals from this and the proposals from previous reasoned opinions have been considered in the regulations for EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, the competent national authority in Belgium (evaluating Member State, EMS-BE) prepared a request to modify the existing MRLs for the active substance spirotetramat in Florence fennels and rhubarbs. The EMS-BE drafted an evaluation report (Belgium, 2018) in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 11 July 2018. To accommodate for the intended uses of spirotetramat, the EMS-BE proposed to raise the existing MRLs for Florence fennels and rhubarbs from the limit of quantification (LOQ) to 4 mg/kg.

Furthermore, in accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer SAS, CropScience division, submitted a request to the competent national authority in Austria (EMS-AT) to modify the MRLs for spirotetramat in the group of other small fruits and berries, kiwi fruits and garlic. The EMS-AT drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 4 October 2018. To accommodate for the intended uses of spirotetramat, the EMS-AT proposed to raise the existing MRLs to 0.6 mg/kg for the small fruits and berries, 4 mg/kg for kiwi fruits and 0.4 mg/kg for garlic.

EFSA assessed these applications and the evaluation reports as required by Article 10 of the MRL regulation. For reasons of efficiency, the two applications were combined in one reasoned opinion. EFSA identified points which needed further clarification, which were requested from the EMS-AT. On 14 November 2018, the EMS-AT submitted a revised evaluation report (Austria, 2018), which replaced the previously submitted evaluation report.

EFSA based its assessment on the revised evaluation reports submitted by the EMS (Austria, 2018; Belgium, 2018), the DAR and its final addendum (Austria, 2008, 2013) prepared under Directive 91/414/EEC, the conclusion on the peer review of the pesticide risk assessment of the active substance spirotetramat (EFSA, 2013), the Commission review report on spirotetramat (European

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1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
2 Commission Implementing Regulation (EU) 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.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
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Commission, 2013) as well as the conclusions from previous EFSA opinions on spirotetramat (EFSA, 2016, 2017).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^5\) and the guidance documents applicable at the date of submission of the application to the respective EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). 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.\(^6\)

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.

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

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

1. **Residues in plants**

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

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

The metabolism of spirotetramat in primary crops was investigated after foliar applications in fruits, roots, leafy and pulses/oilseeds crops in the framework of the EU pesticides peer review (EFSA, 2013). A similar metabolic pathway was observed in all plant groups. The major part of the residues was composed of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside. In the metabolism studies, the possible changes in the stereochemistry of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy were not investigated and a data gap was identified by EFSA (2013). EFSA would like to reiterate the need to address this point, once the guidance document on the assessment of isomers is finalised and implemented.

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

The metabolism of spirotetramat in rotational crops was investigated in root/tuber crops, leafy crops and cereals after application of the active substance to bare soil in the framework of the EU pesticides peer review (EFSA, 2013). Metabolism was more extensive in rotational crops than in primary crops. Spirotetramat and spirotetramat-enol were nearly not detected in rotational crops, where residues were mostly composed of the metabolites spirotetramat-ketohydroxy and spirotetramat-desmethyl-ketohydroxy and their conjugates.

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

The effect of processing on the nature of spirotetramat and its four major metabolites was investigated in the framework of the EU pesticides peer review (EFSA, 2013). Spirotetramat and spirotetramat-enol-glucoside were stable under pasteurisation conditions and progressively degraded to spirotetramat-enol during conditions representative for cooking/boiling/baking (15% degradation for spirotetramat and 10% for spirotetramat-enol-glucoside) and sterilisation (85% degradation for spirotetramat and 40% degradation for spirotetramat-enol-glucoside). Spirotetramat-ketohydroxy was stable under pasteurisation and progressively converted to the metabolite spirotetramat-MA-amide under cooking/boiling/baking (5% degradation) and sterilisation (99% degradation) conditions. Spirotetramat-enol and spirotetramat-monohydroxy were seen to remain stable under all three hydrolysis conditions.

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

\(^6\) Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1.1.4. Methods of analysis in plants

The current residue definition set in the EU MRL regulation includes spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside. A high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) analytical method was reported to be validated in plant matrices at the combined LOQ of 0.05 mg/kg (EFSA, 2016).

A sufficiently validated analytical method is also available to enforce spirotetramat and spirotetramat-enol (residue definition proposed in the framework of the EU pesticides peer review) in plant matrices at the combined LOQ of 0.02 mg/kg (EFSA, 2013).

EFSA concluded that analytical methods are available to quantify residues in high water and high acid content matrices, to which groups the crops under consideration belong, according to both the existing and the proposed enforcement residue definition.

1.1.5. Stability of residues in plants

The storage stability of spirotetramat and its main four metabolites under frozen conditions was assessed in high water content, high oil content and in orange juice in the framework of the EU pesticides peer review (EFSA, 2013). Spirotetramat showed to be unstable in several matrices of the high water content group (lettuce, bean with pods) and in the matrix belonging to the high oil content (nut meal) and high starch content (potato) tested. However, when analysed for the sum of spirotetramat and spirotetramat-enol, residues were concluded to be stable for at least 18 months in high water, high oil and high starch content matrices. Spirotetramat-enol-glucoside, spirotetramat-ketohydroxy and spirotetramat-monohydroxy were stable for at least 18 months in the same matrices. In orange juice, stability was determined for all analytes up to the period of storage of the samples of 5 months. A new storage stability study on kiwi fruits (high acid content matrix) under frozen conditions was provided (Austria, 2018). No significant decline (less than 30% the nominal level) was observed for spirotetramat, spirotetramat-enol, spirotetramat-enol-glucoside, spirotetramat-ketohydroxy and spirotetramat-monohydroxy during a period up to 18 months.

