Focussed assessment of certain existing MRLs of concern for Spinosad

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Abstract

In compliance with Article 43 of Regulation (EC) No 396/2005, the EFSA received from the European Commission a mandate to provide its reasoned opinion on the existing maximum residue levels (MRLs) for spinosad which might lead to consumers intake concerns on the basis of a new toxicological reference value established during the peer review and of the data currently available to EFSA. In order to identify the MRLs of potential concern that require a more detailed assessment, EFSA screened the existing MRLs for spinosad considering the new toxicological reference values and an acute risk could not be excluded for six commodities. Fall-back MRLs for all six commodities were proposed on the basis of the data received under the present assessment.

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Summary

Spinosad was firstly included in Annex I to Directive 91/414/EEC on 1 February 2007 by Commission Directive 2007/06/EC. After the first approval, EFSA published several reasoned opinions on the modifications of the existing maximum residue levels (MRLs), including the assessment of the all existing MRLs in compliance with Article 12(2) of Regulation (EC) No 396/2005 and the evaluation of confirmatory data addressing data gaps identified in the MRL review.

Spinosad was evaluated for renewal of approval in the framework of Commission Regulation (EC) No 1107/2009 and for the first time, a toxicological reference value for acute exposure of the substance was established. Potential exceedances of the threshold value considering the newly established acute reference dose (ARfD) were highlighted during the peer review.

EFSA therefore received on 23 June 2020, a mandate from the European Commission in accordance with Article 43 of Regulation (EC) No 396/2005 to perform a focussed review of the existing MRLs for spinosad taking into consideration the new toxicological reference value as proposed in the Conclusion and, in case of consumer intake concerns, to derive fall-back MRLs that would not lead to unacceptable risk for consumers.

Subsequent to the request from the European Commission, EFSA performed a preliminary risk assessment of the existing EU MRLs for spinosad and for six plant commodities (sweet peppers, lettuces, escarole/broad leaved endives, spinaches, beet leaves (chards) and witloofs) an acute consumer intake concern could not be excluded when the new toxicological reference value was considered. Furthermore, a chronic intake concern was also identified. Therefore, EFSA asked Member States (MS) to provide fall-back good agricultural practices (GAPs) with supporting residue data for those commodities for which the existing MRL leads to a potential acute intake concern.

To be noted that in the conclusion of the peer review, the residue definition for risk assessment was proposed to be extended by further components, pending the submission of additional data and its outcome. In accordance with the mandate, the focused assessment was carried out considering the residue definition for risk assessment as derived during the MRL review and the existing MRLs.

For this assessment, EFSA mainly relied on its previous reasoned opinions, its conclusion on the peer review and the evaluation reports provided by the MSs during the Member State consultation.

The residue data submitted by the MSs in support of the fall-back GAPs were sufficient to derive fall-back MRLs that are safe for consumers for all commodities of concern. Therefore, EFSA recommends that the national authorisations for sweet peppers, lettuce, escaroles, spinaches, beet leaves (chard) and witloofs are being modified in order to comply with the derived fall-back MRLs.

Regarding all other MRLs that are currently in place for spinosad, acute intake calculations were below the ARfD. These MRLs are therefore not considered to be of concern for European consumers and further action is not required.

Nonetheless, EFSA underlines that these conclusions were reached while considering residues of only spinosyn A and D, and it may need to be reconsidered pending revision of the residue definition for risk assessment as proposed by the peer review in the framework of the renewal.
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Background

Spinosad was first included in Annex I to Directive 91/414/EEC\(^1\) which entered into force on 1 February 2007 by Commission Directive 2007/06/EC\(^2\). In accordance with Commission Implementing Regulation (EU) No 540/2011\(^3\), spinosad is approved under Regulation (EC) No 1107/2009, repealing Council Directive 91/414/EEC. After the first approval, EFSA published several reasoned opinions on the modifications of the existing MRLs, including the assessment of the all existing MRLs in compliance with Article 12(2) of Regulation (EC) No 396/2005\(^4\) and the evaluation of confirmatory data addressing data gaps identified in the MRL review (EFSA, 2012a,b, 2013, 2019a).

Spinosad was evaluated for renewal of approval in the framework of Commission Regulation (EC) No 1107/2009. On 03 May 2018, EFSA published its conclusion on the peer review of the pesticide risk assessment of the active substance spinosad (EFSA, 2018a). In the conclusion, the existing acceptable daily intake (ADI) was confirmed and an acute reference dose (ARFD) of 0.1 mg/kg body weight (bw) was proposed. Potential exceedances of the threshold value considering the newly established ARFD was highlighted during the peer review. The new endpoint has not yet been endorsed by risk managers given that the evaluation of the endocrine-disrupting properties of spinosad is not yet completed.

On 19 June 2020, in accordance with Article 43 of Regulation (EC) No 396/2005, the European Commission requested EFSA to perform a focused review of the existing maximum residue levels for spinosad taking into consideration the new toxicological reference value and to derive fall-back MRLs, where appropriate, not leading to unacceptable risk for consumers. According to the mandate, the focused assessment was carried out considering the residue definition for risk assessment as derived during the MRL review and the existing MRLs legally implemented in the EU legislation.

To address the request from the European Commission, EFSA performed a preliminary risk assessment of the existing EU MRLs for spinosad and on 03 July 2020, EFSA asked Member States and UK\(^5\) to provide fall-back GAP with supporting residue data for those commodities (sweet peppers, lettuces, escarole/broad leaved endives, spinaches, beet leaves (chards) and witloofs) for which, according to the preliminary risk assessment, the existing MRL leads to potential acute intake concerns.

All fall-back data received by 04 September 2020 were compiled in a GAP overview file, evaluated and considered by EFSA during the drafting of the reasoned opinion. On the basis of the data received, EFSA prepared in October 2020 a draft reasoned opinion, which was circulated to Member States and UK for commenting via a written procedure. All comments received by 12 November 2020 were evaluated and considered by EFSA during the finalisation of the reasoned opinion.

Key supporting documents to this reasoned opinion are the evaluation reports (Belgium, 2020; Czech Republic, 2020; France, 2020; Germany, 2020; Greece, 2020; Italy, 2020; Netherlands, 2020; Portugal, 2020; Spain, 2020; United Kingdom, 2020), the GAP overview file summarising the fall-back GAPs collected during the data call, the Member States and UK evaluation reports on the data call (EFSA, 2020a) and on the draft reasoned opinion (EFSA, 2020b), and the chronic and acute exposure calculations performed using the EFSA Pesticide Residues Intake Model (PRIMO), revision 3.1 (EFSA, 2018b, 2019b) (Appendix C). Therefore, also these documents are made publicly available.

The active substance and its use pattern

Spinosad is the ISO common name of a mixture of spinosyn A and spinosyn D (in a ratio between 95:5 and 50:50). The IUPAC names are as follows:

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1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 9.8.1991, p. 1-32. Repealed by Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1-50.
2 Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include methraflonone, Bacillus subtilis, spinosad and thiamethoxam as active substances. OJ L 43, 15.2.2007, p. 13–18.
3 Commission Implementing Regulation (EU) No 540/2011 of 23 May 2012011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
4 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
5 The United Kingdom withdrew from EU on 1 February 2020. In accordance with the Agreement on the Withdrawal of the UK from the EU, and with the established transition period, the EU requirements on data reporting also apply to the UK data collected until 31 December 2020.
Focused assessment for certain existing MRLs of concern for spinosad

- 2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)-13-(4-dimethylamino-2,3,4,6-tetraoxo-L-erythropyranosyloxy)-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 (spinosyn A);
- 2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4-tri-O-methyl-α-L-mannopyranosyl)-13-(4-dimethylamino-2,3,4,6-tetraoxo-L-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 (spinosyn D).

