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Modification of the existing maximum residue levels for spirotetramat in leeks, spring onions and honey

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer S.A.S. - Crop Science division submitted a request to the competent national authority in Austria to modify the existing maximum residue levels (MRLs) for the active substance spirotetramat in leeks, spring onions and in honey. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all these crops and honey. Adequate analytical methods for enforcement are available to control the residues of spirotetramat and its metabolites in plant matrices on the commodities under consideration and in honey at the validated limit of quantification (LOQ) of 0.01 mg/kg for each analyte. 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.

Keywords: spirotetramat, leeks, spring onions, honey, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer S.A.S. - Crop Science division submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance spirotetramat in leeks, spring onions and in honey. 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 7 December 2020. To accommodate for the intended NEU/SEU uses of spirotetramat, the EMS proposed to raise the existing MRLs for spring onions and leeks to 1 mg/kg and for honey to raise the existing MRL from the limit of quantification (LOQ) of 0.05 to 0.6 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 13 January 2021, the EMS submitted the requested information in 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 188/2011, the data evaluated under previous MRL assessments, including the review of the existing spirotetramat MRLs under Article 12 of Regulation EC (No) 396/2005 (MRL review) 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 applications was investigated in crops belonging to the groups of fruit crops, root crops, leafy crops and pulses/oilseeds leading to a similar metabolic pattern where the major part of the residues was composed of spirotetramat and its -enol, -ketohydroxy, -monohydroxy and -enol-glucoside metabolites.

Studies investigating the effect of processing on the nature of spirotetramat and its -enol, -ketohydroxy, -monohydroxy and -enol-glucoside metabolites (hydrolysis studies) demonstrated that spirotetramat-enol and spirotetramat-monohydroxy are stable under the standard hydrolysis conditions; parent spirotetramat and two additional metabolites (-ketohydroxy and -enol-glucoside) were found to degrade to a certain extent depending on the test conditions.

In rotational crops, the major residues identified were the parent compound and the same metabolites observed in primary crops.

It is also expected that residues in floral nectar resulting from the use of spirotetramat in primary crops and from the soil uptake in rotational crops consists mainly of spirotetramat and its four metabolites observed in primary and rotational crops. The nectar is processed by bees following a process of regurgitation and then the honey is stored under specific conditions in the beehives, before harvesting. Since there is limited information available whether the enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues, it would be desirable to further investigate these aspects.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of spirotetramat metabolites and the stability of spirotetramat during storage, the residue definition for enforcement proposed during the EU pesticides peer review and confirmed by the MRL 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 residue definitions are applicable to primary crops, rotational crops and processed products as well as honey. The current enforcement residue definition in Regulation (EC) No 396/2005 has not been yet modified according to the proposals of the EU pesticides peer review and the MRL review and includes more spirotetramat metabolites, i.e. 'sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat'.

EFSA concluded that for the crops assessed in this application, metabolism of spirotetramat in primary and in rotational crops, and the possible degradation in processed products have been sufficiently addressed and that the previously derived residue definitions could be considered valid also for honey.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectroscopy (HPLC-MS/MS) are available to quantify residues in the plant crops assessed in this application as well as in honey according to both the current and the proposed enforcement residue definitions and the risk assessment residue definition. These methods enable quantification of each individual analyte at 0.01 mg/kg and of the total residues at or above 0.05 mg/kg (for the current enforcement and risk assessment residue definitions) and at or above 0.02 mg/kg (for the proposed enforcement residue definition).

The available residue trials are sufficient to derive MRL proposals of 1.0 mg/kg for leeks and spring onions according to the current enforcement residue definition and of 0.9 mg/kg according to the residue definition proposed by the EU pesticides peer review and MRL review. Although none of the crops under consideration is considered a melliferous crop, the applicant investigated the potential carry-over of residues from treated primary crops into honey (in this case simulating the transfer of residues from treated orchards (critical existing EU use) to melliferous plants grown under treated orchards available for bees). For investigating the magnitude of the residues of spirotetramat in honey, a sufficient number of semi-field (tunnel) trials were provided. In these trials, beehives were placed in tunnel where *Phacelia tanacetifolia* was treated with spirotetramat during flowering. The study design of the trials was considered appropriate to use the results of the trials for deriving an MRL proposal of 0.6 mg/kg in honey according to the current enforcement residue definition and of 0.5 mg/kg according to the residue definition proposed by the EU pesticides peer review and MRL review. In addition, EFSA assessed the monitoring data from official EU National control programmes conducted by several Member States during 2015–2017, to check the plausibility of the residues found in the supervised residue trials. All of the 75 samples analysed resulted in spirotetramat residue levels below the combined LOQ of 0.05 mg/kg for the existing enforcement residue definition.

Specific studies investigating the magnitude of spirotetramat residues in processed commodities were assessed during the MRL and the EU pesticide peer reviews. No new data were submitted in the framework of this application. Nevertheless, further processing studies for the commodities under assessment are not required as they are not expected to affect the outcome of the risk assessment.

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

Residues of spirotetramat in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally 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 metabolites included in the residue definition are of similar toxicity as the parent active substance.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The short-term exposure assessment was performed only for the commodities assessed in this application. The calculations were based on the highest residues (HR) derived from supervised field trials and the short-term exposure did not exceed the ARfD for any of the crops assessed.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable Codex maximum residue limits (CXLs). EFSA updated the calculation with the relevant supervised trials median residue values (STMR) derived from the residue trials submitted in support of this MRL application. The crops on which no uses were reported in the MRL review were excluded from the exposure calculation. The estimated long-term dietary intake accounted for 25% of the ADI (Dutch toddler).

EFSA concluded that the proposed use of spirotetramat on leeks, spring onions and honey will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health. EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of spirotetramat and further investigation on this matter would in principle be required. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised and intended uses. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

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

Full details of all end points 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)	
Enforcement residue definition (existing): Spirotetramat and its four metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy and BYI08330 enol-glucoside, expressed as spirotetramat (Spi+4)					
Enforcement residue definition (proposed by the EU pesticides peer review and the MRL review): Sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat (Spi+enol)					
0270060	Leeks	0.1*/0.02*[(b)]	1.0	0.9	The submitted data are sufficient to derive an MRL proposal for the NEU/ SEU use. Risk for consumers unlikely.
0220040	Spring onions/green onions and Welsh onions	0.1*/0.02*[(b)]	1.0	0.9	The submitted data are sufficient to derive an MRL proposal for the NEU/ SEU use. Risk for consumers unlikely.
1040000	Honey and other apicultural products**	0.05*	0.6	0.5	The submitted data are sufficient to derive an MRL proposal in honey, reflecting the magnitude of spirotetramat residues in honey from the authorised critical EU uses of spirotetramat on fruit orchards. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
**: Plant residue definition is considered valid also for honey and other apicultural products.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to SANTE/10032/2020.

It must be noted that the investigation of possible risk to honeybees related to the use of spirotetramat is outside the scope of this reasoned opinion. The evaluation of the risk to honeybees was evaluated in the framework of the peer review of spirotetramat at EU level. Additionally, national competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products.

Table of contents

Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for spirotetramat in leeks, spring onions and honey. The detailed description of the intended uses of spirotetramat which are 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 name). 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/EEC[1] to be read in conjunction with Commission Regulation (EU) No 188/2011[2] 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 (EFSA, 2013a). Spirotetramat was approved[3] for the use as an insecticide on 1 May 2014.

The EU MRLs for spirotetramat are established in Annex III of Regulation (EC) No 396/2005[4]. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been completed (EFSA, 2020) and the proposed modifications have been implemented in the draft Regulation SANTE/10032/2020, not entered into force yet. Nevertheless, the conclusions taken therein are considered for the current assessment. The proposals from previous reasoned opinions have been considered in MRL regulations.[5]

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer S.A.S. - Crop Science division submitted an application to the competent national authority in Austria (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance spirotetramat in leeks, spring onions and honey. 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 EFSA on 7 December 2020. To accommodate for the intended uses of spirotetramat, the EMS proposed to raise the existing MRLs for spring onions and leeks from the limit of quantification (LOQ) of 0.1 mg/kg (or 0.02 mg/kg according to SANTE/10032/2020) to 1 mg/kg, and for honey to raise the existing MRL from the LOQ of 0.05 to 0.6 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 13 January 2021, the EMS submitted the requested information in a revised evaluation report (Austria, 2020), which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Austria, 2020), 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, 2014b, 2016, 2017a, 2019a,c), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2020).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017, 2018; OECD, 2011). The assessment is

[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: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=search.as

[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.

