Focussed assessment of certain existing MRLs of concern for methoxyfenozide

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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 methoxyfenozide which might lead to consumers intake concerns on the basis of the new toxicological reference values agreed upon by Member States (MSs) on 13 December 2018. In order to identify the MRLs of potential concern that require a more detailed assessment, EFSA screened the existing MRLs for methoxyfenozide, considering the new toxicological reference values and an acute risk could not be excluded for eight commodities. A fall-back MRL was proposed for tomatoes and the MRL for citrus fruit could be confirmed considering the use of a peeling factor. No other fall-back good agricultural practices (GAPs) were received, and thus, a lowering of the MRLs for peaches, apples, pears and broccoli is proposed.

Keywords: methoxyfenozide, MRL, Regulation (EC) No 396/2005, consumer risk assessment, insecticide

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Summary

Methoxyfenozide was firstly included in Annex I to Directive 91/414/EEC on 1 April 2005 by Commission Directive 2005/3/EC. After the first approval, EFSA published three reasoned opinions on the modifications of the existing MRLs, including the assessment of the existing MRLs in compliance with Article 12(2) of Regulation (EC) No 396/2005.

Methoxyfenozide was evaluated for renewal of approval in the framework of Commission Regulation (EC) No 1107/2009 and the toxicological reference value for acute exposure of the substance was lowered and potential exceedances of the threshold value was flagged.

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 maximum residue levels for methoxyfenozide taking into consideration the new toxicological reference value as noted by the Standing Committee on Plants, Animals, Food and Feed 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 methoxyfenozide and for eight plant commodities (grapefruits, oranges, mandarins, apples, pears, peaches, tomatoes, broccoli), an acute consumer intake concern could not be excluded when considering the lower toxicological reference value derived during the renewal. Therefore, EFSA asked Member States to provide fall-back GAPs with supporting residue data for those commodities for which the existing MRL leads to a potential acute intake concern. In addition, EFSA highlighted during the data call that a peeling factor (PF) for citrus fruits is available that was not considered for the CXLs in the MRL Review. The existing MRLs for citrus fruits correspond to the current CXLs. Member States were requested to express their views on the applicability of the PF.

Considering that Regulation (EU) 2019/158 restricts EU uses to greenhouses, Member States were invited to submit fall-back GAPs in support of the authorised EU uses in greenhouses and report import tolerances. In the framework of the data call, only for tomatoes, a fall-back GAP was reported.

The residue data submitted by the MSs in support of the fall-back GAP for tomatoes were sufficient to derive a fall-back MRL safe for consumers. The peeling factor for citrus fruits established during the peer review was concluded to be applicable for the corresponding CXLs and should be used in the risk assessment. Accordingly, no risk was identified for the existing MRLs in grapefruits, oranges and mandarins.

For all other commodities (apples, pears, peaches, broccoli), fall-back MRLs or refined input values could not be derived since less critical GAPs were not provided by MS and no additional data for a possible refinement was available.

Therefore, MSs are recommended to withdraw their national authorisations for broccoli, apples, pears and peaches and to modify the national authorisations for tomatoes in order to comply with the fall-back MRL derived by EFSA.
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Background

Methoxyfenozide was first included in Annex I to Directive 91/414/EEC on 1 April 2005 by Commission Directive 2005/03/EC. After the first approval, EFSA published several reasoned opinions on the modifications of the existing MRLs, including the assessment of all existing MRLs in compliance with Article 12(2) of Regulation (EC) No 396/2005 (EFSA, 2010, 2012, 2014).

Methoxyfenozide was evaluated for renewal of approval in the framework of Commission Regulation (EC) No 1107/2009. On 6 September 2017, EFSA published its conclusion on the peer review of the pesticide risk assessment of the active substance methoxyfenozide (EFSA, 2017) and concluded on a lower acute reference dose (ARfD). The lower toxicological reference value was agreed in the Standing Committee on Plant, Animal, Food and Feed in December 2018 (European Commission, 2018).

Potential exceedances of the threshold value considering the lower ARfD was 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 maximum residue levels for methoxyfenozide taking into consideration the new toxicological reference value 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 methoxyfenozide and for eight plant commodities (grapefruits, oranges, mandarins, apples, pears, peaches, tomatoes, broccoli), an acute consumer intake concern could not be excluded when considering the lower toxicological reference value derived during the renewal. Therefore, EFSA asked Member States to provide fall-back GAPs with supporting residue data for those commodities for which the existing MRL leads to a potential acute intake concern.

Considering that Regulation (EU) 2019/158 restricts EU uses to greenhouses, Member States were invited to submit fall-back GAPs in support of the authorised EU uses in greenhouses and report import tolerances.

All fall-back data received by 14 August 2020 were evaluated and considered by EFSA during the preparation of the reasoned opinion. In September 2020, the draft reasoned opinion was circulated to Member States for commenting via a written procedure. All comments received by 22 September 2020 were evaluated by EFSA.

Key supporting documents to this reasoned opinion are the Member States consultation reports on the data call (EFSA, 2020a) and on the draft reasoned opinion (EFSA, 2020b), the evaluation report submitted during the data call (Portugal, 2020) and the chronic and acute exposure calculations performed using the EFSA Pesticide Residues Intake Model (PRIMo), revision 3.1 (Appendix C). Therefore, these documents are made publicly available.

The active substance and its use pattern

Methoxyfenozide is the ISO common name for N-tert-butyl-N’-(3-methoxy-o-toluoyl)-3,5-xylohydrazide (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Methoxyfenozide was evaluated in the framework of Directive 91/414/EEC with United Kingdom being the designated rapporteur Member State (RMS). The representative uses supported for the first peer review process were outdoor or indoor foliar spraying applications on fruits (citrus fruits, pome fruits, stone fruits, grapes), fruiting vegetables (tomatoes, peppers) and ornamentals. Methoxyfenozide has been recently peer reviewed by EFSA in the framework of the renewal of the approval of the active substance under Regulation (EC) No 1107/2009 (EFSA, 2017) with United Kingdom as RMS. The

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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, as last amended.
2 Commission Directive 2005/03/EC of 19 January 2005 amending Council Directive 91/414/EEC to include imazosulfuron, laminarin, methoxyfenozide and s-metolachlor as active substances. OJ L 20, 22.1.2005, p. 19-23.
3 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.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.
5 Commission Implementing Regulation (EU) 2019/158 of 31 January 2019 renewing the approval of the active substance methoxyfenozide, as a candidate for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 31, 1.2.2019, p. 21–26.
representative uses evaluated for the renewal included table and wine grapes, maize and sweet corn, 
fruiting vegetables (tomato, pepper, aubergine) and leaf vegetables (lettuce and other salad plants, 
spinach and similar, herbs). Following the peer review under the renewal procedure, a decision on 
renewal of the active substance methoxyfenozide in accordance with Regulation (EC) No 1107/2009 was published by Commission Implementing Regulation (EU) 2019/158, which entered into 
force on 1 April 2019. This approval is restricted to use as insecticide in greenhouses only (European 
Commission, 2018).