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, 2013):

- 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.

It is noted that the residue definition for enforcement currently set under Regulation (EC) No 396/2005 is different and includes all four spirotetramat major metabolites. Therefore, it is equivalent to the residue definition proposed for risk assessment.

These residue definitions are applicable to primary crops, including the crops under concern, and processed products.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

- Florence fennels and rhubarbs, indoor European use

The EMS-BE provided four residue trials conducted on celeries to support the intended use on Florence fennels and rhubarbs; the trials were compliant with the intended good agricultural practices (GAPs). The extrapolation of residue data from celeries to Florence fennels and rhubarbs is possible (European Commission, 2017). According to the EMS, the trials on celeries were analysed with a sufficiently validated analytical method and stored for a period (12 months) for which integrity in high

7 Storage stability data were also provided for dry beans (high protein content matrix). The results were reported in Appendix B.
water content matrices was demonstrated (Belgium, 2018). The data submitted are sufficient to derive, by extrapolation, a MRL proposal.

- Other small fruits and berries (whole group listed in Annex I of Regulation (EC) No 396/2005 under code 0154000), northern European use

In 2016, EFSA already assessed the intended GAP on the group of small fruits and berries (EFSA, 2016). The application was supported by four residue trials on currants and eight trials on grapes. Based on the results of the residue trials, EFSA derived, by extrapolation, a MRL proposal for the group. However, since sufficient data on storage stability in high acid content matrices were missing, EFSA could not conclude on the validity of the trials8 (EFSA, 2016).

In support of the current application, the applicant submitted additional storage stability data (see Section 1.1.5) covering the whole period of storage of the samples (up to 16 months) used to derive the MRL proposal in 2016. Since validity of the residues data has been confirmed, the previously derived MRL proposal is considered sufficiently supported by data.

- Kiwifruits, southern European use

In 2016, EFSA already assessed the intended GAP on kiwi fruits and derived a MRL proposal based on eight GAP-compliant residue trials (EFSA, 2016). Likewise small fruits and berries, EFSA could not conclude on the validity of the trial results because of the lacking of sufficient storage stability in high acid content matrices.

Since the applicant has now submitted additional storage stability data (see Section 1.1.5) covering the whole period of storage of the samples (up to 15 months) used to derive the MRL proposal in 2016, the previously derived MRL proposal is considered sufficiently supported by data.

- Garlic, northern and southern European uses

In support of the current application, the EMS-AT referred to eight NEU and eight SEU residue trials on onions assessed in the framework of the EU pesticides peer review (EFSA, 2013). Since these field trials are compliant (within the 25% tolerance range in application rate) with the intended GAP9 on garlic and the extrapolation of residue data from onion to garlic is possible (European Commission, 2017), the data were sufficient to derive a MRL proposal for garlic.

1.2.2. Magnitude of residues in rotational crops

Among the crops under consideration, only Florence fennel and garlic may be grown in crop rotation. Based on the results of the confined rotational crop studies assessed in the EU pesticides peer review, which were conducted at an higher application rate (1.35N) the intended rate on the crops under consideration (maximum 300 g/ha), significant residue levels are not expected in the edible parts of rotated crops. EFSA concluded that relevant residue levels of spirotetramat and its major metabolites are unlikely to occur in rotational crops provided that spirotetramat is used on Florence fennels and garlic according to the intended GAP.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies are not required, considering the low individual contribution of processed products produced from the crops under consideration to the overall dietary consumer exposure.

1.2.4. Proposed MRLs

The available data were found to be sufficient to derive MRL proposals as well as risk assessment values for Florence fennels, rhubarbs, other small fruits and berries,10 kiwifruits and garlic for the

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8 Storage stability data were available for up to 5 months in an high acid content processed matrix (orange juice). This period was anyway not sufficient to cover the storage of the field trial samples prior to analysis (EFSA, 2016).

9 The intended GAP on garlic foresees the use of two types of formulations: the suspension concentrate (SC) and the oil dispersion (OD). All trials on onions were conducted with the OD formulation. Comparative trials on several crops demonstrated that the two spirotetramat formulation types do not influence the residue behaviour significantly and were considered as providing comparable results (EFSA, 2013, 2017).

10 The slightly lower MRL of 0.06 mg/kg derived according to the existing residue definition (spi + 4) by the EMS-AT is justified by the rounding down of the result from a trial on currants.
current residue definitions. In Section 3, EFSA assessed whether residues on these crops are likely to pose a consumer health risk.

Anticipating that the residue definition for enforcement may be changed in accordance with the recommendation of the EU pesticides peer review, EFSA also derived MRL proposals for the residue definition covering the sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat.

Conversion factors (CF) from enforcement to risk assessment at the intended PHI have been derived (EFSA, 2013, 2016; Belgium, 2018). They are reported in Appendix B (Table B.1.2.1).

2. Residues in livestock

Not relevant as the crops under assessment 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 then 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 the active substance apply to the metabolites included in the residue definition for risk assessment (EFSA, 2013).

