Modification of the existing maximum residue levels for aclonifen in fennel seed and caraway fruit

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant Landesanstalt für Landwirtschaft und Gartenbau (LLG) submitted a request to the competent national authority in Germany to modify the existing maximum residue levels (MRLs) for the active substance aclonifen in fennel seed and caraway fruit. The data submitted in support of the request were found to be sufficient to derive MRL proposals for the crops under consideration. Adequate analytical methods for enforcement are available to control the residues of aclonifen in the plant matrices 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 uses of aclonifen according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Keywords: Aclonifen, fennel seed, caraway fruit, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Landesanstalt für Landwirtschaft und Gartenbau (LLG) 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 fennel seed and caraway fruit. 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 18 March 2020. To accommodate for the intended uses of aclonifen, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) to 0.03 mg/kg.

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 assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of aclonifen following foliar application and soil treatment was investigated in crops belonging to the groups of root crops, cereals/grass 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.

Based on the metabolic pattern identified in metabolism studies, hydrolysis studies, the toxicological significance of metabolites and/or degradation products, the residue definitions for plant products were proposed as aclonifen for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for the crops assessed in this application, 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 are applicable.

The data gap for analytical methods for enforcement of aclonifen in complex matrices such as spices has been previously addressed in the framework of the evaluation of the data submitted to confirm MRLs following the review of existing MRLs. Therefore, sufficiently validated analytical methods based on high-performance liquid chromatography (HPLC) are available to quantify residues in the crops assessed in this application 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 an MRL proposal of 0.03 mg/kg for fennel seed and caraway fruit.

Specific studies investigating the magnitude of aclonifen residues in processed commodities are not required, as significant residues of aclonifen are not expected in raw agricultural commodities and the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

The occurrence of aclonifen residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review. Based on the available information on the nature and magnitude of residues, it was concluded that significant residue levels are unlikely to occur in rotational crops, providing 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 consideration in this MRL application are normally not fed to livestock.

The toxicological profile of aclonifen was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an 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 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). For the calculation of the chronic exposure, EFSA updated the calculation performed in the framework of the MRL review with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of this application and in another EFSA reasoned opinion following the MRL review. The crops for which authorised uses were not reported in the MRL review and in the EFSA reasoned opinion following the MRL review were excluded from the calculation.

No long-term consumer intake concerns were identified; the calculated long-term exposure accounted for a maximum of 1% of the ADI (NL toddler). The contribution of residue expected in the commodities assessed in this application to the overall long-term exposure is insignificant.
EFSA concluded that the proposed use of aclonifen on fennel seed and caraway fruit will not result in a consumer exposure exceeding the toxicological reference value 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–D.

| Code<sup>(a)</sup> | Commodity     | Existing EU MRL/MRL proposals derived in a recent assessment of EFSA (not yet implemented)<sup>(b)</sup> (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                  |
|-------------------|---------------|-------------------------------------------------------------------------------------------------|------------------------|----------------------------------------|
| 0810070           | Fennel seed   | 0.01*(ft)/0.01*                                                                                 | 0.03                   | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely |
| 0820030           | Caraway fruit | 0.01*(ft)/0.01*                                                                                 | 0.03                   | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely |

Enforcement residue definition: Aclonifen

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.

(b): The MRL proposals which were derived in the framework of the assessment of confirmatory data requested in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, have not yet been implemented in the EU MRL legislation (EFSA, 2020).

(ft): The European Food Safety Authority identified some information on analytical methods as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 18 October 2018, or, if that information is not submitted by that date, the lack of it.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue levels (MRLs) for aclonifen in fennel seed and caraway fruit. The detailed description of the intended uses of aclonifen, which are the basis for the current MRL application, is reported in Appendix A.

Aclonifen is the ISO common name for 2-chloro-6-nitro-3-phenoxyaniline (IUPAC name). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Aclonifen was evaluated in the framework of Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS) for the representative use as pre-emergence herbicide in sunflowers. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2008). Aclonifen was approved2 for the use as herbicide on 1 August 2009.