The EU MRLs for methoxyfenozide are established in Annex II of Regulation (EC) No 396/2005. 
Codex maximum residue limits (CXLs) for this active substance were also established by the Codex 
Alimentarius Commission (CAC). Following the review of existing MRLs, the legal limits have been 
modified by Commission Regulation (EU) No 2015/1040.6 The EU MRLs for methoxyfenozide 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 during the Member State consultation 
(EFSA, 2010, 2012, 2014, 2017, 2020a; Portugal, 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 
546/20117 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, 2013).

In order to identify the potential MRLs of concern, EFSA first performed a preliminary risk 
assessment (scenario 1), using the risk assessment values derived from the existing EU uses and 
import tolerances assessed in the Article 12 MRL review, as well as from the CXLs implemented in the 
EU Legislation (EFSA, 2014). It is noted that during the MRL review, the European uses for oranges 
and mandarins were not supported by data and the existing MRL was considered for indicative 
calculation of the consumer exposure. As the MRL finally implemented in the EU legislation for these 
commodities corresponds to the CXL, risk assessment values as derived by the JMPR were considered 
for the preliminary assessment of these crops (FAO, 2012).

Chronic and acute exposure calculations were performed using revision 3.1 of the EFSA PRIMo 
(EFSA, 2018, 2019). The exposures calculated were compared with the toxicological reference values 
for methoxyfenozide, derived by EFSA in the framework of the renewal for the approval of the active 
substance (EFSA, 2017).

The highest chronic exposure was calculated for German child, representing 17% of the acceptable 
daily intake (ADI). Regarding the acute exposure, however, an exceedance of the ARFD was identified 
for oranges, grapefruits, mandarins, pears, peaches, apples, tomatoes and broccoli (boiled) 
representing 265%, 133%, 119%, 138%, 133%, 108%, 105% and 126% of the ARFD, respectively.

Regarding all other MRLs that are currently in place for methoxyfenozide, acute intake calculations 
were below the ARFD. These MRLs are therefore not considered further in the framework of this 
assessment.

With regard to the commodities where an acute risk was identified a data call was launched to 
identify potential fall-back GAPs. Given the approval restriction to indoor applications only, Member 
States were requested to submit indoor GAPs or report any import tolerance authorised.

In response to the data call, only an indoor GAP on tomatoes was reported. This fall-back GAP is 
provided in Appendix A and was already considered in the MRL review (EFSA, 2014). Detailed results 
of the residue trials and the derived fall-back MRL and risk assessment values are reported in 
Appendix B.1.1.

For citrus fruits, as the existing MRL corresponds to the current CXL, the appropriateness of using 
the peeling factor established for oranges in the framework of the MRL review and confirmed by the 
peer review for the renewal was considered. The PF of < 0.3 was derived based on three trials on 
oranges (EFSA, 2017). In the processing studies residue levels ranged between 0.13 and 0.22 mg/kg

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6 Commission Regulation (EU) 2015/1040 of 30 June 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 azoxystrobin, dimoxystrobin, fluroxypyr, 
metoxynenzido, metrafenone, oxadiazyl and tribenuron in or on certain products. OJ L 167, 1.7.2015, p. 10–56.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European 
Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 
155, 11.06.2011, p. 127–175.
in fruits, 0.52–0.94 mg/kg in peel and < 0.05 mg/kg in pulp. Although the highest residue (HR) for citrus in the CXL was much higher (1.7 mg/kg) compared to the HR measured in the processing trial, considering that residues were below the limit of quantification (LOQ) of 0.05 mg/kg in pulp, EFSA considers the derived peeling factor sufficiently conservative, and therefore suitable for the use in the consumer exposure calculations.

For all other commodities, since less critical GAPs were not reported by MS and additional data for a possible refinement were not available, fall-back MRLs or refined input values could not be derived.

A second exposure calculation (scenario 2) was therefore performed considering the peeling factor for citrus fruits and the fall-back residue data for tomatoes and assuming that the existing CXLs for apples, pears, peaches and broccoli will be withdrawn. According to the results of this second calculation, the highest chronic exposure declined to 3% of the ADI (Dutch toddler) and the highest acute exposure was calculated for lettuces, representing 91% of the ARfD. Table 1 gives an overview of the results of the preliminary and the refined acute risk assessment.

Table 1: Assessment of the existing MRLs for which a potential acute risk to European consumers was identified considering the lower toxicological reference value derived during the renewal

| Commodity       | Existing EU MRL (mg/kg) | Proposed MRL (mg/kg) | HR(a) | Acute intake(% ARfD)                          |
|-----------------|------------------------|----------------------|-------|---------------------------------------------|
|                 |                        |                      |       | Preliminary risk assessment (scenario 1)    |
|                 |                        |                      |       | Refined risk assessment (scenario 2)        |
| Oranges         | 2                      | 2                    | 1.7   | 265(b)                                     |
|                 |                        |                      |       | 63(c)                                      |
| Grapefruits     | 2                      | 2                    | 1.7   | 133(b)                                     |
|                 |                        |                      |       | 37(c)                                      |
| Mandarin        | 2                      | 2                    | 1.7   | 119(b)                                     |
|                 |                        |                      |       | 28(c)                                      |
| Pears           | 2                      | –                    | 1     | 138                                        |
|                 |                        |                      |       | –                                          |
| Peaches         | 2                      | –                    | 1.4   | 133                                        |
|                 |                        |                      |       | –                                          |
| Apples          | 2                      | –                    | 1     | 108                                        |
|                 |                        |                      |       | –                                          |
| Tomatoes        | 2                      | 0.6                  | 1.8/ 0.46(d) | 105                                      |
|                 |                        |                      |       | 27(d)                                      |
| Broccoli, boiled| 3                      | –                    | 1.6   | 126                                        |

RAC: Raw agricultural commodity, MRL: maximum residue level, ARfD: acute reference dose.
(a): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.
(b): Results of the acute intake calculations without consideration of the peeling factor.
(c): Results of the calculation considering the peeling factor of < 0.3.
(d): Assessment considering a fall-back GAP.