For the chronic exposure, EFSA used the supervised trial median residues (STMR) derived for the crops under consideration in this application and reported in the most recent EFSA reasoned opinions (EFSA, 2016, 2017). For the remaining commodities of plant and animal origin, the existing MRL values were considered. The short term exposure was conducted only for the crops under consideration in these MRL applications. 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 calculated intake accounted for a maximum of 29% of the ADI (NL toddler diet). The contribution of the residues on the crop under consideration to the total exposure accounted for a maximum of 0.7% of ADI (kiwi fruits). The expected short-term exposure did not exceed the toxicological reference value for any of the products assessed (maximum 16% ARfD for kiwi fruits).

A data gap was identified to address the impact of the possible changes in the stereochemistry of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy on the consumer risk assessment (EFSA, 2013). EFSA would like to reiterate the need to address this point, once the guidance document on the assessment of isomers is finalised and implemented. For the intended uses under consideration, the results of the exposure calculation demonstrated a sufficiently wide safety margin 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 these MRL applications were found to be sufficient to derive MRL proposals for Florence fennels, rhubarbs, other small fruits and berries, kiwi fruits and garlic. EFSA concluded that the intended uses of spirotetramat on these crops will not result in a consumer exposure exceeding the toxicological reference values and therefore are 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
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
| Acronym | Description |
|---------|-------------|
| 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 | 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 |
| InChIKey| International Chemical Identifier Key |
| ISO     | International Organisation for Standardisation |
| IUPAC   | International Union of Pure and Applied Chemistry |
| JMPR    | Joint FAO/WHO Meeting on Pesticide Residues |
| LOQ     | limit of quantification |
| Mo      | monitoring |
| MRL     | maximum residue level |
| MS      | Member States |
| NEU     | northern Europe |
| OECD    | Organisation for Economic Co-operation and Development |
| PBI     | plant-back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| QuEChERS| Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA      | risk assessment |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SEU     | southern Europe |
| STMR    | supervised trials median residue |
| WHO     | World Health Organization |
| YF      | yield factor |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|-------------------------|------------|------------------------------------|-------------|-------------|-------------------------------|--------------|---------|
|                       |                         |            |                                    | Type (b) | Concentration (g/L) | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | g a.s./hl | Water/L/ha | Rate | Unit |          |          |          |          |          |          |
| Blueberries, cranberries, currants, gooseberries, rose hips, mulberries, azaroles, elderberries, other small fruits and berries | NEU | F | Sucking pests | SC | 100 | Foliar spraying | BBCH 71–85 | 1–2 | 14 days | 37.5 | 200–1,200 | 75 | g/ha | 14 | EMS-AT |
| Od | 150 | Foliar spraying | BBCH 71–85 | 1–2 | 14 days | Max. 30 | 500–1,000 | 150 | g/ha | 14 | EMS-AT |
| Kiwi fruits | SEU | F | Sucking pests | SC | 100 | Foliar spraying | BBCH 71–85 | 1–2 | 14 days | Max. 30 | 500–1,000 | 150 | g/ha | 14 | EMS-AT |
| Garlic | NEU | F | Sucking pests | SC | 100 | Foliar spraying | BBCH 13–47 | 1–4 | 7 days | Max. 36 | 200–600 | 72 |          |          |          |          |          |          |
| Od | 150 | Foliar spraying | BBCH 13–47 | 1–4 | 7 days | Max. 36 | 500–1,000 | 150 | g/ha | 7 | EMS-AT |
| SEU | F | Sucking pests | SC | 100 | Foliar spraying | BBCH 13–47 | 1–4 | 7 days | Max. 37.5 | 250–1,000 | 75 | g/ha | 7 | EMS-AT |
| Od | 150 | Foliar spraying | BBCH 13–47 | 1–4 | 7 days | Max. 30 |          |          |          |          |          |          |          |          |          |          |
| Florence fennels | EU | G | Aphids | SC | 100 | Foliar spraying | Until BBCH 49 | 1–2 | 14 days | – | – | 75 | g/ha | 7 | EMS-BE |
| Rhubarbs | EU | G | Aphids | SC | 100 | Foliar spraying | Until BBCH 49 | 1–2 | 14 days | – | – | 75 | g/ha | 7 | EMS-BE |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; a.s.: active substance; SC: suspension 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 | Crops | Applications | Sampling | Comment/Source |
|-----------------------------------|-------------|-------|--------------|----------|----------------|
| Fruit crops                       | Apple       | Foliar: 2 × 576 g/ha, BBCH 69, 71 | 63 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013) |
| Root crops                        | Potato      | Foliar: 3 × 96 g/ha, BBCH 75, 85, 93 | 14 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013) |
| Leafy crops                       | Lettuce     | Foliar: 2 × 72 g/ha, BBCH 41, 45 | 7 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013) |
| Pulses/oilseeds                   | Cotton      | Foliar: 2 × (92+172) g/ha BBCH 15, 85 | 19 DAT, 39 DALA | [azaspirodecenyl-3-14C]-spirotetramat (EFSA, 2013) |

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

| 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, 2013) |
|                                          | 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 |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes | [azaspirodecenyl-3-14C]-spirotetramat-monohydroxy (EFSA, 2013) |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes |
| Spirotetramat-ketohydroxy              | Pasteurisation (20 min, 90°C, pH 4) | Yes | [azaspirodecenyl-3-14C]- spirotetramat-ketohydroxy (EFSA, 2013) |
|                                          | 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 (2013) |

