Setting of an import tolerance for spiromesifen in coffee beans

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Bayer CropScience submitted a request to the competent national authority in Greece to set an import tolerance for the active substance spiromesifen in coffee beans. The data submitted in support of the request were found to be sufficient to derive a maximum residue level (MRL) proposal for coffee beans. Adequate analytical methods for enforcement are available to control the residues of spiromesifen and spiromesifen-enol (M01) on the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg for each compound. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of spiromesifen according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience submitted an application to the competent national authority in Greece (evaluating Member State (EMS)) to set an import tolerance for the active substance spiromesifen in coffee beans. 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 1 June 2018. The EMS proposed to establish maximum residue levels (MRLs) for coffee beans imported from Colombia and Brazil at the level of 0.2 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 from the EMS. On 14 September 2018 the EMS submitted the revised evaluation report, which replaced the previously submitted evaluation report.

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

The metabolism of spiromesifen following foliar applications was investigated in crops belonging to the fruit crop group.

Studies investigating the effect of processing on the nature of spiromesifen (hydrolysis studies) demonstrated that the active substance was hydrolytically unstable and was primarily degraded to spiromesifen-enol (M01).

As the proposed use of spiromesifen is on imported crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the residue definitions for plant products for monitoring and risk assessment proposed in the framework of the European Union (EU) peer review were set as the sum of spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen. The existing enforcement residue definition established in Regulation (EC) No 396/2005 is set as spiromesifen only. The review of the existing MRLs for spiromesifen is on-going.

EFSA concluded that for the crops assessed in this application, metabolism of spiromesifen in primary products and the possible degradation in processed products has been sufficiently addressed. In the present MRL application the same residue definitions as proposed in the framework of the EU pesticides peer review under Commission Regulation (EU) No 188/2011 are applicable. In addition, EFSA also derived a MRL proposal for the existing enforcement residue definition established in Regulation (EC) No 396/2005.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) are available to quantify residues in the crop assessed in this application according to the enforcement residue definition. The methods enable quantification of residues in coffee beans of both parent compound and M01, each at or above the limit of quantification (LOQ) of 0.01 mg/kg.

The available residue trials are sufficient to derive a MRL proposal of 0.2 mg/kg for coffee beans based on the proposed residue definition derived in the peer review and 0.05 mg/kg based on the existing residue definition.

Specific studies investigating the magnitude of spiromesifen residues in processed commodities are not required, as the residue concentrations expected in raw agricultural commodities (RAC) are low.

Residues of spiromesifen in commodities of animal origin were not assessed since the crop under consideration in this MRL application is normally not fed to livestock.

The toxicological profile of spiromesifen 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 0.03 mg/kg body weight (bw) per day and an acute reference dose (ARFD) of 2 mg/kg bw. According to the peer review the toxicity of metabolite M01 included in the residue definition is considered to be covered by the parent.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). The short-term exposure assessment has been performed using the highest residue (HR) for spiromesifen observed in the residue trials for coffee beans. No acute consumer risk was identified in relation to the MRL proposal for coffee beans, the calculated acute exposure to spiromesifen being low (0.005% of the ARFD).
For the chronic risk assessment of spiromesifen, the supervised trial median residue (STMR) from the supervised residue trials of coffee beans and the STMR for tea derived in a previous EFSA assessment was used. For the other commodities, the existing MRLs set in Regulation (EU) No 500/2013 have been used for exposure calculations. The calculated exposure was then compared with the toxicological reference values as derived for spiromesifen. No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 20% of the ADI (WHO Cluster diet B), where the contribution of the residues in coffee beans to the total exposure is accounting for less than 0.05% of the ADI.

EFSA notes that the existing MRLs are established for the enforcement residue definition 'spiromesifen' and no residue data are available to assess the contribution of spiromesifen-enol residues to the total chronic consumer exposure from the existing uses. However, since in the exposure calculation, the MRLs are used instead of the risk assessment values the calculation is considered to be sufficiently conservative and is not likely to underestimate consumer risk.

