Modification of a maximum residue level for mepiquat in cotton seeds

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 the Article 53 of the Regulation (EC) 1107/2009, Greece granted a 120-day emergency authorisation for the use of mepiquat in cotton following an application by the Hellenic Ministry of Rural Development and Food. To accommodate for the use of mepiquat according to the authorised good agricultural practices, Greece submitted an application to set a temporary maximum residue level (tMRL) for the active substance mepiquat in cotton seed in line with Article 16(1) in conjunction with Article 14 of Regulation (EC) No 396/2005. Greece, as evaluating Member State (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. EFSA has assessed the available data and performed a risk assessment as regards the risks to consumers related to the exposure of mepiquat chloride in cotton seed. Several risk management options were derived in response to the request to amend the existing MRL for cotton seed. EFSA did not confirm the need to modify the existing MRLs for animal products as suggested by Greece.

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Keywords: mepiquat, cotton seed, pesticide, temporary MRL, consumer risk assessment

Requestor: European Commission
Question number: EFSA-Q-2017-00689
Correspondence: pesticides.mrl@efsa.europa.eu
Summary

In accordance with the provisions of Article 53 of Regulation (EC) 1107/2009, Greece granted an emergency authorisation for the placing on the market of a plant protection product containing the active substance mepiquat, for a period not exceeding 120-days, for limited and controlled use in cotton. The emergency use is expected to lead to residues exceeding the existing maximum residue level (MRL) established for cotton seeds at 0.05*mg/kg. Thus, Greece has authorised the placing on the market of treated cotton seeds not complying with the existing European Union (EU) MRL within its territory, in accordance with Article 18(4) of Regulation (EC) No 396/2005 (hereinafter referred to as ‘the MRL Regulation’).

In order to amend the existing EU MRL, accommodating for the emergency use of mepiquat on cotton, the Hellenic Ministry of Rural Development and Food (hereafter referred to as evaluating Member State (EMS)) submitted an application under Article 6(2) of the MRL Regulation to raise the MRL for mepiquat in cotton seeds. The EMS drafted an evaluation report in accordance with Article 8 of the MRL Regulation, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA).

The EMS proposed to raise the existing EU MRL in cotton seed from the limit of quantification (LOQ) of 0.05 mg/kg to a temporary MRL of 7 mg/kg. Furthermore, the EMS proposed to modify the existing EU MRLs for ruminant and equine liver from 0.5 to 0.6 mg/kg, for milk from 0.06 to 0.15 mg/kg and for birds’ eggs from the LOQ of 0.05 to 0.07 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS. On 24 October 2017, the EMS submitted the requested information in a revised evaluation report (Greece, 2017), which replaced the previously submitted evaluation report. Based on the revised evaluation report, the conclusions derived by EFSA in the framework of Directive 91/414/EEC and data evaluated under previous MRL assessments, the following conclusions are derived.

The metabolism of mepiquat was investigated in three different crop groups as well as in rotational crops in the framework of the peer review under Directive 91/414/EEC and in the Article 12 MRL review. Studies investigating the effect of processing on the nature of mepiquat (hydrolysis studies) demonstrated that the active substance is stable under processing by pasteurisation baking/brewing/boiling and sterilisation.

Based on the metabolic pattern of mepiquat chloride depicted in primary and rotational crops, the nature of the residues in processed commodities and the toxicological significance of metabolites, the residue definitions for enforcement and risk assessment for plant products were proposed as the sum of mepiquat and its salts expressed as mepiquat chloride. For the use in cotton seed, EFSA concluded that the metabolism of mepiquat chloride in primary crops is sufficiently addressed and the proposed residue definitions are applicable.

Sufficiently validated analytical methods to enforce the residues of mepiquat chloride in cotton seed are available.

A limited number of independent residue trials on cotton seed compliant with the good agricultural practice (GAP) authorised in Greece for the emergency use is available. As cotton is a major crop in southern Europe, additional GAP-compliant residue trials are required to support the setting of a MRL on this crop. Although insufficient residue trials were submitted to derive a definitive MRL on cotton seeds, EFSA has derived proposals for a temporary MRL to accommodate the emergency use of mepiquat chloride for further risk management decision.