### Rotational crop and primary crop metabolism similar?

| Metabolism more extensive in rotational crops than in primary crops (EFSA, 2013) |

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

| Yes | EFSA (2013) |

### Plant residue definition for monitoring (RD-Mo)

| **Existing RD-Mo**: Spirotetramat and its 4 metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy 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, 2013) |

### 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, 2013) |

### 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: HPLC–MS/MS, individual LOQ 0.01 mg/kg per analyte (combined LOQ 0.02 mg/kg). Confirmatory method available. ILV available (EFSA, 2013) |

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; Spi: spirotetramat; spi + enol: spirotetramat plus spirotetramat-enol.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|-----------------------------------|----------|-----------|--------|------------------|-------------------|----------------|
|                                  | High water content | Lettuce | −18 | 6 Months | Spi | EFSA (2013) |
|                                  |          | Bean with pods | −18 | 1 Months | Spi | EFSA (2016) |
|                                  |          | Tomato | −18 | 18 Months | Spi | EFSA (2013) |
|                                  |          | Lettuce | −18 | 2 Months | Spi-enol | EFSA (2016) |
|                                  |          | Bean with pods | −18 | 1 Months | Spi-enol | EFSA (2016) |
|                                  |          | Tomato | −18 | 18 Months | Spi-enol | EFSA (2013) |
|                                  |          | Lettuce, bean with pods, tomato | −18 | 18 Months | Spi + enol | EFSA (2013) |
|                                  |          | Lettuce, bean with pods | −18 | 18 Months | Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | EFSA (2013) |
|                                  | High oil content | Nut (meal) | −18 | > 1 Months | Spi | EFSA (2013) |
|                                  |          | Nut (meal) | −18 | 18 Months | Spi-enol | EFSA (2013) |
|                                  |          | Nut (meal) | −18 | 18 Months | Spi + enol | EFSA (2013) |
|                                  |          | Nut (meal) | −18 | 18 Months | Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | EFSA (2013) |
|                                  | High protein content | Bean (dry) | −18 | 18 Months | Spi, spi-enol | Austria (2018) |
|                                  |          | Bean (dry) | −18 | 18 Months | Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | Austria (2018) |
|                                  | High starch | Potato | −18 | 2 Months | Spi | EFSA (2016) |
|                                  |          | Potato | −18 | 12 Months | Spi-enol | EFSA (2013) |
|                                  |          | Potato | −18 | 18 Months | Spi + enol | EFSA (2013) |
|                                  |          | Potato | −18 | 18 Months | Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | EFSA (2013) |
|                                  | High acid content | Kiwi fruit | −18 | 18 Months | Spi, spi-enol | Austria (2018) |
|                                  |          | Kiwi fruit | −18 | 18 Months | Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | Austria (2018) |
|                                  | Processed products | Orange juice, prune | −18 | 5 Months | Spi | EFSA (2013) |
|                                  |          | Orange juice, prune | −18 | 5 Months | Spi-enol | EFSA (2013) |
|                                  |          | Orange juice, prune | −18 | 5 Months | Spi + enol | EFSA (2013) |
|                                  |          | Orange juice, prune | −18 | 5 Months | Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | EFSA (2013) |
|                                  |          | Tomato paste | −18 | 12 Months | Spi | EFSA (2013) |
|                                  |          | Tomato paste | −18 | 3 Months | Spi-enol | EFSA (2013) |
|                                  |          | Tomato paste | −18 | 12 Months | Spi + enol | EFSA (2013) |
|                                  |          | Tomato paste | −18 | 12 Months | spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy | EFSA (2013) |

