Modification of the existing maximum residue levels for fenhexamid in various crops

European Food Safety Authority (EFSA),
Alba Brancato, Daniela Brocca, Chloe De Lentdecker, Zoltan Erdos, Lucien Ferreira, Luna Greco, Samira Jarrah, Dimitra Kardassi, Renata Leuschner, Christopher Lythgo, Paula Medina, Ileana Miron, Tunde Molnar, Alexandre Nougadere, Ragnor Pedersen, Hermine Reich, 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 applicant Bayer CropScience SAS submitted a request to the competent national authority in Italy to modify the existing maximum residue levels (MRL) for the active substance fenhexamid in plums, blueberries, cranberries, currants, gooseberries and beans with pods. 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 fenhexamid in plant matrices. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of fenhexamid according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Requestor: European Commission
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Correspondence: pesticides.mrl@efsa.europa.eu
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, Bayer CropScience SAS submitted an application to the competent national authority in Italy (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRL) for the active substance fenhexamid in plums, blueberries, cranberries, currants, gooseberries and beans with pods. 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 3 October 2016. To accommodate for the intended uses of fenhexamid, the EMS proposed to raise the existing MRL from 1.5 to 2 mg/kg for plums, from 15 to 20 mg/kg for blueberries, cranberries, currants and gooseberries, and from 5 to 15 mg/kg for beans with pods.

EFSA based its assessment on the evaluation report submitted by the EMS, the renewal assessment report (RAR) (and its final addendum) prepared under Commission Regulation (EU) No 1141/2010, the Commission review report on fenhexamid, the conclusion on the peer review of the pesticide risk assessment of the active substance fenhexamid, the Joint Meeting on Pesticide Residues (JMPR) evaluation report, as well as the conclusions from previous EFSA opinions on fenhexamid.

The metabolism of fenhexamid was investigated in crops belonging to the groups of fruit crops, leafy vegetables and pulses/oilseeds.

Studies investigating the effect of processing on the nature of fenhexamid (hydrolysis studies) demonstrated that pasteurisation, baking/boiling and sterilisation conditions are not expected to have a significant impact on the nature of residues in matrices of plant origin. Processing studies in beans with pods submitted under this application demonstrated that cooking lead to a reduction of the residues in processed commodities. Further processing studies are not required as they are not expected to affect the outcome of the risk assessment.

Based on the metabolic pattern identified in metabolism studies and results of hydrolysis studies, the residue definitions for plant products were proposed as fenhexamid for enforcement and risk assessment. The previously derived residue definitions are applicable.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) and its independent laboratory validation (ILV) 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 (limit of quantification (LOQ)) in the crops assessed.

The available residue trials are sufficient to derive MRL proposals of 2 mg/kg in plums, 20 mg/kg in currants, blueberries, cranberries and gooseberries, and 15 mg/kg in beans with pods.

The occurrence of fenhexamid residues in rotational crops was investigated in the framework of the EU pesticides peer 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 due to the rapid degradation in soil.

Residues of fenhexamid 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 fenhexamid was assessed in the framework of the EU pesticides peer review under Regulation (EC) No 1107/2009 and the data were sufficient to derive an acceptable daily intake (ADI) of 0.2 mg/kg body weight (bw) per day. No acute reference dose (ARfD) was deemed necessary.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMO). In the framework of the MRL review, a comprehensive long-term exposure assessment was performed. EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for crops under consideration and STMRs derived in EFSA opinion published after the MRL review. The estimated long-term dietary intake was below 12% of the ADI. The contribution of residues expected in the commodities under consideration to the overall long-term exposure is below 1% of the ADI.

EFSA concluded that the proposed use of fenhexamid on plums, blueberries, cranberries, currants, gooseberries and beans with pods will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumer health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.
### Enforcement residue definition: fenhexamid

| Code(a) | Commodity        | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------|------------------|------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0140040 | Plums            | 1.5                    | 2                       | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 0154010 | Blueberries      | 15                     | 20                      | The submitted data are sufficient to derive a MRL proposal for the EU use under protected conditions by extrapolation from indoor trials on currants. No consumer health concern was identified |
| 0154020 | Cranberries      | 15                     | 20                      |                                                                                       |
| 0154030 | Currants         | 15                     | 20                      |                                                                                       |
| 0154040 | Gooseberries     | 15                     | 20                      |                                                                                       |
| 0260010 | Beans (with pods)| 5                      | 15                      | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |

MRL: maximum residue level; SEU: southern Europe.