Molecular weight: 732.0 (spinosyn A); 746.0 (spinosyn D)

The chemical structure of the active substance is reported in Appendix E. Spinosad is an active substance belonging to the spinosyn class of insecticides. The compound acts by contact and ingestion causing paralysis of the insect by activation of the nicotinic acetylcholine receptor, but at a different site than nicotine or the neonicotinoids. Spinosad is used in a wide range of crops for the control of different pests. Spinosad is also approved to be used as a biocide (product-type 18, insecticides, acaricides and products to control other arthropods) according to Commission Directive 2010/72/EU6. Furthermore, spinosad is included in Annex II of Regulation (EC) No 889/20087 as a pesticide that may be used in organic farming.

The EU MRLs for spinosad are established in Annex II of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for spinosad were also established by the Codex Alimentarius Commission (CAC). The MRLs derived in the framework of the MRL review and in the following MRL applications (EFSA, 2012a,b, 2013) were legally implemented by Commission Regulation (EU) No 2015/6038. The EU MRLs for spinosad were not modified since the entry into force of the above-mentioned regulation.

**Assessment**

For this assessment, EFSA mainly relied on its previous reasoned opinions, its conclusion on the peer review and the additional information provided by the MSs and UK during the Member State consultation (EFSA, 2012a,b, 2013, 2018a, 2019a,b, 2020a; Belgium, 2020; Czech Republic, 2020; France, 2020; Germany, 2020; Greece, 2020; Italy, 2020; Netherlands, 2020; Portugal, 2020 Spain, 2020; United Kingdom, 2020).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/20119 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011).

The focused assessment was carried out considering the residue definition for risk assessment as derived during the MRL review and the existing MRLs legally implemented in the EU legislation.

1. **Identifying potential MRLs of concern and data call**

In order to identify the potential MRLs of concern when considering the new toxicological reference values, EFSA performed a preliminary risk assessment (scenario 1) of the existing EU MRLs established in the Regulation (EC) 2015/603. The calculations are based on the residue levels in the raw agricultural commodities reported in the most recent EFSA reasoned opinion (2019a), except for cucurbits with inedible peel, where the relevant peeling factor was applied, and for spinaches, escaroles and chards for which the processing factor for spinach cooked leaves was used. The processing factors used in the assessment were established in the framework of the peer review...
Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA PRIMo. The exposures calculated were compared with the toxicological reference values for spinosad, derived by EFSA in the framework of the renewal for the approval of the active substance (EFSA, 2018a).

The highest chronic exposure was calculated for the Dutch toddler, representing 113% of the ADI. Main contributors of the exposure were milk (33%), maize/corn (20%) and spinach (15%). With regard to the acute exposure, an exceedance of the ARfD was identified for witloofs (boiled), escarole/broad-leaved endives (boiled), chards/beet leaves (boiled), lettuces, spinaches and sweet peppers, representing 506%, 321%, 212%, 199%, 181% and 102% of the ARfD, respectively. The MRLs for escarole and witloof were based on existing CXLs.

With regard to the commodities where an acute risk was identified, a data call was launched to identify potential fall-back GAPs. EFSA calculated for each crop concerned the residue concentration that would lead to an intake calculation equivalent to 100% of the ARfD. Table 1 gives an overview of the results of the preliminary acute risk assessment together with these indicative threshold levels derived by inverse modelling.

Table 1: Overview of the MRLs for which acute risk to European consumers could not be excluded and fall-back GAPs were requested

| Commodity                  | Existing EU MRL (mg/kg) | HR(a) | Threshold level(b) (mg/kg) | Acute intake (% ARfD) | Processed (boiled)(c) | Acute intake (% ARfD) |
|----------------------------|-------------------------|-------|---------------------------|-----------------------|-----------------------|-----------------------|
| Sweet peppers/bell peppers| 2                       | 1.72  | 1.68                      | 102%                  | –                     | –                     |
| Lettuces                   | 10                      | 5.24  | 2.63                      | 199%                  | –                     | –                     |
| Escaroles/broad-leaved endives | 10                      | 5.7   | 1.78                      | 321%                  | –                     | –                     |
| Spinaches                  | 15                      | 8.02  | 4.43                      | 112%                  | –                     | –                     |
| Chards/beet leaves         | 15                      | 8.02  | 3.78                      | 212%                  | –                     | –                     |
| Witloofs                   | 10                      | 5.7   | 1.12                      | 226%                  | –                     | –                     |

RAC: Raw agricultural commodity.
(a): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(b): Value is derived by inverse modelling where the residue concentration is calculated that would lead to an intake calculation equivalent to 100% of the ARfD.
(c): For these commodities, the results of the acute intake calculations refer to the consumption of processed (boiled) commodities.

Regarding all other MRLs that are currently in place for spinosad, acute intake calculations were below the ARfD. These MRLs are therefore not considered to be of concern for European consumers and further action is not required.

2. Assessment of GAPs submitted during the data call

The results of the preliminary risk assessment indicated that for six commodities of plant origin (sweet peppers, escaroles, spinaches, lettuce, beet leaves (chard) and witloofs) the current MRL might pose an acute risk to European consumers (see Table 1). For these commodities, EFSA asked MSs to report fall-back GAPs with supporting residue data.

Member States and UK reported several potential fall-back GAPs in various climatic zones (EFSA, 2020a). EFSA prepared a GAP overview file summarising the GAPs collected during the data call.

In order to derive fall-back MRLs and risk assessment values, EFSA considered the less critical GAPs reported during the MSC, as well as all residue trials evaluated in its previous reasoned opinions (EFSA, 2012a,b, 2013, 2019a), the residue trials evaluated in the framework of the peer review and additional data submitted during the data call by MSs and UK (Belgium, 2020; Czech Republic, 2020; EFSA, 2020a; France, 2020; Germany, 2020; Greece, 2020; Italy, 2020; Netherlands, 2020; Portugal, 2020 Spain, 2020; United Kingdom, 2020). Detailed results of the residue trials supporting the less critical GAPs and the derived risk assessment values are reported in Appendix B.1.1.
As the HR values for escaroles, spinach, lettuce, beet leaves (chard) derived from the respective indoor GAPs exceeded the indicative threshold residue levels reported in Table 1, EFSA concluded these indoor GAPs cannot be considered to derive a fall-back MRL. The uses for which a risk for consumers have been identified and the less critical GAPs further considered by EFSA to derive fall-back MRLs are given in Appendix A.1 and Appendix A.2, respectively.

A second exposure calculation (scenario 2) was performed based on the same input values as in the scenario 1, except for the commodities for which an acute concern was identified. An overview of the input values considered in this second calculation is given in Appendix D.

According to the results of scenario 2, considering the most critical fall-back residue data and excluding the existing CXLs for escaroles and witloofs, the highest chronic exposure declined to 95% of the ADI (Dutch toddler) and the highest acute exposure was calculated for Florence fennels (boiled), followed by lettuces, representing 90% and 88% of the ARfD, respectively.

Based on these refined calculations, EFSA concludes that no risk to consumers was identified.

Conclusions and recommendations

The residue data submitted by the MSs and UK in support of the fall-back GAPs were sufficient to derive fall-back MRLs that are safe for consumers for all commodities of concern. Therefore, EFSA recommends that the national authorisations for sweet peppers, lettuce, escaroles, spinach, beet leaves (chard) and witloofs are being modified in order to comply with the derived fall-back MRLs.

Regarding all other MRLs that are currently in place for spinosad, acute intake calculations were below the ARfD. These MRLs are therefore not considered to be of concern for European consumers and further action is not required.

Nonetheless, EFSA underlines that these conclusions were reached while considering residues of only spinosyn A and D, and it may need to be reconsidered pending revision of the residue definition for risk assessment as proposed by the peer review in the framework of the renewal.

A summary of the conclusions and recommendations is provided in Table 2.