Spi: spirotetramat; spi + enol, spirotetramat plus spirotetramat-enol; 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(b) (mg/kg) | HR(c) (mg/kg) | STMR(d) (mg/kg) | CF(e) |
|------------------------------------|-------------------|---------------------------------------------------------------|-------------------------------------------------------------------------------|---------------------------|--------------|-----------------|-------|
| Florence fennel, rhubarbs          | EU                | Mo=RA: 0.081; 0.20; 1.15; 1.44                                 | Residue trials on celeries compliant with GAP. Extrapolation to Florence fennel and rhubarb possible | 4                         | 4            | Mo: 1.36 RA: 1.44 | Mo: 0.50 RA: 0.68 | 1.5   |
|                                    |                   | Mo: 0.03; 0.12; 0.88; 1.36                                     |                                                                                |                           |              |                 |       |
|                                    |                   | RA: 0.081; 0.20; 1.15; 1.44                                    |                                                                                |                           |              |                 |       |
| Other small fruits and berries group | NEU              | Mo=RA: 0.13; 0.14, 0.15, 0.19; 0.20; 0.21; 0.22; 2 × 0.23; 0.25; 0.26; 0.28 | Residue trials on currants (4) and grapes (8) compliant with GAP already assessed by EFSA (2016) Extrapolation to the group of other small fruits and berries possible | 0.7                       | 0.5          | Mo: 0.22 RA: 0.28 | Mo: 0.17 RA: 0.22 | 1.6   |
|                                    |                   | Mo: 0.10; 0.11; 0.12; 0.14; 0.15; 0.16; 0.17; 3 × 0.19; 0.21; 0.22 |                                                                                |                           |              |                 |       |
|                                    |                   | RA: 0.13; 0.14, 0.15, 0.19; 0.20; 0.21; 0.22; 2 × 0.23; 0.25; 0.26; 0.28 |                                                                                |                           |              |                 |       |
| Kiwi fruits                        | SEU               | Mo=RA: 0.16; 0.24; 0.34; 0.39; 0.42; 0.43; 0.49; 2.53          | Residue trials compliant with GAP, already assessed by EFSA (2016)            | 4                         | 3            | Mo: 1.64 RA: 2.53 | Mo: 0.30 RA: 0.41 | 1.2   |
|                                    |                   | Mo: 0.13; 0.20; 0.29; 2 × 0.30; 0.37; 0.41; 1.64               |                                                                                |                           |              |                 |       |
|                                    |                   | RA: 0.16; 0.24; 0.34; 0.39; 0.42; 0.43; 0.49; 2.53            |                                                                                |                           |              |                 |       |
| Garlic                             | NEU               | Mo=RA: 0.05; 0.08; 0.09; 0.10; 2 × 0.11; 0.16; 0.20           | Residue trials on onions compliant with GAP already assessed by EFSA (2013). NEU and SEU residues were merged (U-test, 5%) to derive a more robust MRL. Extrapolation to garlic possible | 0.4                       | 0.3          | Mo: 0.17 RA: 0.20 | Mo: 0.07 RA: 0.10 | 1.6   |
|                                    |                   | Mo: 0.02; 0.05; 0.06; 0.07; 2 × 0.08; 0.13; 0.17               |                                                                                |                           |              |                 |       |
|                                    |                   | RA: 0.05; 0.08; 0.09; 0.10; 2 × 0.11; 0.16; 0.20             |                                                                                |                           |              |                 |       |
|                                    | SEU               | Mo=RA: < 0.05; 0.07; 0.08; 0.09; 0.10; 0.12; 0.14; 0.17       |                                                                                |                           |              |                 |       |
|                                    |                   | Mo: < 0.02; 0.03; 0.04; 0.06; 0.07; 0.09; 0.11; 0.14       |                                                                                |                           |              |                 |       |
|                                    |                   | RA: < 0.05; 0.07; 0.08; 0.09; 0.10; 0.12; 0.14; 0.17       |                                                                                |                           |              |                 |       |

MRL: maximum residue level; GAP: Good Agricultural Practice; Mo: monitoring; RA: 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): MRL calculated according to the existing (spi + 4) and the proposed (spi + enol) residue definition for monitoring.

(c): Highest residue: The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Supervised trials median residue: The median residue for risk assessment refers to the whole commodity and not to the edible portion.

(e): Median conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment as calculated at intended PHI. When the residue definition for monitoring and risk assessment is identical (Mo = RA: spi + 4), the CF is equal to 1.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
|------------------------------------------------------------------------------------------------|----|
| In the confined rotational crop study (at 1.35N the intended application rate on the crops under consideration), spirotetramat was not observed in any of the plant groups investigated (root/tuber crops, leafy crops, cereal (small grain) and plant–back intervals (PBI)). Spirotetramat-enol was quantified in wheat straw and hay only (0.05 mg eq/kg) at PBI 30 days (EFSA, 2013) |

| Residues in rotational and succeeding crops expected based on field rotational crop study? | No |
|------------------------------------------------------------------------------------------------|----|
| Field rotational crop study (total rate 170–180 g/ha, in two foliar applications) confirmed that no significant residues are expected in rotational crops when spirotetramat is applied on a primary crop according to the intended GAPs |

GAP: Good Agricultural Practice.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the MRL applications.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| ARfD | 1 mg/kg bw (European Commission, 2013) |
|------|--------------------------------------|
| Highest IESTI, according to EFSA PRIMO | Kiwi fruits: 15.7% of ARfD |
| | Rhubarbs: 5.36% of ARfD |
| | Florence fennels: 2.34% of ARfD |
| | Currants: 0.22% of ARfD |
| | Gooseberries: 0.16% of ARfD |
| | Blueberries: 0.11% of ARfD |
| | Cranberries: 0.07% of ARfD |
| | Garlic: 0.07% of ARfD |
| | Azarole: 0.03% of ARfD |
| | Other small fruits & berries: < 0.03% of ARfD |

Assumptions made for the calculations

The calculation is based on the highest residue levels expected in raw agricultural commodities.
ADI

Highest IEDI, according to EFSA PRIMo

29% ADI (NL toddler diet)

Contribution of crops assessed:

Kiwi fruits: 0.73% of ADI
Rhubarbs: 0.33% of ADI
Currants: 0.15% of ADI
Florence fennels: 0.13% of ADI
Rose hips: 0.09% of ADI
Elderberries: 0.06% of ADI
Other small fruit & berries: 0.06% of ADI
Garlic: 0.02% of ADI
Gooseberries: 0.02% of ADI
Blueberries: 0.01% of ADI
Cranberries: 0.01% of ADI
Other small fruits & berries: < 0.01% of ADI

Assumptions made for the calculations

The calculation is based on the median residue levels derived for commodities assessed in the current and reported in previous opinions for which proposed MRL modifications were implemented in EU MRL legislation. For citrus, a peeling factor of 0.6 and a conversion factor (CF) for risk assessment of 2 was taken into account. For wine grapes, the processing factor of 0.5, the CF of 1.5 and a yield factor of 0.7 for wine were used (EFSA, 2016). For hops the STMR derived by JMPR (FAO, 2008) was used. For the remaining commodities of plant and animal origin, the existing MRL values were included in the calculation.