Specific studies investigating the magnitude of mepiquat chloride residues in cotton processed commodities were submitted and indicative processing factors for enforcement and risk assessment were derived for cotton crude oil, refined oil, meal, delinted seeds and hulls.

Regarding the magnitude of residues in rotational crops, EFSA concluded that relevant residue levels are unlikely to occur in rotational crops provided that mepiquat chloride is used on cotton according to proposed GAP.

As cotton and its by-products are used as feed product, a potential carry-over into food of animal origin was assessed. The calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species. However, the contribution of mepiquat residues in the crop under consideration for this MRL application to the total livestock exposure was insignificant. In contrast to the EMS, EFSA does not see the need to modify the existing MRLs for commodities of animal origin.
The toxicological profile of mepiquat was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.2 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 0.3 mg/kg bw.

The consumer risk assessment was performed with revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest long-term dietary intake accounted for maximum 3.1% of the ADI (Danish child). The contribution of mepiquat chloride residues in cotton seeds to the total consumer exposure is negligible (< 0.01% of ADI, Dutch child).

The acute consumer exposure for mepiquat residues in cotton seeds is also very low (< 0.01% of the ARfD).

EFSA concluded that the MRL proposal for cotton seeds will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

In the summary table below, EFSA derived several risk management options as regards the possible amendment of the existing MRL for cotton seeds.

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 (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|-----------------|-------------------------|-------------------------|--------------------------------------------------------------------------------------|
| 401090            | Cotton seed     | 0.05*                   | No MRL proposal         | **Option 1:** Only three independent residue trials are available. Since cotton is a major crop in Southern Europe, five additional residue trials compliant with the SEU GAP are required to derive a MRL in cotton seed. Thus, no MRL proposal is derived |
|                   |                 |                         | 8 (temporary)           | **Option 2:** Considering that the emergency authorisation on this crop is granted for a limited period of time (120 days), a proposal for a temporary MRL based on the three independent GAP-compliant residue trials on cotton seed is derived. Based on the limited number of acceptable residue trials, it is concluded that residues of mepiquat chloride in cotton seed are unlikely to pose a consumer health concern, if cotton is treated in accordance with the GAP reported by Greece |
|                   |                 |                         | 5 (temporary)           | **Option 3:** An alternative temporary MRL proposal was derived based on all eight residue trials submitted, noting that these trials were considered as not fully independent because they were performed in a restricted geographical area. Considering that the emergency authorisation on this crop is granted for a limited period of time (120 days), risk managers may accept this deficiency of the residue trials and agree on this alternative temporary MRL proposal. A consumer health concern is unlikely |

MRL: maximum residue level; SEU: southern Europe; GAP: good agricultural practice.

*: 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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Assessment

The detailed description of the intended emergency use of mepiquat in cotton, which is the basis for the current MRL application, is reported in Appendix A.

Mepiquat is the ISO common name for 1,1-dimethylpiperidinium (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E. In formulated products, normally, the variant mepiquat chloride is used as active ingredient.

Mepiquat was evaluated in the framework of Directive 91/414/EEC1 with the United Kingdom designated as rapporteur Member State (RMS) for the representative uses as plant growth regulator in cereals for stem stabilisation. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (2008). Mepiquat was approved2 for the use as a plant growth regulator on 1 March 2009. According to Regulation (EU) No 540/20113, mepiquat is deemed to have been approved under Regulation (EC) No 1107/20094. The process of renewal of the first approval is currently ongoing.

The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015) and the proposed modifications have been implemented in Regulation (EU) No 2016/10155; (Annex II of Regulation (EC) No 396/20056).

By Regulation (EC) No 2016/1015, the MRL for cotton seeds has been lowered from the level of 5 mg/kg to the limit of quantification (LOQ) of 0.05 mg/kg. To accommodate the emergency use in Greece, the EMS proposes to raise the existing European Union (EU) maximum residue level (MRL) to a temporary MRL of 7 mg/kg. Furthermore, the EMS also proposes to modify the existing EU MRLs for ruminant and equine liver from 0.5 to 0.6 mg/kg, for milk from 0.06 to 0.15 mg/kg and for birds’ eggs to 0.07 mg/kg.