Table 2: Summary table

| Code number(a) | Commodity                              | Existing EU MRL (mg/kg) | Outcome of the assessment | MRL (mg/kg) | Comment |
|----------------|----------------------------------------|-------------------------|--------------------------|-------------|---------|
| 0231020        | Sweet peppers/bell peppers             | 2                       | 0.6                      | Fall-back MRL is proposed(b) |
| 0251020        | Lettuces                               | 10                      | 4                        | Fall-back MRL is proposed(b) |
| 0251030        | Escaroles/broad-leaved endives         | 10                      | 3                        | Fall-back MRL is proposed(b) |
| 0252010        | Spinaches                              | 15                      | 4                        | Fall-back MRL is proposed(b) |
| 0252030        | Chards/beet leaves                     | 15                      | 4                        | Fall-back MRL is proposed(b) |
| 0255000        | Witloofs/Belgian endives               | 10                      | 0.02*                    | Fall-back MRL is proposed(b) |
| –              | Other products of plant and animal origin | See Regulation 2015/603 | –                        | Existing MRLs can be maintained(c) |

MRL: maximum residue level.
*: Indicates that the MRL is set at the limit of quantification.
(F): The residue definition is fat soluble.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): The existing EU MRL was identified as a potential MRL of concern. Data supporting a fall-back MRL were submitted by MSs and no risk to consumers is identified for this fall-back MRL.
(c): The existing EU MRL was not identified as a potential MRL of concern.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
Bw body weight
CAC Codex Alimentarius Commission
CF conversion factor for enforcement residue definition to risk assessment residue definition
CS capsule suspension
CXL codex maximum residue limit
d Day
DAR Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT days after treatment
DB dietary burden
DM dry matter
FAO Food and Agriculture Organisation of the United Nations
GAP good agricultural practice
HR highest residue
ISO International Organisation for Standardization
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern European Union
OECD Organisation for Economic Co-operation and Development
PF processing factor
PHI pre-harvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RD residue definition
STMR short-term median residue
## Appendix A – Good Agricultural Practices (GAPs) and residue trials considered by EFSA

### A.1. Authorised uses for which a risk for consumers could not be excluded

| Crop and/or situation | MS or country | F G or I<sup>(a)</sup> | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|---------------|-------------------------|-------------|-------------|--------------------------------|---------|
|                       |               |                        | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days)<sup>(d)</sup> |       |
| Sweet peppers         | IT            | I                       | FO           | 480 g/L     | Foliar treatment | 61–71 | 1–3 | – | – | 0.43 kg a.i./ha | 3 | EFSA (2012a) |
| Lettuces              | IT            | I                       | FO           | 480 g/L     | Foliar treatment | 45   | 1–5 | – | – | 0.22 kg a.i./ha | 3 | EFSA (2012a) |
| Lettuces              | IT, BE, UK, EL, NL | I       | FO           | 480 g/L     | Foliar treatment | 13–49 | 1–3 | 7 | – | 0.096 kg a.i./ha | 3 |       |
| Escaroles             | IT, EL        | F                       | FO           | 480 g/L     | Foliar treatment | 10–49 | 1–3 | 7 | – | 0.096 kg a.i./ha | 3 |       |
| Escaroles             | IT, BE, EL, NL | I                       | FO           | 480 g/L     | Foliar treatment | 10–49 | 1–3 | 7 | – | 0.096 kg a.i./ha | 3 |       |
| Spinaches             | IT            | F                       | FO           | 480 g/L     | Foliar treatment | 45   | 1–5 | – | – | 0.22 kg a.i./ha | 3 | EFSA (2012a) |
| Spinaches             | UK, BE, IT, EL | I                       | FO           | 480 g/L     | Foliar treatment | 1–3 | 7 | – | – | 0.096 kg a.i./ha | 3 |       |
| Chards                | IT            | F                       | FO           | 480 g/L     | Foliar treatment | 45   | 1–5 | – | – | 0.22 kg a.i./ha | 3 | EFSA (2012a) |
| Chards                | UK, BE        | I                       | FO           | 480 g/L     | Foliar treatment | 1–3 | 7 | – | – | 0.096 kg a.i./ha | 3 |       |

**MS:** Member State.

<sup>(a)</sup> Outdoor or field use (F), greenhouse application (G) or indoor application (I).

<sup>(b)</sup> CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

<sup>(c)</sup> 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.

<sup>(d)</sup> PHI – minimum preharvest interval.
### A.2. Authorised uses considered to derive fall-back GAPs

| Crop and/or situation | MS or country | FG or I | Preparation | Application | Application rate per treatment |
|-----------------------|--------------|---------|--------------|-------------|---------------------------------|
|                       |              |         | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days)(d) | Remarks |
| Sweet peppers         | EL, PT       | F       | SC       | 480 g/L    | Foliar treatment – spraying | 14-89 | 1-3 | 7 | – | – | 0.12 kg a.i./ha | 3 |
| Sweet peppers         | EL, IT, PT, ES | I         | SC       | 480 g/L    | Foliar treatment – spraying | 1-3 | 7 | – | – | 0.12 kg a.i./ha | 3 |
| Lettuces              | FR, BE, NL   | F       | SC       | 480 g/L    | Foliar treatment – spraying | 10-49 | 1-3 | 7 | – | – | 0.096 kg a.i./ha | 3 | Same GAP as in MRL Review (EFSA, 2012a) |
| Lettuces              | PT, ES       | F       | SC       | 480 g/L    | Foliar treatment – spraying | 13-49 | 1-3 | 7 | – | – | 0.12 kg a.i./ha | 3 |
| Escaroles             | BE, NL       | F       | SC       | 480 g/L    | Foliar treatment – spraying | 1-3 | 7 | – | – | 0.096 kg a.i./ha | 3 | Same GAP as in MRL Review for FR (EFSA, 2012a) |
| Spinaches             | BE, NL, UK   | F       | SC       | 480 g/L    | Foliar treatment – general (see also comment field) | 1-3 | 7 | – | – | 0.096 kg a.i./ha | 3 |
| Spinaches             | EL/IT        | F       | SC       | 480 g/L    | Foliar treatment – spraying | 10-50 | 1-3 | 7 | – | – | 0.096 kg a.i./ha | 3 |
| Chards                | UK, NL       | F       | SC       | 480 g/L    | Foliar treatment – general (see also comment field) | 1-3 | 7 | – | – | 0.096 kg a.i./ha | 3 |
| Chards                | IT           | F       | SC       | 480 g/L    | Foliar treatment – spraying | 10-50 | 1-3 | 7 | – | – | 0.096 kg a.i./ha | 3 |
| Crop and/or situation | MS or country | Method kind          | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate and unit | PHI (days)(d) | Remarks |
|-----------------------|--------------|----------------------|------------------------------------|----------------|-----------------------------------|--------------------|---------------|---------------|---------|
| Witloofs              | NL           | SC 480 g/L           | Foliar treatment – spraying        | 1              | –                                 | –                  | 0.24 g a.i./m² | 18           | Application rate: 0.24 g/m²; 1–3 L water/m², directly after filling forcing container (same GAP as in MRL Review; EFSA, 2012a) |

MS: Member State.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI – minimum preharvest interval.
## Appendix B – List of end points