Based on these refined calculations, EFSA concludes that no risk to consumers was identified. Therefore, for citrus fruits, the MRLs can be maintained, and for tomatoes, a lower MRL is proposed. However, for apples, pears, peaches and broccoli, no fall-back GAPs were available to EFSA, and the acute consumer intake could not be refined. As an acute risk to European consumers cannot be excluded for these existing EU MRLs, EFSA therefore recommends lowering the MRLs for these commodities to the appropriate LOQ for enforcement purposes.

Conclusions and recommendations

The residue data submitted by the MSs in support of the fall-back GAP for tomatoes were sufficient to derive a fall-back MRL that is safe for consumers. The peeling factor for citrus fruits established during the peer review was concluded to be applicable for the corresponding CXLs and should be used in the risk assessment. Accordingly, no risk was identified for the existing MRLs in grapefruits, oranges and mandarins. For all other commodities (apples, pears, peaches, broccoli), fall-back MRLs or refined input values could not be derived since less critical GAPs were not provided by MS and no additional data for a possible refinement was available.

Therefore, MSs are recommended to withdraw their national authorisations for broccoli, apples, pears and peaches and to modify the national authorisations for tomatoes in order to comply with the fall-back MRL derived by EFSA.

In the framework of this assessment, it can be concluded that there is no need to modify the existing EU MRLs for the other commodities of plant or animal origin. Nevertheless, it is noted that
some EU MRLs were derived based on outdoor uses and Member States are recommended to review their authorisations considering the restriction to greenhouse uses only.

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) | Proposed MRL (mg/kg) | Outcome of the assessment | Comment |
|-----------------|-----------|-------------------------|----------------------|---------------------------|---------|
| 110010          | Grapefruits | 2                       | 2                    | Existing MRL can be maintained(b) |         |
| 110020          | Oranges    | 2                       | 2                    | Existing MRL can be maintained(b) |         |
| 110050          | Mandarins  | 2                       | 2                    | Existing MRL can be maintained(b) |         |
| 130010          | Apples     | 2                       | –                    | A fall-back MRL could not be proposed(c) |         |
| 130020          | Pears      | 2                       | –                    | A fall-back MRL could not be proposed(c) |         |
| 140030          | Peaches    | 2                       | –                    | A fall-back MRL could not be proposed(c) |         |
| 231010          | Tomatoes   | 2                       | 0.6                  | Fall-back MRL is proposed(d) |         |
| 241010          | Broccoli   | 3                       | –                    | A fall-back MRL could not be proposed(c) |         |
|                 | Other products of plant and animal origin | See Regulation 2015/1040 | See Regulation 2015/1040 | EU MRLs not identified as MRLs of potential concern for consumers |         |

MRL: maximum residue level.
(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
(b): The existing EU MRL is safe, considering a peeling factor.
(c): The existing EU MRL was identified as a potential MRL of concern. No uses are currently authorised in EU that could be considered to derive a fall-back MRL. EFSA proposes to lower the MRL to the appropriate LOQ and to withdraw the relevant authorisations within the EU.
(d): The existing EU MRL was identified as a MRL of potential concern. Data supporting a fall-back MRL were submitted by MSs and no risk to consumers is identified for this fall-back MRL.

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**Abbreviations**

- **a.i.** active ingredient
- **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
- **CAS** Chemical Abstract Service
- **CF** conversion factor for enforcement residue definition to risk assessment residue definition
- **CS** capsule suspension
- **CV** coefficient of variation (relative standard deviation)
- **CXL** codex maximum residue limit
| Acronym   | Full Form                                                                 |
|-----------|---------------------------------------------------------------------------|
| DAR       | draft assessment report                                                   |
| DAT       | days after treatment                                                      |
| DB        | dietary burden                                                            |
| DM        | dry matter                                                                |
| DP        | dustable powder                                                           |
| DS        | powder for dry seed treatment                                              |
| EC        | emulsifiable concentrate                                                  |
| EDI       | estimated daily intake                                                    |
| EMS       | evaluating Member State                                                   |
| eq eq     | residue expressed as a.s. equivalent                                       |
| FAO       | Food and Agriculture Organization of the United Nations                    |
| FID       | flame ionisation detector                                                 |
| GAP       | Good Agricultural Practice                                                |
| GC        | gas chromatography                                                        |
| GC-FID    | gas chromatography with flame ionisation detector                         |
| GC-MS     | gas chromatography with mass spectrometry                                |
| GC-MS/MS  | gas chromatography with tandem mass spectrometry                         |
| GS        | growth stage                                                              |
| HR        | highest residue                                                           |
| IEDI      | international estimated daily intake                                       |
| IEStI     | international estimated short-term intake                                 |
| ISO       | International Organisation for Standardization                           |
| IUPAC     | International Union of Pure and Applied Chemistry                         |
| JMPR      | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food   |
|           | and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| LOQ       | limit of quantification                                                   |
| Mo        | Monitoring                                                                |
| MRL       | maximum residue level                                                     |
| MS        | Member States                                                             |
| MS        | mass spectrometry detector                                                |
| MS/MS     | tandem mass spectrometry detector                                         |
| MW        | molecular weight                                                          |
| NEU       | northern European Union                                                   |
| OECD      | Organisation for Economic Co-operation and Development                    |
| PF        | processing factor                                                         |
| PHI       | preharvest interval                                                       |
| PRIMo     | (EFSA) Pesticide Residues Intake Model                                    |
| RA        | risk assessment                                                           |
| RD        | residue definition                                                        |
| RAC       | raw agricultural commodity                                                |
| RD        | residue definition                                                        |
| RMS       | rapporteur Member State                                                   |
| SANCO     | Directorate-General for Health and Consumers                              |
| SC        | suspension concentrate                                                    |
| SEU       | southern European Union                                                   |
| SMILES    | simplified molecular-input line-entry system                              |
| SL        | soluble concentrate                                                       |
| SP        | water soluble powder                                                      |
| STMR      | supervised trials median residue                                          |
| TAR       | total applied radioactivity                                                |
| WHO       | World Health Organization                                                 |
## Appendix A – Summary of the fall-back GAPs considered in the assessment

