Evaluation of confirmatory data following the Article 12 MRL review for spinosad

European Food Safety Authority (EFSA), Himdata Abdourahime, Maria Anastassiadou, Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Chloe De Lentdecker, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Alfonso Lostia, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Stefanie Nave, Ragnor Pedersen, Marianna Raczyk, Hermine Reich, Silvia Ruocco, Angela Sacchi, Miguel Santos, Alois Stanek, Juergen Sturma, Jose Tarazona, Anne Theobald, Benedicte Vagenende, Alessia Verani and Laura Villamar-Bouza

Abstract

The applicant Dow AgroSciences Ltd submitted a request to the competent national authority in the Netherlands to evaluate the confirmatory data that were identified for spinosad in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. The data gaps related to residue trials on globe artichokes, flowering brassica and the nature of residues in processed commodities were satisfactorily addressed. A new feeding study on poultry has been submitted as requested, but the information is not sufficient to derive conversion factors (CF) for risk assessment for poultry liver and eggs to replace the tentative conversion factors obtained from the metabolism study. The new information provided justifies the lowering of the MRLs for flowering brassica and products of poultry origin. The consumer risk assessment performed for spinosad was updated taking into account the acute reference dose (ARFD) which was recently derived by EFSA. Since for spinach a potential consumer intake concern was identified, the lowering of the existing MRL is recommended. For the remaining commodities assessed under this application (globe artichokes, flowering brassica, products derived from poultry), a consumer intake concern was not identified. For a number of commodities for which MRLs have been established previously but which are not subject of the current assessment, EFSA recommends a review of the MRLs because of potential short-term intake concerns.

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: spinosad, confirmatory data, pesticide, MRL review, risk assessment

Requestor: European Commission

Question number: EFSA-Q-2018-00465

Correspondence: pesticides.mrl@efsa.europa.eu
Evaluation of confirmatory data for spinosad to address data gaps identified in the MRL review

Suggested citation: EFSA (European Food Safety Authority), Abdourahime H, Anastassiadou M, Brancato A, Brocca D, Carrasco Cabrera L, De Lentdecker C, Ferreira L, Greco L, Jarrah S, Kardassi D, Leuschner R, Lostia A, Lythgo C, Medina P, Miron I, Molnar T, Nave S, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Sturma J, Tarazona J, Theobald A, Vagenende B, Verani A and Villamar-Bouza L, 2019. Reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for spinosad. EFSA Journal 2019;17(2):5592, 30 pp. https://doi.org/10.2903/j.efsa.2019.5592

ISSN: 1831-4732

© 2019 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

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

In 2012, when the European Food Safety Authority (EFSA) reviewed the existing Maximum Residue Levels (MRLs) for spinosad according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) Four additional residues trials on raspberries supporting the southern outdoor Good Agricultural Practice (GAP) on cane fruits and four additional residues trials on raspberries supporting the indoor GAP on cane fruits;
2) Four residue trials supporting the indoor GAP on swedes and/or turnips;
3) Two additional residues trials performed on cauliflower supporting the southern outdoor GAP on cauliflower and broccoli;
4) Four residue trials supporting the northern outdoor GAP on globe artichoke;
5) Studies about the nature of residues in processed commodities. It should be noted, that such studies are necessary for spinach and cereal grains in particular which are the main contributors to the exposure calculation and usually processed before consumption;
6) A poultry feeding study in order to derive appropriate MRLs and conversion factors for this group of livestock.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2015/603, including footnotes related to data gaps numbers 3, 4, 5 and 6 indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 17 April 2017. Data gap number 1 was not implemented in the MRL regulation, because risk managers decided to set an alternative MRL for blackberries, dewberries and raspberries which was sufficiently supported by data. Data gap number 2 was also not implemented and the MRL for swedes and turnips were kept at the limit of quantification (LOQ) of 0.02 mg/kg.

In accordance with the agreed procedure set out in the working document SANTE/10235/2016, Dow AgroSciences Ltd submitted an application to the competent national authority in the Netherlands (rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 1 June 2018.

In the current document, the new data were assessed by EFSA in view of their impact on the previously performed risk assessment and their impact on existing tentative MRLs.

It is highlighted that EFSA has recently published the conclusion on the peer review of the pesticide risk assessment of the active substance spinosad under Regulation (EC) No 1077/2009. In the EFSA conclusion, revised residue definitions for risk assessment were proposed on a provisional basis and an acute reference dose (ARfD) was derived for spinosad, which was not in place at the time of the MRL review.

The consumer risk assessment in the framework of this reasoned opinion was performed for the residue definitions derived in the MRL review. The chronic risk assessment for spinosad was updated, including the updated input values derived for the crops under consideration; EFSA also performed an acute risk assessment, taking into account the new ARfD for spinosad.

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

The MRLs for spinosad and the consumer risk assessment should be reconsidered in the future, taking into account the outcome of the detailed evaluation of the information that needs to be provided to address the data gaps identified in the framework of the EU pesticides peer review (renewal for spinosad) and the conclusion on residue definitions.
| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|----------------------------|
| 0241000 | Flowering brassica | 2 (ft 1) | 0.8 (further risk management consideration required) | The data gap identified by EFSA has been addressed. Based on the available data on broccoli and cauliflowers, a lower MRL of 0.5 mg/kg is derived for the SEU use on flowering brassica. It is highlighted that in the MRL review EFSA derived a MRL proposal of 0.8 mg/kg for the NEU use on flowering brassica, which was fully supported by data. Thus, data would justify the lowering of the existing MRL. According to the results of the risk assessment performed for the residue definitions derived under the MRL review, a risk for the consumers is unlikely. In the risk management discussion on the lowering of the current MRL, the following points should be noted:  
  - Member States may have granted authorisations for more critical uses than the ones assessed in this reasoned opinion which require maintaining the existing MRL of 2 mg/kg.  
  - The short-term exposure calculated with the MRL of 2 mg/kg exceeds the ARfD derived in the framework of the process of renewal of spinosad (EU peer review) (117% of the ARfD for cauliflower and 132% of the ARfD for broccoli).  
  - A detailed risk assessment taking into account the residue trials supporting the authorised uses is therefore required |
| 0241010 | Broccoli | 2 (ft 1) | 0.15 (further risk management consideration required) | The data gap identified by EFSA has been addressed. The MRL is confirmed. According to the results of the risk assessment performed for the residue definitions derived under the MRL review, a risk for the consumers is unlikely |
| 0241020 | Cauliflower | 2 (ft 1) | 0.15 (further risk management consideration required) | The data gap identified by EFSA has been addressed. The MRL is confirmed. According to the results of the risk assessment performed for the residue definitions derived under the MRL review, a risk for the consumers is unlikely |
| 0241990 | Others flowering brassica | 2 (ft 1) | 0.03 (further risk management consideration required) | The data gap identified by EFSA concerning a feeding study in poultry has been partially addressed. The new study was provided but it does not allow deriving conversion factors (CF) for risk assessment for poultry liver and eggs since the

**Enforcement residue definition:** Spinosad (spinosad, sum of spinosyn A and spinosyn D)
samples have not been analysed for the two metabolites included in the residue definition for risk assessment (i.e. O-demethylated spinosyn D and N-demethylated spinosyn D). According to the risk assessment performed for the residue definitions derived under the MRL review and the tentative CFs derived from the metabolism studies, a risk for the consumers is unlikely. The feeding study suggests to lower the existing MRLs for products of poultry origin. These proposals cover the CXLs for poultry fat (0.2 mg/kg) and eggs (0.01 mg/kg). Further risk management considerations needed, taking into account that the data gap was only partially addressed