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[7].

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 is presented in Appendix B.

The evaluation report submitted by the EMS (Austria, 2020) 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/honey

1.1. Nature of residues and methods of analysis in plants/honey

1.1.1. Nature of residues in primary crops

The metabolism of spirotetramat in primary crops belonging to the group of fruit crops (apples), root crops (potatoes), leafy crops (lettuce) and pulses/oilseeds (cotton) has been investigated in the framework of the EU pesticides peer review (EFSA, 2013a) and the MRL review (EFSA, 2020).

A similar metabolic pattern was observed in all crops tested following foliar applications. 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 stereochemistry of the metabolites spirotetramat-ketohydroxy and spirotetramat-monohydroxy were not investigated and a data gap was identified by EFSA peer review (EFSA, 2013a) and confirmed by the MRL review (EFSA, 2020) and further investigation on this matter would in principle be required.

For leeks and onions, which belong to the crop group of root crops, the metabolic behaviour is sufficiently addressed.

Regarding honey, honey is a product originated from sugary secretions of plants (floral nectar mainly). Based on the similar results of metabolism studies in four different primary crop groups, EFSA expects that residues in floral nectar resulting from the use of spirotetramat in primary crops would also consist mainly of spirotetramat and its four metabolites. The nectar is processed by bees following a process of regurgitation and then the honey is stored under specific conditions in the beehives before harvesting. Further information, whether enzymatic processes occurring in the bee gut involved in the production of honey or the storage in the beehive have an impact on the nature of residues is not available, but in principle would be desirable.

1.1.2. Nature of residues in rotational crops

Leeks and spring onions can be grown in a crop rotation. According to the soil degradation studies evaluated in the framework of the peer review (EFSA, 2013a), the DT90 value of spirotetramat accounts for 3.5 days. However, the DT90 for the sum of two major metabolites (spirotetramat-enol and spirotetramat-ketohydroxy) was calculated to be 105 days (EFSA, 2013a). Thus, the trigger value of 100 days is slightly exceeded, and therefore, the occurrence of spirotetramat residues in rotational crops was further investigated.

On the basis of the rotational crop metabolism studies assessed in the framework of the EU pesticides peer review (EFSA, 2013a) and in the MRL review (EFSA, 2020), it was concluded that the metabolism and distribution of spirotetramat in rotational crops are similar to the metabolic pathway observed in primary crops. Considering this information, EFSA concluded that it is likely that in pollen and nectar collected from rotational crops, the nature of spirotetramat residues will be the same as in primary and rotational crops. For the proposed uses assessed in this application, no further information is required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of spirotetramat residues was investigated in the framework of the EU pesticides peer review (EFSA, 2013a) and the MRL review (EFSA, 2020). Studies investigating the nature of residues in processed commodities were conducted with spirotetramat,

[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.

spirotetramat-enol, spirotetramat-enol-glucoside, spirotetramat-monohydroxy and spirotetramat-ketohydroxy radiolabelled on the azaspirodecenyl-ring simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6).

Spirotetramat and spirotetramat-enol-glucoside were stable under pasteurisation conditions and progressively degraded to spirotetramat-enol during conditions representative for cooking/boiling/baking and sterilisation. Spirotetramat-ketohydroxy was stable under pasteurisation and progressively converted to the metabolite spirotetramat-MA-amide under cooking/boiling/baking and sterilisation conditions. Spirotetramat-enol and spirotetramat-monohydroxy were seen to remain stable under all three hydrolysis conditions (EFSA, 2013a, 2020).

The magnitude of spirotetramat-MA-amide was further investigated in the EU pesticides peer review in processed beans after sterilisation, where metabolite spirotetramat-MA-amide was present in low levels (< 0.01–0.02 mg/kg) and its precursor was not found in the vast majority of the samples from the supervised residue trials (Austria, 2013). Thus, the EU pesticides peer review concluded not to include this metabolite in the residue definition for processed products. The same residue definition as for raw commodities (RAC) applies to processed commodities (EFSA, 2013a).

The process of converting nectar to honey does not involve hydrolytic conditions at elevated temperature; however, honey may be used as an ingredient in processed products that are heat treated. Considering the available studies addressing the nature of residues in processed commodities, it is unlikely that in processed honey products, residues of spirotetramat are degraded to other compounds than the ones already identified.

1.1.4. Methods of analysis in plants/honey

Analytical methods for the determination of spirotetramat residues and residues of spirotetramat-enol, spirotetramat-enol-glucoside, spirotetramat-monohydroxy and spirotetramat-ketohydroxy in plant commodities were assessed during the EU pesticides peer review (EFSA, 2013a) and the MRL review (EFSA, 2020). The methods are sufficiently validated and allow quantifying residues at or above the LOQ of 0.01 mg/kg for each analyte and of the total residues at or above 0.05 mg/kg (for the current enforcement and risk assessment residue definitions) and at or above 0.02 mg/kg (for the proposed enforcement residue definition) in high water, high acid, high fat, high starch and high protein and dry matrices. According to the EU Reference Laboratories for Pesticides Residues (EURL), similar validated analytical methods are available to enforce spirotetramat and spirotetramat-enol at combined LOQ of 0.02 mg/kg by using the QuEChERS method (EURL, 2018). EFSA concludes that for the plant crops under assessment, which are considered matrices with high water content, analytical methods are available to quantify residues for both the existing and the proposed enforcement residue definitions.

Additionally, a new analytical method is provided with the current application for the determination of spirotetramat residues in honey (Austria, 2020). This new analytical method is based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS). Apparent residues in control samples were below 30% of LOQ. Two mass transitions were monitored for each analyte in honey samples. Therefore, the HPLC-MS/MS method is highly specific, and an additional confirmatory method is not necessary. Mean recoveries for each fortification level were within the acceptable range of 70–110% for all analytes and mass transitions and relative standard deviations were always below 20%. For the purpose of the present assessment, the analytical method for the determination of spirotetramat residues in honey can be considered to be fully validated as enforcement method in terms of specificity, linearity, accuracy and precision based on the provisions of the SANCO/825/00 rev 8.1 guidance document (European Commission, 2010b). This method has been validated by an independent laboratory validation for the determination of spirotetramat residues (spirotetramat, -enol, -enol-glucoside, -ketohydroxy and -monohydroxy) with an LOQ of 0.01 mg/kg for each analyte and it is suitable for both enforcement and risk assessment of spirotetramat residues in honey.

1.1.5. Storage stability of residues in plants/honey

The storage stability of spirotetramat and its metabolites (spirotetramat-enol, -enol-glucoside, -ketohydroxy and -monohydroxy) in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2013a) and the MRL review (EFSA, 2020). The storage stability of total spirotetramat and spirotetramat-enol residues was demonstrated for a period of 18 months at −18°C in commodities with high water, high oil and dry/high starch content (EFSA, 2013a, 2020). Spirotetramat-enol-glucoside, spirotetramat-ketohydroxy and spirotetramat-monohydroxy were

also stable for at least 18 months at −18°C in the same matrices (EFSA, 2013a). In high acid and high protein content commodities, the storage stability of spirotetramat and its main four metabolites residues was shown to be 24 months (EFSA, 2020). The longest storage duration for leeks amounted to approximately 11 months. Therefore, the integrity of the plant samples can be granted, and thus, all residue trials data are valid regarding storage stability.

Additionally, a short-term (6 months) storage stability study on honey was provided with this application (Austria, 2020). The stability of spirotetramat and its metabolites (-enol, -enol-glucoside, -ketohydroxy and -monohydroxy) for about 6 months at −18°C was investigated in honey. No significant decrease of residues was observed after the tested period of 6 months in honey. Thus, the residues of spirotetramat and its metabolites (spirotetramat-enol, -enol-glucoside, -ketohydroxy and -monohydroxy) are considered stable under freezer storage conditions at −18°C or below in honey samples for at least 6 months. The longest storage duration for honey amounted to approximately 3 months. Therefore, the integrity of the honey samples can be granted, and thus, all honey residue data are valid regarding storage stability.

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 and confirmed in the MRL review (EFSA, 2013a, 2020):

- 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

The same residue definitions are applicable to rotational crops and processed products.