| Crop and/or situation | MS or country | F G or I<sup>(a)</sup> | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (d)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-------------------------|-----------------------------------|-------------|-----------------|--------------------------------|-------------------|---------|
|                       |               |                         |                                   | Type<sup>(b)</sup> | Conc. a.s. | 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 |               |
| Tomato                | PT            | G                       | caterpillars                      | SC          | 240 g/L | Spraying | BBCH 30–87 | 3 | 14–21 days | 0.0096 | 500–1000 | 0.048–0.096 kg a.i./ha | 1 |

MS: Member State, a.s.: active substance, SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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 Endpoints relevant for the assessment

B.1. Magnitude of residues in plants

B.1.1. Summary of residues data from the supervised residue trials – fall-back

| Crop    | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials relevant to the supported GAPs (mg/kg) | Recommendations/comments (OECD calculations)                                                                 | MRL proposals (mg/kg) | HR (mg/kg)\(^{(b)}\) | STMR (mg/kg)\(^{(c)}\) |
|---------|-------------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|----------------------|----------------------|----------------------|
| Tomatoes| EU                      | 0.08; 0.11; 4 × 0.12; 0.13; 2 × 0.14; 0.16; 0.18; 2 × 0.20; 0.26; 0.29; 0.46                   | Trials on tomatoes compliant with fall-back GAP already assessed under MRL review (EFSA, 2014). MRL\(_{OECD}\): 0.55 | 0.6                  | 0.46                  | 0.14                  |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

\(^{(a)}\): 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.
B.1.2. Processing factors

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Comment/Source |
|---------------------|-----------------------------------|------------------------|----------------|
| Oranges, peeled     | 3                                 | Individual values | Median PF       |
|                     |                                   | < 0.4, < 0.3, < 0.2    | < 0.3           | Residue levels of methoxyfenozide in pulp < 0.05 mg/kg. PF extrapolated to all citrus fruits. (EFSA, 2014, 2017) |

PF: Processing factor (=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

| Highest IEDI, according to EFSA PRIMo vers.3.1 | 0.1 mg/kg bw per day (EFSA, 2017) |
|------------------------------------------------|---------------------------------|
| **Scenario 1: preliminary risk assessment**   | 17% ADI (DE, child)            |
| **Scenario 2: refined risk assessment**       | 3% ADI (NL toddler)            |

**Assumptions made for the calculations**

**Scenario 1: preliminary risk assessment**
The calculation is based on the median residue levels in the raw agricultural commodities.

**Scenario 2: refined risk assessment**
The calculation is based on the median residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied.

The median residue level for apples, pears, peaches and broccoli was disregarded (assuming that the existing CXLs of concern will be withdrawn) and the median residue level for tomatoes resulting from the CXL of concern, is replaced by the median residue levels resulting from the fall-back GAP.

### ARfD

| Highest IESTI, according to EFSA PRIMo | 0.1 mg/kg bw (EFSA, 2017) |
|----------------------------------------|---------------------------|
| **Scenario 1: preliminary risk assessment** | 265% ARfD (oranges) |
|                                        | 133% ARfD (grapefruits)  |
|                                        | 119% ARfD (mandarins)    |
|                                        | 138% ARfD (pears)        |
|                                        | 133% ARfD (peaches)      |
|                                        | 108% ARfD (apples)       |
|                                        | 105% ARfD (tomatoes)     |
|                                        | 126% ARfD (broccoli, boiled) |
| **Scenario 2: refined risk assessment**  | 91% ARfD (lettuce)       |

**Assumptions made for the calculations**

**Scenario 1: preliminary risk assessment**
The calculation is based on the highest residue levels in the raw agricultural commodities.

**Scenario 2: refined risk assessment**
The calculation is based on the highest residue levels in the raw agricultural commodities, except for citrus fruits, where the relevant peeling factor was applied.

The highest residue level for apples, pears, peaches and broccoli was disregarded (assuming that the existing CXLs of concern will be withdrawn) and the highest residue levels for tomatoes resulting from the CXL of concern, is replaced by the highest residue levels resulting from the fall-back GAP.

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, CXL: codex maximum residue limit.
### B.3. Proposed MRLs

| Code number(a) | Commodity       | Existing EU MRL (mg/kg) | Proposed MRL (mg/kg) | Outcome of the assessment | Comment                                                                 |
|----------------|-----------------|-------------------------|----------------------|--------------------------|-------------------------------------------------------------------------|
| 110010         | Grapefruits     | 2                       | 2                    | Existing MRL can be maintained(b) |                                                                          |
| 110020         | Oranges         | 2                       | 2                    | Existing MRL can be maintained(b) |                                                                          |
| 110050         | Mandarins       | 2                       | 2                    | Existing MRL can be maintained(b) |                                                                          |
| 130010         | Apples          | 2                       | –                    | A fall-back MRL could not be proposed(c) |                                                                          |
| 130020         | Pears           | 2                       | –                    | A fall-back MRL could not be proposed(c) |                                                                          |
| 140030         | Peaches         | 2                       | –                    | A fall-back MRL could not be proposed(c) |                                                                          |
| 231010         | Tomatoes        | 2                       | 0.6                  | Fall-back MRL is proposed(d) |                                                                          |
| 241010         | Broccoli        | 3                       | –                    | A fall-back MRL could not be proposed(c) |                                                                          |
| –              | Other products of plant and animal origin |                 | See Regulation 2015/1040 | See Regulation 2015/1040 | EU MRLs not identified as MRLs of potential concern for consumers |

**Enforcement residue definition:** methoxyfenozide

- **MRL:** maximum residue level.
- (a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005.
- (b): The existing EU MRL is safe, considering a peeling factor.
- (c): The existing EU MRL was identified as a potential MRL of concern. No uses are currently authorised in EU that could be considered to derive a fall-back MRL. EFSA proposes to lower the MRL to the appropriate LOQ and to withdraw the relevant authorisations within the EU.
- (d): The existing EU MRL was identified as a MRL of potential concern. Data supporting a fall-back MRL were submitted by MSs and no risk to consumers is identified for this fall-back MRL.
Appendix C – Pesticide Residue Intake Model (PRIMo)