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

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

| Code(a) | Commodity   | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-------------|-------------------------|-------------------------|-----------------------|
| 0620000 | Coffee beans | 0.02*                   | 1) 0.05                 | The submitted data are sufficient to derive an import tolerance for the critical Brazilian GAP reported for coffee beans. The MRL set in the country of origin is 0.2 mg/kg (for a residue definition comprising spiromesifen only). Risk for consumers unlikely |

MRL: maximum residue level; GAP: Good Agricultural Practice.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
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Assessment

The detailed description of the existing uses of spiromesifen authorised in Colombia and Brazil in coffee beans, which are the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Spiromesifen is the ISO common name for 3-mesityl-2-oxo-1-oxaspiro[4.4]non-3-ene-4-yl 3,3-dimethylbutyrate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Spiromesifen was evaluated in the framework of Commission Regulation (EU) No 188/2011 with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as foliar application on various vegetables in permanent greenhouses. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2012a). Spiromesifen was approved for the use as an acaricide and insecticide on 1 October 2013.

The European Union (EU) MRLs for spiromesifen are established in Annexes 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 one reasoned opinion on the modification of MRLs for spiromesifen (EFSA, 2012b). The proposal from this reasoned opinion has been implemented in the EU MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience submitted an application to the competent national authority in Greece (EMS) to set an import tolerance for the active substance spiromesifen in coffee beans. 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 EFSA on 1 June 2018. The EMS proposed to establish an MRL for coffee beans imported from Colombia and Brazil at the level of 0.2 mg/kg. The MRL established in Brazil is 0.2 mg/kg (residue definition spiromesifen); for Columbia no information was reported on the MRL in place in the country of origin. EFSA identified points which needed further clarification, which were requested from the EMS. On 14 September 2018 the EMS submitted the revised evaluation report, which replaced the previously submitted evaluation report.

EFSA based its assessment on the evaluation report submitted by the EMS (Greece, 2017), the draft assessment report (DAR) and its addenda (United Kingdom, 2004, 2007, 2012) prepared under Commission Regulation (EU) No 188/2011, the Commission review report on spiromesifen (European Commission, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance spiromesifen (EFSA, 2012a), as well as the previous EFSA opinion on spiromesifen (EFSA, 2012b).

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

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 might need to be reconsidered in the light of the outcome of the MRL review.

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1 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.
2 Commission Implementing Regulation (EU) No 375/2013 of 23 April 2013 approving the active substance spiromesifen, 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 112, 24.4.2013, p. 15–19.
3 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/pesticides-database/public/?event=pesticide.residue.selection&language=EN
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.
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, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (Greece, 2017) 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 spiromesifen in primary crops was evaluated by the RMS the United Kingdom (United Kingdom, 2004) and reviewed by EFSA and Member States (EFSA, 2012a) in the framework of the peer review under Commission Regulation (EU) No 188/2011. Metabolism studies using dihydrofuranone-3-14C spiromesifen have been performed with tomatoes, lettuce and cotton.

Spiromesifen was the main component of the residue in mature tomato fruits (86% of the total radioactive residue (TRR)), in lettuce (58% TRR), and in cotton seed and gin trash (17% and 26% TRR). Metabolites observed were, among others, spiromesifen-enol (M01) (below 3% TRR in tomato and lettuce and up to 50% TRR in cotton commodities), spiromesifen-4-hydroxymethyl (M02) and its glucoside (M03) (sum ca. 7% TRR in tomato and cotton, 16% in lettuce). A major metabolite in lettuce was also dihydroxy- spiromesifen-enol (M04) (6% TRR). All other components were present in insignificant amounts (EFSA, 2012a). The peer review concluded that the metabolism of spiromesifen was similar in all crop groups investigated.

For the use on coffee beans, EFSA concludes that the metabolism of spiromesifen is sufficiently addressed by the metabolism studies (coffee beans belong to the group of fruit crops and fruiting vegetables).