### B.1. Magnitude of residues in plants

#### B.1.1. Summary of residues data from the supervised residue trials

| Crop | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations) | Fall-back MRL (mg/kg) | HR (mg/kg)<sup>(b)</sup> | STMR (mg/kg)<sup>(c)</sup> |
|------|-----------------------------|-------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------|-----------------|------------------|
| Sweet peppers/bell peppers | SEU | 3 × 0.04; 2 × 0.05; 0.09; 0.14; 0.15; 0.17; 0.18 | Trials on peppers compliant with the fall-back GAP (EFSA, 2018a; Greece, 2020; Italy, 2020; Portugal, 2020) MRLOECD = 0.33 | 0.4 | 0.18 | 0.07 |
| | EU | 0.04; 0.05; 0.06; 0.07; 0.09; 0.11<sup>(d)</sup>; 0.11; 0.22; 0.29; 0.35 | Trials on peppers compliant with the fall-back GAP (EFSA, 2018a; Greece, 2020; Italy, 2020; Portugal, 2020; Spain, 2020) MRLOECD = 0.57 | 0.6 | 0.35 | 0.10 |
| Lettuces | NEU | 2 × 0.05; 0.07; 0.08; 0.10; 0.14; 0.2; 1.44 | Trials on open leaf variety lettuce compliant with the fall-back GAP (Belgium, 2020) MRLOECD = 2.17 | 3 | 1.44 | 0.09 |
| | SEU | Lettuce (open leaf): 2 × 0.14; 0.20; 0.23; 0.51; 0.69; 0.74; 1.38; 1.46; 2.00 Spinaches: 1.03; 2.31 | Trials on lettuces and spinaches with application rates within 25% deviation of the fall-back GAP. (Greece, 2020; Italy, 2020; Portugal, 2020; Spain, 2020). Extrapolation to lettuces is possible MRLOECD = 3.88 | 4 | 2.31 | 0.72 |
| | EU | Lettuce (open leaf): 0.71; 0.73; 2.21; 2.28; 2.4; 2.96; 3.34; 3.78; 4.07 Head lettuce: 1.16; 1.55; 2.30 Spinach: 2.48; 3.49; 4.40; 5.13 | Trials on lettuces and spinaches application rates within 25% deviation. (Greece, 2020; Italy, 2020; Netherlands, 2020). Extrapolation to lettuces is possible. **An acute intake concern is identified** MRLOECD = 8.06 | – | 5.13 | 2.44 |

<sup>(a)</sup> Region/Indoor indicates whether the supervised residue trials were conducted indoors or outdoors.

<sup>(b)</sup> HR (Hazard Ratio) indicates the ratio of the residue levels observed to the MRL.

<sup>(c)</sup> STMR (Safe Target MRL) indicates the safe target MRL based on OECD calculations.
| Crop                        | Region/ Indoor(a) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | Fall-back MRL proposals (mg/kg) | HR (mg/kg)(b) | STMR (mg/kg)(c) |
|-----------------------------|-------------------|-----------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------|-------------------------------|---------------|-----------------|
| Escaroles/ broad-leaved endives | NEU               | $2 \times 0.05; 0.07; 0.08; 0.10; 0.14; 0.2; 1.44$                                             | Trials on open leaf variety lettuce compliant with the fall-back GAP (Belgium, 2020). Extrapolation to escarole is possible. $\text{MRLOECD} = 2.17$ | 3                             | 1.44          | 0.09            |
|                            | SEU               | Lettuce (open leaf): $2 \times 0.14; 0.20; 0.23; 0.51; 0.69; 0.74; 1.38; 1.46; 2.00$     | Trials on lettuces and spinaches with application rates within 25% deviation (Greece, 2020; Italy, 2020; Portugal, 2020; Spain, 2020). Extrapolation to escarole is possible. **An acute intake concern is identified** $\text{MRLOECD} = 3.88$ | –                             | 2.31          | 0.72            |
|                            | EU                | Lettuces: 0.71; 0.73; 2.21; 2.28; 2.4; 2.96; 3.34; 3.78; 4.07 Spinach: 2.48; 3.49; 4.40; 5.13 | Trials on open leaf var. lettuces and spinaches with application rates within 25% deviation (Greece, 2020; Italy, 2020; Netherlands, 2020). Extrapolation to escarole is possible. **An acute intake concern is identified** $\text{MRLOECD} = 8.76$ | –                             | 5.13          | 2.96            |
| Spinaches, Chards/beet leaves | NEU               | $2 \times 0.05; 0.07; 0.08; 0.10; 0.14; 0.2; 1.44$                                             | Trials on open leaf variety lettuce compliant with the fall-back GAP (Belgium, 2020). Extrapolation to spinaches and chards is possible $\text{MRLOECD} = 2.17$ | 3                             | 1.44          | 0.09            |
|                            | SEU               | Lettuce (open leaf): $2 \times 0.14; 0.20; 0.23; 0.51; 0.69; 0.74; 1.38; 1.46; 2.00$     | Trials on lettuces and spinaches compliant with the fall-back GAP (Greece, 2020; Italy, 2020; Portugal, 2020; Spain, 2020). Extrapolation to spinaches and chards possible $\text{MRLOECD} = 3.88$ | 4                             | 2.31          | 0.72            |
|                            | EU                | Lettuces: 0.71; 0.73; 2.21; 2.28; 2.4; 2.96; 3.34; 3.78; 4.07 Spinach: 2.48; 3.49; 4.40; 5.13 | Trials on open leaf var. lettuces and spinaches with application rates within 25% deviation (Greece, 2020; Italy, 2020; Netherlands, 2020). Extrapolation to spinaches and chards is possible. **An acute intake concern is identified** $\text{MRLOECD} = 8.76$ | –                             | 5.13          | 2.96            |
| Witloofs/ Belgian endives   | EU                | $4 \times < 0.02$                                                                             | Trials on witloofs compliant with the fall-back GAP (EFSA, 2012a; Netherlands, 2020) $\text{MRLOECD} = 0.02$ | 0.02*                          | 0.02          | 0.02            |
*: Indicates that the MRL is proposed at the limit of quantification.
(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
(b): Highest residue.
(c): Supervised trials median residue.
(d): Trial result selected at a later sampling interval because it was higher than the trial result observed at the sampling interval compliant with GAP.
### B.1.2. Processing factors

| Processed commodity   | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Comment/Source                                      |
|-----------------------|-----------------------------------|------------------------|-----------------------------------------------------|
|                       |                                   | **Individual values** | **Median PF**                                      |
| Melon, peeling factor | 13                                | 0.37; 0.44, 0.49, 0.56, 0.57, 0.59; 0.69; 0.71, 0.74, 0.74, 0.87, 0.95, 1.00 | 0.69 | Netherlands (2018) Residues in pulp < LOQ of 0.02 mg/kg |
| Spinach, boiled       | 2                                 | 1.1; 0.6               | 0.9 | EFSA (2018a) Extrapolation to escarole and chards   |

**PF**: Processing factor (\(\text{Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo}\)).

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
### B.2. Consumer risk assessment

| ADI | 0.024 mg/kg bw per day (EFSA, 2018a) |
|-----|-----------------------------------|
| Highest IEDI, according to EFSA PRIMo vers.3.1 | **Scenario 1: without risk mitigation measures**
113% ADI (NL toddler)
**Scenario 2: with risk mitigation measures**
95% ADI (NL toddler) |
| Assumptions made for the calculations | **Scenario 1: without risk mitigation measures**
The calculation is based on the median residue levels in the raw agricultural commodities, except for cucurbits with inedible peel, where a peeling factor of 0.69 was applied.
**Scenario 2: with risk mitigation measures**
The same calculation as in scenario 1, except for peppers, lettuce, escaroles, chards, spinach and witloofs where the median residue levels are replaced by those resulting from the respective most fall-back GAPs. The indoor GAPs on lettuces, escaroles, chards and spinach submitted during the data collection were disregarded as the highest residue levels supporting the GAPs were higher than the respective values derived by inverse modelling not resulting in intake concern. |
| ARfD | 0.1 mg/kg bw (EFSA, 2018a) |
| Highest IESTI, according to EFSA PRIMo | **Scenario 1: without risk mitigation measures**
506% ARfD (Witloofs/boiled)
321% ARfD (Escaroles/broad-leaved endives/boiled)
212% ARfD (Chards/beet leaves/boiled)
199% ARfD (Lettuces)
181% ARfD (Spinaches)
102% ARfD (Sweet peppers/bell peppers)
**Scenario 2: with risk mitigation measures**
90% ARfD (Florence fennels, boiled)
88% ARfD (Lettuce) |
| Assumptions made for the calculations | **Scenario 1**: The calculation is based on the highest residue levels in the raw agricultural commodities, except for melons, where the relevant peeling factor, and spinach, escarole and chards for which the processing factor for the boiled processed commodities was applied, and for bulk commodities where the median residue levels were considered.
**Scenario 2: with risk mitigation measures**
The same calculation as in scenario 1, except for peppers, lettuce, escaroles, chards, spinach and witloofs where the highest residue levels are replaced by those resulting from the respective most critical fall-back GAPs. The indoor GAPs on lettuces, escaroles, chards and spinach submitted during the data collection were disregarded as the highest residue levels supporting the GAPs were higher than the respective values derived by inverse modelling not resulting in intake concern. |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; WHO: World Health Organization; ARfD: acute reference dose; IESTI: international estimated short-term intake.
## B.3. Proposed MRLs