It is noted that the residue definition for enforcement currently set under Regulation (EC) No 396/2005 has not been modified yet according to the proposal of the EU pesticides peer review and MRL review (EFSA, 2013a, 2020) and is identical to the residue definition for risk assessment, covering all four spirotetramat metabolites. In the draft Regulation SANTE/10032/2020, however, the enforcement residue definition as proposed by the MRL review has been included. Pending the draft Regulation to enter into force, EFSA derived two different MRL proposals for the crops/commodities under assessment.

EMS proposed that the above plant residue definitions are also valid for honey and other apicultural products, since no new degradation products of spirotetramat-related residues were formed during pasteurisation conditions and no new metabolites were found in rotational crops as described in the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey (European Commission, 2018).

EFSA notes that similarly to other food products, residue definitions need to be derived for honey which should cover the toxicologically relevant compounds present in honey following the use of spirotetramat in crops foraged by bees. Honey is produced by bees following sugary secretions of plants (mainly nectar) through regurgitation, enzymatic conversion and water evaporation followed by storage of honey in beehives. As indicated in the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey (European Commission, 2018), in the absence of specific metabolism studies with honey bees, the residue definition for risk assessment needs to be derived taking into account other sources of information such as studies on the nature of residues in primary and rotational crops and degradation during pasteurisation. As reported in the sections above, metabolism and distribution of spirotetramat in primary and rotational crops are similar (EFSA, 2013a) and spirotetramat and its metabolites (-enol, -enol-glucoside, -ketohydroxy and -monohydroxy) are stable under pasteurisation condition. Therefore, EFSA agrees with the EMS that the above plant residue definitions could be considered valid also for honey and other apicultural products.

1.2. Magnitude of residues in plants/honey

1.2.1. Magnitude of residues in primary crops/honey

In support of the MRL application, the applicant submitted residue trials performed in leeks. In order to determine spirotetramat residues in honey, tunnel residue trials with *Phacelia tanacetifolia* as a surrogate plant were submitted. The samples were analysed for the parent compound and the metabolites included in the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose (Austria, 2020).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Leeks and spring onions

NEU/SEU outdoor cGAP: 2 × 125 g a.s./ha, interval = 14 days, BBCH 41–48, PHI 7 days

The applicant provided eight residue trials in NEU and four residue trials in SEU to determine the residues of spirotetramat in leeks after application of spirotetramat according to the intended GAPs as reported in Appendix A. Half of these residue trials were conducted as decline studies, indicating that residues decline between 7 and 14 days of treatment. All residue trials are considered independent as they were performed in different geographical locations. The number of trials is also sufficient for leeks which is a major crop only in NEU.

The applicant proposed to derive an MRL from the merged NEU and SEU data sets and to extrapolate the derived MRL for leeks to spring/green onions and Welsh onions.

EFSA agreed with the proposal to merge the NEU and SEU data sets since (i) these two data sets are based on the same GAP, (ii) the data sets belong to the same statistical population (U-test) and (iii) the MRL proposal derived from the individual data sets fall into the same MRL class. Moreover, in line with the applicable EU guidance document on crop extrapolation (European Commission, 2017), the extrapolation from leeks to spring/green onions and Welsh onions is acceptable.

Therefore, in leeks and spring/green onions and Welsh onions, an MRL of 1.0 mg/kg is derived for spirotetramat based on the existing enforcement residue definition of spirotetramat and its four metabolites (expressed as spirotetramat), while an MRL of 0.9 mg/kg is derived for spirotetramat based on the proposed enforcement residue definition as sum of spirotetramat and spirotetramat-enol (expressed as spirotetramat).

Honey

Surrogate crop: Phacelia tanacetifolia, 2 × 175 g a.s./ha, interval = 14 days, BBCH 50–65

The applicant provided four residue trials (two conducted in NEU and two in SEU) compliant with the use pattern that was estimated by the applicant to be the most critical with regard to spirotetramat residues in honey. The active substance was applied to *Phacelia tanacetifolia* as a surrogate crop under semi-field conditions (tunnel trials). The nature of the residues determined in honey is based on the major constituents of the residues detected in primary crops, rotational crops and processed crops.

The applicant justified the choice of the surrogate crop and the tested GAP with the following argumentations:

Firstly, *Phacelia tanacetifolia* is a crop that ensures continuous foraging of worker bees and hence production of comb honey and its treatment is quite easy and ensures uniform wetting of the crop and flowers visited by the bees.

Secondly, the choice of the tested use pattern was based on the most critical GAP authorised in EU on a melliferous crop, calculating the fraction reaching the flowering weeds from soil uptake. The applicant substantiated further this approach indicating that for the most critical GAPs authorised in EU on melliferous crops (i.e. Citrus in SEU at 2 × 270 g a.s./ha and Apples in NEU at 2 × 255 g a.s./ha (EFSA, 2020)), the applications take place after flowering and therefore only non-targeted melliferous plants below the treated trees need to be considered. Hence, in order to determine the fraction of the active substance reaching the soil and therefore the flowering weeds after application of spirotetramat on fruit orchards, the applicant applied a formula using interception and wash-off input values as outlined in the EFSA guidance documents for predicting environmental concentrations of active

substances of plant protection products and transformation products of these active substances in soil (EFSA, 2014a, 2017b). This resulted in an application rate of 2 × 175 g a.s./ha on untreated flowering weeds.

The transfer of residues in honey following this application of spirotetramat on a melliferous crop was then further investigated in trials with a surrogate crop, *Phacelia tanacetifolia*. EFSA evaluated the proposed approach and the four residue trials provided for setting MRL in honey making the following considerations.

Firstly, regarding the choice of *Phacelia tanacetifolia* as surrogate crop, EFSA notes that the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residues Levels in honey (European Commission, 2018) indicates that '*it is possible to consider a "worst case" situation, that is, to obtain these data by applying the most critical scenario on a crop representing a worst case in terms of residues in honey (for example, rapeseed (Brassica napus), phacelia, or any other crop with high melliferous capacity) even if this is not a proposed use.*' EFSA therefore agrees with applicant and EMS that *Phacelia tanacetifolia* is a valid surrogate crop for determining the magnitude of pesticides residues and setting MRL in honey.

Secondly, regarding the choice of the tested use pattern, EFSA requested the applicant and EMS to elaborate further on the approach proposed also considering that the wording of the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting MRLs in honey is not very clear in this respect. EFSA agrees with the approach proposed by the applicant and supported by the EMS since the most critical GAPs for melliferous crops have been identified correctly based on the recent MRL review (EFSA, 2020). Moreover, since for these most critical GAPs in citrus and apples, the applications take place after flowering of the treated crops, EFSA agrees to consider the non-targeted melliferous plants below the treated trees to identify the worst-case scenario in terms of application rate by calculating the fraction reaching the soil by means of interception and wash-off.

EFSA further assessed the four provided semi-field/tunnel trials in line with the requirements of the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting MRLs in honey (European Commission, 2018). As described above, the test substance is applied in a realistic worst-case scenario with respect to residue in honey. All tunnel trials were conducted with two foliar applications performed either immediately before or during flowering (BBCH 50–65) of *Phacelia tanacetifolia*, at an application rate of 175 g a.s./ha, with an interval of 12–15 days between the treatments.

The four submitted trials were also performed with a correct design for these semi-field/tunnel trials. On each trial site one tunnel confining the bees was established for both the control and the treated plot. Tunnels were of the required size and access to water was provided. The minimum number of four trials is also met with trials conducted in the same growing season but in different geographical locations.

Honeybee colonies were brought to the test sites on the evening before the first application and remained in the tunnels until the end of sampling. Collection of honey samples was rightly performed when honey reached maturity at the end of flowering (i.e. water content below 20% or after combs closure, whichever occurred first) which occurred 10–13 days after the last application. The honey Technical Guidelines recommend sampling of at least 100 g honey for each sample. EFSA noted that samples collected ranged from 10 to 120 g in the different trials but considered this only as a minor deviation not affecting the validity of the trials. The colony assessment was performed before set-up of the beehives and after sampling of the honey.

Finally, the samples were then analysed for residues of parent spirotetramat and its four metabolites considered in the enforcement and risk assessment residue definitions, with a validated analytical method to generate data in honey (method 01597) which is suitable for both enforcement and risk assessment with an LOQ of 0.01 mg/kg for each analyte (Austria, 2020). The maximum storage period of honey samples prior to analysis was 121 days, which is well below the demonstrated storage stability period of 6 months. The control samples of honey did not contain residues of spirotetramat.