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|------------|----------------|--------------|---------------------------|
| 1016020 | Poultry, fat | 1 (ft 3) | 0.3 (further risk manager consideration required) | |
| 1016030 | Poultry, liver | 0.2 (ft 3) | 0.06 (further risk manager consideration required) | |
| 1016040 | Poultry, kidney | 0.02* | 0.01* (further risk manager consideration required) | |
| 1016050 | Poultry, edible offal | 1 | 0.3 (further risk manager consideration required) | |
| 1016990 | Poultry, other tissues | 0.02* | 0.01* (further risk manager consideration required) | |
| 1030000 | Birds eggs | 0.2 (ft 3) | 0.05 (further risk manager consideration required) | |
| 0231020 | Sweet peppers/bell peppers | 2 | Further risk management consideration required | |
| 0251020 | Lettuces | 10 | | |
| 0251030 | Escaroles/broad-leaved endives | 10 | | |
| 0252030 | Chards/beet leaves | 15 | | |
| 0255000 | Witloofs/Belgian endives | 10 | | |

MRL: maximum residue level; SEU: southern Europe; NEU: northern Europe; ARfD: acute reference dose; CXL: Codex maximum residue limit.
*: 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.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(F): Fat-soluble.

ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap Nos 3 and 4).

ft 2: The European Food Safety Authority identified some information on the nature of residues in processed commodities as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 5).

ft 3: The European Food Safety Authority identified some information on feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 6).
Table of contents

Abstract ................................................................................................................................................... 1
Summary ................................................................................................................................................. 3
Assessment .............................................................................................................................................. 7
1. Residues in plants ........................................................................................................................ 8
   1.1. Nature of residues and methods of analysis in plants .............................................................. 8
   1.1.1. Nature of residues in primary crops ....................................................................................... 8
   1.1.2. Nature of residues in rotational crops .................................................................................... 8
   1.1.3. Nature of residues in processed commodities ........................................................................ 8
   1.1.4. Methods of analysis in plants .................................................................................................. 8
   1.1.5. Stability of residues in plants .................................................................................................. 8
   1.1.6. Proposed residue definitions ................................................................................................... 8
   1.2. Magnitude of residues in plants .................................................................................................. 8
       1.2.1. Broccoli and cauliflower ....................................................................................................... 8
       1.2.2. Globe artichoke .................................................................................................................... 9
   1.3. Magnitude of residues in processed commodities ....................................................................... 9
   1.4. Proposed MRLs ........................................................................................................................ 9
2. Residues in livestock ......................................................................................................................... 9
   2.1. Nature of residues ...................................................................................................................... 9
   2.2. Methods of analysis in livestock ................................................................................................. 10
   2.3. Magnitude of residues in livestock ............................................................................................. 10
       2.3.1. Proposed MRLs ..................................................................................................................... 10
3. Consumer risk assessment .............................................................................................................. 10
4. Conclusion and Recommendations ................................................................................................. 11
References ............................................................................................................................................... 11
Abbreviations ........................................................................................................................................... 12
Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data ....................... 14
Appendix B – List of end points ............................................................................................................ 15
Appendix C – Pesticide Residue Intake Model (PRIMO) .................................................................... 22
Appendix D – Input values for the exposure calculations ................................................................. 25
Appendix E – Used compound codes ................................................................................................. 28
Assessment

The review of existing maximum residue levels (MRLs) for the active substance spinosad\(^1\) according to Article 12 of Regulation (EC) No 396/2005\(^2\) (MRL review) has been performed in 2012 (EFSA, 2012a,b). The European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2015/603\(^3\), including footnotes for the tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 17 April 2017.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016), the applicant, Dow AgroSciences Ltd, submitted an application to the competent national authority in the Netherlands (designated rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided residue field trials on flowering brassica and globe artichokes, a study investigating the nature of residues in processed commodities, processing studies in spinaches and cereals and a poultry feeding study. It is noted that all these data except the processing studies on cereals were also assessed in the peer review in the context of the renewal of the approval of spinosad (EFSA, 2018). The applicant also submitted information related to cucurbits with edible and inedible peel in order to address data gaps relevant for national authorisations of plant protection products containing spinosad. Since this information is not expected to have an impact on the existing MRLs, they have not been assessed under the current application.

EFSA recently finalised the peer review related to the renewal of the approval of the spinosad under Regulation (EC) No 1107/2009 and published the EFSA conclusion in May 2018 (EFSA, 2018). A decision on the renewal of the approval has not yet been taken.

EFSA based its assessment on the evaluation report submitted by the RMS (Netherlands, 2018), the reasoned opinion on the MRL review and the conclusion on the peer of the pesticide risk assessment of the active substance spinosad in accordance with Regulation (EC) No 1107/2009 (EFSA, 2012a, 2018) and additional assessments of spinosad performed after the MRL review (EFSA, 2012b, 2013). For this application, the data requirements established in Regulation (EU) No 544/2011\(^4\) and the relevant guidance documents at the date of publication of the confirmatory data requirements by Regulation (EU) No 2015/603 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\(^5\).

A detailed description of the good agricultural practices (GAPs) for the uses of spinosad, which are relevant for the confirmatory data evaluation, is reported in Appendix A. The applicant proposed a slightly revised GAP with a higher application rate of 120 g/ha compared to the European Union (EU) GAPs on globe artichokes assessed in the MRL review (application rate was 100 g/ha) and three instead of four applications for the Southern EU use.

An updated list of end points, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B. It is highlighted that in the framework of the EU pesticides peer review of spinosad (renewal of the approval), the derivation of an acute reference dose (ARFD) was considered necessary and that more complex residue definitions for risk assessment for plant and animal commodities were proposed (EFSA, 2018). The application to assess the confirmatory data was submitted before the EFSA conclusion was published.

---

1. The structural formula of the parent compound and its major components and metabolites is reported in Appendix E.
2. 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.
3. Commission Regulation (EU) 2015/603 of 13 April 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-naphthylxoyacetic acid, acetochlor, chloropicrin, diflufenican, fluopicoloid, flutolanil and spinosad in or on certain products. OJ L 100, 17.4.2015, p. 10–59.
4. Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
5. Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
The evaluation report submitted by the RMS (Netherlands, 2018) and the exposure calculation using the EFSA pesticides Residues Intake Model (PRIMo) are considered a supporting document to this reasoned opinion and, thus, are made publicly available as a background document to this reasoned opinion.

1. **Residues in plants**

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

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

Not relevant for the current assessment.

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

Not relevant for the current assessment.

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

In order to address data gap number 5,6 a study investigating the effect of processing on the nature of spinosad residues was submitted. This study was previously assessed in the framework of the EU pesticides peer review renewal process (EFSA, 2018). Spinosyn A and spinosyn D, the two components of spinosad, were individually tested and found to be stable under pasteurisation, boiling and baking conditions. Under sterilisation conditions, they degraded to form the 17-pseudoaglycone spinosyn A and 17-pseudoaglycone spinosyn D (up to 14% of applied radioactivity).

The confirmatory data related to the investigation on the nature of residues in processed products (data gap number 5) was formally addressed.

1.1.4. **Methods of analysis in plants**

Not relevant for the current assessment.

1.1.5. **Stability of residues in plants**

Not relevant for the current assessment.

1.1.6. **Proposed residue definitions**

For the current assessment of confirmatory data (MRL review), the residue definition for enforcement and risk assessment derived for in the framework of the MRL review is still applicable (i.e. ‘sum of spinosyn A and spinosyn D’) (EFSA, 2012a).