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

For the import tolerance application, investigations of residues in rotational crops is not required.

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

The effect of processing on the nature of spiromesifen was investigated in studies performed at three test conditions representing pasteurisation, baking/brewing/boiling and sterilisation (20 minutes at 90°C, pH 4; 60 min at 100°C pH 5; 20 min at 120°C, pH 6) (United Kingdom, 2004). The results of the hydrolysis study demonstrated that spiromesifen was hydrolytically not stable and was primarily degraded to spiromesifen-enol (M01) which accounted for up to 89% of the terminal residues after sterilisation, up to 83.5% after baking/brewing/boiling and up to 21% after pasteurisation. Other degradation products were not significant (EFSA, 2012a).

No additional studies were submitted under the current application.

1.1.4. **Methods of analysis in plants**

Analytical methods (high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS)) for the determination of spiromesifen residues in plant commodities were assessed in the DAR and during the peer review under Commission Regulation (EU) No 188/2011 (United Kingdom, 2004, 2007, 2012; EFSA, 2012a).

The HPLC–MS/MS method is considered sufficiently validated for the determination of spiromesifen and its metabolite spiromesifen-enol (M01) in plant matrices with high acid (orange), high water (tomato), high oil (rape seed) content and in dry matrices (wheat grain) at an individually validated limit of quantification (LOQ) of 0.01 mg/kg for both compounds. An acceptable independent laboratory validation (ILV) on tomato and wheat grain was presented (EFSA, 2012a).

An additional method (modification M001, of the analytical method 01038) which has been fully validated for spiromesifen and spiromesifen-enol (M01) in coffee beans and tea and an ILV study has been submitted in the framework of the current application. Residues of spiromesifen and spiromesifen-enol (M01) in coffee beans and tea were extracted with acetonitrile/water (4/1, v/v) and...
analysed with HPLC-MS/MS. The LOQ of the method is 0.01 mg/kg for each analyte and 0.02 mg/kg for the total residue.

### 1.1.5. Stability of residues in plants

Storage stability was investigated in cucumber, melon peel and French bean (high water commodities) for up to 2 years at ≤ −18°C in the peer review (United Kingdom, 2004; EFSA, 2012a). Total residues covering the sum of spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen, were considered sufficiently stable for freezer storage for up to 2 years. According to these studies, there is evidence of conversion of parent to metabolite M01; residues of parent alone were demonstrated to be stable for at least 6 months.

Storage stability information for dry bean (seed), coffee (grain) and citrus (fruit) has been submitted under the current MRL application (Greece, 2017). For high oil content (coffee grain) and high acid content commodities (citrus fruit), the storage stability was demonstrated for 24 months for both spiromesifen and spiromesifen-enol (M01) at −18°C. In dry bean samples, spiromesifen on its own was stable for less than 30 days, whereas the sum of spiromesifen and spiromesifen-enol (M01) was stable for up to 24 months at −18°C.

### 1.1.6. Proposed residue definitions

The following residue definition for both risk assessment and monitoring was concluded on during the peer review (EFSA, 2012a): ‘sum of spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen’.

Based on the available information, it is considered that the residue definitions proposed during the peer review are appropriate for the use assessed in the present application. An appropriate monitoring method is available which covers both compounds in the residue definition (see Section 1.1.4).

It should be noted that the existing enforcement residue definition established in Regulation (EC) No 396/2005 is set as spiromesifen only. Considering the low storage stability of parent spiromesifen, which is not a good marker substance, the residue definition should be revised as proposed in the peer review. The review of the existing MRLs for spiromesifen is on-going and revised MRL proposals for the new residue definition for monitoring will be derived.

### 1.2. Magnitude of residues in plants

#### 1.2.1. Magnitude of residues in primary crops

In support of the MRL application, the applicant submitted 10 residue trials performed in Brazil, Colombia, Guatemala and Mexico compliant with the more critical Brazilian Good Agricultural Practice (GAP). In the five trials conducted in Brazil, spiromesifen was applied as an suspension concentrate (SC) formulation, two times at 0.143–0.145 kg a.s./ha at BBCH 79–85. Residue levels at a 21-day preharvest interval (PHI) ranged between <0.02 and 0.12 mg/kg. In the cases that higher value of residue was observed in a longer PHI, this value was used instead.