EFSA based its assessment on the updated evaluation report submitted by the EMS (Greece, 2017), the DAR (and its final addendum) (United Kingdom, 2005, 2008) prepared under Council Directive 91/414/EEC, the Commission review report on mepiquat (European Commission, 2008), the conclusion on the peer review of the pesticide risk assessment of the active substance mepiquat (EFSA, 2008), as well as the conclusions from EFSA opinion on the review of the existing MRLs for mepiquat according to Article 12 of Regulation (EC) No 396/2005 and a recent MRL application (EFSA, 2015, 2016).

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, 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 546/20118.

The evaluation report submitted by the EMS (Greece, 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.

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

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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 2008/108/EC of 26 November 2008 amending Council Directive 91/414/EEC to include flutolanil, benfluralin, fluazinam, fuberidazole and mepiquat as active substances. OJ L 317, 27.11.2008, p. 6–13.
3 Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
4 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
5 Commission Regulation (EU) 2016/1015 of 17 June 2016 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 1-naphthylacetamide, 1-naphthylacetic acid, chloridazon, fluanid, flubendiamide, fuberidazole, mepiquat and triallate in or on certain products. OJ L 172, 29.6.2016, p. 1–21.
6 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
7 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
8 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L155, 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 nature of mepiquat residues in primary crops has been investigated in cereals (wheat, barley), pulses/oilseeds (cotton) and fruit (grapes) crops (EFSA, 2008); in the framework of the MRL review, an additional study performed on rape seed was provided (EFSA, 2015, 2016). In all these studies, the only relevant component of the residues at harvest was the parent compound (72–90% of the total radioactive residue (TRR)). Some metabolites were present but they did not individually exceed 5% of the TRR and therefore, were not further identified. The non-extractable radioactivity was low (≤ 6% TRR).

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

Cotton 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. The soil degradation studies demonstrated that the degradation rate of mepiquat is moderate. The maximum DT$_{90}$ was 95 days (EFSA 2008), which is below the trigger value of 100 days. Thus, no further studies investigating the nature of mepiquat residues in rotational crops are in principle required. Although not triggered, a confined rotational crop study was performed and assessed by EFSA (2008, 2015). The metabolic pattern depicted in the rotational crops was found to be more extensive than in primary crops and relevant residue levels are unlikely to occur in rotational crops.

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

The effect of processing on the nature of mepiquat was also investigated in the framework of the peer review and it was demonstrated that mepiquat remained stable under the standard hydrolysis conditions representative of pasteurisation, baking/brewing/boiling and sterilisation (EFSA, 2008).

1.1.4. **Methods of analysis in plants**

Sufficiently validated analytical methods are available for the determination of mepiquat residues in high water-, high acid-, high oil- and high starch- content matrices at a LOQ of 0.05 mg/kg (the LOQ was expressed as mepiquat chloride) (EFSA, 2008).

1.1.5. **Stability of residues in plants**

Storage stability of mepiquat residues was demonstrated for a period of 24 months at –20°C in high water (wheat forage) and high starch (wheat grain) content commodities (EFSA, 2008) and for up to 25 months in high oil (cotton seed) content commodities (EFSA, 2015, 2016; Greece, 2017).

1.1.6. **Proposed residue definitions**

A general residue definition for both monitoring and risk assessment in all plant commodities can be proposed as the sum of mepiquat and its salts, expressed as mepiquat chloride (EFSA, 2008, 2015).

1.2. **Magnitude of residues in plants**

1.2.1. **Magnitude of residues in primary crops**

The good agricultural practice (GAP) for cotton seed assessed in the reasoned opinion is reported in Appendix A.

