Modification of the existing maximum residue levels for aclonifen in celeriacs and certain fresh herbs

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

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicants Landesanstalt für Landwirtschaft und Gartenbau Sachsen-Anhalt (LSA) and Dienstleistungszentrum Ländlicher Raum Rheinpfalz (DLR), respectively, submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRL) for the active substance aclonifen in chives, parsley, celery leaves/dill leaves, thyme/savoury and in celeriacs/turnip-rooted celery. The data submitted in support of the request were found to be sufficient to derive MRL proposals for all crops under consideration. Adequate analytical methods for enforcement are available to control the residues of aclonifen in high water 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 exposure to residues resulting from the use of aclonifen according to the reported agricultural practices is unlikely to present a risk to consumer health.

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

Keywords: aclonifen, celeriacs, fresh herbs, pesticide, MRL, consumer risk assessment

Requestor: European Commission

Question number: EFSA-Q-2018-00335; EFSA-Q-2018-00461

Correspondence: pesticides.mrl@efsa.europa.eu
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Landesanstalt für Landwirtschaft und Gartenbau Sachsen-Anhalt (LSA) 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 aclonifen in chives, parsley, celery leaves/dill leaves and thyme/savoury. 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 26 April 2018. To accommodate for the intended uses of aclonifen, the EMS proposed to raise the existing MRLs for chives, celery leaves/dill leaves, parsley and thyme/savoury from the limit of quantification (LOQ) to 0.8 mg/kg. A second application was submitted by the applicant Dienstleistungszentrum Ländlicher Raum Rheinpfalz (DLR) to the competent national authority in Germany to modify the existing MRL for the active substance aclonifen in celeriacs/turnip-rooted celery. The EMS drafted a second evaluation report, which was submitted to the European Commission and forwarded to EFSA on 1 June 2018, proposing to raise the existing MRL of 0.02 to 0.3 mg/kg.

EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 22 October 2018, the EMS submitted revised evaluation reports, which replaced the previously submitted evaluation reports.

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 the two applications, the following conclusions are derived.

The metabolism of aclonifen following foliar and soil application was investigated in crops belonging to the groups of root crops, cereals and pulses/oilseeds. Studies investigating the effect of processing on the nature of aclonifen (hydrolysis studies) demonstrated that the active substance is stable. In rotational crops, the major residue identified was the parent compound.

EFSA concluded that for the crops assessed in these applications, metabolism of aclonifen in primary and in rotational crops, and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions for risk assessment and enforcement purpose (i.e. parent aclonifen) are appropriate. These residue definitions are applicable to primary crops, rotational crops and processed products.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in these applications according to the enforcement residue definition. The methods enable quantification of residues at or above 0.01 mg/kg in the crops assessed (LOQ).

The available residue trials are sufficient to derive MRL proposals for the crops under consideration except for thyme/savoury, where EFSA derived a proposal, but recommends further risk management discussions.

Specific studies investigating the magnitude of aclonifen residues in processed commodities are not required, as the expected exposure is below the trigger value.

The available information on the nature and magnitude of residues allow concluding that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed good agricultural practice (GAP).

Residues of aclonifen in commodities of animal origin were not assessed since the crops under assessment are normally not fed to livestock.

The toxicological profile of aclonifen was assessed in the framework of the European Union (EU) pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.07 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The estimated long-term dietary intake was in the range of 0.1–0.8% of the ADI. The contribution of residues expected in the commodities assessed in these applications to the overall long-term exposure is insignificant. EFSA concluded that the long-term intake of residues of aclonifen resulting from the existing and the intended uses on chives, celery leaves/dill leaves, parsley, thyme/savoury and celeriacs is unlikely to present a risk to consumer 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-D.