It is noted that based on new metabolism studies conducted with spinosyn A and D on tomatoes and cabbages which were found to produce a different metabolic pattern compared to the findings of the previously assessed metabolism studies (assessed in the framework of the MRL review), the EU pesticides peer review provisionally proposed a more complex residue definition for risk assessment in plants, i.e. ‘sum of spinosyn A, spinosyn D, spinosyn B, spinosyn K’ (EFSA, 2018). Since the residue definition was proposed on a provisional basis and certain supporting data are still missing, a formal decision on the implementation of the residue definition and timelines for submitting the supporting information needs to be agreed with risk managers.

1.2. **Magnitude of residues in plants**

1.2.1. **Broccoli and cauliflower**

In order to address data gap number 3,7 the applicant provided two additional residue trials on broccoli and two additional residue trials on cauliflowers conducted in the SEU. The residue trials were previously assessed in the framework of the renewal of the approval of spinosad (EU pesticides peer review) (EFSA, 2018).

---

6 Data gap number 5: Studies about the nature of residues in processed commodities.

7 Data gap number 3: Two additional residues trials performed on cauliflowers supporting the southern outdoor GAP on cauliflowers and broccoli.
Both the old and new residue trials on cauliflowers were conducted with a lower number of applications (3 instead of 4) compared to the critical GAP assessed in the MRL review. Trials on broccoli were fully compliant with the authorised GAP (i.e. 4 applications). Some of the residue trials were designed as decline studies, with samples taken before the last application of spinosad and different intervals after the last treatment. Considering that in the residue decline studies no quantifiable residues were found (< 0.02 mg/kg) before the last application, the additional application is not expected to significantly impact the final residues of spinosad at harvest and the deviation was accepted (EFSA, 2012a, 2018).

Based on the combined data set of available residue data on broccoli and cauliflowers, EFSA concluded that a lower MRL of 0.5 mg/kg for the SEU use on flowering brassica is appropriate.

1.2.2. Globe artichoke

As regards data gap number 4, new residue trials were not submitted. Instead, the applicant provided a revised GAP (see Appendix A) and referred to the residue trials previously assessed in the framework of the renewal of the approval of spinosad (EU pesticides peer review) (EFSA, 2018). Results from NEU and SEU residue trials were combined to derive a more robust MRL, since they were demonstrated to belong to the same statistical population.

The available residue trials confirmed the previously derived tentative MRL of 0.15 mg/kg.

1.3. Magnitude of residues in processed commodities

Data on the magnitude of residues in processed commodities were not requested as confirmatory data in Regulation (EU) No 2015/603. However, it should be noted that in the framework of the renewal of the approval of spinosad processing studies in spinaches were assessed (EFSA, 2018). Under this application, additional processing studies investigating the magnitude of residues in cereals were submitted (Netherlands, 2018).

Samples of wheat and barley treated post-harvest with a dose equivalent to 0.99 g/tonnes were then processed (milling for wheat and barley; malting and brewing for barely) and analysed for spinosyn A and spinosyn D. In the processed products, a concentration of spinosad residues (sum of spinosyn A and spinosyn D) was not observed. An additional processing study on wheat, maize and rice after foliar use (3 applications at 1,064 g/ha) was not considered valid since samples were stored for a period exceeding the demonstrated storage stability.

Due to the limited number of processing studies, EFSA does not recommend to include the derived PF factors in Annex VI of Regulation (EC) No 396/2005.

1.4. Proposed MRLs

The previously derived tentative MRL for globe artichokes is confirmed; the data submitted in support of broccoli and cauliflowers suggested a lower MRL for the authorised SEU use which may be extrapolated to the whole group of flowering brassica. It is noted that the authorised NEU use on flowering brassica assessed in the MRL review, which was fully supported by data, resulted in a higher MRL (0.8 mg/kg).

The confirmatory data submitted for spinaches and cereals do not have an impact on the MRL levels.

2. Residues in livestock

2.1. Nature of residues

No new information was requested as confirmatory data in the framework of the MRL review (EFSA, 2012a); the following residue definitions were derived for food of animal origin:

Ruminants: the residue for both enforcement and risk assessment in ruminants was defined as ‘spinosad (sum of spinosyn A and spinosyn D)’.

Poultry: the residue for enforcement and risk assessment was defined as ‘spinosad (sum of spinosyn A and spinosyn D)’, except for poultry liver and eggs, for which the risk assessment residue definition was proposed as ‘spinosad (sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and

---

8 Data gap number 4: Four residue trials supporting the northern outdoor GAP on globe artichokes.
N-demethylated spinosyn D). Tentative conversion factors for risk assessment of 4 (poultry liver) and 1.5 (eggs) were derived from the metabolism studies.

It is noted that in the context of the renewal of the approval for spinosad (peer review process), more complex residue definitions for risk assessment were proposed on a provisional basis for animal products, i.e. sum of 'spinosyn A, spinosyn D, spinosyn B and N-demethyl spinosyn D' for poultry; and 'sum of spinosyn A, spinosyn D, spinosyn B, N-demethyl spinosyn D and MET A-Li-4 (5b)' for ruminants (EFSA, 2018). Since the residue definitions were proposed on a provisional basis and certain supporting data are still missing, a formal decision on the implementation of the residue definition and timelines for submitting the supporting information needs to be agreed with risk managers.

For the current assessment of the confirmatory data identified in the MRL review, the previously derived residue definitions (EFSA, 2012a) are considered to be still applicable.

2.2. **Methods of analysis in livestock**

No new information was requested as confirmatory data in the framework of the MRL review.

2.3. **Magnitude of residues in livestock**

In order to address data gap number 6,9 the applicant provided a poultry feeding study which was previously assessed in the framework of the process of renewal of spinosad (peer review process) (EFSA, 2018).

Laying hens were dosed at levels of 0.1, 0.3, 1 and 5 mg/kg in feed for 41 days (equivalent to 0.007, 0.020, 0.068 and 0.340 mg/kg body weight (bw) per day), representing 0.1N, 0.3N, 0.9N and 4.7N of the estimated maximum dietary burden in poultry (0.078 mg/kg bw, EFSA, 2013).

Samples of muscle, fat, liver and eggs were analysed for spinosyn A and spinosyn D. The study was appropriate to derive MRL proposals in poultry tissues and eggs. However, since the samples of liver and eggs were not analysed for the metabolites O-demethylated spinosyn D and N-demethylated spinosyn D, the study does not allow deriving conversion factors (CF) for risk assessment for poultry liver and eggs.

Overall, the data gap identified in the MRL review has been only partially addressed.

2.3.1. **Proposed MRLs**

Based on the findings of the feeding study on poultry and considering the maximum dietary burden estimated in the framework of the MRL review, EFSA concluded that the tentative MRLs set for commodities of poultry origin under Regulation (EU) 2015/603 may be lowered.

A validated analytical method is available to enforce MRLs at or above the limit of quantification (LOQ) of 0.01 mg/kg (combined LOQ for the sum of spinosyn A and D) (EFSA, 2018).

For poultry liver and eggs, CF for risk assessment could not be derived from the feeding study submitted. EFSA proposed to apply the CF used in the framework of the MRL review until a final residue definition for poultry products is established.

3. **Consumer risk assessment**

In the framework of the MRL review a comprehensive long-term exposure assessment was performed with revision 2 of the EFSA PRIMo taking into account the existing uses of spinosad at the EU level and the CXLs set for certain commodities (EFSA, 2012a). EFSA now updated this risk assessment with the median residue values for flowering brassica, globe artichokes and poultry products derived in the current assessment and the median residue values proposed by EFSA in reasoned opinions approved after the MRL review (EFSA, 2012b, 2013). To accommodate for the risk assessment residue definition for poultry liver and eggs, the conversion factor derived from the metabolism study was used (EFSA, 2012a). The estimated long-term dietary intake of spinosad was in the range of 4–60% of the ADI (WHO Cluster diet B).