Therefore, in honey, an MRL of 0.6 mg/kg is derived for spirotetramat based on the existing enforcement residue definition as sum of spirotetramat and its four metabolites (expressed as spirotetramat), while an MRL of 0.5 mg/kg is derived for spirotetramat based on the proposed enforcement residue definition as sum of spirotetramat and spirotetramat-enol (expressed as spirotetramat).

EFSA notes that, as indicated in the Technical Guidelines for determining the magnitude of pesticide residues in honey and setting MRLs in honey (European Commission, 2018), consumption of pollen

(including pollen present in honey), royal jelly, propolis, bee wax and honeycomb is negligible. Therefore, there is no need to generate experimental residue data for these commodities.

Magnitude of residues from EU national monitoring program

In the framework of Article 32 of Regulation (EC) No 396/2005 (official national control programmes), monitoring data were submitted to EFSA. A total of 75 samples of honey were analysed for spirotetramat residues in the reference period from 2015 to 2017. All of the samples analysed resulted in spirotetramat residue levels below the combined LOQ of 0.05 mg/kg for the existing enforcement residue definition. The data demonstrated that the MRL proposal for honey derived from the valid semi-field/tunnel residue trials presented in this application is higher than the residue found in market samples of honey.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of spirotetramat residues to crops that are grown in crop rotation has been assessed in the framework of the EU pesticides peer review (EFSA, 2013a) and the MRL review (EFSA, 2020). To conclude on the possible residue uptake in rotational crops following treatment according to the most critical GAP, the MRL review considered the quantitative information available in a confined rotational crops study performed with bare soil application at 406 g a.s./ha. This application rate corresponds to around 2.3N the amount of spirotetramat reaching the soil when considering the most critical GAP currently authorised on peppers, aubergines and tomatoes. On the basis of this confined rotational crop study and considering that the study was overdosed (2.3N) compared to the most critical GAP, it was concluded that relevant residue levels of spirotetramat and its major metabolites are unlikely to occur in rotational crops provided that spirotetramat is applied in compliance with authorised uses (EFSA, 2020).

Since the intended uses for the crops under consideration are less critical compared to the authorised uses assessed in the MRL review (EFSA, 2020), the same conclusion is valid for the current assessment and no residues are expected in succeeding crops, provided that the active substance is applied according to the proposed GAPs.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation on the magnitude of spirotetramat residues was recently assessed in the MRL review (EFSA, 2020) and the overview of the derived processing factors is provided in the EFSA reasoned opinion on the MRL review (EFSA, 2020).

No new data were submitted in the framework of this application. Nevertheless, further processing studies are not required as they are not expected to affect the outcome of the risk assessment considering the low individual contribution of residues in commodities under assessment to the total consumer exposure.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation. In Section 3, EFSA assessed whether residues on these crops and in honey resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as the intended commodities are not used for feed purposes.

3. Consumer risk assessment

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

The toxicological reference values for spirotetramat used in the risk assessment (i.e. ADI of 0.05 mg/kg bw per day and ARfD of 1 mg/kg bw) were derived in the framework of the EU pesticides peer review (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).

Short-term (acute) dietary risk assessment

The short-term exposure assessment was performed only for the commodities assessed in this application. The calculations were based on the HR values derived from supervised field trials and the complete list of input values can be found in Appendix D.1.

The short-term exposure did not exceed the ARfD for any of the crops/commodities assessed in this application and accounted for 4.4% of ARfD for leeks, 1.2% of ARfD for spring onions and for 0.1% of ARfD for honey (see Appendix C).

Long-term (chronic) dietary risk assessment

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable CXLs (EFSA, 2020). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for leeks, spring onions and honey. The crops on which no uses were reported in the MRL review were excluded from the exposure calculation. The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake accounted for 25% of the ADI (Dutch toddler). The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure is presented in more detail in Appendix C.

EFSA concluded that the long-term intake of residues of spirotetramat resulting from the existing, the intended uses and honey is unlikely to present a risk to consumer health. EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of spirotetramat and further investigation on this matter would in principle be required. EFSA notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised and intended uses. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

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 found to be sufficient to derive an MRL proposal for leeks, spring onions and honey.

EFSA concluded that the proposed use of spirotetramat on the assessed crops and honey will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers' health.

EFSA emphasises that the above assessment does not consider the possible impact of plant and livestock metabolism on the isomer ratio of spirotetramat and further investigation on this matter would in principle be required. EFSA further notes that in view of the large margin of safety in the exposure calculations, the potential change of isomer ratios in the final residues is not expected to be of concern for the authorised uses. In case future uses of active substance would lead to a higher consumer exposure, further information regarding the impact of plant and/or livestock metabolism on the isomer ratio might be required.

It must be also noted that the investigation of possible risk to bees related to the use of spirotetramat is outside the scope of this reasoned opinion. The evaluation of the risk to honeybees was evaluated in the framework of the peer review of the approval of spirotetramat at EU level. Additionally, national competent authorities at Member State level should pay attention to the bee health and bee protection when granting authorisations for plant protection products.

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
CAS	Chemical Abstract Service
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council
CIRCA	(EU) Communication & Information Resource Centre Administrator
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
CS	capsule suspension
CV	coefficient of variation (relative standard deviation)
CXL	Codex maximum residue limit
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
DP	dustable powder
DS	powder for dry seed treatment
DT_{90}	period required for 90% dissipation (define method of estimation)
EMS	evaluating Member State
eq	residue expressed as a.s. equivalent
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
GR	Granule
GS	growth stage
HPLC	High-performance liquid chromatography
HPLC-MS	High-performance liquid chromatography with mass spectrometry
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
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS	mass spectrometry detector
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)
RA	risk assessment
RAC	raw agricultural commodity
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

Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs[8]

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)]	Conc. a.s.	Method kind	Range of growth stages and season[(c)]	Number max	Interval between application (days) min	g a.s./hL min–max	Water L/ha min–max	Rate	Unit		
Leeks	NEU	F	Sucking pests (Thrips tabaci THRITB)	OD	150 g/L	Foliar treatment – broadcast spraying	BBCH 41–48	2	14	15.6–62.5	200–800	125	g a.s./ha	7	
Leeks	SEU	F	Sucking pests (Thrips tabaci THRITB)	SC	100 g/L	Foliar treatment – broadcast spraying	BBCH 41–48	2	14	15.6–62.5	200–800	125	g a.s./ha	7	
Spring onions/ green onions and Welsh onions	NEU	F	Sucking pests (Thrips tabaci THRITB)	OD	150 g/L	Foliar treatment – broadcast spraying	BBCH 41–48	2	14	15.6–62.5	200–800	125	g a.s./ha	7	
Spring onions/ green onions and Welsh onions	SEU	F	Sucking pests (Thrips tabaci THRITB)	SC	100 g/L	Foliar treatment – broadcast spraying	BBCH 41–48	2	14	15.6–62.5	200–800	125	g a.s./ha	7	

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; OD: oil dispersion; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.

[8] In the framework of the review of existing MRLs according to Art. 12 of EU Regulation 396/2005 (EFSA, 2020), numerous GAPs were reported for crops that might be attractive to bees for food foraging and that might contribute to the final residues of spirotetramat in honey. However, since the MRL application in honey is not linked to one specific GAP and applies to honey as food item for consumers, the use pattern in phacelia as surrogate crop is not included in this Appendix but described in Section 1.2 of the reasoned opinion.