In the five trials conducted in Colombia, Guatemala and Mexico, spiromesifen was applied in accordance with the Colombian GAP using an SC formulation which was applied twice at 0.129 kg a.s./ha at BBCH 85-88. Samples were collected at 7, 14, 21, 28 and 35 days after harvest. No residues were found above the LOQ (<0.02 mg/kg).

The samples were analysed with a method that allowed a separate analysis of parent and metabolite M01.

The residue trials were considered valid with regard to the storage stability of spiromesifen and the total residues of spiromesifen and M01 and the analytical methods used were sufficiently validated.

EFSA concludes that the submitted residue trials are sufficient to derive an MRL proposal for coffee beans for the more critical GAP authorised in Brazil based on the existing (spiromesifen) and the proposed (sum of spiromesifen and M01 expressed as spiromesifen) residue definition.

#### 1.2.2. Magnitude of residues in rotational crops

Not triggered by the current assessment (see also Section 1.1.2).
1.2.3. Magnitude of residues in processed commodities

The peer review proposed the same residue definition in processed commodities as in primary commodities.

No additional studies were submitted under the current application. Specific studies to assess the magnitude of spiromesifen residues during the processing of coffee beans are not necessary as the total theoretical maximum daily intake (TMDI) for coffee beans amounts to less than 10% of the acceptable daily intake (ADI) (European Commission, 1997d).

1.2.4. Proposed MRLs

EFSA concludes that the information submitted in support of the import tolerance of coffee beans from Brazil and Colombia was sufficient to calculate an MRL proposal of 0.2 mg/kg for the proposed new residue definition. For the existing residue definition that comprises only the parent compound, a MRL of 0.05 mg/kg would be required.

2. Residues in livestock

Not relevant for the current assessment.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The PRIMo model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007). The exposures calculated were then compared with the toxicological reference values derived for spiromesifen during the EU peer review (EFSA, 2012a).

As the MRL review of spiromesifen in accordance with Regulation (EC) No 396/2005 is ongoing, the conclusions reported in this reasoned opinion should be reconsidered in the light of the outcome of the MRL review process.

The short-term exposure assessment has been performed using the highest residue (HR) levels for spiromesifen observed in the supervised residue trials for coffee beans. No acute consumer risk was identified in relation to the MRL proposal for coffee beans, the calculated acute exposure was low (0.005% of the acute reference dose (ARfD)).

For the chronic risk assessment of spiromesifen, supervised trial median residue (STMR) was used from the supervised residue trials for coffee beans. For the other commodities, the existing MRLs set in Regulation (EU) No 500/2013 have been used for exposure calculations. The calculated exposure was then compared with the toxicological reference values as derived for spiromesifen (EFSA, 2012a). No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 20% of the ADI (WHO Cluster diet B), where the contribution of the residues in coffee beans to the total exposure is accounting for less than 0.05% of ADI.

EFSA notes that the existing MRLs are established for the enforcement residue definition ‘spiromesifen’ and no residue data are available to assess the contribution of spiromesifen-enol (M01) residues to the total chronic consumer exposure from the existing uses. However, the calculation is considered to be sufficiently conservative and is not likely to underestimate consumer risk for the following reasons:

- for the exposure calculation, the MRLs are used instead of the risk assessment values which are usually significantly higher than the STMR value which should be used according to the internationally agreed methodology used as input value in the chronic exposure assessment;
- from metabolism studies, the occurrence of M01 is expected to be low in crops for which currently MRLs are set (i.e. in crops belonging to the crop group of fruits and fruiting vegetables and leafy crops) where M01 accounted for less than 3% of the TRR (see Section 1.1.1).

