Modification of the existing maximum residue levels for acequinocyl in citrus fruits

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Agro-Kanesho submitted a request to the competent national authority in Germany to modify the existing maximum residue level (MRLs) for the active substance acequinocyl in citrus fruits. The data submitted in support of the request were found to be sufficient to derive MRL proposals for grapefruits, oranges, lemons, limes and mandarins. Adequate analytical methods for enforcement are available to control the residues of acequinocyl in the commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of acequinocyl according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Agro-Kanesho submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance acequinocyl in citrus fruits. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 7 November 2018. To accommodate for the intended use of acequinocyl, the EMS proposed to raise the existing MRLs in citrus fruits from 0.2 mg/kg (grapefruits, lemons, limes and others) and from 0.4 mg/kg (oranges and mandarins) to 0.5 mg/kg for all citrus fruits.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessment and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of acequinocyl following foliar applications was investigated in crops belonging to the groups of fruit crops (apple, aubergines and oranges).

Studies investigating the effect of processing on the nature of acequinocyl (hydrolysis studies) were not available.

As the proposed uses of acequinocyl are on permanent crops, investigations of residues in rotational crops are not required.

Based on the metabolic pattern identified in metabolism studies and the toxicological significance of metabolites resulted from the use patterns described by the metabolism studies in primary crops, the previously derived residue definitions, i.e. 'acequinocyl' for enforcement and risk assessment are applicable in the framework of the current application.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of residues (limit of quantification (LOQ)) at 0.01 mg/kg in the crops assessed.

Following the EU extrapolation rules, the available residue trials in oranges and mandarins are sufficient to derive MRL proposal of 0.6 mg/kg to be applied to all the crops belonging to the citrus fruit group.

Processing factors (PF) for the crops under assessment were derived from processing studies as well as from the supervised residue trials. A peeling factor of 0.16 was derived from oranges to be applicable to the residues detected in lemons, oranges and grapefruits, while a peeling factor of 0.20 was derived from supervised residue trials to be applied to limes and mandarins. Indicative processing factors were derived for citrus pomace.

As the by-products of crops under consideration are used as feed product (citrus dried pulp), a potential carry-over into food of animal origin was assessed. The calculated indicative livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all ruminant species. However, due to the lack of reliable information on all authorised uses of acequinocyl on other feed items, only an indicative dietary burden calculation could be calculated. Therefore, EFSA proposed to postpone the assessment of residues in animal products considering that the review of the existing MRLs under Article 12 will be performed in due time.

The toxicological profile of acequinocyl was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.023 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.08 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo.

The calculated total chronic intake accounted for 11% of the ADI (Germany, children diet) and the highest contributor of the residues in the citrus fruits under assessment to the total exposure accounting for a maximum of 2.8% (oranges, German children diet).

No acute consumer risk was identified in relation to the MRL proposals for citrus fruits. Therefore, EFSA concluded that the proposed use of acequinocyl on citrus fruits will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

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

| Code\(^{(a)}\) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------|-------------|-------------------------|-------------------------|--------------------------------------------------------------------------------------|
| 0110010     | Grapefruits | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110020     | Oranges     | 0.4                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110030     | Lemons      | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110040     | Limes       | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110050     | Mandarins   | 0.4                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |

Enforcement residue definition: acequinocyl\(^{(F)}\)

MRL: maximum residue level; SEU: southern Europe.
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\(^{(F)}\): Fat soluble.
Assessment

The detailed description of the intended use of acequinocyl in citrus fruits, which is the basis for the current maximum residue level (MRL) application, is reported in Appendix A.

Acequinocyl is the ISO common name for 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Acequinocyl was evaluated in the framework of Directive 91/414/EEC in conjunction with Regulation (EU) No 188/2011 with the Netherlands designated as the rapporteur Member State (RMS) for the representative use as field and greenhouse foliar applications on ornamentals, apples and pears. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2013b). Acequinocyl was approved for the use as an acaricide on 1 September 2014.

The European Union (EU) MRLs for acequinocyl are established in Annexes III of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has not yet been completed. EFSA has issued several reasoned opinions on the modification of MRLs for acequinocyl. The proposals from these reasoned opinions have been considered in the MRL legislation.

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Agro-Kanesho submitted an application to the competent national authority in Germany (evaluating Member State (EMS)) requesting a modification of the existing MRLs for the active substance acequinocyl in citrus fruits. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 7 November 2018. To accommodate for the intended use of acequinocyl, the EMS proposed to raise the existing MRLs of 0.2 mg/kg (applicable to grapefruits, lemons, limes and other, non-specified citrus varieties) and 0.4 mg/kg (applicable to oranges and mandarins) to 0.5 mg/kg for all citrus fruits.

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2018), the DAR (and its final addendum) (Netherlands, 2005, 2013) prepared under Council Directive 91/414/EEC, the Commission review report on acequinocyl (European Commission, 2014), the conclusion on the peer review of the pesticide risk assessment of the active substance acequinocyl (EFSA, 2013b), as well as the conclusions from previous EFSA opinions on acequinocyl (EFSA, 2010a,b, 2013a, 2015b, 2016).