The EU MRLs for aclonifen are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015b) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for aclonifen (EFSA, 2019a) as well as the evaluation of confirmatory data following the Article 12 MRL review for aclonifen (EFSA, 2020).

In accordance with Article 6 of Regulation (EC) No 396/2005, Landesanstalt für Landwirtschaft und Gartenbau (LLG) submitted an application to the competent national authority in Germany (evaluating Member State, EMS) to modify the existing MRLs for the active substance aclonifen in fennel seed and caraway fruit. 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 18 March 2020. To accommodate for the intended uses of aclonifen, the EMS proposed to raise the existing MRLs from the limit of quantification (LOQ) to 0.03 mg/kg.

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

EFSA based its assessment on the evaluation report submitted by the EMS (Germany, 2020), 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), the reasoned opinion on the MRL review under Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015b) and the assessment of its confirmatory data (EFSA, 2020) as well as the conclusions from a previous EFSA opinion on aclonifen (EFSA, 2019a).

For this application, the data requirements established in Regulation (EU) No 544/20114 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 546/20115.

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, 2020) 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.

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1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32.
2. 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.
3. 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.
4. Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
5. Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
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 belonging to the groups of root crops, cereals/grass and pulses/oilseeds has been investigated in the framework of the EU pesticides peer review and the MRL review (EFSA, 2008, 2015b). No additional studies were submitted in support of the current MRL application.

The available metabolism studies were performed by using only aniline-\textsuperscript{14}C-labelled aclonifen. Studies with radiolabelling in the phenyl ring were not considered necessary, 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 (EFSA, 2008, 2015b). Moreover, cleavage of the ether bond was considered only as a very minor pathway in the plant metabolism of aclonifen. Consequently, the EU pesticides peer review concluded that additional metabolism studies with phenyl-labelled aclonifen were not required. From the available metabolism studies, performed with aniline-\textsuperscript{14}C-labelled aclonifen, aclonifen was found to be the main residue.

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

1.1.2. Nature of residues in rotational crops

Aclonifen is authorised or is proposed to be used on fennel seed and caraway fruit that can be grown in rotation with other crops. According to the soil degradation studies evaluated in the framework of the peer review, the DT\textsubscript{90} value of aclonifen ranged from 104 to 649 days (EFSA, 2008). The trigger value of 100 days was exceeded and therefore further studies investigating the nature and magnitude of residues in rotational crops were performed. Based on these studies it was concluded that metabolism in primary and rotational crops is similar (EFSA, 2008, 2015b).

For the proposed use assessed in this application, no further information is required.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of aclonifen was investigated in the framework of a previous MRL application (EFSA, 2019a). It is concluded that aclonifen is hydrolytically stable under standard hydrolysis studies simulating processing conditions representative of pasteurisation, boiling and sterilisation.

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 MRL review (EFSA, 2008, 2015b). 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.

However, during the MRL review EFSA identified a data gap related to ‘an analytical method for enforcement in complex matrices (spices and herbal infusions) or an evaluation report of the available validation data’. Confirmatory data following the MRL review were submitted and evaluated by the EMS and addressed in a recent reasoned opinion by EFSA (2020). The data gap concerning the analytical method for enforcement in complex matrices (spices and herbal infusions) has been addressed by the submission of validation data for a multi-residue method for the determination of aclonifen residues in matrices with high oil content (sunflower seed), high water content (tomato fruit), high acid content (orange fruit), high starch/protein content (wheat grain) as well as in powdered caraway seed (a complex matrix representative of spices for which confirmatory data were requested) (EFSA, 2020). The method, applying a reversed-phase high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) in positive ion mode, was sufficiently validated at an LOQ of 0.01 mg/kg in all matrices under consideration.

EFSA concludes that sufficiently validated analytical methods are now available for enforcing the proposed MRLs for aclonifen in the crops under consideration.
1.1.5. Storage 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 $-18^\circ$C.

Since fennel seed and caraway fruit (seed and fruit spices) belong to the high oil content commodities group, the storage stability is adequately demonstrated for the commodities under assessment.