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

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

Regulation (EC) No 396/20051 (hereinafter referred to as ‘the MRL regulation’) establishes the rules governing the setting of pesticide maximum residue levels (MRLs) at European Union (EU) level. Article 6 of the MRL regulation lays down that any party having a legitimate interest or requesting an authorisation for the use of a plant protection product in accordance with Council Directive 91/414/EEC2, repealed by Regulation (EC) No 1107/20093, shall submit an application to a Member State to modify a MRL in accordance with the provisions of Article 7 of the MRL regulation.

The applicant Bayer CropScience SAS4 submitted an application to the competent national authority in Italy, hereafter referred to as the evaluating Member State (EMS), to modify the existing MRLs for the active substance fenhexamid in plums, blueberries, cranberries, currants, gooseberries and beans with pods. This application was notified to the European Commission and the European Food Safety Authority (EFSA) and was subsequently evaluated by the EMS in accordance with Article 8 of the MRL regulation.

The EMS summarised the data provided by the applicant in an evaluation report which was submitted to the European Commission and forwarded to EFSA on 3 October 2016. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2016-00632 and the following subject:

Fenhexamid: Application to modify MRLs in various crops

Italy proposed to raise the existing MRL of fenhexamid from 1.5 to 2 mg/kg for plums, from 15 to 20 mg/kg for blueberries, cranberries, currants and gooseberries, and from 5 to 15 mg/kg for beans with pods.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps which were requested from the EMS. On 19 April 2017, the EMS submitted a revised evaluation report (Italy, 2017), which replaced the previously submitted evaluation report. The applicant also decided to withdraw the application on azaroles and cherries.

Terms of Reference

In accordance with Article 10 of Regulation (EC) No 396/2005, EFSA shall assess the application and the evaluation report and give a reasoned opinion on the risks to the consumer and where relevant to animals associated with the setting of the requested MRLs. The opinion shall include:

- an assessment of whether the analytical method for routine monitoring proposed in the application is appropriate for the intended control purposes;
- the anticipated limit of quantification (LOQ) for the pesticide/product combination;
- an assessment of the risks of the acceptable daily intake (ADI) and acute reference dose (ARfD) being exceeded as a result of the modification of the MRL;
- the contribution to the intake due to the residues in the product for which the MRLs was requested;
- any other element relevant to the risk assessment.

In accordance with Article 11 of the MRL regulation, EFSA shall give its reasoned opinion as soon as possible and at the latest within three months from the date of receipt of the application.

The evaluation report submitted by the EMS (Italy, 2017) 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.

The active substance and its use pattern

The detailed description of the intended uses of fenhexamid which are the basis for the current MRL application is reported in Appendix A.

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1 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.
2 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.
3 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
4 Bayer CropScience SAS, Rue Jean-Marie Leclair 16, 69009 Lyon, France.
Fenhexamid is the ISO common name for 2′,3′-dichloro-4′-hydroxy-1-methylcyclohexanecarboxanilide (IUPAC). The chemical structure of the active substance is reported in Appendix E.

Fenhexamid was evaluated for renewal of the approval in the framework of Regulation (EC) No 1107/2009 with the United Kingdom designated as rapporteur Member State (RMS) as a fungicide on grapes, strawberry and tomato. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (2014b). The date of the renewal of approval of fenhexamid for the use as fungicide was on 1 January 2016.5

The EU MRLs for fenhexamid are established in Annexes II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2014a) and the proposed modifications have been implemented in the MRL legislation.6 After completion of the MRL review, EFSA has issued one reasoned opinion on the modification of MRLs for fenhexamid (EFSA, 2014c). The proposals from this reasoned opinion has been considered in the same regulation as the MRL review.5

Assessment

EFSA has based its assessment on the evaluation report submitted by the EMS (Italy, 2017), the RAR (and its final addendum) prepared under Commission Regulation (EU) No 1141/2010 (United Kingdom, 2013, 2014), the European Commission review report on fenhexamid (European Commission, 2015), the conclusion on the peer review of the pesticide risk assessment of the active substance fenhexamid (EFSA, 2014b), the JMPR Evaluation report (FAO, 2005), as well as the conclusions from previous EFSA opinions on fenhexamid (EFSA, 2014a,c).

For this application, the data requirements established in Regulation (EU) No 544/20117 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, 2016; 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 546/20118.