Appendix B – List of end points

B.1. Residues in plants

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

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

Primary crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**Sampling (DAT)**	**Comment/Source**
	Fruit crops	Apple	Foliar: 2 × 576 g/ha, BBCH 69, 71	63 DALA	[Azaspirodecenyl-3-^{14}C]-spirotetramat (EFSA, 2013a)
	Root crops	Potato	Foliar: 3 × 96 g/ha, BBCH 75, 85, 93	14 DALA	[Azaspirodecenyl-3-^{14}C]-spirotetramat (EFSA, 2013a)
	Leafy crops	Lettuce	Foliar: 2 × 72 g/ha, BBCH 41, 45	7 DALA	[Azaspirodecenyl-3-^{14}C]-spirotetramat (EFSA, 2013a)
	Pulses/oilseeds	Cotton	Foliar: 2 × (92 + 172) g/ha BBCH 15, 85	19 DAT, 39 DALA	[Azaspirodecenyl-3-^{14}C]-spirotetramat (EFSA, 2013a)
Rotational crops (available studies)	**Crop groups**	**Crop(s)**	**Application(s)**	**PBI (DAT)**	**Comment/Source**
	Root/tuber crops	Turnip	Bare soil, 1 × 406 g/ha	30, 135, 260	[Azaspirodecenyl-3-^{14}C]-spirotetramat (EFSA, 2013a)
	Leafy crops	Swiss chard	Bare soil, 1 × 406 g/ha	30, 135, 260	[Azaspirodecenyl-3-^{14}C]-spirotetramat (EFSA, 2013a)
	Cereal (small grain)	Spring wheat	Bare soil, 1 × 406 g/ha	30, 135, 260	[Azaspirodecenyl-3-^{14}C]-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-^{14}C]-spirotetramat; [azaspirodecenyl-3-^{14}C]-spirotetramat-enol-glucoside (EFSA, 2013a). Both compounds degraded to spirotetramat-enol under cooking/boiling/baking and sterilisation conditions.
	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-^{14}C]-spirotetramat-enol; [azaspirodecenyl-3-^{14}C]-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-^{14}C]-spirotetramat-ketohydroxy (EFSA, 2013a). Spirotetramat-ketohydroxy converted to the metabolite spirotetramat-MA-amide under cooking/boiling/baking (5% degradation) and sterilisation (99% degradation) conditions.
	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, 2020)
Rotational crop and primary crop metabolism similar?	Yes	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	Since in processed beans after sterilisation, the metabolite spirotetramat-MA-amide was present in low levels (< 0.01 to 0.02 mg/kg) and its precursor was not found in the vast majority of the samples from the supervised residue trials (Austria, 2013), the peer review concluded not to include this metabolite in the residue definition for processed products. Thus, the same residue definition as for RAC applies to processed commodities (EFSA, 2013a, 2020).
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, 2013a, 2020)	
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, 2020)	
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs)	Matrices with high water content, high oil content, high acid content, dry/proteaginous: HPLC–MS/MS, individual LOQ 0.01 mg/kg per analyte (combined LOQ 0.02 mg/kg for the proposed RD-Mo). Confirmatory method available. ILV available (EFSA, 2013a, 2020). Difficult matrices (hops): HPLC–MS/MS, individual LOQ 0.1 mg/kg per analyte (combined LOQ 0.2 mg/kg for the proposed RD-Mo). Confirmatory method available. ILV available (EFSA, 2013a, 2020). Honey: HPLC–MS/MS, individual LOQ 0.01 mg/kg per analyte (combined LOQ 0.02 mg/kg for the proposed RD-Mo). ILV available (Austria, 2020). According to the EURLs, the LOQ of 0.02 mg/kg for the proposed RD-Mo is achievable by using the QuEChERS method in routine analyses (EURL, 2018).	

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

B.1.1.2. Stability of residues in plants

Plant products (available studies)	Category	Commodity	T (°C)	Stability period		Compounds covered	Comment/ Source
				Value	Unit		
	High water content	Lettuce	−18	6	Months	Spi	EFSA (2013a)
		Beans with pods	−18	1	Months	Spi	EFSA (2016)
		Tomato	−18	18	Months	Spi	EFSA (2013a)
		Lettuce	−18	2	Months	Spi-enol	EFSA (2016)
		Beans with pods	−18	1	Months	Spi-enol	EFSA (2016)
		Tomato	−18	18	Months	Spi-enol	EFSA (2013a)
		Lettuce, beans with pods, tomato	−18	18	Months	Spi + enol	EFSA (2013a)
		Lettuce, beans with pods	−18	18	Months	Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy	EFSA (2013a)
	High oil content	Nut (meal)	−18	1	Month	Spi	EFSA (2013a)
		Nut (meal)	−18	18	Months	Spi-enol	EFSA (2013a)
		Nut (meal)	−18	18	Months	Spi + enol	EFSA (2013a)
		Nut (meal)	−18	18	Months	Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy	EFSA (2013a)
	High protein content	Beans (dry)	−18	24	Months	Spi, spi-enol	EFSA (2020)
		Beans (dry)	−18	24	Months	Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy	EFSA (2020)
	Dry/High starch	Potato	−18	2	Months	Spi	EFSA (2016)
		Potato	−18	12	Months	Spi-enol	EFSA (2013a)
		Potato	−18	18	Months	Spi + enol	EFSA (2013a)
		Potato	−18	18	Months	Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy	EFSA (2013a)
	High acid content	Kiwi fruit	−18	24	Months	Spi, spi-enol	EFSA (2020)
		Kiwi fruit	−18	24	Months	Spi-ketohydroxy, spi-enol-Glc, spi-monohydroxy	EFSA (2020)
	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-Glc,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-Glc, spi-monohydroxy	EFSA (2013a)
		Honey	−18	6	Months	Spi, –enol, –monohydroxy, –ketohydroxy, –enol–Glc	Austria (2020)

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]
Enforcement residue definition (existing) = Risk Assessment residue definition: Spirotetramat and its four metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy, and BYI08330 enol-glucoside, expressed as spirotetramat **Enforcement residue definition (proposed by the EU pesticides peer review and the MRL review)**: Sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat							
Leeks	NEU	**Existing RD Mo = RD RA:** 0.069; 0.073; 0.075; 0.087; 0.088; 0.17; 0.50; 0.56 **Proposed RD Mo** (EFSA, 2013a, 2020): 0.039; 0.043; 0.045; 0.057; 0.058; 0.13; 0.40; 0.47	Residue trials on leeks compliant with GAP. Extrapolation to spring onions possible. NEU and SEU data set similar (U-test) and merged for MRL derivation.	**1.0** **0.9**	**0.56** **0.47**	**0.088** **0.058**	**1.6**
Leeks	SEU	**Existing RD Mo = RD RA:** 0.058; 0.061; 0.11; 0.50 **Proposed RD Mo** (EFSA, 2013a, 2020): 0.028; 0.031; 0.058; 0.44					
Honey	NEU and SEU	**Existing RD Mo = RD RA:** 0.086; 0.12; 0.13; 0.32 **Proposed RD Mo** (EFSA, 2013a, 2020): 0.056; 0.090; 0.097; 0.25	Semi-field (tunnel) residue trials in *Phacelia tanacetifolia* reflecting the estimated critical application rate of spirotetramat on melliferous crop. MRL derived from all four trials performed in different geographical locations (2 in NEU and 2 in SEU).	**0.6** **0.5**	**0.32** **0.25**	**0.13** **0.09**	**1.4**

MRL: maximum residue level; GAP: Good Agricultural Practice; RD: residue definition; 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): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.
(c): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.
(d): Conversion factor to recalculate residues according to the proposed residue definition for monitoring to the residue definition for risk assessment.

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	In a confined rotational crop study (at 2.3N the most critical GAP currently authorised in EU (EFSA, 2020)), only spirotetramat-enol was quantified in wheat straw and hay (0.05 mg eq/kg) and only at PBI 30 days (EFSA, 2013). Thus, residue levels of spirotetramat and its major metabolites are unlikely to occur in rotational crops, provided that spirotetramat is applied in compliance with the GAPs currently authorized in EU (EFSA, 2020).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Inconclusive	In a field rotational crop study (total rate of 172–180 g a.s./ha applied to the target plant, corresponding to 0.3N the most critical GAP currently authorized in EU), residues of spirotetramat and its metabolites were all < LOQ in mustard green, turnip and wheat, sown as rotational crops 30 days after the last application of spirotetramat to a primary crop (EFSA, 2013a). However, these studies provide only limited information considering that they were underdosed compared to the most critical GAPs currently authorized. Nevertheless, no additional studies are required since based on the confined rotational crop study it could be concluded that no significant residues are expected in rotational crops (see above, EFSA, 2020).

GAP: Good Agricultural Practice; PBI: plant-back interval; a.s.: active substance; LOQ: limit of quantification.