In support of the MRL application, the applicant submitted eight residue trials on cotton conducted in southern Europe in 2005 and 2006. The samples were analysed for the parent mepiquat chloride in accordance 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.
All trials were performed in Greece in sites that were located in the same geographical area, except one trial that was conducted at about 80 km from the other trial sites. According to the manufacturer of the active substance who has performed the trials, the sites were at least 5 km apart and conducted using different crop varieties. Although all trials were compliant with the southern Europe (SEU) GAP on cotton, three trials were considered as fully independent according to the legal data requirements (one trial performed in 2005 and two in 2006). Since cotton is a major crop in Southern Europe at least eight GAP-compliant residue trials are required to derive a MRL proposal.

EFSA proposes the following MRL options for further risk management consideration:

- **Option 1: No MRL proposal**

  Three independent residue trials compliant with the SEU GAP on cotton are insufficient to derive a MRL proposal. At least five additional GAP-compliant residue trials are required to support the setting of the MRL in cotton as it is a major crop in Southern Europe.

  However, considering the emergency situation (Article 53 of Regulation (EC) No 1107/2009) and the request to set an MRL in cotton on a temporary basis in accordance with the provisions of Article 18(4) in conjunction with Article 16 of Regulation (EC) No 396/2005, EFSA proposes the alternative options.

- **Option 2: MRL proposal based on the submitted independent residue trials**

  Based on the results of the three submitted independent residue trials, EFSA calculated a MRL proposal of 8 mg/kg using the OECD MRL calculator, noting that three trials are a weak basis for deriving a MRL proposal. However, for a temporary MRL, the uncertainty resulting from the limited data may be considered acceptable. The STMR to be used for the long-term dietary risk assessment is 1.89 mg/kg.

- **Option 3: MRL proposal based on all the submitted residue trials**

  A temporary MRL proposal of 5 mg/kg is derived, using all eight residue trials submitted in support of the application, noting that the trials are not fully independent. However, for a temporary MRL, the uncertainty resulting from the limited geographical distribution of the residue trials may be considered acceptable. The STMR to be used for the long-term dietary risk assessment is 1.7 mg/kg.

### 1.2.2. Magnitude of residues in rotational crops

Based on the available information on the magnitude of the residues, EFSA concludes that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used on cotton according to proposed GAP.

### 1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in processed commodities of rapeseed and cereals were reported in the framework of the peer review (EFSA, 2008) and during the MRL review (EFSA, 2015, 2016). A new processing study on cotton has been submitted in the framework of this application. Since only two processing residue trials were available, only indicative processing factors for enforcement and risk assessment were derived in cotton crude oil, refined oil, meal, delinted seeds and hull. The details are summarised in the Appendix B.

### 1.2.4. Proposed MRLs

Only three independent trials compliant with the SEU GAP on cotton were provided. The number of residue trials compliant with the SEU use on cotton is insufficient to derive a MRL proposal for this use. At least five additional independent GAP-compliant residue trials would be required to support the setting of the MRL in cotton.

Considering that the emergency authorisation on cotton is granted for a limited period of time (120 days), further risk management considerations are required to decide whether a MRL proposal of 8 mg/kg for mepiquat chloride on cotton seeds derived from the three independent residue trials on cotton seed or of 5 mg/kg derived from all the submitted residue trials should be established or whether the existing MRL should not be amended.
2. Residues in livestock

Cotton seeds may be fed to livestock and therefore the magnitude of mepiquat chloride residues in livestock has to be reassessed.

2.1. Nature of residues and methods of analysis in livestock

The metabolism of mepiquat chloride has been investigated in lactating goats and laying hens and a general residue definition for monitoring was proposed as the sum of mepiquat and its salts, expressed as mepiquat chloride. For risk assessment, the residue definition was set as the sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride (EFSA, 2008). Based on the metabolism data, EFSA derived a conversion factor for monitoring to risk assessment of 1.7 in ruminant liver. In all other animal matrices and since the parent mepiquat was the only significant compound of the total residues, a conversion factor of 1 was deemed to be sufficient. Methods of analysis have been previously assessed by EFSA and considered as sufficiently validated (EFSA, 2013).

Storage stability of mepiquat was demonstrated for a period of 26 months at −18°C in all commodities of animal origin.