### Enforcement residue definition: Aclonifen

| Code<sup>(a)</sup> | Commodity                      | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|-------------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0256020           | Chives                        | 0.02*                   | 0.8 or 0.7              | The MRL proposals reflecting the intended NEU use are sufficiently supported by data. EFSA derived two options for further risk management consideration. MRL proposal of 0.7 mg/kg is based on residue trials in chives, dill leaves, parsley and savoury. MRL proposal of 0.8 mg/kg was derived from the data set excluding the trials on savoury, considering the restrictions on extrapolations established in the EU guidance document as regards thyme. Risk for consumers unlikely. |
| 0256030           | Celery leaves (includes dill leaves) | 0.04                    | 0.8 or 0.7              |                                                                                       |
| 0256040           | Parsley                       | 0.02*                   | 0.8 or 0.7              |                                                                                       |
| 0256070           | Thyme (includes savoury)      | 0.02*                   | No proposal or 0.7      | Specific residue trials on savoury are not sufficient to derive a MRL proposal for thyme. Considering that savoury is a very minor crop, EFSA derived a MRL proposal for risk management consideration, based on a merged data set including residue trials in chives, dill leaves, parsley and savoury; this MRL proposal is not fully compliant with the EU practices on extrapolation of residue trials. Risk for consumers is unlikely. |
| 0213030           | Celeriacs/turnip rooted celeries | 0.02                    | 0.3                     | MRL proposal is sufficiently supported by data. Risk for consumers is unlikely.        |

MRL: maximum residue level; NEU: northern 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.
# Table of contents

Abstract ................................................................................................................................................... 1  
Summary ................................................................................................................................................. 3  
Assessment .............................................................................................................................................. 6  
  1. Residues in plants ........................................................................................................................ 7  
     1.1. Nature of residues and methods of analysis in plants ........................................................... 7  
         1.1.1. Nature of residues in primary crops ................................................................................. 7  
         1.1.2. Nature of residues in rotational crops ............................................................................... 7  
         1.1.3. Nature of residues in processed commodities ............................................................... 7  
         1.1.4. Methods of analysis in plants ........................................................................................... 7  
         1.1.5. Stability of residues in plants ........................................................................................... 7  
         1.1.6. Proposed residue definitions ............................................................................................. 8  
     1.2. Magnitude of residues in plants ................................................................................................ 8  
         1.2.1. Magnitude of residues in primary crops .......................................................................... 8  
         1.2.2. Magnitude of residues in rotational crops ........................................................................ 9  
         1.2.3. Magnitude of residues in processed commodities ........................................................ 9  
         1.2.4. Proposed MRLs ................................................................................................................ 9  
     2. Residues in livestock .................................................................................................................... 9  
     3. Consumer risk assessment ......................................................................................................... 9  
     4. Conclusion and Recommendations ............................................................................................ 10  
References ............................................................................................................................................... 10  
Abbreviations ........................................................................................................................................... 11  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs .......... 12  
Appendix B – List of end points ........................................................................................................ 13  
Appendix C – Pesticide Residue Intake Model (PRIMo) ................................................................ 18  
Appendix D – Input values for the exposure calculations ................................................................. 20  
Appendix E – Used compound codes ............................................................................................. 21
Assessment

The European Food Safety Authority (EFSA) was requested to assess the two applications to modify the existing maximum residue levels (MRLs) for certain fresh herbs and celeriacs. The detailed description of the intended uses of aclonifen in chives, savoury,1 parsley, dill leaves2 and celeriacs, which are the basis for the current MRL applications, is reported in Appendix A.

Aclonifen is the ISO common name for 2-chloro-6-nitro-3-phenoxy-aniline (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Aclonifen was evaluated in the framework of Directive 91/414/EEC3 with Germany designated as rapporteur Member State (RMS) for the representative use as a pre-emergence herbicide in sunflowers. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008). Aclonifen was approved4 for the use as herbicide on 1 August 2009.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015) and the proposed modifications have been considered in recent regulation5 for the European Union (EU) MRL legislation. The EU MRLs for aclonifen are established in Annex II of Regulation (EC) No 396/20056.

In accordance with Article 6 of Regulation (EC) No 396/2005, Landesanstalt für Landwirtschaft und Gartenbau Sachsen-Anhalt (LSA) submitted an application to the competent national authority in Germany (EMS) to modify the MRLs for the active substance aclonifen in chives, parsley, celery leaves/ dill leaves and savoury. 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 26 April 2018. A second application was submitted by the applicant Dienstleistungszentrum Ländlicher Raum Rheinpfalz (DLR) to the competent national authority in Germany (EMS) to modify the existing MRL for the active substance aclonifen in celeriacs/turnip-rooted celery. The EMS drafted a second evaluation report, which was submitted to the European Commission and forwarded to EFSA on 1 June 2018. EFSA assessed the applications and the evaluation reports as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarification, which were requested from the EMS. On 22 October 2018, the EMS submitted revised evaluation reports (Germany, 2018), which replaced the previously submitted evaluation reports.