B.1.2.3. Processing factors

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

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	Leeks: 4.4% of ARfD Spring onions: 1.2% of ARfD Honey: 0.1% of ARfD
Assumptions made for the calculations	The short-term exposure assessment was calculated only for leek, spring onions and honey, by updating the risk assessment values derived in the recent MRL review (EFSA, 2020) with the highest residue levels derived from the residue trials for the commodities assessed under this application according to the proposed enforcement residue definition and applying the derived conversion factors. Calculations performed with PRIMo revision 3.1.

ADI	0.05 mg/kg bw per day (European Commission, 2013)
Highest IEDI, according to EFSA PRIMo	25% of ADI (NL toddler diet) Contribution of crops assessed: Leeks: 0.05% of ADI (GEMS/Food G11) Spring onions: 0.01% of ADI (IE adult) Honey: 0.03% of ADI (DE child)
Assumptions made for the calculations	The long-term exposure assessment was calculated by updating the risk assessment values derived in the recent MRL review (EFSA, 2020) with the median residue levels derived from the residue trials for the commodities assessed under this application according to the proposed enforcement residue definition and applying the derived conversion factors. The crops for which no uses were reported in the MRL review were excluded from the exposure calculation. Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; ADI: acceptable daily intake; IEDI: international estimated daily intake.

B.4. Recommended MRLs

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 four metabolites BYI08330-enol, BYI08330-ketohydroxy, BYI08330-monohydroxy and BYI08330 enol-glucoside, expressed as spirotetramat (Spi + 4)					
Enforcement residue definition (proposed by the EU pesticides peer review and the MRL review): Sum of spirotetramat and spirotetramat-enol, expressed as spirotetramat (Spi+enol)					
0270060	Leeks	0.1*/0.02*[(b)]	1.0	0.9	The submitted data are sufficient to derive an MRL proposal for the NEU/ SEU use. Risk for consumers unlikely.
0220040	Spring onions/green onions and Welsh onions	0.1*/0.02*[(b)]	1.0	0.9	The submitted data are sufficient to derive an MRL proposal for the NEU/ SEU use. Risk for consumers unlikely.

Code[(a)]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)		Comment/justification
		(Spi + 4)	(Spi + 4)	(Spi + enol)	
1040000	Honey and other apicultural products**	0.05*	0.6	0.5	The submitted data are sufficient to derive an MRL proposal in honey, reflecting the magnitude of spirotetramat residues in honey from the authorised critical EU uses of spirotetramat on fruit orchards. Risk for consumers unlikely.

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
**: Plant residue definition is considered valid also for honey and other apicultural products.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): According to SANTE/10032/2020.

Appendix C – Pesticide Residue Intake Model (PRIMo)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2021/01/06

Spirotetramat

LOQs (mg/kg) range from: 0.005 to: 0.01

Toxicological reference values

ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	1
Source of ADI:	EC	Source of ARfD:	EC
Year of evaluation:	2013	Year of evaluation:	2013

Input values

Details – chronic risk assessment | Supplementary results – chronic risk assessment

Details – acute risk assessment/children | Details – acute risk assessment/adults

Comments:

Normal mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	25%	NL toddler	12.67	5%	Spinaches	3%	Apples	2%	Beans (with pods)		0.0%
	17%	DE child	8.73	4%	Apples	2%	Oranges	1%	Spinaches		0.0%
	14%	GEMS/Food G10	7.07	3%	Soyabeans	2%	Lettuces	1%	Tomatoes		0.0%
	14%	GEMS/Food G06	6.97	4%	Tomatoes	0.9%	Soyabeans	0.9%	Table grapes		0.0%
	13%	NL child	6.69	2%	Spinaches	2%	Apples	0.9%	Table grapes		0.0%
	13%	GEMS/Food G11	6.59	3%	Soyabeans	0.9%	Tomatoes	0.9%	Wine grapes		0.1%
	12%	GEMS/Food G07	6.22	2%	Lettuces	1%	Soyabeans	1%	Wine grapes		0.0%
	12%	GEMS/Food G08	6.20	2%	Soyabeans	1%	Lettuces	1%	Tomatoes		0.0%
	12%	SE general	5.83	3%	Lettuces	1%	Chinese cabbages/pe-tsai	0.9%	Potatoes		0.0%
	12%	IE adult	5.82	1%	Wine grapes	1.0%	Peaches	0.9%	Spinaches		0.0%
	11%	GEMS/Food G15	5.52	1%	Soyabeans	1%	Tomatoes	0.9%	Wine grapes		0.0%
	10%	ES child	5.19	3%	Lettuces	1%	Tomatoes	0.9%	Oranges		0.0%
	10%	ES adult	5.05	4%	Lettuces	0.8%	Tomatoes	0.7%	Peaches		0.0%
	10%	PT general	5.03	2%	Wine grapes	1%	Kales	1%	Potatoes		
	9%	IT adult	4.59	3%	Lettuces	1%	Tomatoes	1%	Peaches		0.0%
	9%	RO general	4.55	2%	Tomatoes	1%	Wine grapes	1%	Head cabbages		0.0%
	9%	FR child 3 15 yr	4.39	1%	Oranges	1%	Beans (with pods)	0.9%	Tomatoes		0.0%
	8%	IT toddler	4.22	2%	Lettuces	1%	Tomatoes	1%	Peaches		0.0%
	8%	FR toddler 2 3 yr	4.12	2%	Beans (with pods)	1%	Spinaches	0.9%	Apples		0.1%
	8%	NL general	4.06	1%	Spinaches	0.7%	Escaroles/broad-leaved endives	0.7%	Lettuces		0.0%
	8%	DE women 14-50 yr	3.90	0.8%	Lettuces	0.8%	Oranges	0.8%	Tomatoes		0.0%
	7%	DE general	3.63	0.7%	Wine grapes	0.7%	Lettuces	0.7%	Apples		0.0%
	6%	FR adult	3.04	2%	Wine grapes	0.6%	Beans (with pods)	0.5%	Tomatoes		0.0%
	6%	FR infant	2.98	2%	Spinaches	1%	Beans (with pods)	0.5%	Apples		0.1%
	6%	UK toddler	2.89	0.8%	Oranges	0.8%	Potatoes	0.6%	Tomatoes		0.0%
	6%	UK infant	2.78	0.7%	Potatoes	0.6%	Peas (without pods)	0.5%	Oranges		0.0%
	5%	DK child	2.68	1%	Lettuces	0.7%	Apples	0.6%	Tomatoes		0.0%
	5%	FI 3 yr	2.63	1%	Potatoes	0.6%	Tomatoes	0.5%	Spinaches		0.0%
	5%	UK vegetarian	2.60	1%	Lettuces	0.7%	Wine grapes	0.6%	Tomatoes		0.0%
	5%	PL general	2.38	0.9%	Tomatoes	0.8%	Potatoes	0.6%	Apples		0.0%
	5%	FI 6 yr	2.27	0.9%	Potatoes	0.6%	Lettuces	0.5%	Tomatoes		0.0%
	4%	UK adult	2.15	0.9%	Wine grapes	0.9%	Lettuces	0.5%	Tomatoes		0.0%
	4%	DK adult	2.11	0.8%	Wine grapes	0.7%	Lettuces	0.5%	Tomatoes		0.0%
	4%	FI adult	1.76	1%	Lettuces	0.6%	Tomatoes	0.3%	Wine grapes		0.0%
	3%	LT adult	1.61	0.7%	Potatoes	0.6%	Tomatoes	0.5%	Apples		
	1.0%	IE child	0.49	0.1%	Potatoes	0.1%	Beans (without pods)	0.1%	Apples		0.0%

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

Acute risk assessment/children	Acute risk assessment/adults/general population
Details – acute risk assessment/children	Details – acute risk assessment/adults

The acute risk assessment is based on the ARfD. DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Uni

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

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

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Leeks	0.9/0.75	44
1%	Spring onions/green onions	0.9/0.75	12
0.1%	Honey and other apiculture	0.5/0.35	1.3

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1.0%	Leeks	0.9/0.75	9.9
0.3%	Spring onions/green onions	0.9/0.75	3.4
0.05%	Honey and other apiculture	0.5/0.35	0.48