B.4. Recommended MRLs

| Appendix C-Code(a) | 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 4 metabolites BY108330-enol, BY108330-ketohydroxy, BY108330-monohydroxy and BY108330 enol-glucoside, expressed as spirotetramat (Spi + 4)

**Enforcement residue definition** (proposed): Sum of spirotetramat, spirotetramat-enol, expressed as spirotetramat (Spi + enol)

| 0154010 | Blueberries | 0.1* | 0.7 | 0.5 | The submitted data are sufficient to derive, by extrapolation from data on currants and grapes, a MRL proposal for the NEU use. Risk for consumers unlikely |
| 0154020 | Cranberries | 0.2  | 0.7 | 0.5 |
| 0154030 | Currants (black, red and white) | 0.1* | 0.7 | 0.5 |
| 0154040 | Gooseberries (green, red and yellow) | 0.1* | 0.7 | 0.5 |
| 0154050 | Rose hips | 0.1* | 0.7 | 0.5 |
| 0154060 | Mulberries (black and white) | 0.1* | 0.7 | 0.5 |
| 0154070 | Azaroles/ Mediterranean medlars | 0.1* | 0.7 | 0.5 |
| 0154080 | Elderberries | 0.1* | 0.7 | 0.5 |
| 0154990 | Others small fruits and berries | 0.1* | 0.7 | 0.5 |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue.
### Appendix C – Code (a)

| Code | Commodity                          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------|------------------------------------|-------------------------|-------------------------|-----------------------|
|      |                                    | (Spi + 4)               | (Spi + 4)               | (Spi + enol)          |                       |
| 0162010 | Kiwi fruits (green, red, yellow) | 0.3                     | 4                       | 3                     | The submitted data are sufficient to derive a MRL proposal for the SEU use. Risk for consumers unlikely |
| 0220010 | Garlic                           | 0.1*                    | 0.4                     | 0.3                   | The submitted data are sufficient to derive, by extrapolation from data on onions, a MRL proposal for the NEU and SEU use. Risk for consumers unlikely |
| 0270040 | Florence fennels                  | 0.1*                    | 4                       | 4                     | The submitted data are sufficient to derive, by extrapolation from data on celeris, a MRL proposal for the indoor use. Risk for consumers unlikely |
| 0270070 | Rhubarbs                          | 0.1*                    | 4                       | 4                     |                       |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
BYI08330: code for spirotetramat (spi); (enol): spirotetramat-enol.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
### Appendix C – Pesticide Residue Intake Model (PRIMo)

#### Spirotetramat

| LODs (µg/kg range) | Toxicological reference values |
|-------------------|-------------------------------|
| EU (µg/kg dry matter) | 0.05 |

| Source of ADI: | European Commission |
|----------------|----------------------|
| Year of evaluation: | 2013 |

#### Input values

| LODs (µg/kg range) | Toxicological reference values |
|-------------------|-------------------------------|
| EU (µg/kg dry matter) | 0.05 |

| Source of ADI: | European Commission |
|----------------|----------------------|
| Year of evaluation: | 2013 |

#### Normal mode

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

| No of diets exceeding the ADI | Commodity/group of commodities |
|-------------------------------|-------------------------------|
| Exposure resulting from...   |                                 |

| Commodity/group of commodities | % of ADI |
|--------------------------------|---------|
| **MS Diet**                    |         |
| 29% 14.59 5% 4% 2% Escaroles/broad-leaved endives | 4% |
| 20% 9.89 4% 2% Spinaches | 4% |
| 17% 8.63 3% 1% Soya beans | 4% |
| 16% 8.22 2% Potatoes | 4% |
| 15% 7.45 3% 1% Tomatoes | 4% |
| 15% 7.38 3% 1% Lettuce | 4% |
| 14% 6.99 1% 1% Other leafy brassica | 4% |
| 14% 6.78 2% 1% Spinaches | 4% |
| 13% 6.47 2% 1% Kidney beans | 4% |
| 12% 6.20 3% 1% Lettuce | 4% |
| 12% 6.05 3% 1% Peaches | 4% |
| 12% 5.97 1% 1% tomatoes | 4% |
| 11% 5.57 1% 0% 1% Lettuce | 4% |
| 11% 5.49 4% 1% Tomatoes | 4% |
| 11% 5.27 1% 1% Potatoes | 4% |
| 10% 4.83 2% 1% Tomatoes | 4% |
| 9% 4.66 0.5% 1% Sugar beet roots | 4% |
| 9% 4.51 1% 1% Spinaches | 4% |
| 9% 4.47 1% 1% Spinaches | 4% |
| 9% 4.34 0.5% 1% Sugar beet roots | 4% |
| 9% 4.23 1% 1% Tomatoes | 4% |
| 9% 4.17 1% 1% Rice | 4% |
| 8% 3.85 1% 1% Other leafy and other salad plants | 4% |
| 8% 3.63 1% 1% Potatoes | 4% |
| 7% 3.35 1% 1% Rice | 4% |
| 7% 3.08 1% 1% Tomatoes | 4% |
| 7% 3.04 1% 1% Tomatoes | 4% |
| 7% 3.04 1% 1% Tomatoes | 4% |
| 6% 2.83 1% 1% Tomatoes | 4% |
| 5% 2.62 1% 1% Tomatoes | 4% |
| 4% 2.44 1% 1% Potatoes | 4% |
| 3% 2.24 1% 1% Tomatoes | 4% |
| 2% 2.01 1% 1% Tomatoes | 4% |
| 1% 1.81 1% 1% Tomatoes | 4% |