In 2013, when the most recent consumer risk assessment was performed, the setting of an acute reference dose was not considered necessary. However, in the meantime, in the framework of the renewal of the approval of spinosad (EU pesticides peer review) an ARfD of 0.1 mg/kg bw was

---

9 Data gap number 6: A poultry feeding study in order to derive appropriate MRLs and conversion factors for this group of livestock.
proposed (EFSA, 2018), which has not yet been formally adopted by the European Commission. EFSA performed an acute risk assessment for the crops under consideration for confirmatory data. The calculated short-term exposure to residues in flowering brassica, globe artichokes and poultry products did not exceed the ARfD. For spinaches, an exceedance of the ARfD was noted (181% of the ARfD).

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

EFSA also confirms the results of the acute risk assessment presented in the EFSA conclusion (EFSA, 2018) with regard to certain uses assessed under the MRL review, for which an exceedance of the ARfD was identified, i.e. peppers (108%), lettuces (141%), scarole (498%), beet leaves/chard (141%) and witloofs (264%).

4. Conclusion and Recommendations

In order to address data gaps identified in the framework of the MRL review, the applicant submitted residue trials on globe artichokes, flowering brassica, a study investigating the effect of processing on the nature of spinosad residues and a poultry feeding study. The data gaps are considered to be addressed, except the information needed to derive CF for risk assessment for poultry liver and eggs to replace the tentative conversion factors obtained from the metabolism study. The new information provided justifies the lowering of the MRLs for flowering brassica and products of poultry origin. The previously derived tentative MRLs for globe artichokes and cereals are confirmed.

The chronic risk assessment performed for spinosad was updated; EFSA also performed an acute risk assessment, taking into account the acute reference dose (ARfD) derived for spinosad during the process of renewal of the approval of the active substance (EU pesticides peer review). Since for spinach a potential acute consumer intake concern was identified, the lowering of the existing MRL is recommended. For the remaining commodities assessed under this application (globe artichokes, flowering brassica, products derived from poultry), a consumer intake concern was not identified.

For a number of additional commodities for which MRLs have been established previously but which are not subject of the current assessment, EFSA also recommends a re-evaluation taking into account the results of the acute risk assessment based on the recently derived ARfD.

The MRLs for spinosad and the consumer risk assessment should be reconsidered taking into account the outcome of the detailed evaluation of the information that needs to be provided to address the data gaps identified in the framework of the EU pesticides peer review (renewal for spinosad) and the conclusion on residue definitions.

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

References

EFSA (European Food Safety Authority), 2011. Reasoned Opinion on the modification of the existing MRLs for spinosad in various crops. EFSA Journal 2011;9(9):2352, 30 pp. https://doi.org/10.2903/j.efsa.2011.2352

EFSA (European Food Safety Authority), 2012a. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for spinosad according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(3):2630, 89 pp. Available online: www.efsa.europa.eu/efsajournal. https://doi.org/10.2903/j.efsa.2012.2630

EFSA (European Food Safety Authority), 2012b. Reasoned opinion on the modification of the existing MRLs for spinosad in celery, fennel, raspberries and blackberries. EFSA Journal 2012;10(6):2770, 27 pp. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2013. Reasoned opinion on the modification of the existing MRLs for spinosad in small fruit and berries and several commodities of animal origin. EFSA Journal 2013;11(11):3447, 38 pp. Available online: www.efsa.europa.eu/efsajournal

EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance spinosad. EFSA Journal 2018;16(5):5252, 33 pp. https://doi.org/10.2903/j.efsa.2018.5252
European Commission, 2006. Review report for the active substance spinosad Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 14 July 2006 in view of the inclusion of spinosad in Annex I of Directive 91/414/EEC. SANCO/1428/2001 – rev. final 14 July 2006.

European Commission, 2016. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3pp., Brussels, 17 June 2016.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.3, 13 June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2001. Spinosad In: Pesticide residues in food. Evaluations 2001. Part I - Residues. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 171, 707–861.

FAO (Food and Agriculture Organization of the United Nations), 2004. Spinosad In: Pesticide residues in food. Evaluations 2001. Part I - Residues. Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 178, 226–231.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.

FAO (Food and Agriculture Organization of the United Nations), 2011. Spinosad: In: Pesticide residues in food – 2011. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues. FAO Plant Production and Protection Paper 211, 255–259 and 418–423.

Netherlands, 2018. Evaluation report on confirmatory data for the evaluation of MRLs for Spinosad according to Article 12 of Regulation (EC) No 396/2005. April 2018, as revised in September, 2018, 44 pp.

Abbreviations

- a.s. active substance
- ADI acceptable daily intake
- ARfD acute reference dose
- BBCH growth stages of mono- and dicotyledonous plants
- bw body weight
- CF conversion factor for enforcement to risk assessment residue definition
- CXL Codex maximum residue limit
- DAR draft assessment report
- DAT days after treatment
- FAO Food and Agriculture Organization of the United Nations
- GAP Good Agricultural Practice
- HR highest residue
- IEDI international estimated daily intake
- IESTI international estimated short-term intake
- InChIKey International Chemical Identifier Key
- IUPAC International Union of Pure and Applied Chemistry
- LOQ limit of quantification
- Mo monitoring
- MRL maximum residue level
- MS Member States
- NEU northern Europe
- OECD Organisation for Economic Co-operation and Development
- PeelF peeling factor
- PF processing factor
- PHI preharvest interval
- PRIMO (EFSA) Pesticide Residues Intake Model
- RA risk assessment
- RD residue definition
- RMS rapporteur Member State
- SANCO Directorate-General for Health and Consumers
- SC suspension concentrate
- SEU southern Europe

www.efsa.europa.eu/efsajournal 12 EFSA Journal 2019;17(2):5592
| Acronym | Description                                      |
|---------|--------------------------------------------------|
| STMR    | supervised trials median residue                |
| TAR     | total applied radioactivity                      |
| WHO     | World Health Organization                        |
## Appendix A – Summary of GAPs assessed in the evaluation of confirmatory data

| 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                     | g a.s./hL min–max | Water L/ha min–max | Rate Unit |          |
| Broccoli              | SEU (IT)                | F            | Insects                           | SC          | 480 g/hL    | Foliar                          | BBCH 19–49(e)    | 1–4     | 0.10 kg/ha | 3         |
| Cauliflower           | SEU (IT)                | F            | Insects                           | SC          | 480 g/hL    | Foliar                          | BBCH 19–49(e)    | 1–4     | 0.10 kg/ha | 3         |
| Globe artichokes      | NEU                     | F            | Insects                           | SC          | 480 g/hL    | Foliar                          | BBCH 10–49       | 1–3     | 0.120 kg/ha 7 | MRL review assessed a GAP with an application rate of 100 g/ha |
|                       | SEU                     | F            | Insects                           | SC          | 480 g/hL    | Foliar                          | BBCH 10–49       | 1–3     | 0.120 kg/ha 7 | MRL review assessed a GAP with an application rate of 100 g/ha and with 4 applications |

**GAP:** Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SC: suspension concentrate; MRL: maximum residue level.

(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.

(e): A typo was spotted for the upper range of the BBCH growth stage (reported as "99") in the GAP table of the reasoned opinion on the review of the existing MRLs for spinosad (EFSA, 2012a).
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. Residue definitions in plants

The residue definition for risk assessment as established in the framework of the MRL review apply to the confirmatory data.

| Plant residue definition for monitoring (RD-Mo) | Spinosad, sum of spinosyn A and spinosyn D |
|-----------------------------------------------|------------------------------------------|
| Plant residue definition for risk assessment (RD-RA) | **MRL review:** Spinosad, sum of spinosyn A and spinosyn D (EFSA, 2012a) |
| | **Peer review (renewal of the approval for spinosad):** Sum of spinosyn A, spinosyn D, spinosyn B, spinosyn K (provisional)\(^{(a)}\) (EFSA, 2018) |

\(^{(a)}\): Pending the magnitude of residues in field trials analysed for the relevant compounds included in the risk assessment residue definition and their toxicological relevance (EFSA, 2018).