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

As the review of the existing MRLs under Article 12 of Regulation 396/2005 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the MRL review that will provide a more comprehensive review of the European uses of acequinocyl.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (Germany, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1 Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2 Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ L 53, 26.2.2011, p. 51–55.
3 Commission Implementing Regulation (EU) No 496/2014 of 14 May 2014 approving the active substance acequinocyl, 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 143, 15.5.2014, p. 1–5.
4 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
5 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
6 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

The metabolism of acequinocyl in primary crops was evaluated in the fruit crop group (apples, aubergines, oranges) in the framework of the peer review under Commission Regulation (EU) No 188/2011 (EFSA, 2013b). In orange fruits treated with acequinocyl (1 application of 1.05 kg/ha), the concentrations of radioactivity declined from 0.63 mg eq./kg measured immediately after the application to 0.42 mg eq./kg after 14 days and 0.24 mg eq./kg after 21 days. Parent compound was the predominant compound, present at 36% and 40% total radioactive residue (TRR) at 14 and 21 DAT (days after treatment), respectively.

An overview of the available metabolism studies is presented in Appendix B.1.

1.1.2. Nature of residues in rotational crops

Since the application assessed in the reasoned opinion foresees the use in permanent crops (citrus trees), the possible occurrence of residues in succeeding crops resulting from the use on primary crops is not relevant (European Commission, 1997c).

1.1.3. Nature of residues in processed commodities

Studies investigating the nature of residues under standard processing conditions (i.e. pasteurisation, boiling and sterilisation) have not been provided.

Considering that significant residues are expected in the whole fruit (see Section 1.2.1), processing studies would be desirable. However, considering the high partition coefficient (Log _K_{ow} > 6.2, EFSA, 2013b) and considering that there is a low transfer of residues to the edible part of the fruit with residues in the pulp being lower than 0.1 mg/kg, these studies are considered not triggered for the current MRL application.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of acequinocyl residues were assessed during the peer review under Commission Regulation (EU) No 188/2011 (EFSA, 2013b). For the determination of acequinocyl in matrices with high water and high acid content a high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) method has been validated at the limit of quantification (LOQ) of 0.01 mg/kg. An independent laboratory validation (ILV) study has been submitted and assessed previously (EFSA, 2013b).

As citrus fruits belong to high acid content commodity group, EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRLs.

1.1.5. Stability of residues in plants

A study investigating storage stability of acequinocyl in high acidic content commodities is not available. Instead, the applicant referred to a storage stability study in apples, assessed in the framework of the peer review under Commission Regulation (EU) No 188/2011 (EFSA, 2013b). Acequinocyl was found to be stable for 18 months in apples when stored at −18°C. Similarly, its metabolite acequinocyl-OH (R1 metabolite) was stable for the same period.

Although in the EU guidance document, apples are classified as high water content commodities, the study provides valid information on the storage stability in acidic commodities, considering that the pH in apples is also acidic. Additionally, EMS provided information on a study in oranges where residues determination proved the stability of residues of acequinocyl and its metabolite acequinocyl-OH in acidic matrices for 5 months (oranges) and 3 months in orange juice, oranges oil and dried pulp (Germany, 2018). This information has been considered in a supportive manner. Overall, EFSA shares the view of the EMS that there is sufficient evidence to conclude that the residue trials submitted in support of the MRL application are valid in terms of storage stability.
1.1.6. Proposed residue definitions

Based on the metabolic pathway identified in metabolism studies, the residue definition was proposed as follows (EFSA, 2013b):

- Residue definition for risk assessment: acequinocyl
- Residue definition for enforcement: acequinocyl.

The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review and mentioned above.

For the uses in citrus fruits, EFSA concludes that the metabolism of acequinocyl is sufficiently addressed and the residue definition for enforcement and risk assessment applicable.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the current MRL application, nine residue trials conducted on oranges and eight residue trials conducted on mandarins in SEU were submitted. In these trials the crops were treated twice (in an application rate of 0.418–0.613 kg/ha instead of 1 × 0.197 to 0.492 kg/ha); the interval between the treatment ranged from 1 to 4 months. The samples were taken at the day of the last treatment and on several sampling points up to 43 days after the treatment. In total, 14 decline studies are available. The samples were analysed for the parent compound and the R1 metabolite. Peel and pulp were analysed separately and residues for the whole fruit were recalculated taking into account the mass ratios. The samples were stored for up to 11 months.

Although the residue trials were not fully compliant with the GAP under assessment, EFSA considers them valid since a significant decline of acequinocyl residues was observed over time. Therefore, the contribution of the first treatment to the final residues is considered to be minor.

According to the assessment of the EMS, the analytical methods used to analyse the samples from the residue trials were sufficiently validated and fit for purpose (Germany, 2018).

Considering the available data on storage stability (Section 1.1.5), EFSA agrees with the EMS to consider the residue trials as valid in terms of storage stability (Germany, 2018).

The two data sets (oranges and mandarins) were found to belong to the same statistical population (Kruskal–Wallis, H-test < 5%); therefore, both data sets were merged to derive the MRL proposal.

In accordance with the EU guidance document (European Commission, 2017), oranges and mandarins are major crops; a minimum of eight trials is required to derive an MRL by extrapolation for the whole group of citrus fruits (0110000). Based on the merged residue trials on oranges and mandarins (in total 17 residue trials), EFSA derived an MRL proposal of 0.6 mg/kg applicable to grapefruits (0110010), oranges (0110020), lemons (0110030), limes (00110040) and mandarins (0110050).

The results of the residue trials, the related risk assessment input values (highest residue, median residue) and the MRL proposals are summarised in Appendix B.1.2.1.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current assessment.