| Code number\(^{(a)}\) | Commodity                  | Existing EU MRL (mg/kg) | Outcome of the assessment | MRL (mg/kg) | Comment                  |
|----------------------|---------------------------|-------------------------|---------------------------|-------------|--------------------------|
| 0231020              | Sweet peppers/bell peppers | 2                       |                           | 0.6         | Fall-back MRL is proposed\(^{(b)}\) |
| 0251020              | Lettuces                  | 10                      |                           | 4           | Fall-back MRL is proposed\(^{(b)}\) |
| 0251030              | Escaroles/broad-leaved endives | 10                     |                           | 3           | Fall-back MRL is proposed\(^{(b)}\) |
| 0252010              | Spinaches                 | 15                      |                           | 4           | Fall-back MRL is proposed\(^{(b)}\) |
| 0252030              | Chards/beet leaves        | 15                      |                           | 4           | Fall-back MRL is proposed\(^{(b)}\) |
| 0255000              | Witloofs/Belgian endives  | 10                      |                           | 0.02*       | Fall-back MRL is proposed\(^{(b)}\) |
| –                    | Other products of plant and animal origin | See Regulation 2015/603 |                           | See Regulation 2015/603 | Existing MRLs can be maintained\(^{(c)}\) |

**Enforcement residue definition:** Spinosad (spinosad, sum of spinosyn A and spinosyn D)\(^{(F)}\)

\(^{(a)}\): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.

\(^{(b)}\): The existing EU MRL was identified as a potential MRL of concern. Data supporting a fall-back MRL were submitted by MSs and no risk to consumers is identified for this fall-back MRL.

\(^{(c)}\): The existing EU MRL was not identified as a potential MRL of concern.

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MRL: maximum residue level.

\*: Indicates that the MRL is set at the limit of quantification.

\(^{(F)}\): The residue definition is fat soluble.

\(^{(a)}\): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.

\(^{(b)}\): The existing EU MRL was identified as a potential MRL of concern. Data supporting a fall-back MRL were submitted by MSs and no risk to consumers is identified for this fall-back MRL.

\(^{(c)}\): The existing EU MRL was not identified as a potential MRL of concern.
Appendix C – Pesticide Residue Intake Model (PRIMo)

**PRIMo(scenario 1)**

- **LOQs (mg/kg) range from:** 0.01 to 10.0
- **ADI (mg/kg bw per day):** 0.024
- **ARfD (mg/kg bw):** 0.1
- **Source of ADI:** EFSA
- **Source of ARfD:** EFSA

EFSA PRIMo revision 3.1; 2019/03/19

Year of evaluation: 2018

No of diets exceeding the ADI: 1

113% 27.00 33% 20% 15% Spinaches
49% 11.70 16% 13% 7% Milk: Cattle
48% 11.49 12% 11% 4% Bananas
47% 11.22 13% 12% 5% Spinaches
45% 10.77 21% 4% 4% Tomatoes
45% 10.19 21% 8% 4% Bananas
40% 9.68 13% 7% 7% Milk: Cattle
40% 9.49 13% 12% 2% Spinaches
39% 9.40 11% 6% 4% Rice
39% 9.40 11% 6% 4% Spinaches
39% 9.08 11% 6% 4% Milk: Cattle
38% 9.09 9% 7% 7% Milk: Cattle
38% 9.08 16% 9% 3% Spinaches
38% 9.08 16% 9% 3% Milk: Cattle
37% 8.92 12% 4% 3% Milk: Cattle
36% 8.65 13% 4% 2% Barley
34% 8.26 12% 4% 4% Milk: Cattle
33% 7.88 15% 6% 3% Maize/corn
33% 7.80 19% 5% 1% Tomatoes
32% 7.58 11% 11% 3% Bananas
32% 7.43 10% 4% 2% Barley
29% 7.04 10% 7% 3% Milk: Cattle
27% 6.41 12% 7% 2% Spinaches
25% 5.73 13% 5% 2% Milk: Cattle
24% 5.33 13% 5% 2% Lettuces
24% 5.33 13% 5% 2% Milk: Cattle
23% 4.96 13% 5% 2% Milk: Cattle
22% 4.63 13% 5% 2% Milk: Cattle
21% 4.29 13% 5% 2% Milk: Cattle
20% 3.95 13% 5% 2% Milk: Cattle
19% 3.62 13% 5% 2% Milk: Cattle
18% 3.29 13% 5% 2% Milk: Cattle
17% 2.96 13% 5% 2% Milk: Cattle
16% 2.62 13% 5% 2% Milk: Cattle
15% 2.29 13% 5% 2% Milk: Cattle
14% 1.95 13% 5% 2% Milk: Cattle
13% 1.62 13% 5% 2% Milk: Cattle
12% 1.28 13% 5% 2% Milk: Cattle
11% 0.95 13% 5% 2% Milk: Cattle
10% 0.62 13% 5% 2% Milk: Cattle
9% 0.29 13% 5% 2% Milk: Cattle
8% 0.06 13% 5% 2% Milk: Cattle
7% 0.03 13% 5% 2% Milk: Cattle
6% 0.01 13% 5% 2% Milk: Cattle
5% 0.00 13% 5% 2% Milk: Cattle
4% 0.00 13% 5% 2% Milk: Cattle
3% 0.00 13% 5% 2% Milk: Cattle
2% 0.00 13% 5% 2% Milk: Cattle
1% 0.00 13% 5% 2% Milk: Cattle
0% 0.00 13% 5% 2% Milk: Cattle

**Conclusion:**

The estimated TMDI/NEDI/IEDI was in the range of 0 % to 112.5 % of the ADI.

For 1 diet(s), the ADI is exceeded.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Details – acute risk assessment/children

| Commodity                        | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------------|---------------------------|---------------------|-----------------------|
| Escaroles/broad-leaved           | 10/5.7                    | 229                 | 229%                  |
| Witloofs/Belgian endives         | 10/5.7                    | 226                 | 226%                  |
| Lettuces                         | 10/5.24                   | 199                 | 199%                  |
| Spinaches                        | 15/5.02                   | 181                 | 181%                  |
| Chards/beet leaves               | 15/5.02                   | 125                 | 125%                  |
| Sweet peppers/bell peppers       | 2/1.72                    | 102                 | 102%                  |
| Bananas                          | 2.0/5.85                  | 83                  | 83%                   |
| Celeries                         | 2/1.98                    | 74                  | 74%                   |
| Melons                           | 10/4.44                   | 67                  | 67%                   |
| Cauliflowers                     | 2/1.12                    | 65                  | 65%                   |
| Kohlrabies                       | 2/1.1                     | 57                  | 57%                   |
| Watermelons                      | 10/4.44                   | 54                  | 54%                   |
| Head cabbages                    | 2/1.1                     | 49                  | 49%                   |
| Parsley                          | 2/1.1                     | 48                  | 48%                   |
| Kales                            | 2/1.1                     | 47                  | 47%                   |