EFSA based its assessment on the evaluation reports submitted by the EMS (Germany, 2018), the DAR and its addendum (Germany, 2006, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on aclonifen (European Commission, 2012), the conclusion on the peer review of the pesticide risk assessment of the active substance aclonifen (EFSA, 2008) as well as the reasoned opinion on the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015).

For these applications, the data requirements established in Regulation (EU) No 544/20117 and the guidance documents applicable at the date of submission of the applications to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2015; OECD, 2011). 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 546/20118.

---

1 According to the food classification used for setting MRLs under Regulation (EC) No 396/2005 savoury is classified under thyme. Thus, the MRL set for thyme is applicable to savoury and was requested to be modified to cover the intended use on savoury.

2 According to the food classification used for setting MRLs under Regulation (EC) No 396/2005 dill leaves are classified under celery leaves. Thus, the MRL set for celery leaves is applicable to dill leaves and was requested to be modified to cover the intended use on dill leaves.

3 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.

4 Commission Directive 2008/116/EC of 15 December 2008 amending Council Directive 91/414/EEC to include aclonifen, imidacloprid and metazachlor as active substances. OJ L 337, 16.12.2008, p. 86–91.

5 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/ep-pesticides-database/public/?event=pesticide.residue.selection&language=EN

6 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.

7 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.

8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation reports 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. **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 aclonifen in primary crops (root crops, cereals/grass and pulses/oilseeds) has been investigated in the framework of EU pesticides peer review and the MRL review (EFSA, 2008, 2015). No additional studies were submitted in support of the current MRL applications.

The available metabolism studies were performed by using only aniline-14C-labelled aclonifen. Studies with radiolabelling in the phenyl ring were not considered necessary (EFSA, 2008, 2015), because metabolites resulting from the cleavage of the ether bond of the phenyl ring (i.e. phenol and hydroquinone) are considered naturally occurring in plants. Moreover, cleavage was considered only as a very minor pathway in the plant metabolism of aclonifen. Consequently, additional metabolism studies with phenyl-labelled aclonifen were not required.

From the available metabolism studies, performed with aniline-14C-labelled aclonifen, aclonifen was found to be the main residue.

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

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

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review (EFSA, 2008), the DT90 value of aclonifen was higher than 100 days, ranging from 104 to 649 days. Therefore, studies investigating the nature and magnitude of residues in rotational crops were performed (Germany, 2006, 2011).

Based on these studies it was concluded that metabolism in primary and rotational crops is similar (EFSA, 2008, 2015).

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

The applicants submitted standard hydrolysis studies simulating processing conditions representative of pasteurisation, boiling and sterilisation (Germany, 2018). It is concluded that aclonifen is hydrolytically stable under the representative conditions.

1.1.4. **Methods of analysis in plants**

Analytical methods for the determination of aclonifen residues in plant commodities were assessed during the EU pesticides peer review and the MRL review (EFSA, 2008, 2015).

Sufficiently validated methods to control residues of aclonifen in high water content and dry/high starch content commodities at the limit of quantification (LOQ) of 0.01 mg/kg and in high oil content commodities at the LOQ of 0.02 mg/kg were provided (EFSA, 2015).

EFSA concludes that sufficiently validated analytical methods are available for enforcing the proposed MRL for aclonifen in the crops under consideration.

1.1.5. **Stability of residues in plants**

The storage stability of aclonifen in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2008). Aclonifen is shown to be stable for 24 months in high water content and high oil content commodities and for 12 months in dry/high starch content commodities when stored at –18°C.
1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary and rotational crops metabolism studies, the following residue definitions were proposed (EFSA, 2018, 2015):

- residue for risk assessment: aclonifen
- residue definition for enforcement: aclonifen

The residue definition for enforcement set in Regulation (EC) No 396/2005 is identical with the above mentioned residue definition.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the current MRL applications, the applicants submitted residue trials performed in chives, parsley, dill leaves, savoury and on celeriacs/turnip rooted celeries. The samples were analysed for the parent compound in accordance with the residue definition for enforcement and risk assessment. According to the assessments of the EMS, the analytical methods used to analyse the residue trials were sufficiently validated and fit for purpose (Germany, 2018).

The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

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.