1.2.3. Magnitude of residues in processed commodities

In 17 residue trials, residues of acequinocyl were analysed separately in peel and pulp (Germany, 2018). Available data allowed calculating a peeling of 0.21 for mandarins and 0.17 for oranges. These peeling factors are similar to the ones derived by EFSA previously in the framework of another MRL application (peeling factors (oranges, 0.14; mandarins, 0.15), EFSA, 2010a). Both data sets were merged to derive a single peeling factor of 0.20 for mandarins and 0.16 for oranges that were used for the refinement of the consumer exposure.

In addition, in some of the residue studies, the harvested oranges and mandarins were processed into canned fruit, juice and marmalade. For one trial on oranges and mandarins, respectively, a processing factor of 2.25 for dried citrus pomace was derived. Considering also the data available in a

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8 A MRL of 0.5 mg/kg has been proposed by EMS (Germany, 2018). The difference in the MRL proposal that EFSA derived from the same residue trials from which EMS derived its proposal has its nature in the identification of replicates and the application of the rules established in the EFSA guideline for Residues trials and MRL calculations (EFSA, 2015a)
previous reasoned opinion (EFSA, 2010a,b), an indicative processing factor of 3.7 was derived by EFSA for citrus dried pulp which can be used for the estimation of the livestock dietary burden.

The compilation of the information on the processing studies is presented in Appendix B, B.1.2.3.

1.2.4. Proposed MRLs

The data submitted by the applicant are sufficient to calculate MRL proposals for the residue definition established in Regulation (EC) No 396/2005 for grapefruits, oranges, lemons, limes and mandarins.

2. Residues in livestock

As the by-products of citrus fruits are used as feed item, the possible impact of the intended uses on citrus fruit on the magnitude of acequinocyl residues in livestock should be taken into account.

EFSA calculated an indicative dietary burden, considering residues in citrus dried pulp and apple pomace. For apple pomace, the residue concentration was estimated using the existing MRL and a default processing factor for apple pomace. The calculations are indicative, since the detailed knowledge of all authorised uses of acequinocyl on products that can be used for feed purpose is currently not available. Furthermore, the use of the MRL for apples instead of the highest residue (HR) is likely to overestimate the calculated exposure. Although the calculated maximum dietary burden exceeded the trigger value for ruminants (beef cattle) and for swine, EFSA is of the opinion that given the limited reliable information on the dietary exposure to livestock the possible modification of the existing MRLs for animal products should be postponed.

Considering that a comprehensive exposure assessment will be performed in the near future in the framework of the review of the existing MRLs under Article 12 of Regulation (EC) No 396/2005, the detailed assessment of the residues in commodities of animal origin should be performed under the MRL review.

3. Consumer risk assessment

The toxicological profile of the active substance acequinocyl was assessed in the framework of the peer review under Directive 91/414/EEC in conjunction with Regulation (EU) No 188/2011 (EFSA, 2013b; European Commission, 2014). The following toxicological reference values were derived: acute reference dose (ARfD) 0.08 mg/kg body weight (bw) and acceptable daily intake (ADI) 0.023 mg/kg bw per day.

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different sub-groups of the EU population (EFSA, 2007).

To calculate the refined chronic exposure, EFSA used median residue values (STMR) derived from the residue trials in citrus fruits (see Table B.1.2.1) and the STMR values reported in previous EFSA reasoned opinions (EFSA, 2010a,b, 2013a, 2015b, 2016). For the remaining commodities of plant and animal origin, EFSA used the existing MRLs established in Regulation (EU) No 2017/623.10

For the acute exposure, EFSA calculated two scenarios: In Scenario 1, the acute exposure assessment was performed according to the internationally agreed methodology, assuming the consumption of citrus fruit containing residues at the HR level as observed in supervised field trials in the whole fruit (Table B.1.2.1), while in scenario 2 the calculation was based on the expected highest residue in the peeled citrus fruit. A variability factor accounting for the inhomogeneous distribution on the individual items consumed was included in both scenarios. The input values used for the dietary exposure calculation are summarised Appendix D.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The calculated total chronic intake accounted for 11% of the ADI (Germany, children diet); oranges were found to be the highest contributor among the citrus fruits accounting for a maximum of 2.8% (German children diet).

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9 The calculation of the long-term exposure (chronic exposure) is based on the mean consumption data representative for 22 national diets collected from MS surveys plus 1 regional and 4 cluster diets from the WHO GEMS Food database; for the acute exposure assessment the most critical large portion consumption data from 19 national diets collected from Member States surveys are used. The complete list of diets incorporated in EFSA PRIMo is given in its reference section (EFSA, 2007).

10 Commission Regulation (EU) 2017/623 of 30 March 2017 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acequinocyl, amitraz, coumaphos, difluafenican, flumequine, metribuzin, permethrin, pyraclostrobin and streptomycin in or on certain products (Text with EEA relevance.) C/2017/2018. OJ L 93, 6.4.2017, p. 1–29 (BG, ES, CS, DA, DE, ET, EL, EN, FR, HR, IT, LV, LT, HU, MT, NL, PL, PT, RO, SK, SL, FI, SV).

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No acute consumer risk was identified in relation to the MRL proposals for citrus fruits. In scenario 1 the highest exposure was estimated for oranges (61% of the ARfD); in scenario 2 (peeled citrus fruit), the short-term exposure for oranges accounted for 9.9% of the ARfD. Further information on the results of the consumer risk assessment are available in Appendix B, Section B.3.

EFSA concludes that the proposed use of acequinocyl on citrus fruits will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a health risk to consumers.