• PRIMo (scenario 1)

Methoxyfenozide (F)

Toxicological reference values

| Source of ADI | ADI (mg/kg bw per day) | Source of ARfD | ARfD (mg/kg bw) |
|---------------|------------------------|---------------|----------------|
| EFSA          | 0.1                    | EFSA          | 0.1            |

LOQs (mg/kg) range from: 0.01 to: 1.0

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|-------------------------------|----------------------------------|-----------------------------------------------|
| Mandarins                    | 17%                              | 17%                                            |
| Pears                         | 15%                              | 15%                                            |
| Apples                        | 10%                              | 10%                                            |
| Sugar beet roots              | 10%                              | 10%                                            |
| Apples                        | 7%                               | 7%                                             |
| Lettuces                      | 7%                               | 7%                                             |
| Mandarins                    | 6%                               | 6%                                             |
| Sugar beet roots              | 6%                               | 6%                                             |
| Apples                        | 5%                               | 5%                                             |
| Mandarins                    | 5%                               | 5%                                             |
| Apples                        | 4%                               | 4%                                             |
| Wine grapes                   | 4%                               | 4%                                             |
| Mandarins                    | 3%                               | 3%                                             |
| Apples                        | 3%                               | 3%                                             |
| Wine grapes                   | 3%                               | 3%                                             |
| Apples                        | 2%                               | 2%                                             |
| Oranges                       | 2%                               | 2%                                             |
| Apples                        | 1%                               | 1%                                             |
| Wine grapes                   | 1%                               | 1%                                             |
| Apples                        | 0.5%                             | 0.5%                                           |
| Oranges                       | 0.5%                             | 0.5%                                           |

Estimated long-term dietary intake (TMDI/IEDI/ESDI) was below the ADI.

The detailed tables of residues of methoxyfenozide (F) are available to present a public health concern.

Conclusion:

The estimated long-term dietary intake (TMDI/IEDI/ESDI) was below the ADI.

www.efsa.europa.eu/efsajournal 15 EFSA Journal 2020;18(12):6330
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for all crops

#### Unprocessed commodities

| Commodity         | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity         | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------------|---------------------------|---------------------|-----------------------|-------------------|---------------------------|---------------------|-----------------------|
| Oranges           | 2/2                       | 265                 | 265%                  | Oranges           | 2/2                       | 61                  | 61%                   |
| Pears             | 2/1                       | 138                 | 138%                  | Pears             | 2/1                       | 36                  | 36%                   |
| Peaches           | 2/1.4                     | 133                 | 133%                  | Peaches           | 2/1.4                     | 31                  | 31%                   |
| Mandarins         | 2/2                       | 119                 | 119%                  | Mandarins         | 2/2                       | 29                  | 29%                   |
| Apples            | 2/1                       | 108                 | 108%                  | Apples            | 2/1                       | 25                  | 25%                   |
| Tomatoes          | 2/1.8                     | 105                 | 105%                  | Tomatoes          | 2/1.8                     | 18                  | 18%                   |
| Lettuces          | 4/2.39                    | 91                  | 91%                   | Lettuces          | 4/2.39                    | 15                  | 15%                   |
| Broccoli          | 3/1.6                     | 67                  | 67%                   | Broccoli          | 3/1.6                     | 10                  | 10%                   |
| Plums             | 2/1.4                     | 59                  | 59%                   | Plums             | 2/1.4                     | 8                  | 8%                    |
| Lemons            | 2/1.7                     | 58                  | 58%                   | Lemons            | 2/1.7                     | 6                  | 6%                    |
| Spinaches         | 4/2.39                    | 54                  | 54%                   | Spinaches         | 4/2.39                    | 4                  | 4%                    |
| Apricots          | 2/1.4                     | 49                  | 49%                   | Apricots          | 2/1.4                     | 3                  | 3%                    |
| Table grapes      | 1/0.57                    | 42                  | 42%                   | Table grapes      | 1/0.57                    | 2                  | 2%                    |

#### Processed commodities

| Commodity                | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodity                | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|--------------------------|---------------------------|---------------------|-----------------------|--------------------------|---------------------------|---------------------|-----------------------|
| Broccoli/boiled         | 3/1.6                     | 126                 | 126%                  | Broccoli/boiled         | 3/1.6                     | 39                  | 39%                   |
| Spinaches/frozen; boiled| 4/2.39                    | 74                  | 74%                   | Spinaches/frozen; boiled| 4/2.39                    | 30                  | 30%                   |
| Peas/canned             | 5/1.36                    | 24                  | 24%                   | Peas/canned             | 5/1.36                    | 9.8                 | 9.8%                  |
| Oranges/juice           | 2/0.44                    | 23                  | 23%                   | Oranges/juice           | 2/0.44                    | 9.0                 | 9.0%                  |
| Peas (with pods)/boiled | 2/0.38                    | 15                  | 15%                   | Peas (with pods)/boiled | 2/0.38                    | 6.7                 | 6.7%                  |
| Sugar beets (root)/sugar| 0.31.32                   | 12                  | 12%                   | Sugar beets (root)/sugar| 0.31.32                   | 6.2                 | 6.2%                  |
| Apples/juice            | 2/0.18                    | 10                  | 10%                   | Apples/juice            | 2/0.18                    | 4.8                 | 4.8%                  |
| Wine grapes/juice       | 1/0.13                    | 5.8                 | 5.8%                  | Wine grapes/juice       | 1/0.13                    | 3.6                 | 3.6%                  |
| Peaches/juice           | 2/0.34                    | 5.6                 | 5.6%                  | Peaches/juice           | 2/0.34                    | 3.4                 | 3.4%                  |
| Courgettes/boiled       | 0.30.15                   | 5.3                 | 5.3%                  | Courgettes/boiled       | 0.30.15                   | 3.0                 | 3.0%                  |
| Carrots/juice           | 0.5.0.13                   | 4.7                 | 4.7%                  | Carrots/juice           | 0.5.0.13                   | 2.8                 | 2.8%                  |