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in primary and rotational crops metabolism studies, the results of hydrolysis studies, the toxicological significance of metabolites and/or degradation products and the capabilities of enforcement analytical methods, the following residue definitions were proposed:

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

The same residue definitions are applicable to rotational crops and processed products.

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 this MRL application related to the post-emergence use in fennel seed and caraway fruit, the applicant provided in total 10 outdoor trials (2 trials on caraway, 4 trials on fennel and 4 trials on anise). The samples were analysed for the parent compound in line with the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the analytical methods used were sufficiently validated and fit for purpose (Germany, 2020). However, three of these trials (one each in caraway, fennel and anise) were disregarded by the EMS since the storage stability period was longer than the provided storage stability studies. EFSA agrees with this conclusion from the EMS. The remaining residue trials were adequately covered by storage stability (Germany, 2020).

Therefore, in total seven trials are available in support of the proposed northern Europe (NEU) Good Agricultural Practice (GAP). EFSA noted that the trials were performed in the same location in Germany but over different growing seasons for each different crop (caraway, fennel and anise). Generally, trials should be spread over different Member States from both residue areas and seasons. However, in some case one factor might be sufficient to conclude that two studies conducted in the same location on the same crop variety with the same experimental conditions but over two different growing seasons are independent and considered as separate trials (EFSA, 2015a).

In accordance with the EU guidance document on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017), fennel seed and caraway fruit belong to minor crops and a minimum of four trials is required to derive an MRL for each single minor crop or a minimum of six trials is required to derive an MRL by extrapolation for the whole subgroup of seed spices and fruit spices. The EMS combined residue data from seven trials on caraway (1), fennel (3) and anise (3) to derive the MRL proposal for fennel and caraway.

However, EFSA notes that two of these trials considered by the EMS for the MRLs setting were performed with the last application at a later growth stage (BBCH 39–50 and 39–51) than the one set in the intended GAP (BBCH 14–16). This could lead to an overestimation of the residue levels at harvest. Since samples of seeds from these trials were collected 67 and 97 days after last treatment and the samples from the other trials, where treatment occurred at intended BBCH growth stage, were collected 71 and 132 days after last application, EFSA assumes that the preharvest interval (PHI) under practical conditions is in this range and accepted the deviation. Hence, EFSA agreed to consider also these two trials for the MRL setting deriving therefore an MRL proposal of 0.03 mg/kg as derived by the EMS in the evaluation report.

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

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 (equivalent to 6N the application rate for the crop under assessment) (EFSA, 2008). Total radioactive residues were below 0.1 mg/kg in spinach (leafy crops) and barley (cereals) at all three rotational intervals. In carrots (root crops) 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). 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 to bare soil of 2.4 kg a.s./ha (equivalent to 4N the application rate for the crop under assessment) were evaluated in the framework of MRL review (EFSA, 2015b). 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 application, 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. However, considering the low residue levels found in the raw commodities and that the crops under consideration are only minor contributors to the overall long-term exposure accounting for less than 10% of the ADI, 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. In Section 3, EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as fennel seed and caraway fruit are not used for feed purposes.

3. Consumer risk assessment

EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019b). This exposure assessment model contains food consumption data for different sub-groups 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 (FAO, 2016).

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 (European Commission, 2012).

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, 2015b). EFSA updated the calculation with the relevant supervised trials median residue (STMR) values derived from the residue trials submitted in support of this application and in another EFSA reasoned opinion following the MRL review (EFSA, 2019a) and in the framework of the evaluation of the data submitted to confirm MRLs following the review of existing MRLs (EFSA, 2020). The crops for which authorised uses were not reported in the MRL review process (EFSA, 2015b, 2020) or in the EFSA reasoned opinion following the MRL review (EFSA, 2019a) were excluded from the calculation. The input values used in the exposure calculations are summarised in Appendix D.1.

The estimated long-term dietary intake is up to 1% of the ADI (NL toddler). The contribution of residues expected in the commodities assessed in this application 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 assessed in this MRL application is unlikely to present a risk to consumer health. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

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 this MRL application were found to be sufficient to derive an MRL proposal for fennel seed and caraway fruit. The data gap for analytical methods for enforcement of aclonifen in complex matrices such as spices has been previously addressed in the framework of the evaluation of the data submitted to confirm MRLs following the review of existing MRLs. Therefore, the proposed MRLs can be adequately enforced.