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for grapefruits, oranges, lemons, limes and mandarins.

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

The MRL recommendations are summarised in Appendix B, Section B.4.

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Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| a.s. | active substance |
| ADI | acceptable daily intake |
| ARfd | acute reference dose |
| BBCH | growth stages of mono- and dicotyledonous plants |
| bw | body weight |
| CF | conversion factor for enforcement to risk assessment residue definition |
| DAR | draft assessment report |
| DAT | days after treatment |
| DM | dry matter |
| EMS | evaluating Member State |
| GAP | Good Agricultural Practice |
| HPLC–MS/MS | high-performance liquid chromatography with tandem mass spectrometry |
| HR | highest residue |
| IEDI | international estimated daily intake |
| IESTI | international estimated short-term intake |
| ILV | independent laboratory validation |
| InChiKey | International Chemical Identifier Key |
| ISO | International Organisation for Standardisation |
| IUPAC | International Union of Pure and Applied Chemistry |
| K<sub>ow</sub> | octanol/water partition coefficient |
| LOQ | limit of quantification |
| MRL | maximum residue level |
| MS | Member States |
| NEU | northern Europe |
| OECD | Organisation for Economic Co-operation and Development |
| PBI | plant-back interval |
| PF | processing factor |
| PHI | preharvest interval |
| PRIMo | (EFSA) Pesticide Residues Intake Model |
| RA | risk assessment |
| RAC | raw agricultural commodity |
| RD | residue definition |
| RMS | rapporteur Member State |
| SANCO | Directorate-General for Health and Consumers |
| SC | suspension concentrate |
| SEU | southern Europe |
| SMILES | simplified molecular-input line-entry system |
| STMR | supervised trials median residue |
TAR  total applied radioactivity
TRR  total radioactive residue
WHO  World Health Organization
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|------------------------|-------------|-------------|-------------------------------|----------------|---------|
| Citrus fruits (Oranges, mandarins, grapefruits, lemons, limes) | SEU F | Spider mites | SC | 164 g/L | Spray | 51–89 | 1 | n.a. | 1,000–3,000 | 197–492 g/ha | 21 |

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

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
### Appendix B – List of end points

#### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Fruit crops                       | Apple       | Foliar: 1 × 750 g/ha | 14, 21, 30 DAT | Radiolabelled active substance: 14C-(U)-phenyl or 14C-dodecyl | EFSA (2010a,b) EFSA (2013b) |
|                                   | Aubergine   | Soil and foliar: 1 × 600 g/ha | 7, 14 DAT | Radiolabelled active substance: 14C-(U)-phenyl or 14C-dodecyl | EFSA (2010a,b) EFSA (2013b) |
|                                   | Orange      | Foliar: 1 × 1,050 g/ha | 14, 21, 30 DAT | Radiolabelled active substance: 14C-(U)-phenyl or 14C-dodecyl | EFSA (2010a,b) EFSA (2013b) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|-------------------------------------|-------------|---------|----------------|-----------|----------------|
|                                     |             |         |                |           | Not triggered for the current assessment |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Not investigated | – |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Not investigated | – |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Not investigated | – |
|                                          | Other processing conditions | – | – |
Can a general residue definition be proposed for primary crops?

No

Metabolism studies only cover the fruit crops group (EFSA, 2013b)

Rotational crop and primary crop metabolism similar?

Not investigated

Rotational crop studies were not available and they are not triggered by the current assessment

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

Not investigated

Rotational crop studies were not available and they are not triggered by the current assessment

Plant residue definition for monitoring (RD-Mo)

Acequinocyl (only for fruit crop group)

Plant residue definition for risk assessment (RD-RA)

Acequinocyl (only for fruit crop group)

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

Matrices with high water content and high acid content matrices:
HPLC–MS/MS, LOQ 0.01 mg/kg
EFSA, 2013b

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source       |
|-----------------------------------|-------------------|-----------|--------|------------------|-------------------|----------------------|
|                                   |                   |           |        |                  |                   |                      |
| High water content                | Apple             | –18       | 18     | Months           | Acequinocyl       | EFSA (2013b)         |
| High water content                | Apple             | –18       | 18     | Months           | Acequinocyl-OH    | (R1 metabolite)      | EFSA (2013b)         |
| High acid content                 | Orange            | –18       | 5      | Months           | Acequinocyl       | Germany (2018)       |

DAT: days after treatment; PBI: plant-back interval; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
**B.1.2. Magnitude of residues in plants**

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

| Commodity | Region/Indoor (a) | Residue levels observed in the supervised residue trials (b) (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | HR(c) | STMR(d) (mg/kg) | CF(e) |
|-----------|-------------------|---------------------------------------------------------------|-----------------|-------------------------|------|-----------------|------|
| Citrus fruits | SEU | Residues in the whole fruit: Oranges: 0.03, 0.08, 0.099, 0.15, 0.16, 0.19, 0.24, 0.26, 0.37 | Residue trials in mandarins and oranges not fully compliant with the GAP (2 applications instead of 1 as reported according to the GAP for the intended use) Both populations merged for deriving a single value since Kruskal–Wallis stated no statistical significance difference between populations Extrapolation to the whole group of citrus fruits acceptable according to EU extrapolation guidance document (European Commission, 2017) | 0.6 | 0.37 | 0.17 | – |
|           |                   | Mandarins: 0.02, 0.1, 0.12, 0.17, 0.2, 0.21, 0.23, 0.25 | Residues in the pulp: | 5 × < 0.01, < 0.01, 0.015, 0.017, 0.025, 0.026, 0.029, 0.03, 0.038, 0.038, 0.04, 0.055, 0.07 | | | |
|           |                   | Merged data set (oranges and mandarins) 0.02, 0.03, 0.08, 0.099, 0.1, 0.12, 0.15, 0.16, 0.17, 0.19, 0.2, 0.21, 0.23, 0.24, 0.25, 0.26, 0.37 | | | | | |

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Residue determinations were performed in oranges and mandarins peel and pulp and recalculated for the whole fruit by using mass balance.