### Details – acute risk assessment/adults

| Commodity                        | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------------|---------------------------|---------------------|-----------------------|
| Chards/beet leaves/boiled        | 10/5.02                   | 152                 | 152%                  |
| Escaroles/broad-leaved/boiled    | 10/5.7                    | 115                 | 115%                  |
| Lettuces/boiled                 | 10/5.24                   | 105                 | 105%                  |
| Spinaches/boiled                | 15/5.02                   | 64                  | 64%                   |
| Parsley/boiled                   | 2/1.1                     | 52                  | 52%                   |
| Head cabbages/boiled             | 2/1.1                     | 46                  | 46%                   |
| Florence fennel/boiled           | 0.6/1.98                  | 37                  | 37%                   |
| Spinaches/boiled                | 15/5.02                   | 32                  | 32%                   |
| Sweet peppers/bell peppers/boiled| 2/1.72                   | 28                  | 28%                   |
| Chinese cabbages/pe-tsai/boiled  | 2/1.1                     | 26                  | 26%                   |
| Broccoli/boiled                 | 2/1.12                    | 27                  | 27%                   |
| Cauliflowers/boiled              | 2/1.1                     | 26                  | 26%                   |
| Kales/boiled                     | 2/1.1                     | 21                  | 21%                   |

### Results for adults

**Processed commodities**

| Commodity                        | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------------|---------------------------|---------------------|-----------------------|
| Witloofs/boiled                  | 10/5.7                    | 105                 | 105%                  |
| Chards/beet leaves/boiled        | 15/5.02                   | 85                  | 85%                   |
| Celeries/boiled                 | 2/1.98                    | 67                  | 67%                   |
| Spinaches/boiled                | 15/5.02                   | 38                  | 38%                   |
| Spinaches/boiled                | 0.6/1.98                  | 27                  | 27%                   |
| Pumpkins/boiled                 | 2/1.12                    | 23                  | 23%                   |
| Kales/boiled                     | 2/1.1                     | 21                  | 21%                   |
| Maize/oil/boiled                | 2/1.78                    | 9%                  | 9%                    |
| Maize/oil/boiled                | 1/0.64                    | 5%                  | 5%                    |
| Courgettes/boiled               | 0.3/0.17                  | 4%                  | 4%                    |

**Unprocessed commodities**

| Commodity                        | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|----------------------------------|---------------------------|---------------------|-----------------------|
| Witloofs/boiled                  | 10/5.7                    | 105                 | 105%                  |
| Chards/beet leaves/boiled        | 15/5.02                   | 85                  | 85%                   |
| Celeries/boiled                 | 2/1.98                    | 67                  | 67%                   |
| Spinaches/boiled                | 15/5.02                   | 38                  | 38%                   |
| Spinaches/boiled                | 0.6/1.98                  | 23                  | 23%                   |
| Courgettes/boiled               | 0.3/0.17                  | 4%                  | 4%                    |

**Conclusion:**

The estimated short-term intake (IESTI) exceeded the toxicological reference value for 6 commodities.

For processed commodities, the toxicological reference value was exceeded in one or several cases.

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation) 6

No of processed commodities for which ARfD/ADI is exceeded (IESTI): 3

No of unprocessed commodities for which ARfD/ADI is exceeded (IESTI): 6
**PRIMo(scenario 2)**

**Spinosad (F)**

### Toxicological reference values

| Source or ADI | Year of evaluation | EFSA PRIMo revision | 2019/03/19 |
|---------------|-------------------|--------------------|-------------|
| ADI (mg/kg bw per day) | 0.024 | EFSA | 2018 |
| ARfD (mg/kg bw) | 0.1 | EFSA | 2018 |

### Source of ADI

1. EFSA
2. EFSA

### Source of ARfD

1. EFSA
2. EFSA

### No of diets exceeding the ADI

---

### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure Resulting From | Exposure exceeding ADI |
|--------------------------------|------------------------|------------------------|
|                                  |                        |                        |

### Normal mode

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

| Commodity/group of commodities | Exposure exceeding ADI |
|--------------------------------|------------------------|
|                                  |                        |

### Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of spinosad (F) is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

## Acute risk assessment / children

| Commodity                      | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI | IESTI |
|-------------------------------|---------------------------|---------------------|--------------|-------|
| Lettuces                      | 4.2/31                    | 88                  | 88%          | 52%   |
| Bananas                       | 2/0.85                    | 83                  | 83%          | 52%   |
| Melons                        | 1/0.44                    | 67                  | 67%          | 52%   |
| Cauliflowers                  | 2/1.12                    | 65                  | 65%          | 52%   |
| Escaroles/broad-leaved        | 3/1.44                    | 58                  | 58%          | 52%   |
| Kohrables                     | 2/1.1                     | 57                  | 57%          | 52%   |
| Watermelons                   | 1/0.44                    | 54                  | 54%          | 52%   |
| Spinaches                     | 4/2.31                    | 52                  | 52%          | 52%   |
| Head cabbages                 | 2/1.1                     | 49                  | 49%          | 52%   |
| Kales                         | 2/1.1                     | 48                  | 48%          | 52%   |
| Parsley                       | 6/0.4                      | 47                  | 47%          | 52%   |
| Broccoli                      | 2/1.2                     | 47                  | 47%          | 52%   |
| Peaches                       | 0.6/0.39                  | 37                  | 37%          | 52%   |
| Chards/beet leaves            | 4/2.31                    | 36                  | 36%          | 52%   |

## Acute risk assessment / adults/general population

| Commodity                      | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI | IESTI |
|-------------------------------|---------------------------|---------------------|--------------|-------|
| Parsley                       | 60/43                     | 52                  | 52%          | 52%   |
| Head cabbages                 | 2/1.1                     | 46                  | 46%          | 52%   |
| Celeries                      | 2/1.98                    | 32                  | 32%          | 52%   |
| Red mustards                  | 1/0.57                    | 30                  | 30%          | 52%   |
| Florence fennels              | 0.6/1.98                  | 37                  | 37%          | 52%   |
| Lufftios                      | 2/4.31                    | 28                  | 28%          | 52%   |
| Chinese cabbages/fennel       | 2/1.1                     | 28                  | 28%          | 52%   |
| Broccoli                      | 2/1.2                     | 27                  | 27%          | 52%   |
| Cauliflowers                  | 2/1.2                     | 26                  | 26%          | 52%   |
| Kales                         | 2/1.1                     | 21                  | 21%          | 52%   |
| Bananas                       | 2/0.85                    | 18                  | 18%          | 52%   |
| Watermelons                   | 1/0.44                    | 18                  | 18%          | 52%   |

## Processed commodities

| Commodity                      | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | % of ARfD/ADI | IESTI |
|-------------------------------|---------------------------|---------------------|--------------|-------|
| Florence fennels/boiled       | 0.6/1.98                  | 90                  | 90%          | 52%   |
| Broccoli/boiled              | 2/1.12                    | 88                  | 88%          | 52%   |
| Cauliflowers/boiled          | 2/1.12                    | 78                  | 78%          | 52%   |
| Chards/beet leaves/boiled    | 4/2.31                    | 72                  | 72%          | 52%   |
| Pumpkins/boiled              | 1/0.64                    | 57                  | 57%          | 52%   |
| Kales/boiled                 | 2/1.1                     | 50                  | 50%          | 52%   |
| Spinaches/boiled             | 4/1.96                    | 27                  | 27%          | 52%   |
| Kohrables/boiled             | 2/1.1                     | 23                  | 23%          | 52%   |
| Brussels sprouts/boiled      | 2/1.1                     | 16                  | 16%          | 52%   |
| Peaches/fennel               | 0.6/0.39                  | 10                  | 10%          | 52%   |
| Leeks/boiled                 | 0.2/0.17                  | 9.7                 | 9%           | 52%   |
| Wheat/milling (flour)         | 2/0.7                     | 8.4                 | 8%           | 52%   |
| Courgettes/boiled            | 0.3/0.17                  | 6.0                 | 6%           | 52%   |
| Rice/milling (polishing)     | 2/0.28                    | 4.3                 | 4%           | 52%   |
| Chinese cabbages/boiled      | 4/2.31                    | 28                  | 28%          | 52%   |
| Broccoli/boiled              | 2/1.2                     | 27                  | 27%          | 52%   |
| Kohrables/boiled             | 2/1.1                     | 25                  | 25%          | 52%   |
| Spinaches/boiled             | 4/1.96                    | 16                  | 16%          | 52%   |
| Maize/boiled                 | 2/1.7                     | 8.8                 | 8%           | 52%   |
| Grape leaves/canned          | 10/5.7                    | 4.7                 | 4%           | 52%   |
| Peaches/canned               | 0.6/0.39                  | 3.2                 | 3%           | 52%   |

Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of spinosad (F) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
### Appendix D – Input values for the exposure calculations

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| **Risk assessment residue**|                         |                       |                         |                       |
| definition:                |                         |                       |                         |                       |
| Citrus fruits              | 0.01                    | STMR × eelF (EFSA, 2019a) | 0.01                    | HR × PeelF (EFSA, 2019a) |
| Tree nuts                  | 0.03                    | STMR (CXL) (EFSA, 2019a) | 0.05                    | HR (CXL) (EFSA, 2019a) |
| Pome fruits                | 0.05                    | STMR (EFSA, 2019a)     | 0.15                    | HR (EFSA, 2019a)      |
| Apricots, Peaches         | 0.21                    | STMR (EFSA, 2019a)     | 0.39                    | HR (EFSA, 2019a)      |
| Cherries, Plums           | 0.03                    | STMR (CXL) (EFSA, 2019a) | 0.11                    | HR (CXL) (EFSA, 2019a) |
| Table, wine grapes        | 0.08                    | STMR (CXL) (EFSA, 2019a) | 0.39                    | HR (CXL) (EFSA, 2019a) |
| Strawberries              | 0.12                    | STMR (EFSA, 2019a)     | 0.24                    | HR (EFSA, 2019a)      |
| Blackberries              | 0.35                    | STMR (EFSA, 2019a)     | 0.58                    | HR (EFSA, 2019a)      |
| Dewberries                | 0.14                    | STMR (CXL) (EFSA, 2019a) | 0.42                    | HR(CXL) (EFSA, 2019a) |
| Raspberries               | 0.35                    | STMR (EFSA, 2019a)     | 0.58                    | HR (EFSA, 2019a)      |
| Other small fruits &      | 0.34                    | STMR (EFSA, 2019a)     | 0.66                    | HR (EFSA, 2019a)      |
| berries                   |                         |                       |                         |                       |
| Table olives              | 0.02                    | STMR (EFSA, 2019a)     | 0.02                    | HR (EFSA, 2019a)      |
| Kiwi fruits               | 0.02                    | STMR (EFSA, 2019a)     | 0.05                    | HR (EFSA, 2019a)      |
| Passion fruit             | 0.23                    | STMR (CXL) (EFSA, 2019a) | 0.33                    | HR (CXL) (EFSA, 2019a) |
| Bananas                   | 0.62                    | STMR (EFSA, 2019a)     | 0.85                    | HR (EFSA, 2019a)      |
| Papayas                   | 0.21                    | STMR (EFSA, 2019a)     | 0.23                    | HR (EFSA, 2019a)      |
| Potatoes                  | 0.02                    | STMR (EFSA, 2019a)     | 0.02                    | HR (EFSA, 2019a)      |
| Radishes                  | 0.08                    | STMR (EFSA, 2019a)     | 0.10                    | HR (EFSA, 2019a)      |
| Garlic, Onions,           | 0.05                    | STMR (EFSA, 2019a)     | 0.05                    | HR (EFSA, 2019a)      |
| Shallots                  |                         |                       |                         |                       |
| Spring onions             | 0.20                    | STMR (CXL)( EFSA, 2019a) | 1.50                    | HR (CXL)( EFSA, 2019a) |
| Tomatoes, Aubergines      | 0.25                    | STMR (EFSA, 2019a)     | 0.57                    | HR (EFSA, 2019a)      |
| Peppers                   | 0.33                    | STMR (EFSA, 2019a)     | 1.72                    | HR (EFSA, 2019a)      |
|                          | 0.1                     | STMR (Fall-back)       | 0.35                    | HR (Fall-back)        |
| Cucurbits, edible peel    | 0.08                    | STMR (EFSA, 2019a)     | 0.17                    | HR (EFSA, 2019a)      |
| Cucurbits, inedible       | 0.1                     | STMR (EFSA, 2019a) × PeelF (EFSA, 2018a) | 0.44                    | HR (EFSA, 2019a) × PeelF (EFSA, 2018a) |
| peel                     |                         |                       |                         |                       |
| Sweet corn                | 0.01                    | STMR (EFSA, 2019a)     | 0.01                    | HR (EFSA, 2019a)      |
| Flowering brassica        | 0.11                    | STMR (EFSA, 2019a)     | 0.79                    | HR (EFSA, 2019a)      |
| Head brassica             | 0.27                    | STMR (EFSA, 2019a)     | 1.1                     | HR (CXL) (EFSA, 2019a) |
| Chinese cabbage           | 0.27                    | STMR (EFSA, 2019a)     | 1.1                     | HR (CXL) (EFSA, 2019a) |
| Kale                      | 0.54                    | STMR (EFSA, 2019a)     | 1.1                     | HR (CXL) (EFSA, 2019a) |
| Kohlrabies                | 0.27                    | STMR (EFSA, 2019a)     | 1.1                     | HR (CXL) (EFSA, 2019a) |
| Lamb's lettuces           | 1.90                    | STMR (EFSA, 2019a)     | 5.70                    | HR (CXL) (EFSA, 2019a) |
| Lettuces                  | 4.29                    | STMR (EFSA, 2019a)     | 5.24                    | HR (EFSA, 2019a)      |
|                          | 0.72                    | STMR (Fall-back)       | 2.31                    | HR (Fall-back)        |
| **Scorole (broad-leaf**    | 1.90                    | STMR (EFSA, 2019a)     | 5.70                    | HR (CXL) (EFSA, 2019a) |
| **endive**                |                         |                       |                         |                       |
|                          | 0.09                    | STMR (Fall-back)       | 1.44                    | HR (Fall-back)        |
| **Cresses, Land cresses** | 1.90                    | STMR (EFSA, 2019a)     | 5.70                    | HR (CXL) (EFSA, 2019a) |
| **Rocket, rucola**        | 1.90                    | STMR (EFSA, 2019a)     | 5.70                    | HR (CXL) (EFSA, 2019a) |
| **Red mustard**           | 1.90                    | STMR (EFSA, 2019a)     | 5.70                    | HR (CXL) (EFSA, 2019a) |
| **Baby leaf crops**       | 4.90                    | STMR (EFSA, 2019a)     | 8.02                    | HR (EFSA, 2019a)      |
| **Spinaches, Beet**       | 4.90                    | STMR (EFSA, 2019a)     | 8.02                    | HR (EFSA, 2019a)      |
| **leaves (chard)**        | 0.72                    | STMR (Fall-back)       | 2.31                    | HR (Fall-back)        |
| Commodity                     | Chronic risk assessment | Acute risk assessment |
|------------------------------|-------------------------|-----------------------|
|                              | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| Purslane                     | 1.90                    | STMR (EFSA, 2019a)    | 5.70                    | HR (CXL)(EFSA, 2019a) |
| Vine leaves                  | 1.90                    | STMR (EFSA, 2019a)    | 5.70                    | HR (CXL)(EFSA, 2019a) |
| Water cress                  | 1.90                    | STMR (EFSA, 2019a)    | 5.70                    | HR (CXL)(EFSA, 2019a) |
| Witloof                      | 1.90                    | STMR (EFSA, 2019a)    | 5.70                    | HR (CXL)(EFSA, 2019a) |
|                              | 0.02*                   | STMR (Fall-back)      | 0.02*                   | HR (Fall-back)        |
| Chervil                      | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Chives                       | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Celery leaves                | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Parsley                      | 10.0                    | STMR (EFSA, 2019a)    | 43.0                    | HR (EFSA, 2019a)      |
| Sage, Rosemary               | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Thyme, Basil                 | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Bay leaves (laurel)          | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Tarragon                     | 4.90                    | STMR (EFSA, 2019a)    | 8.02                    | HR (EFSA, 2019a)      |
| Beans (with pods)            | 0.07                    | STMR (EFSA, 2019a)    | 0.12                    | HR (EFSA, 2019a)      |
| Legume vegetables,           | 0.04                    | STMR (EFSA, 2019a)    | 0.21                    | HR (CXL)(EFSA, 2019a) |
|         except beans with     |                         |                       |                         |                       |
|         pods                   |                         |                       |                         |                       |
| Celeries                     | 0.65                    | STMR (EFSA, 2019a)    | 1.98                    | HR (EFSA, 2019a)      |
| Fennel                       | 0.65                    | STMR (EFSA, 2019a)    | 1.98                    | HR (EFSA, 2019a)      |
| Globe artichokes             | 0.04                    | STMR (EFSA, 2019a)    | 0.07                    | HR (EFSA, 2019a)      |
| Leeks                        | 0.07                    | STMR (EFSA, 2019a)    | 0.17                    | HR (EFSA, 2019a)      |
| Soya beans                   | 0.01                    | STMR (EFSA, 2019a)    | 0.01                    | STMR(CXL)(EFSA, 2019a)|
| Cotton seeds                 | 0.01                    | STMR (EFSA, 2019a)    | 0.01                    | STMR (EFSA, 2019a)    |
| Olives for oil production    | 0.02                    | STMR (EFSA, 2019a)    | 0.02                    | STMR (EFSA, 2019a)    |
| Cereals                      | 0.70                    | STMR (EFSA, 2019a)    | 0.95                    | HR (EFSA, 2019a)      |
| Swine meat                   | 0.21                    | STMR (EFSA, 2019a)    | 0.33                    | HR (EFSA, 2019a)      |
| Swine fat                    | 0.89                    | STMR (EFSA, 2019a)    | 1.36                    | HR (EFSA, 2019a)      |
| Swine liver                  | 0.34                    | STMR (EFSA, 2019a)    | 0.61                    | HR (EFSA, 2019a)      |
| Swine kidney                 | 0.19                    | STMR (EFSA, 2019a)    | 0.28                    | HR (EFSA, 2019a)      |
| Swine edible offal           | 0.89                    | STMR (EFSA, 2019a)    | 1.36                    | HR (EFSA, 2019a)      |
| Bovine meat                  | 0.08                    | STMR (CXL)(EFSA, 2019a)| 0.3                    | MRL (CXL)(EFSA, 2019a)|
| Bovine fat                   | 0.08                    | STMR (CXL)(EFSA, 2019a)| 3                     | MRL (CXL)(EFSA, 2019a)|
| Bovine liver                 | 0.66                    | STMR (CXL)(EFSA, 2019a)| 2                     | MRL (CXL)(EFSA, 2019a)|
| Bovine kidney                | 0.31                    | STMR (CXL)(EFSA, 2019a)| 1                     | MRL (CXL)(EFSA, 2019a)|
| Bovine edible offal          | 0.66                    | MRL (CXL)(EFSA, 2019a)| 3                     | MRL (CXL)(EFSA, 2019a)|
| Sheep, goat meat            | 0.28                    | STMR (EFSA, 2019a)    | 0.57                    | HR (EFSA, 2019a)      |
| Sheep, goat fat             | 1.18                    | STMR (EFSA, 2019a)    | 2.31                    | HR (EFSA, 2019a)      |
| Sheep, goat liver           | 0.50                    | STMR (EFSA, 2019a)    | 1.05                    | HR (EFSA, 2019a)      |
| Sheep, goat kidney          | 0.30                    | STMR (EFSA, 2019a)    | 0.46                    | HR (EFSA, 2019a)      |
| Sheep, goat edible offal    | 1.18                    | STMR (EFSA, 2019a)    | 2.31                    | HR (EFSA, 2019a)      |
| Horse meat                  | 0.28                    | STMR (EFSA, 2019a)    | 0.57                    | HR (EFSA, 2019a)      |
| Horse fat                   | 1.18                    | STMR (EFSA, 2019a)    | 2.31                    | HR (EFSA, 2019a)      |
| Horse liver                 | 0.50                    | STMR (EFSA, 2019a)    | 1.05                    | HR (EFSA, 2019a)      |
| Horse kidney                | 0.30                    | STMR (EFSA, 2019a)    | 0.46                    | HR (EFSA, 2019a)      |
| Horse edible offal          | 1.18                    | STMR (EFSA, 2019a)    | 2.31                    | HR (EFSA, 2019a)      |
| Commodity         | Chronic risk assessment | Acute risk assessment |
|-------------------|-------------------------|-----------------------|
|                   | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Poultry meat      | 0.03                    | STMR (EFSA, 2019a)    | 0.08                | HR (EFSA, 2019a)      |
| Poultry fat       | 0.03                    | STMR (EFSA, 2019a)    | 0.31                | HR (EFSA, 2019a)      |
| Poultry liver     | 0.15                    | STMR (STMR<sub>Mo</sub> × CF (4)) (EFSA, 2019a) | 0.23                | HR (HR<sub>Mo</sub> × CF (4)) (EFSA, 2019a) |
| Poultry edible offal | 0.03                | STMR (fat) (EFSA, 2019a) | 0.31                | HR (fat) (EFSA, 2019a) |
| Milks             | 0.13                    | STMR (EFSA, 2019a)    | 0.13                | STMR (EFSA, 2019a)    |
| Birds’ eggs       | 0.06                    | STMR (STMR<sub>Mo</sub> × CF (1.5)) (EFSA, 2019a) | 0.07                | HR (HR<sub>Mo</sub> × CF (1.5)) (EFSA, 2019a) |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; PeelF: peeling factor; CF: conversion factor.