Chives, parsley, celery leaves (dill leaves) and thyme (savoury)

In support of the MRL application related to the post-emergence use in chives, parsley, dill leaves and savoury, the applicant provided in total 12 outdoor trials (1 trial in chives, 4 trials in parsley, 4 trials in dill leaves and 3 trials in savoury). One of the trials on dill leaves was disregarded since it was not considered compliant with the intended good agricultural practice (GAP) (i.e. trial was performed with only one application instead of two and a longer preharvest interval (PHI)). Thus, in total 11 valid outdoor trials are available.

In accordance with the EU guidance document (European Commission, 2015), chives, parsley and celery leaves (covering also dill leaves) are minor crops; a minimum six trials is required to derive a MRL by extrapolation for the whole subgroup of ‘herbs and edible flowers’ (0256000). Any representative of this subgroup, except sage (0256050), rosemary (0256060), thyme (0256070), laurel/bay leave (0256090) can be used for extrapolation to the whole subgroup of herbs and edible flowers. Sage, rosemary, thyme and laurel were excluded from the extrapolation rules because of the different dry matter content and because of a different level of essential oils.

To follow the extrapolation recommendation, EFSA derived a MRL proposal of 0.8 mg/kg based on the merged trials on chives, parsley and dill leaves (in total eight trials). Considering that the crop under assessment is savoury (and not thyme), which is considered to be more similar to the other herbs, EFSA calculated a second MRL proposal (0.7 mg/kg), based on all 11 valid trials submitted.

For savoury, EFSA derived two possible options for risk management consideration: no MRL proposal, considering that the number of trials in savoury is insufficient to derive a MRL proposal or 0.7 mg/kg, which was derived from the 11 residue trials described above. Although this MRL proposal is not fully compliant with the agreed provisions for deriving MRLs (European Commission, 2015) it might be an acceptable option considering that savoury is a very minor crop.

The pre-emergence GAP on chives is supported by three valid outdoors trials on dill leaves (1 × 1,800 g a.i./ha, PHI 56–61, pre-emergence application) showing that all the residue values are below the limit of detection (LOD) of the method. The three available residue trials on celery leaves (dill leaves) and with all residue levels < LOD are therefore sufficient to be extrapolated to chives in accordance with the EU guidance document (European Commission, 2017).

Celeriacs/turnip rooted celeries

In total, four outdoor trials compliant with northern Europe (NEU) GAP are available to support the intended use in celeriacs/turnip rooted celeries.
1.2.2. Magnitude of residues in rotational crops

The rotational crop metabolism studies were assessed in the peer review based on a study where bare soil was treated with aclonifen at 3.7 kg/ha (Germany, 2006). While in carrots (roots) significant residues were measured ranging from 0.491 mg eq/kg (plant-back interval (PBI) 29 days) to 0.035 mg eq/kg (PBI 365 days, residues were below 0.1 mg/kg in the other crops, spinach and barley, at all three rotational intervals.

Confirmatory data were requested since a data gap was set because of significant residues found in carrots (EFSA, 2008). Therefore, two rotational crops field trials investigating the magnitude of aclonifen residues in turnips planted 30 and 60 days after application of 2.4 kg a.s./ha were evaluated in the framework of MRL review (Germany, 2011; EFSA, 2015). According to the results of both studies, no residues are expected in root and tuber vegetables grown in rotation with crops treated with aclonifen (residues were below the LOQ of 0.01 mg/kg in all samples of leaves and roots analysed).

EFSA concluded that in rotational crops grown after the use of aclonifen according to the GAPs assessed in the current MRL applications, residues above the LOQ are not expected.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies for the crops under assessment are not available. Considering that in some trials submitted in these applications the residues measured are higher than 0.1 mg/kg, additional processing studies for the crops under consideration would be required. However, considering that the crops under consideration are only minor contributors to the overall long-term exposure accounting for less than 1% of the acceptable daily intake (ADI) and considering that standard hydrolysis studies showed that aclonifen is hydrolytically stable EFSA concluded that there is no need of specific processing studies for the crops under assessment.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for the commodities under evaluation.

2. Residues in livestock

Not relevant as crops under consideration are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (EFSA, 2007).

In the framework of the EU pesticides peer review, an ADI of 0.07 mg/kg body weight (bw) per day was set while an acute reference dose (ARfD) was not allocated as considered as not necessary (EFSA, 2008).

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses approved in the EU (EFSA, 2015). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of the crops assessed in these MRL applications. The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake was up to 0.8% of the ADI. The contribution of residues expected in the commodities assessed in these applications to the overall long-term exposure is insignificant as also shown in Appendix B.2.