(c): Highest residue. The highest residue for risk assessment refers to the whole commodity and not to the edible portion.

(d): Supervised trials median residue according to the residue definition for monitoring.

(e): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.

Underlined values: residue values at longer (a maximum of 36 days PHI was considered) or slightly shorter PHI (a minimum PHI of 20 days was considered when no data at longer PHI was available) than the intended use (PHI 21 days).
B.1.2.2. Residues in rotational crops

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

- Not triggered
- Citrus fruits are permanent crops

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

- Not triggered
- Citrus fruits are permanent crops

B.1.2.3. Processing factors

| Processed commodity | Number of valid studies(a) | Processing Factor (PF) | CF_P(b) | Comment/Source |
|---------------------|-----------------------------|------------------------|---------|----------------|
| Oranges peeling factor (whole fruit/orange pulp) | 10 | 0.04, 0.08, 0.11, 0.13, 0.14, 0.15, 0.17, 0.20, 0.29, 0.33 | 0.16 | – | EFSA (2010a,b) (only one value; 0.14) Germany (2018)(c) |
| Mandarins peeling factor (whole fruit/peel) | 9 | 0.05, 0.08, 0.13, 0.14, 0.15, 0.19, 0.22, 0.38, 0.50 | 0.20 | – | EFSA (2010a,b) (only one value; 0.14) Germany (2018)(c) |
| Mandarins/canned fruit | 3 | 0.13, 0.03, 0.09 | 0.08 | – | Germany (2018)(c) |
| Mandarins/marmalade | 4 | 3 × 0.02, 0.004 | 0.02 | – | Germany (2018)(c) |
| Mandarins/ juice | 4 | 1.10, 0.15, 0.57, 0.24 | 0.41 | – | Germany (2018)(c) |
| Oranges/wet pomace | 2 | 1.18, 1.34 | – | – | Germany (2018)(c); EFSA (2010a,b) |
| Mandarins/wet pomace | 2 | 2.89, 2.49 | – | – | Germany (2018)(c); EFSA (2010a,b) |
| Oranges/dried pomace(d) | 2 | 2.87, 5.3 | – | – | Germany (2018)(c); EFSA (2010a,b) |
| Mandarins/dried pomace(d) | 2 | 1.63, 4.5 | – | – | Germany (2018)(c); EFSA (2010a,b) |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).  
(b): Conversion factor for risk assessment in the processed commodity; mean of the individual conversion factors for each processing residues trial.  
(c): Calculations of peeling factors and other processing factors were performed by EFSA from the information extracted in the ER (Germany, 2018) and considering the information in previous reasoned opinions (EFSA, 2010a,b).  
(d): EMS derived a processing factor of 2.25 for citrus pomace that was used for animal exposure estimations (Germany, 2018). However, EFSA has considered the whole available information considering the information of processing commodities as well provided in previous reasoned opinions (EFSA, 2010a,b) to derive an indicative PF of 3.7 (median of the dried pomace processing factors in oranges and mandarins.) This PF was used to replace the default PF of 10 for citrus dried pulp in the animal model 2017.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|---------------------------|---------------------------|-----------------------|
| Cattle (all) | 0.006 | 0.006 | 0.25 | 0.25 | Beef cattle | Apple pomace, wet | Y |
| Cattle (dairy only) | 0.005 | 0.005 | 0.13 | 0.13 | Dairy cattle | Apple pomace, wet | Y |
| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Dietary burden expressed in mg/kg DM | Most critical subgroup (a) | Most critical commodity (b) | Trigger exceeded (Y/N) |
|-----------------------------|---------------------------------------------|-------------------------------------|---------------------------|---------------------------|------------------------|
| Sheep (all)                 | 0.005                                       | 0.13                               | Lamb                      | Apple pomace, wet         | Y                      |
| Sheep (ewe only)            | 0.004                                       | 0.13                               | Ram/Ewe                   | Apple pomace, wet         | Y                      |
| Swine (all)                 | 0.002                                       | 0.10                               | Swine (breeding)          | Citrus dried pulp         | Y                      |
| Poultry (all)               | –                                           | –                                  | –                         | –                         | –                      |
| Poultry (layer)             | –                                           | –                                  | –                         | –                         | –                      |
| Fish                        | N/A                                         | –                                  | –                         | –                         | –                      |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

B.3. Consumer risk assessment

ARfD 0.08 mg/kg bw (EFSA, 2013b)

Highest IESTI, according to EFSA PRIMo

| Scenario 1 – considering the residues in the whole fruit |
|--------------------------------------------------------|
| Grapefruit: 41.3% of ARfD |
| Oranges: 61.3% of ARfD |
| Lemons: 15.9% of ARfD |
| Limes: 9.4% of ARfD |
| Mandarins: 25.7% of ARfD |

| Scenario 2 – considering the residues in the edible part |
|--------------------------------------------------------|
| Grapefruit: 6.7% of ARfD |
| Oranges: 9.9% of ARfD |
| Lemons: 2.6% of ARfD |
| Limes: 1.8% of ARfD |
| Mandarins: 4.9% of ARfD |

Assumptions made for the calculations

The calculation is based on the highest residue levels (HR) expected in raw agricultural commodities. Scenario 1 considers highest residue in the whole fruit, whilst scenario 2 considers the application of the peeling factor as described in Section B.1.2.3.