2.2. Magnitude of residues in livestock

As the crop under consideration and its by-products are used as feed product, a potential carry-over into food of animal origin was assessed. The livestock dietary burden calculation performed in the framework of the MRL review (EFSA, 2015, 2016) has been updated. The contribution of residues of mepiquat chloride in linseed, sunflower and rapeseed meals were excluded from this calculation since risk managers decided to lower the MRLs to the LOQ since the uses on these crops were not sufficiently supported by sufficient data (EFSA, 2015, 2016).

EFSA calculated two scenarios, with and without the contribution of residues of cotton by products, to estimate whether the emergency use has a significant impact on the expected residues in food of animal origin. The calculations were performed using the animal dietary intake calculator implementing the OECD Guidance Documents (OECD, 2009, 2013).

For both scenarios the calculated livestock dietary burden exceeded the trigger value of 0.1 mg/kg dry matter (DM) for all relevant species. However, the contribution of mepiquat residues resulting from the use of mepiquat chloride on cotton according to the intended use to the total livestock exposure was insignificant and therefore a modification of the existing MRLs for commodities of animal origin was considered unnecessary.

EFSA therefore concluded that there is no need to modify the existing MRLs for animal products.

It is noted that the EMS proposed to raise existing MRLs for ruminant and equine liver, milk and for birds’ eggs. The conclusion was reached on the basis of a dietary burden calculation which did not take into account the fact that the uses of mepiquat on linseed, sunflower seed and rapeseed had to be revoked due to the lowering of the MRL to the LOQ. Thus, the feed items derived from these crops should not be included in the dietary burden calculation.

3. Consumer risk assessment

The consumer intake calculation was performed with revision 2 of the EFSA PRIMo (EFSA, 2007). For the calculation of the chronic exposure, the STMR value derived from the supervised field trials (option 2) was used as input value for cotton seeds. For the other plant and animal commodities, the STMR values derived in MRL review (EFSA, 2015, 2016) (except for linseed, rape seed and sunflower seed for which the MRL proposals were not taken over in the current EU legislation) and the STMR value for cultivated fungi (EFSA, 2016) were selected as input values. The input parameters for the dietary exposure assessment are summarised in the Appendix B. For the calculation of the acute risk assessment, only the crop under consideration was used.

The highest long-term dietary intake accounted for maximum 3.1% of the acceptable daily intake (ADI) (Danish child). The contribution of mepiquat chloride residues in cotton seed to the total consumer exposure is negligible (< 0.01% of ADI, Dutch child).

The acute consumer exposure calculation for cotton seeds is low (< 0.01% of the acute reference dose (ARfD)).
The dietary risk assessment showed that the emergency use of mepiquat in cotton seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a concern for public health.

4. Conclusion and Recommendations

Based on this assessment, EFSA proposes the following MRL options for further risk management consideration:

- **Option 1: No MRL proposal**
  Taking into account that only three independent residue trials compliant with the SEU GAP on cotton are available, at least five additional GAP-compliant residue trials are required to support the setting of the MRL in cotton seed as it is a major crop in SEU.
  However, considering the emergency situation (Article 53 of Regulation (EC) No 1107/2009) and the request to set an MRL in cotton on a temporary basis in accordance with the provisions of Article 18(4) in conjunction with Article 16 of Regulation (EC) No 396/2005, EFSA proposes the following option for risk management consideration.

- **Option 2: MRL proposal based on the submitted independent residue trials**
  Based on the results of the three submitted independent residue trials, EFSA calculated a MRL of 8 mg/kg using the OECD MRL calculator. The STMR to be used for the long-term dietary risk assessment is 1.89 mg/kg.

- **Option 3: MRL proposal based on all the submitted residue trials**
  Taking into account the submitted eight residue trials on cotton to derive a tentative MRL, EFSA calculated a MRL of 5 mg/kg using the OECD MRL calculator. The STMR to be used for the long-term dietary risk assessment is 1.7 mg/kg.
  Considering that the emergency authorisation on these crops is granted for a limited period of time (120 days), further risk management considerations are required to decide whether the proposed MRLs should be established for a limited time period.
  EFSA concluded that the proposed emergency use of mepiquat on cotton seed will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.
  The MRL recommendations are summarised in Appendix B.