B.1.1.2. Stability of residues in plant

Not relevant for the current application.
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|------------------------|--------------------------|--------------------------|
| Broccoli  | SEU                         | EFSA (2012a,b): 0.05, 0.10, 0.14, 0.23                        | Combined data set of residue trials on broccoli and cauliflowers. Trials on broccoli with 3 instead of 4 applications; the deviation was accepted and all trials were concluded as GAP compliant. | 0.5                    | 0.27                     | 0.11                     |
| Cauliflowers | EFSA (2012a,b)<sup>(e)</sup>: 0.12 | EFSA (2018): <0.02, 0.02, <0.05 | Underlined value, higher residue observed at a longer PHI. Samples analysed for spinosyn A and D. Extrapolation to the whole group of flowering brassica is possible. |            |                          |                          |
| Globe artichoke | NEU                         | EFSA (2018): <0.02, 0.02, 0.04, 0.06 | Combined data set of NEU and SEU GAP-compliant residue trials already assessed by EFSA (2018). Underlined value, higher residue observed at a longer PHI. Samples analysed for spinosyn A and D. | 0.15                    | 0.07                      | 0.04                     |
|            | SEU                         | EFSA (2018): <0.02, 0.03, 0.04, 0.07 |                               |                          |                          |                          |

MRL: maximum residue level; GAP: Good Agricultural Practice; PHI: preharvest interval.

<sup>(a)</sup>: 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.

<sup>(b)</sup>: Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

<sup>(c)</sup>: Supervised trials median residue. The median residue for risk assessment refers to the whole commodity and not to the edible portion.

<sup>(d)</sup>: Supervised trials median residue according to the residue definition for monitoring.

<sup>(e)</sup>: Both Applicant and RMS could not retrieve the residue trial on cauliflowers supporting the value of 1.12 mg/kg reported during the MRL review (EFSA, 2012a). Assuming it was an error, the value has been excluded from the data set.
B.1.2.2. Processing factors

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Comment/Source |
|---------------------|------------------------------------|------------------------|----------------|
|                     | Individual values | Median PF | |
| Spinach, cooked leaves | 2 | 0.6; 1.1 | 0.9 | Indicative\(^{(b)}\) (EFSA, 2018) |
| Barley, pearled      | 1 | 0.06     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Barley brewing, malt | 1 | 0.52     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Barley, malt sprouts | 1 | 0.38     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Barley, beer         | 1 | < 0.02   | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Barley, brewer’s yeast | 1 | < 0.02   | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Barley, flocs        | 1 | < 0.02   | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, flour (type 550) | 1 | 0.33     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, whole meal flour | 1 | 0.78     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, bran          | 1 | 0.88     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, germ          | 1 | 0.42     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, middlings     | 1 | 0.17     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, shorts        | 1 | 0.37     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, gluten (dried) | 1 | 0.97     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, gluten feed meal | 1 | 0.49     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |
| Wheat, starch (dried) | 1 | 0.04     | –   | Indicative\(^{(b)}\) (Netherlands, 2018) |

(a): Two trials with grains treated post-harvest and processed at the same time and in the same location were considered as not independent (Netherlands, 2018). The mean value of the two trials is reported. Samples analysed for spinosyn A and spinosyn D only.

(b): An indicative PF is derived due to the limited data set.

B.2. Residues in livestock

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

The residue definition for risk assessment as established in the framework of the MRL review apply to confirmatory data.

Animal residue definition for monitoring (RD-Mo)

Spinosa, sum of spinosyn A and spinosyn D

Animal residue definition for risk assessment (RD-RA)

| MRL review: | Ruminants/Swine/Poultry (except liver and eggs) spinosad, sum of spinosyn A and spinosyn D (EFSA, 2012a) |
| Poultry, liver and eggs: | Spinosad, sum of spinosyn A, spinosyn D, O-demethylated spinosyn D and N-demethylated spinosyn D (EFSA, 2012a) |

Peer review (renewal of the approval for spinosad)

| Ruminants: | Sum of spinosyn A, spinosyn D, spinosyn B, N-demethyl spinosyn D and MET A-Li-4(5b) (provisional)\(^{(0)}\) (EFSA, 2018) |
| Poultry: | sum of spinosyn A, spinosyn D, spinosyn B and N-demethyl spinosyn D (provisional)\(^{(0)}\) (EFSA, 2018) |

Fat soluble residues

| Yes | EFSA (2012a) |

(a): Pending the outspending data gaps identified in the framework of the EU pesticides peer review renewal (EFSA, 2018).
### B.2.1.2. Stability of residues in livestock

Not relevant for the current application.

### B.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N level | MRL proposal (mg/kg) | CF | STMR (mg/kg) | HR (mg/kg) |
|------------------|-----------------------------------------------|-----------------------------|----------------------|----|---------------|------------|
|                  | Mean (mg/kg) | Highest (mg/kg) | STMR<sub>Mo</sub> (mg/kg) | HR<sub>Mo</sub> (mg/kg) |    |       |       |
| **Poultry (all diets)** | | | | | | | |
| Closest feeding level<sup>(a)</sup>: | | | | | | | |
| Meat<sup>(b)</sup> | 0.020 | 0.020 | 0.026 | 0.026 | 0.03 | 1.0 | 0.03 0.03 |
| Muscle | 0.165 | 0.183 | 0.032 | 0.309 | 0.3 | 1.0 | 0.03 0.31 |
| Fat | 0.032 | 0.053 | 0.037 | 0.057 | 0.06 | 4.0<sup>(c)</sup> | 0.15 0.23 |
| Liver | | | | | | | |
| **Poultry (layer only)** | | | | | | | |
| Closest feeding level<sup>(a)</sup>: | | | | | | | |
| Eggs<sup>(d)</sup> | 0.022 | 0.023 | 0.043 | 0.046 | 0.05 | 1.5<sup>(c)</sup> | 0.06 0.07 |

**STMR**: supervised trials median residue; **HR**: highest residue; **MRL**: maximum residue level; **CF**: conversion factor; **bw**: body weight; **Mo**: monitoring.

<sup>(a)</sup> Closest feeding level and N dose rate related to the maximum dietary burden.

<sup>(b)</sup> The median and highest residue values were calculated considering 90% of the residue derived for muscle and 10% of the residue derived for fat (FAO, 2009).

<sup>(c)</sup> Tentative conversion factors for risk derived from the metabolism study on laying hens (EFSA, 2012a).

<sup>(d)</sup> Highest residue level from at day 35 for laying hens.