Acute assessment undertaken only for the commodities under assessment.
ADI

Highest IEDI, according to EFSA PRIMo

| Scenario 1 – considering the residues in the whole fruit | Scenario 2 – considering the residues in the edible part |
|-------------------------------------------------------|-------------------------------------------------------|
| Grapefruits: < 1% of ADI                              | Grapefruits: < 1% of ADI                              |
| Oranges: 2.8% of ADI                                  | Oranges: < 1% of ADI                                  |
| Lemons: < 1% of ADI                                   | Lemons: < 1% of ADI                                   |
| Limes: < 1% of ADI                                    | Limes: < 1% of ADI                                    |
| Mandarins: < 1% of ADI                                | Mandarins: < 1% of ADI                                |

Contribution of crops assessed:

Assumptions made for the calculations

The calculation is based on the median residue levels (STMRs) derived for raw agricultural commodities applicable for grapefruits, oranges, mandarins, limes and lemons and derived from the residue trials in oranges and mandarins. For scenario 1, the residue value in the whole fruit was considered, whilst in scenario 2, the residues in the edible part of the crops were considered by applying appropriate peeling factors. Additionally, STMR values derived in previous assessments and the EU MRLs established in Reg (EU) No 2017/623 were considered for chronic exposure estimations.

B.4. Recommended MRLs

| Code(a) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|-------------------------|-------------------------|-----------------------|
| 0110010 | Grapefruits | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110020 | Oranges    | 0.4                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110030 | Lemons     | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110040 | Limes      | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110050 | Mandarins  | 0.4                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |

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

Modifications made for the calculations

The calculation is based on the median residue levels (STMRs) derived for raw agricultural commodities applicable for grapefruits, oranges, mandarins, limes and lemons and derived from the residue trials in oranges and mandarins. For scenario 1, the residue value in the whole fruit was considered, whilst in scenario 2, the residues in the edible part of the crops were considered by applying appropriate peeling factors. Additionally, STMR values derived in previous assessments and the EU MRLs established in Reg (EU) No 2017/623 were considered for chronic exposure estimations.

B.4. Recommended MRLs

| Code(a) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|------------|-------------------------|-------------------------|-----------------------|
| 0110010 | Grapefruits | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110020 | Oranges    | 0.4                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110030 | Lemons     | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110040 | Limes      | 0.2                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |
| 0110050 | Mandarins  | 0.4                     | 0.6                     | The submitted data are sufficient to derive an MRL proposal for the intended SEU uses. Risk for consumers unlikely |

MRL: maximum residue level; SEU: southern Europe.

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

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Acetamiprid

**Status of the active substance:** Approved

**Code no.:** 0.01

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

| Source of LOQ | ADI (mg/kg bw per day): | ARfD (mg/kg bw): |
|---------------|--------------------------|------------------|
| EU            | 0.023                    | 0.08             |

**Source of ADI:** EFSA

**Year of evaluation:** 2013

**No of diets exceeding ADI:** ---

**Highest contributor to MS diet (in % of ADI):**

| Commodity/group of commodities | TMDI (range) in % of ADI |
|-------------------------------|--------------------------|
| Milk and cream                | 1.4                      |
| Tomatoes                      | 2.5                      |
| Oranges                       | 2.3                      |
| Apples                        | 1.6                      |

**Conclusion:**

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

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**Commodity/group of commodities**

- **TMDI values in % of ADI**
- **Highest contributor to MS diet**
- **2nd contributor to MS diet**
- **3rd contributor to MS diet**
- **pTMRLs at LOQ (in % of ADI)**

**Notes:**

- The TMDI values were calculated based on the pTMRLs for each commodity.
- The TMDI values were then compared to the ADI to determine if any diet exceeded the ADI.
- The highest contributor to each MS diet is presented, along with the 2nd and 3rd contributors, if applicable.

**Identification of existing MRLs for acetamiprid in citrus fruits**

[www.efsa.europa.eu/efsajournal 2017(8):5746]
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD. For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002): for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

### Table: No of commodities for which ARfD/ADI is exceeded

| Unprocessed commodities | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): | No of commodities for which ARfD/ADI is exceeded: |
|-------------------------|-------------------------------------------------|-------------------------------------------------|---------------------------------|
| | Highest % of ARfD/ADI | Commodity | pTMRL (mg/kg) | Highest % of ARfD/ADI | Commodity | pTMRL (mg/kg) | Highest % of ARfD/ADI | Commodity | pTMRL (mg/kg) |
| | | | | | | | | | |
| | 61.3 | Oranges | 0.37/- | 44.3 | Oranges | 0.37/- | 11.8 | Oranges | 0.37/- | 9.2 | Oranges | 0.37/- | 9.2 | Oranges | 0.37/- |
| | 41.3 | Grapefruit | 0.37/- | 19.4 | Mandarins | 0.37/- | 3.2 | Lemons | 0.37/- | 2.3 | Lemons | 0.37/- | 2.3 | Lemons | 0.37/- |
| | 25.7 | Mandarins | 0.37/- | 11.8 | Lemons | 0.37/- | 3.0 | Limes | 0.37/- | 2.2 | Limes | 0.37/- | 2.2 | Limes | 0.37/- |
| | 9.3 | Limes | 0.37/- | 6.7 | Limes | 0.37/- | 3.0 | Limes | 0.37/- | 2.2 | Limes | 0.37/- | 2.2 | Limes | 0.37/- |
| | | | | | | | | | |
| No of critical MRLs (IESTI 1): | --- | --- | --- |
| No of critical MRLs (IESTI 2): | --- | --- | --- |