A selected list of end points of the studies assessed by EFSA in the framework of the MRL review, including the end points of studies submitted in support of the current MRL application, are presented in Appendix B.

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 fenhexamid in primary crops belonging to the group of fruit crops, leafy crops and pulses/oilseeds has been investigated in the framework of the MRL review. The metabolism of fenhexamid was considered as fully elucidated in all investigated crops and a residue definition limited to fenhexamid was proposed for enforcement risk assessment (EFSA, 2014a).

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

1.1.2. Nature of residues in rotational crops

Beans can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use on primary crops has to be assessed. According to the soil degradation studies evaluated in the framework of the peer review, the DT90 value of fenhexamid is

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5 Commission Implementing Regulation (EU) 2015/1201 of 22 July 2015 renewing the approval of the active substance fenhexamid in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 195, 23.7.2015, p. 37–40.

6 Commission Regulation (EU) 2015/1200 of 22 July 2015 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for amidosulfuron, fenhexamid, kresoxim-methyl, thiacloprid and trifloxystrobin in or on certain products. OJ L 195, 23.7.2015, p. 1–36.

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 Text with EEA relevance. 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.
expected to be lower than 10 days which is far below the trigger value of 100 days (United Kingdom, 1998). Further investigation of residues in rotational crops is not required and relevant residues in rotational crops are not expected due to the rapid degradation of the parent compound in soil.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of fenhexamid was investigated in the framework of the EU pesticides peer review (United Kingdom, 1998). It was concluded during the MRL review that no significant impact on the nature of residues in the processed commodities is expected; therefore, the same residue definition as for primary crops is applicable (EFSA, 2014a).

1.1.4. Methods of analysis in plants

Analytical methods for the determination of fenhexamid residues were assessed during the EU pesticides peer review for the renewal of the approval of the active substance (EFSA, 2014b). An analytical method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) and its independent laboratory validation (ILV) were evaluated and concluded validated for the determination of parent fenhexamid an LOQ of 0.01 mg/kg in acidic, high water, high oil, high protein and high starch content matrices (EFSA, 2014b).

The methods are sufficiently validated for residues of fenhexamid in the crops under consideration.

1.1.5. Stability of residues in plants

The storage stability of fenhexamid in plants stored under frozen conditions was investigated in the framework of the EU pesticides peer review for the renewal of the approval of the active substance and the MRL review (EFSA, 2014a,b). The storage stability of fenhexamid was demonstrated for a period of 12–13 months at \(-18^\circ C\) in commodities with high water content and for a period of 17 months at \(-18^\circ C\) in commodities with high acid content (EFSA, 2014a,b).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in 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 for risk assessment: fenhexamid
- residue definition for enforcement: fenhexamid

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 MRL application, the applicant submitted residue trials performed in plums, currants and beans with pods. 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 methods used were sufficiently validated and fit for purpose.

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

1.2.1.1. Plums (SEU GAP, 4 × 0.75 kg/ha, preharvest interval (PHI) 1 day)

In support of the southern Europe (SEU) good agricultural practice (GAP), eight GAP-compliant residue trials on plums were provided. The trials were conducted in southern France, Spain, Italy and Greece over two seasons. Five additional GAP-compliant residue trials already evaluated by EFSA are available. A total of 13 residue trials were used for the MRL calculation.

The number and quality of the trials is sufficient to derive a MRL proposal of 2 mg/kg for plums.
1.2.1.2. Currants, blueberries, cranberries, gooseberries (indoor GAP, 4 × 0.75 kg/ha, PHI 3 days, SEU GAP, 4 × 0.75 kg/ha, PHI 1 days)

Nine residue trials on currants under protected conditions have been provided in support of the application. It is noted that eight of these trials have been submitted previously in the framework of the MRL review to support the existing use on currants. The trials were assessed by EFSA in 2014 (EFSA, 2014a) and an MRL proposal of 15 mg/kg was derived. With this application, one additional trial was provided and it was suggested to extrapolate to the other minor crops (i.e. blueberries, cranberries, gooseberries) in accordance with the EU guidance document (European Commission, 2016).

The number and quality of the trials is sufficient to derive a MRL proposal of 20 mg/kg in currants, blueberries, cranberries and gooseberries reflecting the indoor GAP.

For the SEU outdoor GAP, no supporting residue trials were provided. Thus, no MRL proposal can be derived.