**Notes:**
- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of Spirotetramat is unlikely to pose a public health concern.
### Acute risk assessment/children

| Commodities                                    | MRL/input for RA (µg/kg) | Exposure (µg/kg bw) |
|------------------------------------------------|---------------------------|---------------------|
| Kiwi fruits (green, red, yellow)               | 4/2.53                    | 157                 |
| Florence fennel                               | 4/1.44                    | 54                  |
| Rhubarbs                                      | 4/1.44                    | 2.5                 |
| Elderberries/juice                            | 0.7/0.22                  | 7                   |
| Garlic                                        | 0.7/0.41                  | 56                  |
| Azarole/Mediterranean                         | 0.7/0.28                  | 2.4                 |

**Exposure to toxicological reference value (RA)**

**Highest % of ARfD/ADI**: 4%

**ARfD/ADI**: 4.14 µg/kg bw

**Exposure**: 157 µg/kg bw

**Highest % of Exposure**: 4%

**RA**: 357 µg/kg bw

| Commodities                                    | MRL/input for RA (µg/kg) | Exposure (µg/kg bw) |
|------------------------------------------------|---------------------------|---------------------|
| Rhubarbs/sauce/puree                           | 0.7/0.41                  | 56                  |
| Florence fennel                               | 4/1.44                    | 2.5                 |
| Elderberries/juice                             | 0.7/0.22                  | 7                   |
| Garlic                                        | 0.7/0.41                  | 56                  |
| Azarole/Mediterranean                         | 0.7/0.28                  | 2.4                 |

### Acute risk assessment/adults/general population

| Commodities                                    | MRL/input for RA (µg/kg) | Exposure (µg/kg bw) |
|------------------------------------------------|---------------------------|---------------------|
| Kiwi fruits (green, red, yellow)               | 4/2.53                    | 157                 |
| Florence fennel                               | 4/1.44                    | 54                  |
| Rhubarbs                                      | 4/1.44                    | 2.5                 |
| Elderberries/juice                            | 0.7/0.22                  | 7                   |
| Garlic                                        | 0.7/0.41                  | 56                  |
| Azarole/Mediterranean                         | 0.7/0.28                  | 2.4                 |

**Exposure to toxicological reference value (RA)**

**Highest % of ARfD/ADI**: 4%

**ARfD/ADI**: 4.14 µg/kg bw

**Exposure**: 157 µg/kg bw

**Highest % of Exposure**: 4%

**RA**: 357 µg/kg bw

| Commodities                                    | MRL/input for RA (µg/kg) | Exposure (µg/kg bw) |
|------------------------------------------------|---------------------------|---------------------|
| Rhubarbs/sauce/puree                           | 0.7/0.41                  | 56                  |
| Florence fennel                               | 4/1.44                    | 2.5                 |
| Elderberries/juice                             | 0.7/0.22                  | 7                   |
| Garlic                                        | 0.7/0.41                  | 56                  |
| Azarole/Mediterranean                         | 0.7/0.28                  | 2.4                 |

### Show results of IESTI calculation only for crops with GAPs under assessment

| Commodities                                    | MRL/input for RA (µg/kg) | Exposure (µg/kg bw) |
|------------------------------------------------|---------------------------|---------------------|
| Kiwi fruits (green, red, yellow)               | 4/2.53                    | 157                 |
| Florence fennel                               | 4/1.44                    | 54                  |
| Rhubarbs                                      | 4/1.44                    | 2.5                 |
| Elderberries/juice                            | 0.7/0.22                  | 7                   |
| Garlic                                        | 0.7/0.41                  | 56                  |
| Azarole/Mediterranean                         | 0.7/0.28                  | 2.4                 |

| Commodities                                    | MRL/input for RA (µg/kg) | Exposure (µg/kg bw) |
|------------------------------------------------|---------------------------|---------------------|
| Rhubarbs/sauce/puree                           | 0.7/0.41                  | 56                  |
| Florence fennel                               | 4/1.44                    | 2.5                 |
| Elderberries/juice                             | 0.7/0.22                  | 7                   |
| Garlic                                        | 0.7/0.41                  | 56                  |
| Azarole/Mediterranean                         | 0.7/0.28                  | 2.4                 |

### Details – acute risk assessment/children

The acute risk assessment is based on the ARfD.

The calculation is performed with the MRL and the peeling/processing factor (PF), taking into account the residue in the edible portion and/or the conversion factor for the residue definition (CF). For case 2a, 2b and 3 calculations a variability factor of 3 is used. Since this methodology is not based on internationally agreed principles, the results are considered as indicative only.

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short term intake of residues of Spiroteramat is unlikely to present a public health risk.

For processed commodities, no exceedance of the MRL was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not applicable.