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7 Commission Regulation (EU) No 500/2013 of 30 May 2013 amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetamiprid, Adoxophyes orana granulovirus strain BV-0001, azoxystrobin, clothianidin, fenpyrazamine, heptamaloxyloglucan, metrafenone, Paecilomyces lilacinus strain 251, propiconazole, quizalofop-P, spiromesifen, tebuconazole, thiamethoxam and zucchini yellow mosaic virus - weak strain in or on certain products. OJ L 151, 4.6.2013, p. 1-32.
The input values used for the dietary exposure calculation are summarised in Appendix D and 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 coffee beans.

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 2 of the EFSA PRIMo. Input values for the exposure calculations are shown in Appendix D. The exposures calculated were compared with the toxicological reference values for spiromesifen, derived by EFSA (2012a) during the EU peer review. Details of the PRIMo calculation are given in Appendix C. The highest chronic exposure was calculated for WHO cluster diet B, representing 20% of the ADI, and the highest acute exposure was calculated for coffee beans was negligible (0.005% of the ARfD). The risk assessment is affected by uncertainties related to the lack of data on occurrence of spiromesifen-enol (M01) residues in commodities with authorised uses. However, since in the exposure calculation the MRLs are used instead of the risk assessment values the calculation is considered to be sufficiently conservative and is not likely to underestimate consumer risk. This assumption is confirmed by the preliminary results of the chronic risk assessment performed in the framework of the MRL review which will be finalised in due time.

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

The MRL recommendation is summarised in Appendix B.4.

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Abbreviations

- a.s. active substance
- ADI acceptable daily intake
- AR applied radioactivity
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CF conversion factor for enforcement to risk assessment residue definition
- DAR draft assessment report
- DAT days after treatment
- EMS evaluating Member State
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
- HR highest residue
- IEDI international estimated daily intake
- IESTI international estimated short-term intake
- InChiKey International Chemical Identifier Key
- ILV independent laboratory validation
- ISO International Organisation for Standardisation
- IUPAC International Union of Pure and Applied Chemistry
- LOQ limit of quantification
- MRL maximum residue level
- NEU northern Europe
- OECD Organisation for Economic Co-operation and Development
- PBI plant-back interval
- PHI preharvest interval
- PRIMo (EFSA) Pesticide Residues Intake Model
- 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
- SMILES simplified molecular-input line-entry system
- SRM selected reaction monitoring
- STMR supervised trials median residue
- TMDI theoretical maximum daily intake
- TRR total radioactive residue
- WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|--------------------------|------------------------------------|-------------|-------------|-------------------------------|
|                       |                          |                                    | Type (b)    | Concentration (a.s.) | Method | Range of growth stages & season (c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate Unit | PHI (days)(d) | Remarks |
| Coffee Colombia        | F                        | Oligonychus yothersi               | SC 240 g/L  | Spraying | From 5 insects per leaf | 1-2 | 5 days | 350 | 0.12 kg a.s./ha | 35 |
| Coffee Brazil          | F                        | Oligonychus ilicis                 | SC 240 g/L  | Spraying | Beginning of infestation, before leaf browning occurs | 1-2 | 400-800 | 0.12 kg a.s./ha | 21 |