### Table: No of commodities for which ARfD/ADI is exceeded

| Processed commodities | No of commodities for which ARfD/ADI is exceeded: | No of commodities for which ARfD/ADI is exceeded: |
|-----------------------|-------------------------------------------------|---------------------------------|
| | Highest % of ARfD/ADI | Processed commodities | pTMRL (mg/kg) | Highest % of ARfD/ADI | Processed commodities | pTMRL (mg/kg) |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

### Conclusion:

For Acquinocyl, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

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**Notes:*****) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL.

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

- **Status of the active substance:** Approved
- **Code no.** 0.023
- **LOQ (mg/kg bw):** 0.01
- **Proposed LOQ:*** 0.08

### Toxicological end points

- **ADI (mg/kg bw per day):** 0.023
- **ARfD (mg/kg bw):** 0.08
- **Source of ADI:** EFSA
- **Source of ARfD:** EFSA
- **Year of evaluation:** 2013

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | 1st contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|----------------------------------------|----------------------------------------|----------------------------------------|---------------------------|
|                               |                                         |                                         |                                         |                           |
| **MS Diet**                    |                                         |                                         |                                         |                           |
| 2                                    |                                         |                                         |                                         |                           |
| 2 UK Toddler                     | 0.2 Milk and cream                      | 0.8 Apples                             | 0.4 Oranges                            | 1.4                       |
| 2 NL child                        | 2.8 Apples                              | 1.3 Milk and cream                     | 0.4 Oranges                            | 2.3                       |
| 2 WHO Cluster diet B             | 1.3 Tomatoes                            | 0.4 Apples                             | 0.4 Wheat                              | 1.6                       |
| 2 WHO Cluster diet E             | 0.5 Milk and cream                      | 0.5 Apples                             | 0.4 Tomatoes                           | 1.3                       |
| 2 UK Infant                      | 0.7 Apples                              | 0.5 Milk and cream                     | 0.3 Tomatoes                           | 1.2                       |
| 3 DK child                        | 1.0 Apples                              | 1.1 Apples                             | 0.3 Pears                              | 1.5                       |
| 3 FR infant                      | 0.4 Apples                              | 0.3 Pears                              | 0.3 Potatoes                           | 1.6                       |
| 3 IE adult                        | 0.5 Apples                              | 0.5 Apples                             | 0.2 Wine grapes                        | 1.3                       |
| 3 ES child                       | 0.5 Milk and cream                      | 0.5 Apples                             | 0.2 Wine grapes                        | 1.1                       |
| 3 WHO Regional European diet      | 0.5 Tomatoes                            | 0.5 Apples                             | 0.2 Milk and cream                     | 1.0                       |
| 3 WHO Cluster diet D             | 0.4 Tomatoes                            | 0.3 Apples                             | 0.3 Wheat                              | 1.1                       |
| 3 NL general                      | 0.5 Apples                              | 0.3 Milk and cream                     | 0.2 Oranges                            | 0.8                       |
| 3 WHO Cluster diet F             | 0.3 Tomatoes                            | 0.3 Apples                             | 0.2 Milk and cream                     | 1.0                       |
| 3 FR all population              | 0.8 Wine grapes                         | 0.2 Apples                             | 0.2 Milk and cream                     | 0.5                       |
| 3 IT kids/toddler                | 0.6 Tomatoes                            | 0.4 Apples                             | 0.3 Wheat                              | 0.5                       |
| 3 ES adult                       | 0.3 Tomatoes                            | 0.3 Apples                             | 0.2 Milk and cream                     | 0.7                       |
| 3 LT adult                       | 0.8 Apples                              | 0.3 Tomatoes                           | 0.2 Milk and cream                     | 0.6                       |
| 3 PL general population           | 0.9 Apples                              | 0.4 Tomatoes                           | 0.2 Milk and cream                     | 0.6                       |
| 3 DK adult                       | 0.3 Apples                              | 0.3 Tomatoes                           | 0.2 Milk and cream                     | 0.6                       |
| 3 UK vegetarian                  | 0.3 Tomatoes                            | 0.3 Apples                             | 0.2 Sugar beet (root)                  | 0.4                       |
| 1 IT adult                       | 0.5 Tomatoes                            | 0.3 Apples                             | 0.2 Wheat                              | 0.6                       |
| 1 UK Adult                       | 0.2 Milk and cream                      | 0.2 Tomatoes                           | 0.2 Apples                             | 0.5                       |
| 1 FI adult                       | 0.2 Milk and cream                      | 0.2 Tomatoes                           | 0.2 Apples                             |                           |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Acequinocyl is unlikely to present a public health concern.
### Acute risk assessment/children – refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002): for lettuce, a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce, the calculation was performed with a variability factor of 3.