D.2. Consumer risk assessment

| Commodity                     | Chronic risk assessment | Acute risk assessment |
|-------------------------------|-------------------------|-----------------------|
|                               | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Citrus fruits                 | 0.22                    | STMR \times CF \times 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 \times CF \times PF \times YF (EFSA, 2016) | 0.17 | STMR (EFSA, 2016) |
| Strawberries                  | 0.08                    | STMR (EFSA, 2016)     | 0.28                | HR (a)               |
| Other small fruits and berries| 0.22                    | STMR (a)              |                      |                       |
| Table olives                  | 0.72                    | STMR (EFSA, 2016)     |                      |                       |
| Kaki/Jap. persimmons          | 0.14                    | STMR (EFSA, 2016)     |                      |                       |
| Kiwi fruits                   | 0.41                    | STMR (a)              | 2.53                | HR (a)               |
| 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                   | 0.20                | HR                   |
| Onions                        | 0.11                    | STMR (EFSA, 2016)     |                      |                       |
| Shallots                      | 0.10                    | STMR (EFSA, 2016)     |                      |                       |
| Solanaceae, except pepper     | 0.44                    | STMR (EFSA, 2016)     |                      |                       |
| Peppers                       | 0.95                    | STMR (EFSA, 2016)     |                      |                       |
| Cucurbita                     | 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          | 1.44                | HR      |
| Globe artichokes                  | 0.41                | STMR (EFSA, 2016) |                     |         |
| Rhubarbs                          | 0.68                | STMR          | 1.44                | HR      |
| 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 (b)                        | 0.007               | STMR (EFSA, 2016) (c) |                 |         |
| Fat tissue (b)                    | 0.012               | STMR (EFSA, 2016) (c) |                 |         |
| Liver (b)                         | 0.166               | STMR (EFSA, 2016) (c) |                 |         |
| Kidney (b)                        | 0.024               | STMR (EFSA, 2016) (b) |                 |         |
| Edible offal (b)                  | 0.166               | STMR (EFSA, 2016) (c) |                 |         |
| Poultry tissues                   | 0.022               | STMR (EFSA, 2016) (c) |                 |         |
| Milks                             | 0.003               | STMR (EFSA, 2016) (c) |                 |         |
| Bird eggs                         | 0.022               | STMR (EFSA, 2016) (c) |                 |         |
| Other products of plant and animal origin | Existing MRLs (LOQ) as in Regulation (EU) 2017/1016 | | | |

STMR: supervised trials median residue; CF: conversion factor for enforcement to risk assessment residue definition; PF: processing factor; YF: yield factor; HR: highest residue; LOQ: limit of quantification; MRL: maximum residue level.

(a): The safety for the consumers was already assessed in a previous opinion (EFSA, 2016).
(b): Swine, bovine, sheep, goat, equine, other farm animals.
(c): 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, 2013).
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChIKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| Spirotetramat (BYI 08330) | **ethyl cis-8-methoxy-2-oxo-3-(2,5-xyl)-1-azaspiro [4.5]dec-3-en-4-yl carbonate**<br>**O=CC(=O)OC1=C(C(=O)N[C@][@]21CC[C@H](CC2)OC)c1cc(C)ccc1C**<br>**CLSVBJIHYWPGQY-GGYDESQDSA-N** | ![Structural formula](image1) |
| Spirotetramat-enol (5s,8s)-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]dec-3-en-2-one | **Cc1cc(C=2C(=O)N[C@]3(CC[C@H](CC3)OC)C=2O) c(C)c1**<br>**IDJHEUJYGFDX-QGGXVJLZSA-N** | ![Structural formula](image2) |
| Spirotetramat-ketohydroxy (5s,8s)-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2,4-dione | **Cc1cc(c(C)cc1)C1(O)C(=O[O]OOC)[O]C=2O)c(C)c1**<br>**XOVCVOLJZHNHLA-GESSKKQJSA-N** | ![Structural formula](image3) |
| Spirotetramat-monohydroxy (5s,8s)-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one | **Cc1cc(C2C(=O)N[C@]3(CC[C@H](CC3)OC)C=2O)c(C)c1**<br>**HPQGJNTUXNUIDL-RMVSHPHESA-N** | ![Structural formula](image4) |
| Spirotetramat-enol-glucoside (spirotetramat-enol-Glc) (5s,8R)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl β-D-glucopyranoside | **Cc1cc(c(C)cc1)C1–C(O[C@H][20][C@H][CO][C@H][O][C@H][O][C@H][20][C@H][20][C@H][OC]CC)NC1=O**<br>**UZUGTDHNPYPH-XUHFFAOYSA-N** | ![Structural formula](image5) |
| Spirotetramat-MA-amide cis-1-[2-(2,5-dimethylphenyl)(hydroxy)acetamido]-4-methoxycyclohexanecarboxylic acid | **unstated stereochemistry**<br>**CO[C@H][1CC[C@](NC(=O)CC2cc(c)c2C)c2C](CC1)(=O)O**<br>**BQMSZLYWPQFG-ZSGNYVCVSAN** | ![Structural formula](image6) |
| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|------------------------------------------------|----------------------------------|
| 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) |
| | Cc1cc(c(C)c1)C1=C(OC2O[C@@H][C@@H](O)[C@@H](O)[C@@H]20)C(=O)O)C2(C[C@H](OC)CC2)NC1=O | |
| | BKIJPFZWNISEGV-QEKYSDTLSA-N | |

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

(a): The metabolite name in bold is the name used in the conclusion.

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

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