**MRL:** maximum residue level; **GAP:** Good Agricultural Practice; **NEU:** northern European Union; **SEU:** southern European Union; **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 | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Tomato      | 2 Foliar, 24-day interval, 0.44 and 0.38 kg a.s./ha | 7 (maturity) | Radiolabelled active substance: dihydrofuranone-3-14C (EFSA, 2012a) |
| Root crops                        | Cotton      | 2 Foliar, 24-day interval, 0.3 kg a.s./ha, 0.225 kg a.s./ha (4 plants), 0.347 kg a.s./ha (4 plants) | 7 | Radiolabelled active substance: dihydrofuranone-3-14C (EFSA, 2012a) |
| Leafy crops                       | Lettuce     | 3 Foliar, 7-day interval, 0.3 kg a.s./ha, 1 Foliar, 1 kg a.s./ha | 21 | Radiolabelled active substance: dihydrofuranone-3-14C (EFSA, 2012a) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Not available and not triggered     |             |         |                |           |                |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | No         | Spiromesifen was primarily degraded to spiromesifen-enol (M01) which accounted for up to 21% of the terminal residues (EFSA, 2012a) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | No         | Spiromesifen was hydrolytically not stable and was primarily degraded to spiromesifen-enol (M01) which accounted for up to 83.5% of the terminal residues (EFSA, 2012a) |
| Sterilisation (20 min, 120°C, pH 6)      | No         | Spiromesifen primarily degraded to spiromesifen-enol (M01) which accounted for up to 89% of the terminal residues (EFSA, 2012a) |
| Other processing conditions             | –          | –       | –              |
Can a general residue definition be proposed for primary crops?

Yes

The metabolism of spiromesifen was similar in all crop groups investigated.

Rotational crop and primary crop metabolism similar?

Not triggered

Not relevant for the current application (import tolerance).

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

Yes

The sum of spiromesifen and spiromesifen-enol is stable during processing, no further significant metabolite formed.

Plant residue definition for monitoring (RD-Mo)

Regulation (EC) No 396/2005: spiromesifen;
Peer review: spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen (EFSA, 2012a)

Plant residue definition for risk assessment (RD-RA)

Spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen

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

High water content, high oil content, high acid content and dry matrices (EFSA, 2012a):
- Analytical technique HPLC–MS/MS
- LOQ: 0.02 mg/kg (combined, individually validated to 0.01 mg/kg)
- Confirmation by monitoring 1 additional SRM transition
- ILV available for high water (tomato) and dry (wheat grain) commodities
- Extended DFG-S19

Coffee beans and tea: HPLC–MS/MS, LOQ 0.01 mg/kg for each analyte and 0.02 mg/g for the total residue.
ILV available.
(Greece, 2017)

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                | Cucumber, melon peel, French bean | ≤ −18 | 24 Months | Sum of spiromesifen and spiromesifen-enol (M01) | United Kingdom (2004), EFSA (2012a) |
|                                   | French beans | −18 | 6 Months | spiromesifen | United Kingdom (2004) |
| High oil content                  | Coffee (grain) | −18 | 24 Months | Sum of spiromesifen and M01 | Greece (2017) |
|                                   | −18 | 24 Months | spiromesifen | Greece (2017) |
| High protein content              | Dry bean | −18 | 24 Months | Sum of spiromesifen and M01 | Greece (2017) |
|                                   | −18 | < 30 Days | spiromesifen | Greece (2017) |
| High acid content                 | citrus | −18 | 24 Months | Sum of spiromesifen and M01 | Greece (2017) |
|                                   | −18 | 24 Months | Spiromesifen | Greece (2017) |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; SRM: selected reaction monitoring.
### 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) |
|---------------|------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|---------------|
| Coffee grains | Import tolerance| Spiromesifen and Spiromesifen-
enol (M01) expressed as spiromesifen: 8 × < 0.02; 0.04; 0.12 | Residue trials on coffee beans compliant with Brazilian GAP                   | 0.2                    | 0.12         | 0.02          |
| Coffee grains | Import tolerance| Spiromesifen 9 × < 0.01, 0.02                                   | Residue trials on coffee beans compliant with Brazilian GAP                   | 0.05                   | 0.02         | 0.01          |

MRL: maximum residue level; GAP: Good Agricultural Practice.
(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.
B.1.2.2. Residues in rotational crops

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

| Not triggered | The present MRL application is an import tolerance |
|---------------|--------------------------------------------------|

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

| Not triggered | The present MRL application is an import tolerance |
|---------------|--------------------------------------------------|

MRL: maximum residue level.

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 for the current assessment.