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

| Unprocessed commodities | No of critical MRLs (ESTI 1) | No of critical MRLs (ESTI 2) |
|-------------------------|-----------------------------|-----------------------------|
| Commodity               | pTMRL/threshold MRL (mg/kg) | Commodity                   | pTMRL/threshold MRL (mg/kg) |
| Oranges                 | 9.9                         | Oranges                     | 1.6                         |
| Grapefruit              | 6.7                         | Grapefruit                  | 1.1                         |
| Mandarinis              | 4.9                         | Mandarinis                  | 0.9                         |
| Limes                   | 1.8                         | Limes                       | 0.4                         |
| Lemons                  | 2.6                         | Lemons                      | 0.4                         |

| Processed commodities   | No of commodities for which ARfD/ADI is exceeded (IESTI 1): | No of commodities for which ARfD/ADI is exceeded (IESTI 2): |
|-------------------------|-------------------------------------------------------------|-------------------------------------------------------------|
| Commodity               | pTMRL/threshold MRL (mg/kg)                                 | Commodity                     | pTMRL/threshold MRL (mg/kg) |
| Oranges                 | 7.2                                                         | Oranges                     | 1.9                         |
| Grapefruit              | 6.7                                                         | Grapefruit                  | 1.5                         |
| Mandarinis              | 3.7                                                         | Mandarinis                  | 1.2                         |
| Limes                   | 1.3                                                         | Limes                       | 0.5                         |

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

**Notes:**
- The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
- pTMRL: provisional temporary MRL.

### Conclusion:

For Acequinocyl, IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

| Feed commodity       | Median dietary burden | Maximum dietary burden |
|----------------------|-----------------------|------------------------|
|                      | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Apple pomace, wet    | 0.50 MRL(a) × PF (5)  | 0.50 MRL(a) × PF (5)   |
| Citrus dried pulp    | 0.63 STMR × PF (3.7)(b)| 0.63 STMR × PF (3.7)(b)|

Risk assessment residue definition: Acequinocyl

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For apple pomace, the exposure calculation has been performed considering the EU MRL instead of the STMR since no information on STMR is available at EU level. The default PF of 5 was applied.
(b): For citrus dried pulp the default processing factor of 10 has been replaced to an empirical value of 3.7 derived from the available data set (see Section B.1.2.3).

D.2. Consumer risk assessment

| Commodity                                | Chronic exposure assessment | Acute exposure assessment |
|------------------------------------------|-----------------------------|---------------------------|
|                                          | Input (mg/kg)               | Comment                   | Input (mg/kg) | Comment                                      |
| Risk assessment residue definition: Acequinocyl |                              |                           |              |                                             |
| Scenario 1(a) Grapefruits, oranges, lemons, mandarins | 0.17 STMR (Table B.1.2.1) | 0.37 HR (Table B.1.2.1) |
| Scenario 2(b) Grapefruits, oranges, lemons | 0.03 STMR (Table B.1.2.1) × PF (0.16) | 0.06 HR (Table B.1.2.1) × PF (0.16) |
| Scenario 2(b) Mandarin, limes            | 0.03 STMR (Table B.1.2.1) × PF (0.20) | 0.07 HR (Table B.1.2.1) × PF (0.20) |
| Gherkin                                  | 0.01 STMR (EFSA, 2016)      | Acute risk assessment undertaken only with regard to the crops under consideration |
| Plums                                    | 0.01 STMR (EFSA, 2015b)     |                           |
| Cherries                                 | 0.027 STMR (EFSA, 2015b)    |                           |
| Cucumbers                                | 0.02 STMR (EFSA, 2013a)     |                           |
| Hops                                     | 2.6 STMR (EFSA, 2010b)      |                           |
| Peaches                                  | 0.014 STMR (EFSA, 2010a)    |                           |
| Grapes                                   | 0.045 STMR (EFSA, 2010a)    |                           |
| Tomatoes                                 | 0.1 STMR (EFSA, 2010a)      |                           |
| Aubergines                               | 0.1 STMR (EFSA, 2010a)      |                           |
| Other plant and animal commodities       | MRL                         | MRLs in Reg (EU) 2017/623 |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor; MRL: maximum residue level.
(a): Scenario 1 considered the residues in the whole fruits.
(b): Scenario 2 considered the residues only in the edible part of the fruits. Likewise, a PF of 0.16 was applied to the residues in the oranges, lemons and grapefruits, whilst a PF of 0.20 applied to mandarins and limes. A consideration was given to the expected thickness of the peel in order simulate possible transfer of residues through the peel.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChIKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|---------------------------------|-------------------------------------------------|-------------------------------|
| **Acequinocyl**                 | 3-dodecyl-1,4-dihydro-1,4-dioxo-2-naphthyl acetate  | ![Structural formula](image) |
|                                 | CC(=O)OC2=C(CCCCCCCCCCCCCC)(=O)c1cccc1C2=O     |                               |
|                                 | QDRXWCVUNHOGA-UHFFFAOYSA-N                      |                               |
| **R1 Metabolite** Acequinocyl-OH | 2-dodecyl-3-hydroxy-1,4-naphthoquinone          | ![Structural formula](image) |
|                                 | O=C2c1cccc1C(=O)C(O)                            |                               |
|                                 | =C2CCCCCCCCCC                                 |                               |
|                                 | KUUFMNYPHOKBFD-UHFFFAOYSA-N                    |                               |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChIKey: International Chemical Identifier Key.

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

<sup>(b)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).