1.2.1.3. Beans with pods (SEU GAP, 3 × 0.75 kg/ha, PHI 1 day)

In support of the SEU GAP, eight GAP-compliant residue trials on beans with pods were provided. The trials were conducted in southern France, Spain, Italy and Portugal in 2014. The number and quality of the trials is sufficient to derive a MRL proposal of 15 mg/kg in beans with pods.

1.2.2. Magnitude of residues in rotational crops

The possible transfer of fenhexamid residues to crops that are grown in crop rotation has been assessed in the MRL review (EFSA, 2014a). EFSA concluded that fenhexamid residue levels in rotational crops are not expected to be of concern due to the rapid degradation in soil.

1.2.3. Magnitude of residues in processed commodities

During the MRL review, EFSA recommended several processing factors. A number of studies on fenhexamid residues in processed fruits and vegetables give evidence that residues in juice and preserve are expected to be lower compared to the residues in the raw agricultural commodity (United Kingdom, 1998; FAO, 2005). Processing studies in beans with pods submitted under this application for the fruit and pulses/oilseed crop groups demonstrated that cooking leads to a reduction of the residues in the processed product.

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, (see Appendix B.1.2.1). In Section 3, EFSA assessed whether residues on these crops resulting from the intended are likely to pose a consumer health risk.

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 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 (EFSA, 2007).

The toxicological reference value for fenhexamid used in the risk assessment (i.e. ADI) was derived in the framework of the EU pesticides peer review (EFSA, 2014b). The setting of an ARfD was concluded to be not necessary for the active substance. No acute consumer risk assessment was performed.

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed, taking into account the existing uses at EU level and the acceptable Codex maximum residue limit (CXLs) (EFSA, 2014a). EFSA updated the calculation with the relevant STMR values derived from the residue trials submitted in support of this MRL application for crops under consideration and STMRs derived in the EFSA opinion published after the MRL review (EFSA, 2014c). The input values used in the exposure calculations are summarised in Appendix D.2.
The estimated long-term dietary intake was below 12% of the ADI. The contribution of residues expected in the commodities assessed in this application to the overall long-term exposure was below 1% and is presented in more detail in Appendix D.2.

EFSA concluded that the long-term intake of residues of fenhexamid resulting from the existing and the intended uses is unlikely to present a risk to consumer health.

Conclusions and recommendations

The data submitted in support of this MRL application 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 fenhexamid in plant matrices under consideration.

Based on the risk assessment results, EFSA concluded that the intake of residues resulting from the use of fenhexamid according to the reported agricultural practices is unlikely to present a risk to consumer 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), 2014a. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for fenhexamid according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2014;12(1):3536, 57 pp. https://doi.org/10.2903/j.efsa.2014.3536

EFSA (European Food Safety Authority), 2014b. Conclusion on the peer review of the pesticide risk assessment of the active substance fenhexamid. EFSA Journal 2014;12(7):3744, 95 pp. https://doi.org/10.2903/j.efsa.2014.3744

EFSA (European Food Safety Authority), 2014c. Reasoned opinion on the modification of the existing MRLs for fenhexamid in various berries. EFSA Journal 2014;12(7):3785, 19 pp. https://doi.org/10.2903/j.efsa.2014.3785

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, 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/9522 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev. 4.

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, 2015. Review report for the active substance fenhexamid. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 29 May 2015 in view of the approval of fenhexamid as active substance in accordance with Regulation (EC) No 1107/2009. SANTE/11960/2014 Rev.2, 29 May 2015.

European Commission, 2016. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.2.

FAO (Food and Agriculture Organization of the United Nations), 2005. Fenhexamid. In: Pesticide residues in food – 2005. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 183.

Italy, 2017. Evaluation report on the modification of MRLs for fenhexamid in plums, blueberries, cranberries, currants, gooseberries and beans (fresh with pods), September 2016. updated in April 2017, 89 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

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73. ENV/JM/MONO(2013)8, 04 September 2013.

United Kingdom, 1998. Draft assessment report on the active substance fenhexamid prepared by the rapporteur Member State United Kingdom in the framework of Council Directive 91/414/EEC, July 1998.