EFSA concluded that the long-term intake of residues of aclonifen resulting from the existing and the intended uses in these MRL applications is unlikely to present a risk to consumer health. A short-term (acute) dietary risk assessment was not required since no ARfD was derived.

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

The data submitted in support of these MRL applications were found to be sufficient to derive an MRL proposal for chives, celery leaves/dill leaves, parsley, thyme/savoury and celeriacs/turnip rooted celeriaceae.

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

The MRL recommendations are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance aclonifen. EFSA Journal 2008;6(10):RN-149, 80 pp. https://doi.org/10.2903/j.efsa.2008.149r

EFSA (European Food Safety Authority), 2015. Review of the existing maximum residue levels for aclonifen according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13(11):4323, 37 pp. https://doi.org/10.2903/j.efsa.2015.4323

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2012. Review report for the active substance aclonifen. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 26 September 2008 in view of the inclusion of aclonifen in Annex I of Council Directive 91/414/EEC. SANCO/161/08-rev. 2, 28 September 2012.

European Commission, 2015. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev. 10.1, 1 December 2015.

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

FAO (Food and Agriculture Organization of the United Nations), 2016. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 3rd Edition. FAO Plant Production and Protection Paper 225, 298 pp.

Germany, 2006. Draft assessment report on the active substance aclonifen prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EEC, August 2006. Available online: www.efsa.europa.eu

Germany, 2008. Final addendum to the draft assessment report on the active substance aclonifen, compiled by EFSA, June 2008. Available online: www.efsa.europa.eu

Germany, 2011. Evaluation report prepared under the review Article 12 of Regulation (EC) No 396/2005. Review of the existing MRLs for aclonifen, June 2011. Available online: www.efsa.europa.eu/Germany, 2018a. Evaluation report on the modification of MRLs for aclonifen in fresh herbs and edible flowers. October 2018, 28 pp.

Germany, 2018. Evaluation report on the setting of MRL for aclonifen in celeriac. October 2018, 30 pp.
OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

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
CF conversion factor for enforcement to risk assessment residue definition
CS capsule suspension
DAR draft assessment report
DAT days after treatment
DT₉₀ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
eq residue expressed as a.s. equivalent
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-ECD gas chromatography with electron capture detector
HR highest residue
IEDI international estimated daily intake
InChIKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOD limit of detection
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
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SC suspension concentrate
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F or G | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|--------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |                         |        | [Chives (fresh)]                  | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   | Light to medium soil           |
|                       |                         |        | Blackgrass, annual dicotyledonous | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   | Heavy soils                     |
|                       |                         |        | weeds, annual bluegrass           | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   |                     |
|                       |                         |        | [Savoury (fresh)]                 | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   |                     |
|                       |                         |        | [Parsley (fresh)]                 | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   |                     |
|                       |                         |        | [Dill (fresh)]                    | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   |                     |
|                       |                         |        | [Celeriacs]                       | SC 600      | Spraying    | PHI 300–600; rate 200–400 g/ha | 3–7 days   |                     |

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

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

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

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

(d): PHI: minimum preharvest interval. ‘F’ means that PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e.g. harvest) and the setting of a PHI in days is therefore not required.
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 |
|----------------------------------|-------------|---------|----------------|----------------|---------------|
|                                  | Root crops | Potato  | Foliar, 1 × 1.5 kg a.s./ha | 42             | Radiolabelled active substance: aniline-14C-labelled aclonifen (EFSA, 2008) |
|                                  |            |         | Soil, 1 × 2.5 kg a.s./ha     | 93             |               |
|                                  | Cereals/ grass | Wheat    | Foliar, 1 × 0.303 kg a.s./ha | 0, 22, 41, 152 |               |
|                                  |            |         | Soil, 1 × 3.25 kg a.s./ha    | 0, 54, 76, 108 |               |
|                                  | Pulses/oilseeds | Peas    | Foliar, 1 × 0.394 kg a.s./ha | 0, 42, 57, 93  |               |
|                                  |            |         | Soil, 1 × 2.79 kg a.s./ha    | 0, 70, 78, 108 |               |

| Rotary crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|----------------------------------|-------------|---------|----------------|-----------|---------------|
|                                  | Root/tuber crops | Carrots | Bare soil, 3.7 kg a.s./ha | 29, 120, 365 | EFSA (2008) |
|                                  | Leafy crops | Spinaches | Bare soil, 3.7 kg a.s./ha | 29, 120, 365 |               |
|                                  | Cereal (small grain) | Barley | Bare soil, 3.7 kg a.s./ha | 29, 120, 365 |               |

| Processed commodities (hydrolysis study) | Conditions                  | Stable?     | Comment/Source |
|------------------------------------------|-----------------------------|-------------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Not triggered | Germany (2018) |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered |               |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Not triggered |               |
|                                          | Other processing conditions |             |                |
Can a general residue definition be proposed for primary crops?  
Yes  
EFSA (2008)