### B.3. Consumer risk assessment

| ARfD | Not necessary (European Commission, 2006) 0.1 mg/kg bw (EFSA, 2018) |
|------|-------------------------------------------------------------------|

| Highest IESTI, according to EFSA PRIMO | Broccoli: 16% of ARfD (SEU use); 46% of ARfD (NEU use) | Cauliflowers: 18% of ARfD (SEU use); 52% of ARfD (NEU use) | Spinaches: 181% of ARfD | Globe artichokes: 1.4% of ARfD | Poultry tissues: 0.9% of ARfD (meat) | Eggs: 0.9% of ARfD |

**Assumptions made for the calculations**

The calculation is based on the highest residue levels expected for the crop assessed and for the edible products of poultry. The tentative CF of 4 (poultry liver) and 1.5 (eggs) were applied. Risk assessment conducted according to the residue definition for plant and animal products derived in the MRL review.
### ADI

0.024 mg/kg bw per day (European Commission, 2006)

### Highest IEDI, according to EFSA PRIMo

- 60% ADI (WHO Cluster diet B)
- Contribution of crops assessed:
  - Broccoli: 0.18% of ADI
  - Cauliflowers: 0.21% of ADI
  - Spinaches: 14% of ADI
  - Globe artichokes: 0.03% of ADI
  - Poultry tissues: 0.16% of ADI (meat)
  - Eggs: 0.34% of ADI

### Assumptions made for the calculations

The calculation is based on the median residue levels derived in the raw agricultural commodities that were assessed in the current and previous assessment (EFSA, 2012a, b, 2013), applying a peeling factor for citrus. The tentative CF of 4 (poultry liver) and 1.5 (eggs) were applied.

Risk assessment conducted according to the residue definition for plant and animal products derived in the MRL review.

The contribution of commodities where no GAP or safe CXLs was reported in the framework of the MRL review and subsequent Art 10 MRL assessments were not included in the calculation.

---

### B.4. Recommended MRLs

| Code(a)  | Commodity      | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                 |
|---------|----------------|-----------------|--------------|------------------------------------------------------------------------------------------|
| 0241000 | Flowering brassica | 2 (ft 1)        | 0.8 (further risk management consideration required)                                         |
| 0241010 | Broccoli       | 2 (ft 1)        |              |                                                                                           |
| 0241020 | Cauliflower    | 2 (ft 1)        |              |                                                                                           |
| 0241990 | Others flowering brassica | 2 (ft 1) |                                                                                           |

**Enforcement residue definition:** Spinosad (spinosad, sum of spinosyn A and spinosyn D)(f)

The data gap identified by EFSA has been addressed. Based on the available data on broccoli and cauliflowers, a lower MRL of 0.5 mg/kg is derived for the SEU use on flowering brassica.

It is highlighted that in the MRL review EFSA derived a MRL proposal of 0.8 mg/kg for the NEU use on flowering brassica, which was fully supported by data. Thus, data would justifiy the lowering of the existing MRL. According to the results of the risk assessment performed for the residue definitions derived under the MRL review, a risk for the consumers is unlikely.

In the risk management discussion on the lowering of the current MRL, the following points should be noted:
- Member States may have granted authorisations for more critical uses than the ones assessed in this reasoned opinion which require maintaining the existing MRL of 2 mg/kg.
| Code(a) | Commodity          | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                 |
|--------|--------------------|----------------|---------------|-----------------------------------------------------------------------------------------|
| 0252010 | Spinaches         | 15 (ft 2)      | Further risk management consideration required | The data gap identified by EFSA concerning investigation on the nature of residues of spinosad in processing products has been addressed. The current MRL of 15 mg/kg is sufficiently supported by data. A long-term risk for the consumers is unlikely, considering the residue definition for risk assessment in plants and animals derived in the MRL review. Considering the ARfD derived recently in the framework of the process of renewal of spinosad (EU peer review), an acute intake concern was identified. Further risk management measures are recommended |
| 0270050 | Globe artichokes | 0.15 (ft 1)   | 0.15          | The data gap identified by EFSA has been addressed. The MRL is confirmed. According to the results of the risk assessment performed for the residue definitions derived under the MRL review, a risk for the consumers is unlikely |
| 0500000 | Cereals           | 2 (ft 2)       | 2             |                                                                                          |
| 0500010 | Barley            | 2 (ft 2)       | 2             | The data gap identified by EFSA concerning investigation on the nature of residues of spinosad in processing products has been addressed. The MRL is confirmed. According to the results of the risk assessment performed for the residue definitions derived under the MRL review, a risk for the consumers is unlikely |
| 0500000 | Maize/corn        | 2 (ft 2)       | 2             |                                                                                          |
| 0500040 | Common millet     | 2 (ft 2)       | 2             |                                                                                          |
| 0500050 | Oat               | 2 (ft 2)       | 2             |                                                                                          |
| 0500060 | Rice              | 2 (ft 2)       | 2             |                                                                                          |
| 0500070 | Rye               | 2 (ft 2)       | 2             |                                                                                          |
| 0500080 | Sorghum           | 2 (ft 2)       | 2             |                                                                                          |
| 0500090 | Wheat             | 2 (ft 2)       | 2             |                                                                                          |
| 0500990 | Others cereals    | 2 (ft 2)       | 2             |                                                                                          |
| 1016010 | Poultry, muscle   | 0.2 (ft 3)     | 0.03 (further risk manager consideration required) | The data gap identified by EFSA concerning a feeding study in poultry has been partially addressed. The new study was provided but it does not allow deriving conversion factors (CF) for risk assessment for poultry liver and eggs since the samples have not been analysed for the two metabolites included in the residue definition for risk assessment (i.e. O-demethylated spinosyn D and N-demethylated spinosyn D). According to the risk assessment performed for the residue definitions derived under the MRL review and the tentative CFs derived from the metabolism studies, a risk for the consumers is unlikely. The feeding study suggests to lower the existing MRLs for products of poultry origin. These proposals cover the CXLs for poultry fat (0.2 mg/kg) and eggs (0.01 mg/kg). Further risk management considerations needed, taking into account that the data gap was only partially addressed |
| 1016020 | Poultry, fat      | 1 (ft 3)       | 0.3 (further risk manager consideration required) |                                                                                          |
| 1016030 | Poultry, liver    | 0.2 (ft 3)     | 0.06 (further risk manager consideration required) |                                                                                          |
| 1016040 | Poultry, kidney   | 0.02*          | 0.01* (further risk manager consideration required) |                                                                                          |
| 1016050 | Poultry, edible offal | 1             | 0.3 (further risk manager consideration required) |                                                                                          |
| Code(a) | Commodity                  | Existing MRL(b) | Proposed MRL              | Conclusion/recommendation                                                                 |
|--------|----------------------------|-----------------|---------------------------|------------------------------------------------------------------------------------------|
| 1016990 | Poultry, other tissues     | 0.02*           | 0.01* (further risk manager consideration required) |                                                                                         |
| 1030000 | Birds eggs                 | 0.2 (ft 3)      | 0.05 (further risk manager consideration required) | EFSA confirms the previously derived recommendation (EFSA conclusion) to review of the MRLs for the mentioned commodities because a potential short-term consumer health risk cannot be excluded, considering the recently derived ARfD |
| 0231020 | Sweet peppers/bell peppers | 2               | Further risk management consideration required |                                                                                         |
| 0251020 | Lettuces                   | 10              |                           |                                                                                         |
| 0251030 | Escaroles/broad-leaved endives | 10             |                           |                                                                                         |
| 0252030 | Chards/beet leaves         | 15              |                           |                                                                                         |
| 0255000 | Witloofs/Belgian endives   | 10              |                           |                                                                                         |

MRL: maximum residue level; SEU: southern Europe; NEU: northern Europe; ARfD: acute reference dose; CXL: Codex maximum residue limit.

*: 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.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(F): Fat-soluble.

ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap Nos 3 and 4).

ft 2: The European Food Safety Authority identified some information on the nature of residues in processed commodities as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 5).

ft 3: The European Food Safety Authority identified some information on feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 6).
Appendix C – Pesticide Residue Intake Model (PRIMo)

| Commodity/group of commodities | TMDI values in % of ADI | No of diets exceeding ADI: | 3rd contributor to MS diet (in % of ADI) |
|--------------------------------|-------------------------|---------------------------|-----------------------------------------|
| Wheat                         | 60.0 WHO Cluster diet B | 24.9                      | 7.2 Milk                                  |
| Milk and cream                |                         | 15.9                      | 13.8 Wheat                                |
| Lettuce                       |                         | 21.0                      | 7.6 Wheat                                 |
| Milk and cream                |                         | 7.2                       | 14.4 Spinach                              |
| Lettuce                       |                         |                           | 7.6 Wheat                                 |
| Spinach                       |                         |                           | 6.8 Milk and cream                        |
| Milk and cream                |                         |                           | 4.2 Spinach                               |
| Wheat                         |                         |                           | 3.8 Bananas                               |
| Milk and cream                |                         |                           | 6.8 Milk and cream                        |
| Lettuce                       |                         |                           | 4.4 Other cereal                          |
| Milk and cream                |                         |                           | 1.6 Rice                                  |
| Lettuce                       |                         |                           | 2.1 Parsley                               |
| Wheat                         |                         |                           | 2.8 Milk and cream                        |
| Milk and cream                |                         |                           | 2.8 Bananas                               |
| Milk and cream                |                         |                           | 5.0 Other cereals                         |
| Lettuce                       |                         |                           | 2.2 Rye                                   |
| Milk and cream                |                         |                           | 2.7 Milk and cream                        |
| Lettuce                       |                         |                           | 2.1 Other cereal                          |
| Milk and cream                |                         |                           | 4.7 Bananas                               |
| Lettuce                       |                         |                           | 2.9 Spinach                               |
| Milk and cream                |                         |                           | 1.4 Matoes                                |
| Lettuce                       |                         |                           | 1.5 Milk and cream                        |
| Milk and cream                |                         |                           | 1.8 Milk and cream                        |
| Lettuce                       |                         |                           | 2.0 Rye                                   |
| Milk and cream                |                         |                           | 2.1 Milk and cream                        |
| Lettuce                       |                         |                           | 1.6 Milk and cream                        |
| Wheat                         |                         |                           | 2.0 Rye                                   |
| Milk and cream                |                         |                           | 0.4 Apples                                |
| Milk and cream                |                         |                           |                                          |
| Lettuce                       |                         |                           |                                          |

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of spinosad is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

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.

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.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.
| Processed commodities | pTMRL (mg/kg) | ARfD/ADI | pTMRL (mg/kg) |
|-----------------------|--------------|----------|--------------|
| Elderberry juice      | 1.5/-        | 0.96/-   | 2.1          |
| Wheat flour           | 2/-          |          |              |
| Grape juice           | 0.5/-        |          |              |
| Apple juice           | 0.3/-        |          |              |
| Currant juice         | 1.5/-        |          |              |
| Tomato juice          | 0.7/-        |          |              |
| Peach juice           | 0.6/-        |          |              |
| Maize flour           | 2/-          |          |              |

***) pTMRL: provisional temporary MRL for unprocessed commodity.

Conclusion:
For Spinusad, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short term intake (ESTI 1) exceeded the ARfD/ADI for 6 commodities. For processed commodities, no exceedance of the ARfD/ADI was identified. Also, the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 4 commodities.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not applicable.

D.2. Input values for the exposure calculations

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               |
|                                  |                         |                       |
| Citrus fruits                    | 0.01                    | STMR × PeelF (EFSA, 2012a) |
| Tree nuts                        | 0.03                    | STMR (FAO, 2011)      |
| Pome fruits                      | 0.05                    | STMR (EFSA, 2012a)    |
| Apricots, Peaches                | 0.21                    | STMR (EFSA, 2012a)    |
| Cherries, Plums                  | 0.03                    | STMR (EFSA, 2012a)    |
| Table, wine grapes               | 0.08                    | STMR (EFSA, 2012a)    |
| Strawberries                     | 0.12                    | STMR (EFSA, 2012a)    |
| Blackberries                     | 0.35                    | STMR (EFSA, 2012b)    |
| Dewberries                       | 0.14                    | STMR (EFSA, 2012b)    |
| Other small fruits & berries     | 0.34                    | STMR (EFSA, 2013)     |
| Table olives                     | 0.02                    | STMR (EFSA, 2012a)    |
| Kiwi fruits                      | 0.02                    | STMR (EFSA, 2012a)    |
| Passion fruit                    | 0.23                    | STMR (FAO, 2011)      |
| Bananas                          | 0.62                    | STMR (EFSA, 2012a)    |
| Papayas                          | 0.21                    | STMR (EFSA, 2012a)    |
| Potatoes                         | 0.02                    | STMR (EFSA, 2012a)    |
| Radishes                         | 0.08                    | STMR (EFSA, 2012a)    |
| Garlic, Onions, Shallots         | 0.05                    | STMR (EFSA, 2012a)    |
| Spring onions                    | 0.20                    | STMR (FAO, 2011)      |
| Tomatoes, Aubergines             | 0.25                    | STMR (EFSA, 2012a)    |
| Peppers                          | 0.33                    | STMR (EFSA, 2012a)    |
| Cucurbits, edible peel           | 0.08                    | STMR (EFSA, 2012a)    |
| Cucurbits, inedible peel         | 0.14                    | STMR (EFSA, 2012a)    |
| Sweet corn                       | 0.01                    | STMR (EFSA, 2012a)    |
| Flowering brassica               | 0.11                    | STMR                   |
| Head brassica                    | 0.27                    | STMR (EFSA, 2012a)    |
| Chinese cabbage                  | 0.27                    | STMR (EFSA, 2012a)    |
| Kale                             | 0.54                    | STMR (EFSA, 2013)     |
| Kohlrabies                       | 0.27                    | STMR (EFSA, 2012a)    |
| Lamb’s lettuces                  | 1.90                    | STMR (EFSA, 2012a)    |
| Lettuces                         | 4.29                    | STMR (EFSA, 2012a)    |
| Scarole (broad-leaf endive)      | 1.90                    | STMR (EFSA, 2012a)    |
| Cresses, Land cresses            | 1.90                    | STMR (EFSA, 2012a)    |
| Rocket, rucola                   | 1.90                    | STMR (EFSA, 2012a)    |
| Red mustard                      | 1.90                    | STMR (EFSA, 2012a)    |
| Baby leaf crops                  | 4.90                    | STMR (EFSA, 2012a)    |
| Spinaches                        | 4.90                    | STMR (EFSA, 2012a)    |
| Commodity                              | Chronic risk assessment | Acute risk assessment |
|----------------------------------------|-------------------------|-----------------------|
|                                        | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Beet leaves (chard)                    | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Purslanes                              | 1.90 STMR (EFSA, 2012a) | 5.70 HR (FAO, 2001)   |
| Vine leaves                            | 1.90 STMR (EFSA, 2012a) | 5.70 HR (FAO, 2001)   |
| Water cress                            | 1.90 STMR (EFSA, 2012a) | 5.70 HR (FAO, 2001)   |
| Witloof                                | 1.90 STMR (EFSA, 2012a) | 5.70 HR (FAO, 2001)   |
| Chervil                                | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Chives                                 | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Celery leaves                          | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Parsley                                | 10.0 STMR (EFSA, 2012a) | 43.0 HR (EFSA, 2012a) |
| Sage, Rosemary                         | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Thyme, basil                           | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Bay leaves (laurel)                    | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Tarragon                               | 4.90 STMR (EFSA, 2012a) | 8.02 HR (EFSA, 2012a) |
| Beans (with pods)                      | 0.07 STMR (EFSA, 2012a) | 0.12 HR (EFSA, 2012a) |
| Legume vegetables, except beans with pods | 0.04 STMR (EFSA, 2012a) | 0.21 HR (FAO, 2001) |
| Celeries                               | 0.65 STMR (EFSA, 2012b) | 1.98 HR (EFSA, 2012b) |
| Fennel                                 | 0.65 STMR (EFSA, 2012b) | 1.98 HR (EFSA, 2012b) |
| Globe artichokes                       | 0.04 STMR               | 0.07 HR                |
| Leeks                                  | 0.07 STMR (EFSA, 2012a) | 0.17 HR (EFSA, 2012a) |
| Soya beans                             | 0.01 STMR (EFSA, 2012a) | 0.01 STMR (FAO, 2001) |
| Cotton seeds                           | 0.01 STMR (EFSA, 2012a) | 0.01 STMR (EFSA, 2012a) |
| Olives for oil production              | 0.02 STMR (EFSA, 2012a) | 0.02 STMR (EFSA, 2012a) |
| Cereals                                | 0.70 STMR (EFSA, 2012a) | 0.95 HR (EFSA, 2012a) |
| Swine meat                             | 0.21 STMR (EFSA, 2013)  | 0.33 HR (EFSA, 2013)  |
| Swine fat                              | 0.89 STMR (EFSA, 2013)  | 1.36 HR (EFSA, 2013)  |
| Swine liver                            | 0.34 STMR (EFSA, 2013)  | 0.61 HR (EFSA, 2013)  |
| Swine kidney                           | 0.19 STMR (EFSA, 2013)  | 0.28 HR (EFSA, 2013)  |
| Swine edible offal                      | 0.89 STMR (EFSA, 2013)  | 1.36 HR (EFSA, 2013)  |
| Bovine meat(a)                         | 0.08 STMR (FAO, 2011)   | 0.3 MRL (FAO, 2011)   |
| Bovine fat(a)                          | 0.08 STMR (FAO, 2011)   | 3 MRL (FAO, 2011)     |
| Bovine liver(a)                        | 0.66 STMR (FAO, 2011)   | 2 MRL (FAO, 2011)     |
| Bovine kidney(a)                       | 0.31 STMR (FAO, 2011)   | 1 MRL (FAO, 2011)     |
| Bovine edible offal(a)                 | 0.66 MRL (FAO, 2011)    | 3 MRL (FAO, 2011)     |
| Sheep, goat meat                       | 0.28 STMR (EFSA, 2013)  | 0.57 HR (EFSA, 2013)  |
| Sheep, goat fat                        | 1.18 STMR (EFSA, 2013)  | 2.31 HR (EFSA, 2013)  |
| Sheep, goat liver                      | 0.50 STMR (EFSA, 2013)  | 1.05 HR (EFSA, 2013)  |
| Sheep, goat kidney                     | 0.30 STMR (EFSA, 2013)  | 0.46 HR (EFSA, 2013)  |
| Sheep, goat edible offal               | 1.18 STMR (EFSA, 2013)  | 2.31 HR (EFSA, 2013)  |
| Horse meat                             | 0.28 STMR (EFSA, 2013)  | 0.57 HR (EFSA, 2013)  |
| Horse fat                              | 1.18 STMR (EFSA, 2013)  | 2.31 HR (EFSA, 2013)  |
| Horse liver                            | 0.50 STMR (EFSA, 2013)  | 1.05 HR (EFSA, 2013)  |
| Horse kidney                           | 0.30 STMR (EFSA, 2013)  | 0.46 HR (EFSA, 2013)  |
| Horse edible offal                     | 1.18 STMR (EFSA, 2013)  | 2.31 HR (EFSA, 2013)  |
| Poultry meat                           | 0.03 STMR               | 0.08 HR                |
| Poultry fat                            | 0.03 STMR               | 0.31 HR                |
| Poultry liver                          | 0.15 STMR (STMR_{Mo} × CF (4)) | 0.23 HR (HR_{Mo} × CF (4)) |
### Commodity