United Kingdom, 2013. Renewal Assessment Report (RAR) on the active substance fenhexamid prepared by the rapporteur Member State United Kingdom in the framework of Commission Regulation (EU) No 1141/2010, April 2013. Available online: www.efsa.europa.eu

United Kingdom, 2014. Final Addendum to the Renewal Assessment Report on fenhexamid, compiled by EFSA, May 2014. Available online: www.efsa.europa.eu

Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
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
DT<sub>90</sub> 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
GPC gel permeation chromatography
IEDI international estimated daily intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC liquid chromatography
LOQ limit of quantification
Mo monitoring
MRL maximum residue level
MS/MS tandem mass spectrometry detector
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant back interval
PF processing factor
PHI pre-harvest interval
PRImo (EFSA) Pesticide Residues Intake Model
RA risk assessment
RAC raw agricultural commodity
RAR renewal assessment report
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
WG water-dispersible granule
WHO World Health Organization
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

#### Summary of the critical GAPs for uses of Fenhexamid WG 50 and Fenhexamid SC 500 in the relevant crops

| Formulation   | Zone | Region | F or I | Country (critical GAP)                        | Mode of application                  | Spray interval/appl. timing | No. of applic. | Max. appl. rate (kg a.s./ha) | PHI (days) |
|---------------|------|--------|--------|----------------------------------------------|--------------------------------------|----------------------------|----------------|-------------------------------|------------|
| **Plum**      |      |        |        |                                              |                                      |                            |                |                               |            |
| Fenhexamid WG 50 | S    | EU-S   | F      | Portugal(\textsuperscript{a}), Spain(\textsuperscript{a}) | Foliar treatment – spraying          | 7 days BBCH 61-69 + BBCH 81-89 | 2              | 0.750                         | 1          |
|                | S    | EU-S   | F      | Greece(\textsuperscript{a})                     | Foliar treatment – spraying          | 7 days BBCH 61-89            | 2              | 0.750                         | 1          |
| Fenhexamid SC 500 | S    | EU-S   | F      | Croatia(\textsuperscript{a}), Cyprus(\textsuperscript{b}), Greece(\textsuperscript{b}), Portugal(\textsuperscript{b}), Spain(\textsuperscript{b}) | Foliar treatment – spraying          | 7 days BBCH 61-69 + BBCH 81-89 | 2              | 0.750                         | 1          |
| **Other small fruit (blueberry, cranberry currant, gooseberry)** |      |        |        |                                              |                                      |                            |                |                               |            |
| Fenhexamid WG 50 | I    | EU     | G      | Austria(\textsuperscript{a}), Belgium(\textsuperscript{a}), Netherlands(\textsuperscript{a}) | Foliar treatment – spraying          | 8 days BBCH 56-89            | 1-4            | 0.750                         | 3          |
| Fenhexamid SC 500 | S    | EU-S   | F      | Portugal(\textsuperscript{b}), Spain(\textsuperscript{b}) | Foliar treatment – spraying          | 10 days BBCH 55-89           | 2              | 0.750                         | 1          |
| **Beans with pods** |      |        |        |                                              |                                      |                            |                |                               |            |
| Fenhexamid WG 50 | S    | EU-S   | F      | Portugal(\textsuperscript{a}), Spain(\textsuperscript{a}) | Foliar treatment – spraying          | 10 days BBCH 55-79           | 1-3            | 0.750                         | 1          |
| Fenhexamid SC 500 | S    | EU-S   | F      | Cyprus(\textsuperscript{b}), Greece(\textsuperscript{b}), Portugal(\textsuperscript{b}), Spain(\textsuperscript{b}) | Foliar treatment – spraying          | 8 days BBCH 55-79            | 1-3            | 0.750                         | 1          |

GAP: good agricultural practice; WG: water-dispersible granule; SC: suspension concentrate; PHI: preharvest interval; BBCH: growth stages of mono- and dicotyledonous plants; a.s.: active substance.

Zone: N: northern authorisation zone; C: central authorisation zone; S: southern authorisation zone; I: Interozone.

Region: Residue region: EU-N: northern Europe; EU-S: southern Europe; F: Field; G: Greenhouse; I: Indoor.

Italics or #: home and garden uses.

(a): Submitted under Art 43.
(b): Not yet registered, submitted under Art 33.
### 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) |
|-----------------------------------|-------------|-------------|----------------|----------------|
| Fruit crops                       | Grapes      | Foliar spray, G | 0, 14         |
|                                  | Apples      | Foliar spray, F | 0, 7          |
|                                  | Tomatoes    | Foliar spray, G | 10            |
|                                  | Lettuce     | Foliar spray, G | 7             |
| Pulses/oilseeds                   | Field Peas  | Foliar spray, G | Hay: 9         |
|                                  |             |              | Vines, pods: 21|
|                                  |             |              | Dry seeds: 77  |