EFSA concluded that the proposed use of aclonifen on fennel seed and caraway fruit 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.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CF conversion factor for enforcement to risk assessment residue definition
DAR draft assessment report
DAT days after treatment
DT₉₀ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-ECD gas chromatography with electron capture detector
HPLC high performance liquid chromatography
HPLC-MS/MS high performance liquid chromatography with tandem mass spectrometry
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
LOQ limit of quantification
MRL maximum residue level
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
TMDI theoretical maximum daily intake
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 | F G or I (a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) (d) | Remarks |
|-----------------------|-------------------------|--------------|-----------------------------------|-------------|-------------|-----------------------------|----------------|---------|
|                       |                         |              |                                   | Type (b)    | Conc. a.s.  | Method kind                  | Range of growth stages & season (c) | Number min-max | Interval between application (min) | g a.s./hL min-max | Water L/ha min-max | Unit |                   |
| Caraway fruit         | NEU F                   | Monocotyledonous weeds | SC 600 g/L | Foliar treatment – broadcast spraying | 14–16 | 1–2 | 7 | 200–400 | 300 g/ha | n/a | PHI is driven by the time elapsed between last application and commercial harvest |
| Fennel seed           | NEU F                   | Monocotyledonous weeds | SC 600 g/L | Foliar treatment – broadcast spraying | 14–16 | 1–2 | 7 | 200–400 | 300 g/ha | n/a | PHI is driven by the time elapsed between last application and commercial harvest |

MRL: maximum residue level; GAP: Good Agricultural Practice; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; n/a: not applicable; SC: suspension concentrate.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.
(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.
(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. 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-U-14C]-aclonifen (EFSA, 2008, 2015b) |
|                                   |             | 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 |                |

| Rotational 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 | Radiolabelled active substance: [aniline-U-14C]-aclonifen (EFSA, 2008, 2015b) |
| 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) | Yes     | Radiolabelled active substance: [aniline-U-14C]-aclonifen (EFSA, 2008, 2015b) |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     |                |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Yes     |                |
|                                          | Other processing conditions |         |                |
Can a general residue definition be proposed for primary crops?  
Yes  
EFSA (2008, 2015b)

Rotational crop and primary crop metabolism similar?  
Yes  
EFSA (2008, 2015b)

Residue pattern in processed commodities similar to residue pattern in raw commodities?  
Yes  
EFSA (2019a)

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, 2015b):  
LOQ: 0.01 mg/kg in high water and dry/high starch content commodities  
LOQ: 0.02 mg/kg in high oil content commodities  
HPLC–MS/MS (EFSA, 2020):  
LOQ: 0.01 mg/kg in high oil, high water, high acid and high starch/protein content matrices, spices.

B.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       |                   |                |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; GC-ECD: gas chromatography with electron capture detector; 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<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) | CF<sup>(d)</sup> |
|-------------------------|-----------------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|--------------------------|----------------|
| Caraway, fennel seeds   | NEU                         | 5 × < 0.01; 0.01, 0.014                                          | Residue trials on caraway (n = 1), fennel (n = 3) and anise (n = 3) compliant with GAP were combined for the MRL proposal | 0.03                   | 0.014                    | 0.01                     | n/a           |

*: Indicates that the MRL is proposed at the limit of quantification.
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): 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

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No (leafy crops, cereals) | Inconclusive (root crops) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | no | According to the results of two rotational field studies in turnips, no residues (<LOQ of 0.01 mg/kg) are expected in root and tuber vegetables grown in rotation with crops treated with aclonifen at 2.4 kg/ha (EFSA, 2015b) |

LOQ: limit of quantification.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| ARfD | Not deemed necessary (European Commission, 2012) |
| ADI | 0.07 mg/kg bw per day (European Commission, 2012) |
| Highest IEDI, according to EFSA PRIMo | 1% ADI (NL toddler diet) |
| Contribution of crops assessed is insignificant |

Assumptions made for the calculations: The calculation is based on the median residue levels derived for the crops under assessment in this application and from a previous reasoned opinion (EFSA, 2019a) as well as input values from the MRL review and its confirmatory data (EFSA, 2015b, 2020). Crops on which authorised uses were not reported in the MRL review and in the EFSA reasoned opinion following the MRL review were excluded from the calculation. Calculation performed using rev.3.1 of EFSA PRIMo.