| Commodity             | Chronic risk assessment | Acute risk assessment |
|-----------------------|-------------------------|-----------------------|
|                       | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Poultry kidney        | 0.01 LOQ                | 0.01 LOQ              |
| Poultry edible offal  | 0.03 STMR (fat)         | 0.31 HR (fat)         |
| Milks                 | 0.13 STMR (EFSA, 2013)  | 0.13 STMR (EFSA, 2013) |
| Birds’ eggs           | 0.06 STMR (STMR<sub>Mo</sub> x CF (1.5)) | 0.07 HR (HR<sub>Mo</sub> x CF (1.5)) |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; PeelF: peeling factor; CF: conversion factor; NEU: northern Europe; LOQ: limit of quantification; Mo: monitoring.

(a): The MRL accommodates external animal treatment in cattle (FAO, 2004).
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-------------------------------------------------|---------------------------------|
| Spinosad                      | Spinosad is a mixture of 50–95% spinosyn A and 50–5% spinosyn D | ![Spinosad Structure](attachment:image1.png) |
| spinosyn A                    | \((2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2\-\((6\text{-deoxy}-2,3,4\text{-tri-O-methyl-}\alpha\text{-L-mannopyranosyloxy})\)\-13\-\((4\text{-dimethylamino}-2,3,4,6\text{-tetradeoxy-}\beta\text{-D-erythropyranosyloxy})\)\-9\text{-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione} | ![Spinosyn A Structure](attachment:image2.png) |
| spinosyn B                    | \((2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2\-\((6\text{-deoxy}-2,3,4\text{-tri-O-methyl-}\alpha\text{-L-mannopyranosyloxy})\)\-13\-\((4\text{-methylamino}-2,3,4,6\text{-tetradeoxy-}\beta\text{-D-erythropyranosyloxy})\)\-9\text{-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione} | ![Spinosyn B Structure](attachment:image3.png) |
| spinosyn D                    | \((2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2\-\((6\text{-deoxy}-2,3,4\text{-tri-O-methyl-}\alpha\text{-L-mannopyranosyloxy})\)\-13\-\((4\text{-dimethylamino}-2,3,4,6\text{-tetradeoxy-}\beta\text{-D-erythropyranosyloxy})\)\-9\text{-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione} | ![Spinosyn D Structure](attachment:image4.png) |
| Code/trivial name(a) | IUPAC name/SMILES notation/InChIKey(b) | Structural formula(c) |
|---------------------|---------------------------------------|----------------------|
| **Spinosin K**      | (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3-di-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetrahydroxy-β-D-erythropyanosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione | ![Structural formula of Spinosin K](image) |
| **17-pseudoaglycone** | (2R,3aS,5aR,5bS,9S,13S,14R,15aR,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-9-ethyl-13-hydroxy-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-14-methyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione | ![Structural formula of 17-pseudoaglycone spinosin A](image) |
| **spinosyn A**      | (2S,3aS,5aR,5bS,9S,13S,14R,15aR,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-9-ethyl-13-hydroxy-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-octadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione | ![Structural formula of 17-pseudoaglycone spinosyn D](image) |
| Code/trivial name(a) | IUPAC name/SMILES notation/InChiKey(b) | Structural formula(c) |
|---------------------|--------------------------------------|-----------------------|
| **O-demethylated spinosyn D** (O-demethyl spinosyn D) | (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,4-di-O-methyl-α-L-mannopyranosyloxy)-13-(4-dimethylamino-2,3,4,6-tetrahydroxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione | ![Structural formula](image.jpg) |
| **N-demethylated spinosyn D** (N-demethyl spinosyn D) | (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyloxy)-13-(4-methylamino-2,3,4,6-tetrahydroxy-β-D-erythropyranosyloxy)-9-ethyl-2,3,3a,5a,5b,6,7,9,10,11,12,13,14,15,16a,16b-hexadecahydro-4,14-dimethyl-1H-as-indaceno[3,2-d]oxacyclododecine-7,15-dione | ![Structural formula](image.jpg) |

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).