Rotational crop and primary crop metabolism similar?  
Yes  
EFSA (2008)

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Yes  
Germany (2018a,b)

Plant residue definition for monitoring (RD-Mo)  
Aclonifen

Plant residue definition for risk assessment (RD-RA)  
Aclonifen

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)  
GC-ECD (EFSA, 2008, 2015):  
LOQ: 0.01 mg/kg in high water and dry/high starch commodities.  
LOQ: 0.02 mg/kg in high oil content commodities.

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; GC-ECD: gas chromatography with electron capture detector; LOQ: limit of quantification

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| Tomatoes, peas, potatoes| ≤ 18   | 24 Months        | Aclonifen         | EFSA (2008)    |
|                                    | High oil content  | Sunflower seeds    | ≤ 18   | 24 Months        |                   |                |
|                                    | Dry/High starch   | Maize grain        | ≤ 18   | 12 Months        |                   |                |
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-----------|---------------------|---------------------------------------------------------------|-----------------|------------------------|-------------------|------------------|----|
| Chives, parsley, celery leaves (dill leaves), thyme (savory) (post-emergence GAP: 2 × 0.3 kg/ha, 7–10 days interval, PHI 21 days) | NEU | Chives: 0.47 Parsley: 0.11, 0.054, 0.12, 0.027 Dill leaves: < 0.01, 0.012, 0.035 Savory: 2 × < 0.01, 0.3 | All residue trials compliant with GAP Two MRL proposals were derived: Option 1: all residue trials were pooled; Option 2: residue trials in savory were excluded, considering the restrictions for extrapolation (European Commission, 2015) | 1) 0.7 2) 0.8 | 0.47 | 0.04 | – |
| Thyme (savory) | NEU | Savory: 2 × < 0.01, 0.3 | Number of trials insufficient to derive MRL proposal. Alternative option: 0.7 mg/kg (see option 1 above) | No proposal or 0.7 | See above | See above | – |
| Celery leaves (dill leaves) (pre-emergence GAP) | NEU | 3 < 0.01 | Residue trials compliant with pre-emergence GAP for chives Extrapolation to chives is possible with all residue levels < LOQ Covered by more critical post-emergence GAP | 0.30 | 0.10 | 0.04 | – |
| Celeriacs/turnip rooted celeries | NEU | 0.072, 0.099, < 0.01, 0.012 | Residue trials compliant with GAP. Portion analysed is root body and celeriac leaves | 0.30 | 0.10 | 0.04 | – |

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

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

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

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

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops

| Question                                                                 | Yes                                                                 | No                                                                 |
|--------------------------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------|
| Residues in rotational and succeeding crops expected based on confined   | Residues above the LOQ may occur in root and tuber vegetables grown  | According to the results of two rotational field studies in turnips,  |
| rotational crop study?                                                  | in rotation with crops treated with aclonifen at an exaggerated rate | no residues are expected in root and tuber vegetables grown in       |
|                                                                         | of 3.7 kg/ha (2.4 N rate for celeriac and 6 N rate for fresh herbs)  | rotation with crops treated with aclonifen at 2.4 kg/ha (EFSA, 2015) |

LOQ: limit of quantification.

B.1.2.3. Processing factors

No processing studies were submitted and are not required in the framework of the present MRL applications considering that standard hydrolysis studies showed that aclonifen is hydrolytically stable (Germany, 2018).