Radiolabelled active substance: $^{14}$C-phenyl

Reference: EFSA (2014a)

| Rotational crops (available studies) | Crop groups         | Crop(s) | Application(s) | PBI (DAT)     |
|--------------------------------------|---------------------|---------|----------------|---------------|
| Root/tuber crops                     | Turnip              | Bare soil application | 1st: 110     |
|                                     |                     |         |                | 2nd: 237      |
|                                     |                     |         |                | 3rd: 390      |
| Leafy crops                         | Swiss chard         | Bare soil application | 1st: 75      |
|                                     |                     |         |                | 2nd: 191      |
|                                     |                     |         |                | 3rd: 363      |
| Cereal                              | Wheat               | Bare soil application | 1st: 63/89/131|
|                                     |                     |         |                | 2nd: 177/239/299|
|                                     |                     |         |                | 3rd: 352/406/447|
|                                     |                     |         | Forage/hay/grain & straw |

Radiolabelled active substance: $^{14}$C-phenyl

Reference: FAO (2005)

| Processed commodities (hydrolysis study) | Conditions                        | Investigated? |
|------------------------------------------|-----------------------------------|---------------|
|                                         | Pasteurisation (20 min, 90°C, pH 4)| Yes           |
|                                         | Baking, brewing and boiling (60 min, 100°C, pH 5)| Yes           |
|                                         | Sterilisation (20 min, 120°C, pH 6) | Yes           |
|                                         | Comment                           |               |
|                                         | Reference EFSA (2014a)            |               |
Can a general residue definition be proposed for primary crops?
Yes

Rotational crop and primary crop metabolism similar?
Yes. The metabolic pathway is similar but an intensive degradation of fenhexamid was observed

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

Plant residue definition for monitoring (RD-Mo)
Fenhexamid

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

Conversion factor (monitoring to risk assessment)
Not required

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Fenhexamid residues in plant and plant products were determined by extraction with acetone/water and the resulting extracts extracted with ethyl acetate/cyclohexane. The ethyl acetate/cyclohexane extracts were evaporated to dryness (in the case of bean seed and oilseed rape seed the extracts were first cleaned up using GPC), reconstituted in methanol/water and the resulting extracts analysed by LC-MS/MS monitoring for the precursor ion m/z 302 and the product ion m/z 97 (and 55 for confirmation). The limit of determination was 0.01 mg/kg. Acceptable validation (orange/tomato/wheat grain/bean seed/oilseed rape) and ILV (orange/tomato/wheat grain/oilseed rape) data were submitted (EFSA, 2014a)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category             | Commodity                  | T (°C) | Stability (months) |
|-----------------------------------|-----------------------|----------------------------|--------|-------------------|
| High water content                | Peaches, plums, cherries, tomatoes | –18 | 12               |
| High oil content                  | –                     | –                          | –      | –                 |
| Dry/High starch                   | –                     | –                          | –      | –                 |
| High acid content                 | Grapes, strawberries  | –18 | 17               |

Comment:
Reference EFSA (2014a), FAO (2005)
B.1.2. Magnitude of residues in plants

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

| Crop (supervised trials) | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments (OECD calculations unrounded/rounded, mg/kg) | MRL proposals (mg/kg) | HR_{Mo}^{(b)} (mg/kg) | STMR_{Mo}^{(c)} (mg/kg) | CF^{(d)} |
|--------------------------|------------------|---------------------------------------------------------------|------------------------------------------------------|----------------------|-----------------------|------------------------|---------|
| Plums (4 × 0.75 kg/ha, PHI 1 day) | SEU | 2 × < 0.05*, 0.11, 0.20, 0.21, 0.37(e), 0.37, 0.48(e), 0.50(e), 0.55(e), 0.58, 0.91(e), 0.97 | MRL_{OECD} = 1.60/2.0 | 2.0 | 0.97 | 0.48 | 1 |
| Currants (4 × 0.75 kg/ha, PHI 3 days) | Indoor | 2.70(e), 2.80(e), 3.60, 4.20, 4.90(e), 5.20, 6.90, 8.50, 8.70 | MRL_{OECD} = 15.83/20 Extrapolation to blueberries, cranberries and gooseberries | 20 | 8.70 | 4.90 | 1 |
| Beans with pods (3 × 0.75 kg/ha, PHI 1 day) | SEU | 0.12, 0.75, 0.88, 0.92, 1.50, 2.0(e), 2.90, 6.90 | MRL_{OECD} = 10.63/15 | 15 | 6.90 | 1.21 | 1 |

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

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

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

(b): Highest residue according to the residue definition for monitoring.