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

B.4. Recommended MRLs

| Code(a) | Commodity | Existing EU MRL/MRL proposals derived in a recent assessment of EFSA (not yet implemented)(b) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
| --- | --- | --- | --- | --- |
| 0810070 | Fennel seed | 0.01*(ft)/0.01* | 0.03 | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely |

Enforcement residue definition: Aclonifen

ARfD: acute reference dose; bw: body weight; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.
| Code\(^{(a)}\) | Commodity        | Existing EU MRL/MRL proposals derived in a recent assessment of EFSA (not yet implemented)\(^{(b)}\) (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------|------------------|--------------------------------------------------------------------------------------------------|-------------------------|--------------------------------------------------------------------------------------------|
| 0820030     | Caraway fruit    | 0.01\(^{*}(ft)/0.01^*\)                                                                         | 0.03                    | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers 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.

\(^{(b)}\): The MRL proposals which were derived in the framework of the assessment of confirmatory data requested in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005, have not yet been implemented in the EU MRL legislation (EFSA, 2020).

\(^{(ft)}\): The European Food Safety Authority identified some information on analytical methods as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 18 October 2018, or, if that information is not submitted by that date, the lack of it.
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Acclonifen

**Toxicological reference values**

| Parameter              | Value          | Source of ADI | Source of ARfD |
|------------------------|----------------|---------------|---------------|
| ADI (mg/kg bw per day) | not necessary  |                |               |
| ARfD (mg/kg bw)        |                |                |               |

**Input values**

- **LOQs (mg/kg)** range from: 0.05 to: 0.07

**Details – acute risk assessment**

- **Source of ADI:**
- **Source of ARfD:**

**Details – chronic risk assessment**

- **Chronic risk assessment:** JMPR methodology (IEDI/TMDI)

**Chronic risk assessment:**

- **MRLs set at under assessment**
- **LOQs (mg/kg):**

**Refined calculation mode**

**Cattle diet**

| Commodity/group of commodities | Exposure resulting from | 3rd contributor to MS | Year of evaluation | Expsoure (in % of ADI) | MRLs of the LOQ (in % of ADI) |
|--------------------------------|-------------------------|-----------------------|--------------------|------------------------|-------------------------------|
| Milk: Cattle                   |                         |                       |                    |                        |                               |
| No of diets exceeding the ADI |                         |                       |                    |                        |                               |
|                                |                         |                       |                    |                        |                               |

**Details – acute risk assessment/children**

**Details – acute risk assessment/adults**

**Conclusion:**

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

The long-term intake of residues of Acclonifen is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Show results for all crops

| Unprocessed commodities | Results for children | Results for adults |
|--------------------------|----------------------|--------------------|
| No of commodities for which ARfD/ADI is exceeded (IESTI): | — | — |

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------------------------|-------------|--------------------------|---------------------|------------------------|-------------|--------------------------|---------------------|

| Processed commodities | Results for children | Results for adults |
|------------------------|----------------------|--------------------|
| No of processed commodities for which ARfD/ADI is exceeded (IESTI): | — | — |

| Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI | Processed commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|------------------------|------------------------|--------------------------|---------------------|------------------------|------------------------|--------------------------|---------------------|