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Leeks/boiled	0.9/0.75	43

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Leeks/boiled	0.9/0.75	13

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 present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment[a]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition (plants): sum of spirotetramat, spirotetramat-enol, spirotetramat-ketohydroxy, spirotetramat-monohydroxy and spirotetramat-enol-glucoside, expressed as spirotetramat						
Grapefruits	0.5	MRL review	0.20	STMR-RAC × CF × PeF	0.37	HR-RAC × CF × PeF
Oranges	0.5	MRL review	0.20	STMR-RAC × CF × PeF	0.37	HR-RAC × CF × PeF
Lemons	0.5	MRL review	0.20	STMR-RAC × CF × PeF	0.37	HR-RAC × CF × PeF
Limes	0.5	MRL review	0.20	STMR-RAC × CF × PeF	0.37	HR-RAC × CF × PeF
Mandarins	0.5	MRL review	0.20	STMR-RAC × CF × PeF	0.37	HR-RAC × CF × PeF
Almonds	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Brazil nuts	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Cashew nuts	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Chestnuts	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Coconuts	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Hazelnuts/cobnuts	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Macadamia	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Pecans	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Pine nut kernels	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Pistachios	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Walnuts	0.5	Codex MRL	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Apples	0.7	Codex MRL	0.14	STMR-RAC × CF	0.64	HR-RAC × CF
Pears	0.7	Codex MRL	0.14	STMR-RAC × CF	0.64	HR-RAC × CF
Quinces	0.7	Codex MRL	0.14	STMR-RAC × CF	0.64	HR-RAC × CF
Medlar	0.7	Codex MRL	0.14	STMR-RAC × CF	0.64	HR-RAC × CF
Loquats/Japanese medlars	0.7	Codex MRL	0.14	STMR-RAC × CF	0.64	HR-RAC × CF
Apricots	3	Codex MRL	1.56	STMR-RAC × CF	1.92	HR-RAC × CF
Cherries (sweet)	3	Codex MRL	1.56	STMR-RAC × CF	1.92	HR-RAC × CF
Peaches	3	Codex MRL	1.56	STMR-RAC × CF	1.92	HR-RAC × CF
Plums	3	Codex MRL	1.56	STMR-RAC × CF	1.92	HR-RAC × CF
Table grapes	2	Codex MRL	0.43	STMR-RAC × CF	1.40	HR-RAC × CF
Wine grapes	2	Codex MRL	0.43	STMR-RAC × CF	1.40	HR-RAC × CF
Strawberries	0.3	MRL review	0.13	STMR-RAC × CF	0.40	HR-RAC × CF
Blueberries	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Cranberries	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Currants (red, black and white)	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Gooseberries (green, red and yellow)	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Rose hips	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Mulberries (black and white)	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment[a]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Azarole/Mediterranean medlar	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Elderberries	0.5	MRL review	0.20	STMR-RAC × CF	0.27	HR-RAC × CF
Table olives	1.5	MRL review	0.30	STMR-RAC × CF	1.00	HR-RAC × CF
Kumquats	0.1	Existing EU MRL	0.10	MRL × CF	0.10	MRL × CF
Kaki/Japanese persimmons	0.4	MRL review	0.13	STMR-RAC × CF	0.23	HR-RAC × CF
Kiwi fruits (green, red, yellow)	3	MRL review	0.36	STMR-RAC × CF	1.97	HR-RAC × CF
Litchis/lychees	15	Codex MRL	1.62	STMR-RAC × CF	9.88	HR-RAC × CF
Avocados	0.4	MRL review	0.12	STMR-RAC × CF	0.21	HR-RAC × CF
Bananas	0.4	MRL review	0.09	STMR-RAC × CF × PeF	0.13	HR-RAC × CF × PeF
Mangoes	0.3	MRL review	0.16	STMR-RAC × CF	0.36	HR-RAC × CF
Papayas	0.4	Codex MRL	0.17	STMR-RAC × CF	0.23	HR-RAC × CF
Granate apples/ pomegranates	0.4	MRL review	0.20	STMR-RAC × CF	0.22	HR-RAC × CF
Guavas	2	MRL review	0.55	STMR-RAC × × CF	0.96	HR-RAC × CF
Pineapples	0.15	MRL review	0.07	STMR-RAC × CF	0.14	HR-RAC × CF
Potatoes	0.8	Codex MRL	0.11	STMR-RAC × CF	0.48	HR-RAC × CF
Beetroots	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Carrots	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Celeriacs/turnip-rooted celeries	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Horseradishes	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Jerusalem artichokes	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Parsnips	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Parsley roots/ Hamburg roots parsley	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Radishes	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Salsifies	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Swedes/rutabagas	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Turnips	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Garlic	0.3	MRL review	0.10	STMR-RAC × CF	0.26	HR-RAC × CF
Onions	0.4	Codex MRL	0.11	STMR-RAC × CF	0.58	HR-RAC × CF
Shallots	0.3	MRL review	0.10	STMR-RAC × CF	0.26	HR-RAC × CF
Spring onions/green onions and Welsh onions	0.9	Proposed MRL	0.10	STMR-RAC × CF	0.75	HR-RAC × CF
Tomatoes	1	Codex MRL	0.52	STMR-RAC × CF	1.06	HR-RAC × CF
Sweet peppers/bell peppers	1	MRL review	0.30	STMR-RAC × CF	0.82	HR-RAC × CF
Aubergines/egg plants	1	Codex MRL	0.52	STMR-RAC × CF	1.06	HR-RAC × CF
Okra/lady's fingers	1	Codex MRL	0.52	STMR-RAC × CF	1.06	HR-RAC × CF
Cucumbers	0.2	Codex MRL	0.06	STMR-RAC × CF	0.38	HR-RAC × CF
Gherkins	0.2	Codex MRL	0.06	STMR-RAC × CF	0.38	HR-RAC × CF
Courgettes	0.2	Codex MRL	0.06	STMR-RAC × CF	0.38	HR-RAC × CF

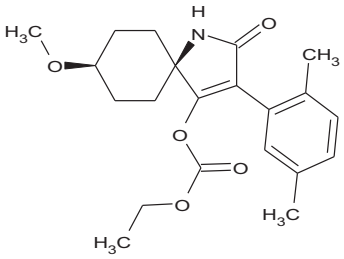
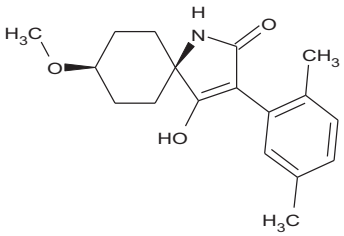
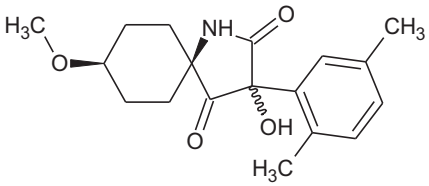
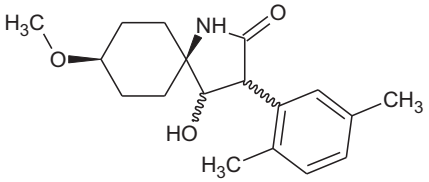
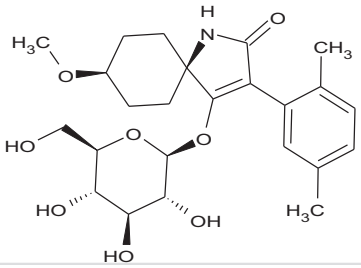
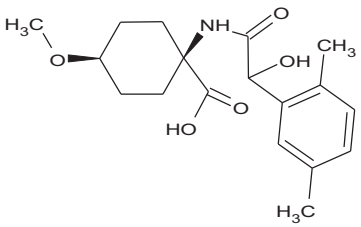
Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment[a]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Melons	0.2	Codex MRL	0.06	STMR-RAC × CF	0.38	HR-RAC × CF
Pumpkins	0.2	Codex MRL	0.06	STMR-RAC × CF	0.38	HR-RAC × CF
Watermelons	0.2	Codex MRL	0.06	STMR-RAC × CF	0.38	HR-RAC × CF
Sweet corn	1.5	Codex MRL	0.31	STMR-RAC × CF	0.72	HR-RAC × CF
Broccoli	1	Codex MRL	0.43	STMR-RAC × CF	1.05	HR-RAC × CF
Cauliflowers	1	Codex MRL	0.43	STMR-RAC × CF	1.05	HR-RAC × CF
Brussels sprouts	0.3	MRL review	0.12	STMR-RAC × CF	0.24	HR-RAC × CF
Head cabbages	2	Codex MRL	0.36	STMR-RAC × CF	2.14	HR-RAC × CF
Chinese cabbages/pe-tsai	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Kales	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Kohlrabies	1.5	MRL review	0.42	STMR-RAC × CF	0.64	HR-RAC × CF
Lamb's lettuce/corn salads	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Lettuces	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Escaroles/broad-leaved endives	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Cress and other sprouts and shoots	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Land cress	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Roman rocket/rucola	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Red mustards	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Baby leaf crops (including brassica species)	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Spinaches	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Purslanes	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Chards/beet leaves	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Watercress	7	Codex MRL	3.64	STMR-RAC × CF	6.50	HR-RAC × CF
Witloofs/Belgian endives	0.03	MRL review	0.02	STMR-RAC × CF	0.02	HR-RAC × CF
Chervil	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Chives	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Celery leaves	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Parsley	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Sage	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Rosemary	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Thyme	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Basil and edible flowers	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Laurel/bay leaves	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Tarragon	4	MRL review	1.89	STMR-RAC × CF	3.71	HR-RAC × CF
Beans (with pods)	2	MRL review	1.17	STMR-RAC × CF	2.75	HR-RAC × CF
Beans (without pods)	1.5	Codex MRL	0.52	STMR-RAC × CF	0.87	HR-RAC × CF
Peas (with pods)	2	MRL review	1.17	STMR-RAC × CF	2.75	HR-RAC × CF
Peas (without pods)	1.5	Codex MRL	0.52	STMR-RAC × CF	0.87	HR-RAC × CF
Lentils (fresh)	1.5	Codex MRL	0.52	STMR-RAC × CF	0.87	HR-RAC × CF
Celeries	4	MRL review	0.75	STMR-RAC × CF	2.04	HR-RAC × CF