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

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

(e): Peak residue determined after the PHI.
B.1.2.2. Residues in succeeding crops

Confined rotational crop study (quantitative aspect)

Relevant residues of fenhexamid in rotational crops are not expected due to the rapid degradation in soil. Reference: EFSA (2014a)

Field rotational crop study

B.1.2.3. Processing factors

| Processed commodity       | Number of valid studies(a) | Processing Factor (PF) | CFP(b) |
|---------------------------|----------------------------|------------------------|--------|
|                           | Individual values          | Median PF              |        |
| Plum jam                  | 1                          | < 1                    | 1      |
| Plum prune                | 1                          | < 2                    | < 2    | 1      |
| Plum, canned              | 1                          | 1                      | 1      |
| Plum, dried (prunes)      | 1                          | 2                      | 2      | 1      |
| Bean cooked               | 3                          | 0.31, 0.38, 1.1        | < 0.38 | 1      |

(a): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).
(b): Conversion factor for risk assessment in the processed commodity is the same as derived from the raw commodities.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

No ARfD has been considered necessary.

ADI

0.2 mg/kg bw per day (EFSA, 2014a)

Highest IEDI, according to EFSA PRIMo

11.6% ADI (FR all population)

Contribution of crops assessed:

Plums: 0.079% of ADI (IE adult)

Currants: 0.32% of ADI (NL child)

Beans with pods: 0.66% of ADI (FR toddler diet)

Assumptions made for the calculations

The calculation is based on the median residue levels derived for raw agricultural commodities that were assessed in the current or in previous assessments (EFSA, 2014a, c)

The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.
## B.4. Recommended MRLs

| Code\(^{(a)}\) | Commodity       | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|---------------|-----------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 0140040       | Plums           | 1.5                     | 2                       | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |
| 0154010       | Blueberries     | 15                      | 20                      | The submitted data are sufficient to derive a MRL proposal for the EU use under protected conditions by extrapolation from indoor trials on currants. No consumer health concern was identified |
| 0154020       | Cranberries     | 15                      | 20                      |                                                                                       |
| 0154030       | Currants        | 15                      | 20                      |                                                                                       |
| 0154040       | Gooseberries    | 15                      | 20                      |                                                                                       |
| 0260010       | Beans (with pods) | 5                       | 15                      | The submitted data are sufficient to derive a MRL proposal for the SEU use. No consumer health concern was identified |

MRL: maximum residue level; SEU: southern Europe.

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

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRIMo)

Fenhexamid

| Status of the active substance: | Included |
|--------------------------------|----------|
| Cod no.                        | Proposed LOQ |

| Toxicological end points |
|--------------------------|-------------|
| ADI (mg/kg bw per day):   | 0.2         |
| ARfD (mg/kg bw):          | n.n.        |
| Source of ADI:            | EFSA        |
| Source of ARfD:           | EFSA        |
| Year of evaluation:       | 2014        |