Conclusion:
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity                      | Input value (mg/kg) | Comment                        |
|--------------------------------|---------------------|--------------------------------|
| Caraway                        | 0.01                | STMR, current assessment       |
| Fennel                         | 0.01                | STMR, current assessment       |
| Chives                         | 0.04                | STMR (EFSA, 2019a)            |
| Parsley                        | 0.04                | STMR (EFSA, 2019a)            |
| Celery leaves (dill leaves)    | 0.04                | STMR (EFSA, 2019a)            |
| Thyme (savory)                 | 0.04                | STMR (EFSA, 2019a)            |
| Celeriacs                      | 0.04                | STMR (EFSA, 2019a)            |
| Potatoes                       | 0.02                | STMR (EFSA, 2015b)            |
| Carrots                        | 0.01*               | STMR (EFSA, 2015b)            |
| Horseradish                    | 0.02                | STMR (EFSA, 2015b)            |
| Jerusalem artichokes           | 0.01*               | STMR (EFSA, 2015b)            |
| Parsnips                       | 0.01*               | STMR (EFSA, 2015b)            |
| Garlic                         | 0.02                | STMR (EFSA, 2015b)            |
| Onions                         | 0.02                | STMR (EFSA, 2015b)            |
| Shallots                       | 0.02                | STMR (EFSA, 2015b)            |
| Tomatoes                       | 0.01*               | STMR (EFSA, 2015b)            |
| Peppers                        | 0.02*               | STMR (EFSA, 2020)             |
| Sweet corn                     | 0.02                | STMR (EFSA, 2015b)            |
| Beans (fresh, with pods)       | 0.02                | STMR (EFSA, 2015b)            |
| Beans (fresh, without pods)    | 0.02                | STMR (EFSA, 2015b)            |
| Peas (fresh, with pods)        | 0.02                | STMR (EFSA, 2015b)            |
| Peas (fresh, without pods)     | 0.01*               | STMR (EFSA, 2015b)            |
| Lentils (fresh)                | 0.01*               | STMR (EFSA, 2015b)            |
| Celery                         | 0.01*               | STMR (EFSA, 2015b)            |
| Fennel                         | 0.01*               | STMR (EFSA, 2015b)            |
| Globe artichokes               | 0.02                | STMR (EFSA, 2015b)            |
| Beans (dry)                    | 0.02                | STMR (EFSA, 2015b)            |
| Lentils (dry)                  | 0.02                | STMR (EFSA, 2015b)            |
| Peas (dry)                     | 0.02                | STMR (EFSA, 2015b)            |
| Lupins (dry)                   | 0.01*               | STMR (EFSA, 2015b)            |
| Sunflower seed                 | 0.02*               | STMR (EFSA, 2015b)            |
| Maize grain                    | 0.01*               | STMR (EFSA, 2015b)            |
| Sorghum grain                  | 0.01*               | STMR (EFSA, 2015b)            |
| Herbal infusions (dried, flowers) | 0.01*       | STMR (EFSA, 2020)             |
| Herbal infusions (dried, leaves) | 0.01*          | STMR (EFSA, 2020)             |
| Spices (seeds)                 | 0.01*               | STMR (EFSA, 2020)             |
| Spices (fruits and berries)    | 0.01*               | STMR (EFSA, 2020)             |
| Swine meat                     | 0.01*               | STMR (EFSA, 2015b)            |
| Swine fat                      | 0.01*               | STMR (EFSA, 2015b)            |
| Swine liver                    | 0.01*               | STMR (EFSA, 2015b)            |
| Swine kidney                   | 0.01*               | STMR (EFSA, 2015b)            |
| Ruminant meat                  | 0.01*               | STMR (EFSA, 2015b)            |
| Ruminant fat                   | 0.01*               | STMR (EFSA, 2015b)            |
| Ruminant liver                 | 0.01*               | STMR (EFSA, 2015b)            |
| Ruminant kidney                | 0.01*               | STMR (EFSA, 2015b)            |
| Ruminant milk                  | 0.01*               | STMR (EFSA, 2015b)            |
*: Indicates that the MRL is proposed at the limit of quantification.
STMR: supervised trials median residue.
## 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(ccc1Oc1ccccc1)[N+][(O-)]=O            |                                 |
|                                 | DDBMQDADIHOWIC-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 2018.2.2 ACD/Labs 2018 Release (File version N50E41, Build 103230, 21 July 2018).
- <sup>(c)</sup> ACD/ChemSketch 2018.2.2 ACD/Labs 2018 Release (File version C60H41, Build 106041, 07 December 2018).