B.3. Consumer risk assessment

| ARfD | 2 mg/kg bw (EFSA, 2012a) |
|------|--------------------------|

Highest IESTI, according to EFSA PRIMo

Coffee beans: 0.005% of ARfD

Assumptions made for the calculations

The calculation is based on the highest residue levels (HR) expected for raw agricultural commodities (coffee beans) based on the GAP-compliant supervised residue trials submitted in support of this MRL application

| ADI | 0.03 mg/kg bw per day (EFSA, 2012a) |
|-----|-----------------------------------|

Highest IEDI, according to EFSA PRIMo

Risk assessment results for spiromesifen:

20% ADI (WHO Cluster diet B)
Contribution of crops assessed:
Coffee beans: 0.022% of ADI

Assumptions made for the calculations

Exposure calculation assumption for spiromesifen:
The chronic calculation is based on the median residue levels (STMR) available for raw agricultural commodities (coffee beans) based on the GAP-compliant supervised residue trials and the MRLs set in Regulation (EU) No 500/2013
The existing MRLs are established for the enforcement residue definition spiromesifen. However, the margin of safety for the calculated exposure is considered sufficient to conclude that the possible contribution of spiromesifen-enol residues from the existing uses to the total consumer exposure would cause no consumer intake concerns

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

| Code<sup>(a)</sup> | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|---------------|-------------------------|-------------------------|----------------------------------------------------------------------------------------|
| 0620000           | Coffee beans  | 0.02*                   | 1) 0.05 2) 0.2          | The submitted data are sufficient to derive an import tolerance for the critical Brazilian GAP reported for coffee beans. The MRL set in the country of origin is 0.2 mg/kg (residue definition parent spiromesifen) Risk for consumers unlikely |

**Enforcement residue definition:**

1) Spiromesifen (existing residue definition in Regulation (EC) No 396/2005)
2) Spiromesifen and spiromesifen-enol (M01) expressed as spiromesifen (proposed residue definition derived in the peer review)

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

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).

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

#### Spiromesifen

**Status of the active substance:**
- Code no.

**LOQ (mg/kg bw):** 0.02

**Proposed LOQ:**

| Toxicological end points | ADI (mg/kg bw per day): |
|--------------------------|-------------------------|
|                          | 0.03                    |

**ADI (mg/kg bw):**
- 2

**ARfD (mg/kg bw):**
- 2

**Source of ADI:** EFSA

**Source of ARfD:** EFSA

**Year of evaluation:** 2012

**Year of evaluation:** 2012

#### Chronic risk assessment – refined calculations

| Highest calculated TMDI in % of ADI | Commodity/group of commodities | 2nd contributor to MS diet in % of ADI | 3rd contributor to MS diet in % of ADI | Commodity/group of commodities | TMDI at LOQ in % of ADI |
|-------------------------------------|--------------------------------|--------------------------------------|--------------------------------------|--------------------------------|-------------------------|
| WHO Cluster diet B                 | Tomatoes                       | Tea                                  | Beans (with pods)                    | 2.7                            | 1.1                     |
| IE adult                           | Tea                             | Tomatoes                             | Strawberries                         | 1.3                            | 0.8                     |
| FR toddler                         | Beans (with pods)               | Tomatoes                             | Strawberries                         | 0.8                            | 2.1                     |
| DE child                           | Tomatoes                        | Strawberries                         | Apples                              | 0.8                            | 2.6                     |
| NL child                           | Tomatoes                        | Beans (with pods)                    | Tea                                  | 1.7                            | 1.4                     |
| UK cluster diet D                  | Tomatoes                        | Tea                                  | Beans (with pods)                    | 2.6                            | 0.7                     |
| UK Toddler                         | Tomatoes                        | Tomatoes                             | Strawberries                         | 1.3                            | 1.2                     |
| FR infant                          | Beans (with pods)               | Tea                                  | Tomatoes                             | 1.9                            | 1.5                     |
| WHO cluster diet E                 | Tea                             | Tomatoes                             | Wheat                                | 2.4                            | 1.0                     |
| UK vegetarian                      | Tea                             | Tomatoes                             | Sugar beet (root)                    | 2.1                            | 1.6                     |
| WHO regional European diet         | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.3                            | 1.6                     |
| Cluster diet B                    | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet D                    | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.5                            | 1.5                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.0                            | 1.0                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.6                            | 1.6                     |
| ES child                           | Beans (with pods)               | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |
| Cluster diet F                     | Tomatoes                        | Tea                                  | Sugar beet (root)                    | 1.9                            | 1.9                     |