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | MS Diet | TMDI (range) in % of ADI |
|--------------------------------|---------|--------------------------|
|                                |         | minimum – maximum        |
| **Highest calculated TMDI values in % of ADI** | **Highest contributor to MS diet (in % of ADI)** | **2nd contributor to MS diet (in % of ADI)** | **3rd contributor to MS diet (in % of ADI)** | **pTMRLs at LOQ (in % of ADI)** |
| **11.6** | FR all population | 8.6 | Wine grapes | 1.1 | Other lettuce and other salad plants | 0.5 | Lettuce |
| **10.3** | WHO Cluster diet B | 3.9 | Wine grapes | 2.1 | Lettuce | 0.6 | Peaches |
| **7.6** | IE adult | 2.7 | Wine grapes | 1.1 | Peaches | 0.6 | Kiwi |
| **7.3** | DE child | 2.7 | Table grapes | 0.6 | Strawberries | 0.7 | Apricots |
| **7.1** | PT General population | 5.3 | Wine grapes | 0.7 | Peaches | 0.6 | Table grapes |
| **6.3** | WHO cluster diet E | 3.5 | Wine grapes | 0.6 | Lettuce | 0.3 | Table grapes |
| **6.1** | NL Child | 1.6 | Table grapes | 1.2 | Scarrone (broad-leaf endive) | 0.6 | Lettuce |
| **5.3** | ES adult | 3.1 | Lettuce | 0.9 | Wine grapes | 0.4 | Peaches |
| **5.2** | IT adult | 2.2 | Lettuce | 0.9 | Other lettuce and other salad plants | 0.7 | Peaches |
| **4.7** | WHO regional European diet | 2.2 | Lettuce | 0.5 | Wine grapes | 0.4 | Peaches |
| **4.4** | IT Kids/toddler | 1.7 | Lettuce | 0.7 | Peaches | 0.6 | Other lettuce and other salad |
| **4.1** | NL general | 1.4 | Wine grapes | 0.7 | Lettuce | 0.7 | Scarrone (broad-leaf endive) |
| **4.0** | WHO Cluster diet F | 1.7 | Lettuce | 1.3 | Wine grapes | 0.2 | Table grapes |
| **3.7** | DK adult | 3.0 | Wine grapes | 0.2 | Peaches | 0.2 | Table grapes |
| **3.6** | ES child | 2.4 | Lettuce | 0.4 | Peaches | 0.2 | Tomatoes |
| **3.5** | UK Adult | 2.3 | Wine grapes | 0.7 | Lettuce | 0.1 | Table grapes |
| **3.4** | UK vegetarian | 1.7 | Wine grapes | 0.6 | Lettuce | 0.2 | Table grapes |
| **2.9** | FR toddler | 1.0 | Strawberries | 0.7 | Beans (with pods) | 0.4 | Table grapes |
| **2.6** | WHO cluster diet D | 0.8 | Wine grapes | 0.4 | Table grapes | 0.4 | Herbs |
| **2.2** | DK child | 0.8 | Lettuce | 0.4 | Table grapes | 0.2 | Kiwi |
| **2.1** | UK Toddler | 0.5 | Table grapes | 0.3 | Strawberries | 0.3 | Currants (red, black and white) |
| **1.8** | FR infant | 0.8 | Strawberries | 0.5 | Beans (with pods) | 0.2 | Table grapes |
| **1.8** | FR adult | 0.7 | Wine grapes | 0.4 | Lettuce | 0.2 | Currants (red, black and white) |
| **1.7** | SE general population 95th percentile | 0.3 | Kiwi | 0.3 | Peaches | 0.3 | Strawberries |
| **1.5** | PL general population | 0.7 | Table grapes | 0.2 | Tomatoes | 0.1 | Peaches |
| **1.2** | UK Infant | 0.4 | Strawberries | 0.2 | Apricots | 0.2 | Currants (red, black and white) |
| **0.7** | LT adult | 0.4 | Lettuce | 0.1 | Tomatoes | 0.1 | Strawberries |

**Conclusion:**

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

| Commodities | pTMRL | threshold MRL |
|-------------|-------|---------------|
| ARfD/ADI    |       |               |

No of critical MRLs (IESTI 1):

No of critical MRLs (IESTI 2):

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

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

pTMRL: provisional temporary MRL.

All calculations are performed with a variability factor of 5.

| Commodities | ARfD/ADI | pTMRL |
|-------------|----------|-------|
|              |          |       |

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

** pTMRL: provisional temporary MRL for unprocessed commodity.

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***) pTMRL: provisional temporary MRL.
Appendix D – Input values for the exposure calculations

D.1. Livestock dietary burden calculations

Not relevant.

D.2. Consumer risk assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Plums                            | 0.48                    | STMR                  | –                    | –                     |
| Blueberries, cranberries, currants, gooseberries | 4.90                    | STMR                  | –                    | –                     |
| Beans (fresh with pods)          | 1.21                    | STMR                  | –                    | –                     |
| Azaroles (kiwiberries)           | 4.60                    | STMR (EFSA, 2014c)    | –                    | –                     |
| Other commodities                | Input values as listed in Table 4-1 of the Reasoned Opinion on the review of the existing MRLs (EFSA, 2014a) | – | – |

STMR: supervised trials median residue; MRL: maximum residue level.
### Appendix E – Used compound codes

| Code/trivial name | Chemical name/SMILES notation\(^{(a)}\) | Structural formula\(^{(a)}\) |
|-------------------|------------------------------------------|-----------------------------|
| fenhexamid        | 2',3'-dichloro-4'-hydroxy-1- methylcyclohexanecarboxanilide O=C(Nc1ccc(O)(Cl)c1Cl)C2(C)CCCCC2 | ![Structural formula](image) |

SMILES: simplified molecular-input line-entry system.

\(^{(a)}\): (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008).