#### Conclusion:

The estimated short term intake (IESTI) exceeded the toxicological reference value for 7 commodities. For processed commodities, the toxicological reference value was exceeded in one or several cases.
### PRIMo (scenario 2)

#### Toxicological reference values

| LOQs (mg/kg) | ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|-------------|------------------------|----------------|
| 0.01 - 0.02 | 0.1                    | 0.1            |

Source of ADI: EFSA

Source of ARfD: EFSA

#### EFSA PRIMo revision 3.1; 2019/03/19

Year of evaluation: 2017

No of diets exceeding the ADI: ---

### Normal mode

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

**Input values**
- Details – chronic risk assessment
- Supplementary results – chronic risk assessment
- Details – acute risk assessment/children
- Details – acute risk assessment/adults

#### Exposure resulting from

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Table grapes                   | 3%                                | 3.09                                          |
| Table grapes                   | 2%                                | 2.32                                          |
| Spinaches                      | 2%                                | 2.18                                          |
| Sugar beet roots               | 2%                                | 2.04                                          |
| Tomatoes                       | 2%                                | 1.90                                          |
| Oranges                        | 2%                                | 1.71                                          |
| Spinaches                      | 2%                                | 1.66                                          |
| Lettuces                       | 2%                                | 1.60                                          |
| Wine grapes                    | 2%                                | 1.57                                          |
| Tomatoes                       | 1%                                | 1.48                                          |
| Spinaches                      | 1%                                | 1.43                                          |
| Milk: Cattle                   | 1%                                | 1.40                                          |
| Chards/beet leaves             | 1%                                | 1.39                                          |
| Carrots                        | 1%                                | 1.34                                          |
| Sugar beet roots               | 1%                                | 1.31                                          |
| Tomatoes                       | 1%                                | 1.30                                          |
| Spinaches                      | 1%                                | 1.27                                          |
| Lettuces                       | 1%                                | 1.25                                          |
| Spinaches                      | 1%                                | 1.20                                          |
| Lettuces                       | 1%                                | 1.17                                          |
| Tomatoes                       | 1%                                | 1.15                                          |
| Spinaches                      | 1%                                | 1.13                                          |
| Lettuces                       | 1%                                | 1.09                                          |
| Tomatoes                       | 1%                                | 1.05                                          |
| Spinaches                      | 1%                                | 1.03                                          |
| Lettuces                       | 1%                                | 1.00                                          |
| Tomatoes                       | 1%                                | 0.97                                          |
| Spinaches                      | 1%                                | 0.94                                          |
| Lettuces                       | 1%                                | 0.91                                          |
| Tomatoes                       | 1%                                | 0.88                                          |
| Spinaches                      | 1%                                | 0.85                                          |
| Lettuces                       | 1%                                | 0.83                                          |
| Tomatoes                       | 1%                                | 0.80                                          |
| Spinaches                      | 1%                                | 0.77                                          |
| Lettuces                       | 1%                                | 0.75                                          |
| Tomatoes                       | 1%                                | 0.72                                          |
| Spinaches                      | 1%                                | 0.70                                          |
| Lettuces                       | 1%                                | 0.67                                          |
| Tomatoes                       | 1%                                | 0.65                                          |
| Spinaches                      | 1%                                | 0.63                                          |
| Lettuces                       | 1%                                | 0.60                                          |
| Tomatoes                       | 1%                                | 0.57                                          |
| Spinaches                      | 1%                                | 0.54                                          |
| Lettuces                       | 1%                                | 0.51                                          |
| Tomatoes                       | 1%                                | 0.48                                          |
| Spinaches                      | 1%                                | 0.45                                          |
| Lettuces                       | 1%                                | 0.42                                          |
| Tomatoes                       | 1%                                | 0.39                                          |
| Spinaches                      | 1%                                | 0.36                                          |
| Lettuces                       | 1%                                | 0.33                                          |
| Tomatoes                       | 1%                                | 0.30                                          |
| Spinaches                      | 1%                                | 0.27                                          |
| Lettuces                       | 1%                                | 0.25                                          |
| Tomatoes                       | 1%                                | 0.22                                          |
| Spinaches                      | 1%                                | 0.19                                          |
| Lettuces                       | 1%                                | 0.16                                          |
| Tomatoes                       | 1%                                | 0.13                                          |
| Spinaches                      | 1%                                | 0.10                                          |
| Lettuces                       | 1%                                | 0.07                                          |
| Tomatoes                       | 1%                                | 0.04                                          |
| Spinaches                      | 1%                                | 0.01                                          |
| Lettuces                       | 1%                                | 0.00                                          |
| Tomatoes                       | 1%                                | 0.00                                          |

#### Conclusion:

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long-term intake of residues of methoxyfenozide (F) is unlikely to present a public health concern.

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

### Details – acute risk assessment/children

The acute risk assessment is based on the ARID.

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

### Results for children

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-------------|--------------------------|----------------------|-------|
| 91%                   | Lettuces    | 4/2.39                   | 91                   |       |
| 68%                   | Oranges     | 2/0.51                   | 68                   |       |
| 59%                   | Plums       | 2/1.4                    | 59                   |       |
| 56%                   | Sweet peppers/bell peppers | 2/0.94               | 56                   |       |
| 54%                   | Spinaches   | 4/2.39                   | 54                   |       |
| 49%                   | Apricots    | 2/1.4                    | 49                   |       |
| 42%                   | Table grapes | 1/0.57                  | 42                   |       |
| 40%                   | Grapefruits | 2/0.51                   | 40                   |       |
| 37%                   | Chards/beet leaves | 4/2.39              | 37                   |       |
| 30%                   | Mandarins   | 2/0.51                   | 30                   |       |
| 27%                   | Tomatoes    | 0.6/0.46                 | 27                   |       |
| 25%                   | Quinces     | 2/1                     | 25                   |       |
| 23%                   | Melons      | 0.3/0.15                 | 23                   |       |
| 22%                   | Peas        | 5/3.4                    | 22                   |       |
| 21%                   | Avocados    | 0.7/0.41                 | 21                   |       |

### Results for adults

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

### Details – acute risk assessment/adults

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

For processed commodities, no exceedance of the ARfD/ADI was identified.