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| Parameter                                                                 | Value                                                                 |
|--------------------------------------------------------------------------|----------------------------------------------------------------------|
| ADI                                                                       | 0.07 mg/kg bw per day (EFSA, 2008)                                     |
| Highest IEDI, according to EFSA PRIMo                                    | 0.8% ADI (diet)                                                       |
| Assumptions made for the calculations                                      | Contribution of crops assessed is insignificant                       |
|                                                                          | The calculation is based on the median residue levels derived for the |
|                                                                          | crops under assessment and the input values derived from the MRL     |
|                                                                          | review (EFSA, 2015).                                                 |
|                                                                          | Although for each of the four commodities part of the group of        |
|                                                                          | fresh herbs a MRL was proposed, the STMR used in PRIMo model was      |
|                                                                          | assigned to the whole group of herbs and edible flowers (256000)     |
|                                                                          | and it was derived from the merged dataset from trials on chives,    |
|                                                                          | parsley and dill leaves. The rationale to assign the STMR to the     |
|                                                                          | entire subgroup is that the available national food surveys are      |
|                                                                          | mainly related to the subgroup rather than to the individual related |
|                                                                          | commodities                                                          |

ADI: acceptable daily intake; bw: body weight; IEDI: international estimated daily intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; STMR: supervised trials median residue.
## B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------------|-----------|------------------------|-------------------------|-----------------------|
| 0256020       | Chives    | 0.02*                  | 0.8 or 0.7              | The MRL proposals reflecting the intended NEU use are sufficiently supported by data. EFSA derived two options for further risk management consideration. MRL proposal of 0.7 mg/kg is based on residue trials in chives, dill leaves, parsley and savoury. MRL proposal of 0.8 mg/kg was derived from the data set excluding the trials on savoury, considering the restrictions on extrapolations established in the EU guidance document as regards thyme. Risk for consumers unlikely. |
| 0256030       | Celery leaves (includes dill leaves) | 0.04                  | 0.8 or 0.7              | |
| 0256040       | Parsley   | 0.02*                  | 0.8 or 0.7              | |
| 0256070       | Thyme (includes savoury) | 0.02*                 | No proposal or 0.7      | Specific residue trials on savoury are not sufficient to derive a MRL proposal for thyme. Considering that savoury is a very minor crop, EFSA derived a MRL proposal for risk management consideration, based on a merged data set including residue trials in chives, dill leaves, parsley and savoury; this MRL proposal is not fully compliant with the EU practices on extrapolation of residue trials. Risk for consumers is unlikely. |
| 0213030       | Celeriacs/turnip rooted celeries | 0.02                  | 0.3                     | MRL proposal is sufficiently supported by data. Risk for consumers is unlikely. |

\(\text{MRL: maximum residue level; NEU: northern Europe.}\)
\(*: \text{Indicates that the MRL is set at the limit of analytical quantification (LOQ).}\)
\((a): \text{Commodity code number according to Annex I of Regulation (EC) No 396/2005.}\)
Appendix C – Pesticide Residue Intake Model (PRIMO)

### Aclonifen

| Status of the active substance: | Included  |
|-------------------------------|-----------|
| LOQ (mg/kg bw):               | Proposed LOQ: |

#### Toxicological end points

| ADI (mg/kg bw per day): | 0.07 |
|-------------------------|------|
| Source of ADI:          | EFSA |
| Year of evaluation:     | 2008 |
| ARfD (mg/kg bw):        | n.n. |
| Source of ARfD:         | EFSA |
| Year of evaluation:     | 2008 |

#### No of diets exceeding ADI:

| Commodity / group of commodities | pTMRLs at LOQ (in % of ADI) |
|---------------------------------|-----------------------------|
| Milk and cream                  | 0.00 Sunflower seed         |
| Milk and cream                  | 0.00 Beans                  |
| Milk and cream                  | 0.00 Beans (with pods)      |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Meat           |
| Milk and cream                  | 0.00 Bovine: Mea...
Acute risk assessment is not necessary.

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.

Conclusion:
As no ARfD was considered necessary, it is concluded that the short-term intake of Aclonifen residues is unlikely to present a public health concern.

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 (IESTI 1): ---
No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---

No of critical MRLs (IESTI 1) ---
No of critical MRLs (IESTI 2) ---

No of commodities for which ARfD/ADI is exceeded:

| Proc. | Highest % of ARfD/ADI | pTMRL/ threshold MRL (mg/kg) | --- | --- |
|-------|------------------------|-----------------------------|-----|-----|
|       | Processed commodities  |                             | --- | --- |
|       | Highest % of ARfD/ADI  | pTMRL/ threshold MRL (mg/kg) | --- | --- |
|       | processed commodities  |                             |     |     |