**Conclusion:**
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of spiromesifen is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.
For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.
In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002); for lettuce, a variability factor of 5 was used.
In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.
Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

### Table: Acute risk assessment

| Commodity          | pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) | pTMRL/ threshold MRL (mg/kg) |
|--------------------|------------------------------|------------------------------|------------------------------|------------------------------|
| Coffee beans       | 0.005                        | 0.005                        | 0.005                        | 0.005                        |
| Tomato juice       | 0.9                          | 0.9                          | 0.9                          | 0.9                          |
| Passion fruit juice| 0.4                          | 0.4                          | 0.4                          | 0.4                          |
| Apple juice        | 0.1                          | 0.1                          | 0.1                          | 0.1                          |
| Orange juice       | 0.02                         | 0.02                         | 0.02                         | 0.02                         |
| Carrot juice       | 0.02                         | 0.02                         | 0.02                         | 0.02                         |

### Conclusion:
For spiromesifen, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.
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           | Chronic risk assessment | Acute risk assessment |
|---------------------|-------------------------|-----------------------|
|                     | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Coffee beans        | 0.02                    | STMR (Section B.1.2.1) | 0.12                | HR (Section B.1.2.1)  |
| Tea                 | 20.40                   | STMR (EFSA, 2012b)    |                      |                          |
| All other commodities | EU MRL                 | Reg. (EU) No 500/2013 |                      |                          |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level.
## Appendix E – Used compound codes

| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|----------------------|----------------------------------------|-----------------------|
| spiromesifen         | 3-mesityl-2-oxo-1-oxaspiro[4.4]non-3-en-4-yl 3,3-dimethylbutyrate<br>CC(C)(C)CC(=O)OC1=C(C(=O)OC21CCCC2) c1c(C)c(C)c1C<br>GOLXNESZZPUPJE-UHFFFAOYSA-N | ![Spiromesifen](image1.png) |
| **M01** spiromesifen-enol | 4-hydroxy-3-mesityl-1-oxaspiro[4.4]non-3-en-2-one<br>Cc1cc(C)c1C1=C(O)C2(CCCC2)OC1=O<br>UWNPKBJDSGDYAU-UHFFFAOYSA-N | ![Spiromesifen-enol](image2.png) |
| **M02** spiromesifen-4-hydroxymethyl | 4-hydroxy-3-[4-(hydroxymethyl)]-2,6-dimethylphenyl]-1-oxaspiro[4.4]non-3-en-2-one<br>Cc1cc(CO)c1C1=C(O)C2(CCCC2)OC1=O<br>VNFLRKJAPAQOKF-UHFFFAOYSA-N | ![Spiromesifen-4-hydroxymethyl](image3.png) |
| **M03** 4-hydroxymethylglucoside | 4-(4-hydroxy-2-oxo-1-oxaspiro[4.4]non-3-en-3-yl)-3,5-dimethylbenzyl D-glucopyranoside<br>O[CC@@H]1[CC@H](O)[C@H](O)[C@H](CO)OC1OCc1cc(C)c(C2=C(C)C3(CCCC3)OC2=O)c(C)c1<br>XOYBLSGORXOIJAR-QLHHPHAVSA-N | ![4-hydroxymethylglucoside](image4.png) |
| **M04** Dihydroxy- spiromesifen-enol | 4,x,y-trihydroxy-3-(2,4,6-trimethylphenyl)-1-oxaspiro[4.4]non-3-en-2-one<br>Unknown positions | ![Dihydroxy-spiromesifen-enol](image5.png) |

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).