### Unprocessed commodities

#### Results for children

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-------------|--------------------------|----------------------|-------|
| 74%                   | Chards/beet leaves/boiled | 4/2.39               | 74                   |       |
| 33%                   | Spinaches/frozen; boiled | 4/2.39              | 33                   |       |
| 24%                   | Peas/canned | 5/1.36                  | 24                   |       |
| 13%                   | Pumpkins/boiled | 0.3/0.15             | 13                   |       |
| 12%                   | Beans (with pods)/boiled | 2/0.99              | 12                   |       |
| 12%                   | Sugar beets (root)/sugar | 0.3/0.12            | 12                   |       |
| 6%                    | Wine grapes/juice | 1/0.13                | 6.8                  |       |
| 5%                    | Courgettes/boiled | 0.30/0.15            | 5.3                  |       |
| 5%                    | Carrots/juice | 0.50/0.13              | 4.7                  |       |
| 3%                    | Gherkins/pickled | 0.30/0.15            | 3.4                  |       |
| 3%                    | Oranges/juice | 2/0.06                 | 3.2                  |       |
| 3%                    | Plums/juice | 2/0.34                 | 3.2                  |       |
| 1%                    | Tomatoes/sauce/puree | 0.6/0.14           | 1.3                  |       |
| 1%                    | Quinces/jam | 2/0.43                 | 1.3                  |       |
| 1%                    | Tomatoes/juice | 0.6/0.05             | 1.00                 |       |

#### Results for adults

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

### Processed commodities

#### Results for children

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | IESTI |
|-----------------------|-----------------------|--------------------------|----------------------|-------|
| 74%                   | Chards/beet leaves/boiled | 4/2.39               | 74                   |       |
| 33%                   | Spinaches/frozen; boiled | 4/2.39              | 33                   |       |
| 24%                   | Peas/canned | 5/1.36                  | 24                   |       |
| 13%                   | Pumpkins/boiled | 0.3/0.15             | 13                   |       |
| 12%                   | Beans (with pods)/boiled | 2/0.99              | 12                   |       |
| 12%                   | Sugar beets (root)/sugar | 0.3/0.12            | 12                   |       |
| 6%                    | Wine grapes/juice | 1/0.13                | 5.8                  |       |
| 5%                    | Courgettes/boiled | 0.30/0.15            | 5.3                  |       |
| 5%                    | Carrots/juice | 0.50/0.13              | 4.7                  |       |
| 3%                    | Gherkins/pickled | 0.30/0.15            | 3.4                  |       |
| 3%                    | Oranges/juice | 2/0.06                 | 3.2                  |       |
| 3%                    | Plums/juice | 2/0.34                 | 3.2                  |       |
| 1%                    | Tomatoes/sauce/puree | 0.6/0.14            | 1.3                  |       |
| 1%                    | Quinces/jam | 2/0.43                 | 1.3                  |       |
| 1%                    | Tomatoes/juice | 0.6/0.05             | 1.00                 |       |

#### Results for adults

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

### Conclusion:

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

A short-term intake of residues of methoxyfenozide (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