*: Indicates that the input value is proposed at the limit of quantification.
Crops in bold indicate the commodities of relevance in the assessment.
### Appendix E – Used compound code(s)

| Code/trivial name<sup>(a)</sup> | Chemical name/SMILES notation<sup>(b)</sup> | Structural formula<sup>(b)</sup> |
|-------------------------------|-----------------------------------------------|---------------------------------|
| Spinosad                      | Spinosad is a mixture of 50–95% spinosyn A and 50–5% spinosyn D | |  
| spinosyn A                    | (2R,3aS,5aR,5bS,9S,13S,14R,16aS,16bR)-2-(6-deoxy-2,3,4,6-tetra-O-methyl-α-L-mannopyranosyl)-13-(4-dimethylamino-2,3,4,6-tetra-O-methyl-β-D-erythropyranosyl)-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 |  
|                              | CN(C)(C@H)1CC[C@@H](O[C@@H]1C)O[C@@H]6CCC[C@@H](CC)OC(=O)[C@@H]5C(=C[C@@H]3[C@H]2C[C@@H](C[C@H]23)O[C@@H]40[C@@H](C[C@H]1)(OC)[C@@H]40)(C(=O)[C@@H]6C |  
| spinosyn D                    | (2S,3aR,5aS,5bS,9S,13S,14R,16aS,16bS)-2-(6-deoxy-2,3,4,6-tetra-O-methyl-α-L-mannopyranosyl)-13-(4-dimethylamino-2,3,4,6-tetra-O-methyl-β-D-erythropyranosyl)-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 |  
|                              | CN(C)(C[H]1CC[O][C[H]1C][O][C[H]6CCC[O][C[H](CC)OC(=O)[C[H]5C(=C(C[H]2C(C[H](C[C[H]23)(O[C[H](C[C[H](OC)(C[H]40)(C(=O)[C[H]6C |  

<sup>(a)</sup>: The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup>: ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019). ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).