---

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

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---
No of commodities for which ARfD/ADI is exceeded (IESTI 2): ---
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Commodity                     | Chronic risk assessment |
|-------------------------------|-------------------------|
|                               | Input value (mg/kg)     |
|                               | Comment                 |
| Chives                        | 0.04                    | STMR, current assessment |
| Parsley                       | 0.04                    | STMR, current assessment |
| Celery leaves (dill leaves)   | 0.04                    | STMR, current assessment |
| Thyme (savoury)               | 0.04                    | STMR, current assessment |
| Celeriac                      | 0.04                    | STMR, current assessment |
| Potatoes                      | 0.02                    | STMR (EFSA, 2015)       |
| Carrots                       | 0.01*                   | STMR (EFSA, 2015)       |
| Celeriac                      | 0.01*                   | STMR (EFSA, 2015)       |
| Horseradish                   | 0.02                    | STMR (EFSA, 2015)       |
| Jerusalem artichokes          | 0.01*                   | STMR (EFSA, 2015)       |
| Parsnips                      | 0.01*                   | STMR (EFSA, 2015)       |
| Garlic                        | 0.02                    | STMR (EFSA, 2015)       |
| Onions                        | 0.02                    | STMR (EFSA, 2015)       |
| Shallots                      | 0.02                    | STMR (EFSA, 2015)       |
| Tomatoes                      | 0.01*                   | STMR (EFSA, 2015)       |
| Peppers                       | 0.02                    | STMR (EFSA, 2015)       |
| Sweet corn                    | 0.02                    | STMR (EFSA, 2015)       |
| Beans (fresh, with pods)      | 0.02                    | STMR (EFSA, 2015)       |
| Beans (fresh, without pods)   | 0.02                    | STMR (EFSA, 2015)       |
| Peas (fresh, with pods)       | 0.02                    | STMR (EFSA, 2015)       |
| Peas (fresh, without pods)    | 0.01*                   | STMR (EFSA, 2015)       |
| Lentils (fresh)               | 0.01*                   | STMR (EFSA, 2015)       |
| Celery                        | 0.01*                   | STMR (EFSA, 2015)       |
| Fennel                        | 0.01*                   | STMR (EFSA, 2015)       |
| Globe artichokes              | 0.02                    | STMR (EFSA, 2015)       |
| Beans (dry)                   | 0.02                    | STMR (EFSA, 2015)       |
| Lentils (dry)                 | 0.02                    | STMR (EFSA, 2015)       |
| Peas (dry)                    | 0.02                    | STMR (EFSA, 2015)       |
| Lupins (dry)                  | 0.01*                   | STMR (EFSA, 2015)       |
| Sunflower seed                | 0.02*                   | STMR (EFSA, 2015)       |
| Maize grain                   | 0.01*                   | STMR (EFSA, 2015)       |
| Sorghum grain                 | 0.01*                   | STMR (EFSA, 2015)       |
| Herbal infusions (dried, flowers) | 0.01*               | STMR (EFSA, 2015)       |
| Herbal infusions (dried, leaves) | 0.01*                | STMR (EFSA, 2015)       |
| Spices (seeds)                | 0.01*                   | STMR (EFSA, 2015)       |
| Spices (fruits and berries)   | 0.01*                   | STMR (EFSA, 2015)       |
| Swine meat                    | 0.01*                   | STMR (EFSA, 2015)       |
| Swine fat                     | 0.01*                   | STMR (EFSA, 2015)       |
| Swine liver                   | 0.01*                   | STMR (EFSA, 2015)       |
| Swine kidney                  | 0.01*                   | STMR (EFSA, 2015)       |
| Ruminant meat                 | 0.01*                   | STMR (EFSA, 2015)       |
| Ruminant fat                  | 0.01*                   | STMR (EFSA, 2015)       |
| Ruminant liver                | 0.01*                   | STMR (EFSA, 2015)       |
| Ruminant kidney               | 0.01*                   | STMR (EFSA, 2015)       |
| Ruminant milk                 | 0.01*                   | STMR (EFSA, 2015)       |

STMR: supervised trials median residue.

*: Indicates that the input value is proposed at the limit of quantification.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|---------------------------------|
| Aclonifen                     | 2-chloro-6-nitro-3-phenoxyaniline              | ![Structural formula](image)    |
|                               | Clc1c(N)c(ccc1Oc1cccc1)[N+][O-]=O             |                                 |
|                               | DDBMQQADHIC-UHFFFAOYSA-N                      |                                 |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).