### D.1. Consumer risk assessment

| Commodity | Chronic risk assessment |  | Acute risk assessment |  |
|-----------|-------------------------|---|-----------------------|---|
|           | Input value (mg/kg)     | Comment | Input value (mg/kg)   | Comment |
| **Risk assessment residue definition: methoxyfenozide** | | | | |
| Grapefruit, lemons, limes | 0.28 | STMR (CXL) (EFSA, 2014) | 1.7 | HR (CXL) (EFSA, 2014) |
| | 0.08 | STMR (CXL) × PF (0.3) (EFSA, 2014) | 0.48 | HR (CXL) × PF (0.3) (EFSA, 2014) |
| Oranges, Mandarins | 0.28 | STMR (CXL) (FAO, 2012) | 1.7 | HR (CXL) (FAO, 2012) |
| | 0.08 | STMR (CXL) × PF (0.3) (EFSA, 2014) | 0.48 | HR (CXL) × PF (0.3) (EFSA, 2014) |
| Tree nuts | 0.021 | STMR (CXL) (EFSA, 2014) | 0.07 | HR (CXL) (EFSA, 2014) |
| Apples | 0.43 | STMR (CXL) (EFSA, 2014) | 1 | HR (CXL) (EFSA, 2014) |
| | – | No fall-back available | – | No fall-back available |
| Pears | 0.43 | STMR (CXL) (EFSA, 2014) | 1 | HR (CXL) (EFSA, 2014) |
| | – | No fall-back available | – | No fall-back available |
| Quinces | 0.43 | STMR (CXL) (EFSA, 2014) | 1 | HR (CXL) (EFSA, 2014) |
| Medlar | 0.43 | STMR (CXL) (EFSA, 2014) | 1 | HR (CXL) (EFSA, 2014) |
| Loquat | 0.43 | STMR (CXL) (EFSA, 2014) | 1.4 | HR (CXL) (EFSA, 2014) |
| Apricots | 0.34 | STMR (CXL) (EFSA, 2014) | 1.4 | HR (CXL) (EFSA, 2014) |
| Cherries | 0.34 | STMR (CXL) (EFSA, 2014) | 1.4 | HR (CXL) (EFSA, 2014) |
| Peaches | 0.34 | STMR (CXL) (EFSA, 2014) | 1.4 | HR (CXL) (EFSA, 2014) |
| | – | No fall-back available | – | No fall-back available |
| Plums | 0.340 | STMR (CXL) (EFSA, 2014) | 1.40 | HR (CXL) (EFSA, 2014) |
| Table grapes | 0.260 | STMR (EFSA, 2014) | 0.57 | HR (EFSA, 2014) |
| Wine grapes | 0.330 | STMR (CXL) (EFSA, 2014) | 0.84 | HR (CXL) (EFSA, 2014) |
| Strawberries | 0.240 | STMR (CXL) (EFSA, 2014) | 1.20 | HR (CXL) (EFSA, 2014) |
| Blueberries | 0.130 | STMR (CXL) (EFSA, 2014) | 2.00 | HR (CXL) (EFSA, 2014) |
| Cranberries | 0.085 | STMR (CXL) (EFSA, 2014) | 0.39 | HR (CXL) (EFSA, 2014) |
| Avocados | 0.130 | STMR (CXL) (EFSA, 2014) | 0.41 | HR (CXL) (EFSA, 2014) |
| Papaya | 0.310 | STMR (CXL) (EFSA, 2014) | 0.33 | HR (CXL) (EFSA, 2014) |
| Granate apples/pomegranates | 0.125 | STMR (EFSA, 2014) | 0.36 | HR (CXL) (EFSA, 2014) |
| Sweet potatoes | 0.010 | STMR (CXL) (EFSA, 2014) | 0.01 | HR (CXL) (EFSA, 2014) |
| Commodity                        | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------|-----------------------|
|                                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Carrots                         | 0.130                   | STMR (CXL) (EFSA, 2014)| 0.31                | HR (CXL) (EFSA, 2014) |
| Radishes                        | 0.080                   | STMR (CXL) (EFSA, 2014)| 0.12                | HR (CXL) (EFSA, 2014) |
| **Tomatoes**                    | 0.2                     | STMR (CXL) (EFSA, 2014)| 1.8                 | HR (CXL) (EFSA, 2014) |
|                                 | 0.14                    | STMR (Fall-back)       | 0.46                | HR (Fall-back)         |
| Sweet peppers/bell peppers      | 0.16                    | STMR (CXL) (EFSA, 2014)| 0.94                | HR (CXL) (EFSA, 2014) |
| Aubergines/eggplants            | 0.14                    | STMR (EFSA, 2014)      | 0.46                | HR (CXL) (EFSA, 2014) |
| Cucurbits with edible peel      | 0.09                    | STMR (CXL) (EFSA, 2014)| 0.15                | HR (CXL) (EFSA, 2014) |
| Melons                          | 0.09                    | STMR (CXL) (EFSA, 2014)| 0.15                | HR (CXL) (EFSA, 2014) |
| Pumpkins                        | 0.09                    | STMR (CXL) (EFSA, 2014)| 0.15                | HR (CXL) (EFSA, 2014) |
| Sweet corn                      | 0.02                    | STMR (CXL) (EFSA, 2014)| 0.02                | HR (CXL) (EFSA, 2014) |
| **Broccoli**                    | 0.94                    | STMR (CXL) (EFSA, 2014)| 1.60                | HR (CXL) (EFSA, 2014) |
|                                 | –                       | No fall-back available | –                   | No fall-back available |
| Lettuces and salad plants       | 1.13                    | STMR (EFSA, 2014)      | 2.39                | HR (EFSA, 2014)       |
| Spinaches and similar Leaves    | 1.13                    | STMR (CXL) (EFSA, 2014)| 2.39                | HR (CXL) (EFSA, 2014) |
| Herbs and edible flowers        | 1.13                    | STMR (EFSA, 2014)      | 2.39                | HR (EFSA, 2014)       |
| Beans (with pods)               | 0.07                    | STMR (CXL) (EFSA, 2014)| 0.99                | HR (CXL) (EFSA, 2014) |
| Beans, peas (without pods)      | 0.05                    | STMR (CXL) (EFSA, 2014)| 0.18                | HR (CXL) (EFSA, 2014) |
| Peas (with pods)                | 0.1                     | STMR (CXL) (EFSA, 2014)| 0.81                | HR (CXL) (EFSA, 2014) |
| Beans (dry)                     | 0.05                    | STMR (CXL) (EFSA, 2014)| 0.22                | HR (CXL) (EFSA, 2014) |
| Peas (dry)                      | 0.17                    | STMR (CXL) (EFSA, 2014)| 3.40                | HR (CXL) (EFSA, 2014) |
| Peanuts/groundnuts              | 0.01                    | STMR (CXL) (EFSA, 2014)| 0.02                | HR (CXL) (EFSA, 2014) |
| Cotton seeds                    | 0.46                    | STMR (CXL) (EFSA, 2014)| 4.90                | HR (CXL) (EFSA, 2014) |
| Sugar beet roots                | 0.11                    | STMR (CXL) (EFSA, 2014)| 0.18                | HR (CXL) (EFSA, 2014) |
| Swine and ruminant meat         | 0.01                    | STMR (CXL) (EFSA, 2014)| 0.053               | HR (CXL) (EFSA, 2014) |
| Swine and ruminant fat tissue   | 0.036                   | STMR (CXL) (EFSA, 2014)| 0.24                | HR (CXL) (EFSA, 2014) |
| Swine and ruminant liver        | 0.025                   | STMR (CXL) (EFSA, 2014)| 0.096               | HR (CXL) (EFSA, 2014) |
### Commodity

| Commodity                     | Chronic risk assessment          | Acute risk assessment          |
|-------------------------------|----------------------------------|--------------------------------|
|                               | Input value (mg/kg) | Comment                               | Input value (mg/kg) | Comment                               |
| Swine and ruminant kidney     | 0.025 STMR (CXL) (EFSA, 2014) |                                   | 0.096 HR (CXL) (EFSA, 2014) |
| Poultry meat, liver, fat      | 0.01* STMR (CXL) (EFSA, 2014)  |                                   | 0.01* HR (CXL) (EFSA, 2014)  |
| Cattle, sheep, goat and horse milk | 0.004 STMR (CXL) (EFSA, 2014) |                                   | 0.004 STMR (CXL) (EFSA, 2014) |
| Birds eggs                    | 0.003 STMR (CXL) (EFSA, 2014)  |                                   | 0.003 HR (CXL) (EFSA, 2014)  |

STMR: supervised trials median residue, CXL: codex maximum residue limit, HR: highest residue.

*: Indicates that the input value is proposed at the limit of quantification.

Crops in bold indicate the commodities of relevance in the assessment (for which an acute intake concern was identified under scenario 1).
## Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | Chemical name/SMILES notation<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|---------------------------------------------|--------------------------------|
| methoxyfenozide                 | $N'-$tert-butyl-$N'$-(3,5-dimethylbenzoyl)-3-methoxy-2-methylbenzohydrazide | ![Structural formula](image) |
|                                 | QCAWEPFNJXQPAN-UHFFFAOYSA-N                 |                                |
|                                 | Cc1c(cccc1OC)(=O)NN(C(=O)c1 cc(C)cc(C)c1)C(C)(C)C |                                |

SMILES: simplified molecular-input line-entry system.

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

<sup>(b)</sup> ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 03 Sep 2019).

<sup>(c)</sup> ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 Aug 2019).