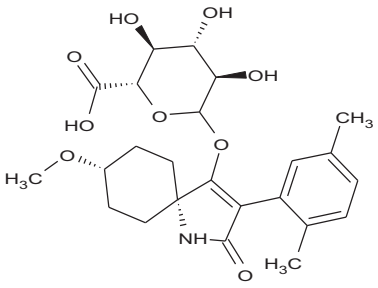
Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment[a]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Florence fennels	4	MRL review	0.75	STMR-RAC × CF	2.04	HR-RAC × CF
Globe artichokes	1	Codex MRL	0.41	STMR-RAC × CF	0.74	HR-RAC × CF
Leeks	0.9	Proposed MRL	0.10	STMR-RAC × CF	0.75	HR-RAC × CF
Rhubarbs	4	MRL review	0.75	STMR-RAC × CF	2.04	HR-RAC × CF
Beans	2	MRL review	0.25	STMR-RAC × CF	0.25	STMR-RAC × CF
Lentils	2	Codex MRL	0.21	STMR-RAC × CF	0.21	STMR-RAC × CF
Peas	2	MRL review	0.25	STMR-RAC × CF	0.25	STMR-RAC × CF
Lupins/lupini beans	2	Codex MRL	0.21	STMR-RAC × CF	0.21	STMR-RAC × CF
Soyabeans	4	MRL review	0.39	STMR-RAC × CF	0.39	STMR-RAC × CF
Cotton seeds	0.4	Codex MRL	0.09	STMR-RAC × CF	0.09	STMR-RAC × CF
Olives for oil production	1.5	MRL review	0.30	STMR-RAC × CF	0.30	STMR-RAC × CF
HOPS (dried)	15	Codex MRL	5.16	STMR-RAC × CF	5.88	HR-RAC × CF
Chicory roots	0.07	MRL review	0.05	STMR-RAC × CF	0.12	HR-RAC × CF
Risk assessment residue definition (animal): Sum of spirotetramat-enol and spirotetramat-enol-GA expressed as spirotetramat						
Swine: Muscle/meat	0.05	MRL review	0.02	STMR-RAC × CF	0.03	HR-RAC × CF
Swine: Fat tissue	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01	HR-RAC × CF
Swine: Liver	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Swine: Kidney	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Bovine: Muscle/meat	0.05	MRL review	0.02	STMR-RAC × CF	0.03	HR-RAC × CF
Bovine: Fat tissue	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Bovine: Liver	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Bovine: Kidney	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Sheep: Muscle/meat	0.05	MRL review	0.02	STMR-RAC × CF	0.03	HR-RAC × CF
Sheep: Fat tissue	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Sheep: Liver	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Sheep: Kidney	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Goat: Muscle/meat	0.05	MRL review	0.02	STMR-RAC × CF	0.03	HR-RAC × CF
Goat: Fat tissue	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Goat: Liver	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Goat: Kidney	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Equine: Muscle/meat	0.05	MRL review	0.02	STMR-RAC × CF	0.03	HR-RAC × CF
Equine: Fat tissue	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Equine: Liver	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Equine: Kidney	0.7	MRL review	0.24	STMR-RAC × CF	0.83	HR-RAC × CF
Poultry: Muscle/meat	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Poultry: Fat tissue	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Poultry: Liver	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Milk: Cattle	0.005*	MRL review	0.005*	STMR-RAC × CF	0.005*	STMR-RAC × CF
Milk: Sheep	0.005*	MRL review	0.005*	STMR-RAC × CF	0.005*	STMR-RAC × CF
Milk: Goat	0.005*	MRL review	0.005*	STMR-RAC × CF	0.005*	STMR-RAC × CF
Milk: Horse	0.005*	MRL review	0.005*	STMR-RAC × CF	0.005*	STMR-RAC × CF

Commodity	Existing/ proposed MRL	Source/ type of MRL	Chronic risk assessment		Acute risk assessment[(a)]	
			Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Eggs: Chicken	0.01*	MRL review	0.01*	STMR-RAC × CF	0.01*	HR-RAC × CF
Honey and other apiculture products	0.5	Proposed MRL	0.13	STMR-RAC × CF	0.35	HR-RAC × CF

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; PeF: Peeling factor.
*: Indicates that the value at the limit of quantification.
(a): Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

Appendix E – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Spirotetramat (BYI 08330)	ethyl *cis*-8-methoxy-2-oxo-3-(2,5-xylyl)-1-azaspiro [4.5]dec-3-en-4-yl carbonate O=C(OCC)OC1=C(C(=O)N[C@@]21CC[C@H](CC2) OC)c1cc(C)ccc1C CLSVJBIHYWPGQY-GGYDESQDSA-N	
Spirotetramat-enol	(5*s*,8*s*)-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)cc1 IDJJHEIUIYGFDX-QGGXVJLZSA-N	
Spirotetramat-ketohydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-3-hydroxy-8-methoxy-1-azaspiro[4.5]decane-2,4-dione Unstated stereochemistry Cc1cc(c(C)cc1)C1(O)C(=O)N[C@]2(CC[C@H](CC2) OC)C1=O XOVCVOLJZHNHLA-GESSKKQQSA-N	
Spirotetramat-monohydroxy	(5*s*,8*s*)-3-(2,5-dimethylphenyl)-4-hydroxy-8-methoxy-1-azaspiro[4.5]decan-2-one Unstated stereochemistry Cc1cc(C2C(=O)N[C@@]3(CC[C@@H](CC3)OC) C2O)c(C)cc1 HPQGJNTUXNUIDL-RMVSHPHESA-N	
Spirotetramat-enol-glucoside (spirotetramat-enol-Glc)	(5*s*,8*R*)-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]2O[C@H](CO) [C@H](O)[C@H](O)[C@H]2O)[C@]2(CC[C@H] (OC)CC2)NC1=O UZUGTDHNHPYPHX-UHFFFAOYSA-N	
Spirotetramat-MA-amide	*cis*-1-[2-(2,5-dimethylphenyl)(hydroxy) acetamido]-4-methoxycyclohexanecarboxylic acid unstated stereochemistry CO[C@@H]1CC[C@](NC(=O)C(O)c2cc(C)ccc2C) (CC1)C(=O)O BQMSZJLYWPKQFG-ZSGNYYCVSA-N	

Code/trivial name[a]	IUPAC name/SMILES notation/InChiKey[b]	Structural formula[c]
Spirotetramat-enol-GA	(5*s*,8*S*)-3-(2,5-dimethylphenyl)-8-methoxy-2-oxo-1-azaspiro[4.5]dec-3-en-4-yl D-glucopyranosiduronic acid Cc1cc(c(C)cc1)C1=C(OC2O[C@@H]([C@@H](O)[C@H](O)[C@H]2O)C(=O)O)[C@]2(CC[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 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).
(c): ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).