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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
DM dry matter
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
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
LOQ limit of quantification
Mo monitoring
MRL maximum residue level
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development

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| Acronym | Description |
|---------|-------------|
| PBI     | plant back interval |
| PF      | processing factor |
| PHI     | preharvest interval |
| PRIMo   | (EFSA) Pesticide Residues Intake Model |
| RA      | risk assessment |
| RAC     | raw agricultural commodity |
| RD      | residue definition |
| RMS     | rapporteur Member State |
| SANCO   | Directorate-General for Health and Consumers |
| SC      | suspension concentrate |
| SEU     | southern Europe |
| SL      | soluble concentrate |
| SP      | water-soluble powder |
| STMR    | supervised trials median residue |
| TMDI    | theoretical maximum daily intake |
| TRR     | total radioactive residue |
| WHO     | World Health Organization |
# Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | Unit | PHI<sup>(d)</sup> | Remarks |
|-----------------------|-------------------------|-----------------------|------------------------------------|-------------|----------------|--------------------------------|------|-----------------|---------|
| Cotton (emergency use)| Greece | F | Plant growth regulator | SL 50 g/L | SP | BBCH 50–69 | 1 | 400 | g a.s./ha | – | Maximum total dose of 75 g mepiquat chloride/ha Interval between applications is 14 days |

NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SL: soluble concentrate; SP: water-soluble powder.

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

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

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

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

B.1. Residues in plants

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

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

| Primary crops          | Crop groups | Crop(s)       | Application(s)       | Sampling (DAT) | Comment/source                                      |
|------------------------|-------------|---------------|----------------------|----------------|-----------------------------------------------------|
|                        | Fruit crops | Grapes        | Foliar, 2 × 1.1 kg a.s./ha | 98             | EFSA (2008) Ring labelled 14C- mepiquat chloride     |
|                        | Cereals/grass| Wheat         | Foliar, 1 × 0.7 kg a.s./ha | 0, 8, 71       | EFSA (2008) Ring labelled 14C- mepiquat chloride     |
|                        |             | Barley        | Foliar, 1 × 0.91 kg a.s./ha | 16, 37, 52     |                                                     |
|                        | Pulses/oilseeds | Cotton   | Foliar, 1 × 0.16 kg a.s./ha | 15, 67         | EFSA (2008) Ring labelled 14C- mepiquat chloride     |
|                        |             | Rapeseed      | Foliar, 2 × 0.3 kg a.s./ha | 63             | EFSA (2015)                                         |

| Rotational crops        | Crop groups | Crop(s)       | Application(s)       | PBI (DAT)      | Comment/source                                      |
|-------------------------|-------------|---------------|----------------------|----------------|-----------------------------------------------------|
|                        | Root/tuber crops | Radish      | Bare soil, 0.7 kg a.s./ha | 29, 120, 365   | EFSA (2008) Ring labelled 14C-mepiquat chloride      |
|                        | Leafy crops  | Lettuce       | Bare soil, 0.7 kg a.s./ha | 29, 120, 365   | EFSA (2008) Ring labelled 14C-mepiquat chloride      |
|                        | Cereal (small grain) | Wheat      | Bare soil, 0.7 kg a.s./ha | 29, 120, 365   | EFSA (2008) Ring labelled 14C-mepiquat chloride      |

| Processed commodities   | Conditions | Stable? | Comment/source |
|-------------------------|------------|---------|----------------|
|                        | Pasteurisation (20 min, 90°C, pH 4) | Yes     | EFSA (2008)     |
|                        | Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | EFSA (2008)     |
|                        | Sterilisation (20 min, 120°C, pH 6) | Yes     | EFSA (2008)     |
|                        | Other processing conditions         | –       | –               |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval.

Modified a maximum residue level for mepiquat in cotton seeds

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Can a general residue definition be proposed for primary crops?
Yes

Rotational crop and primary crop metabolism similar?
Yes

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

Plant residue definition for monitoring (RD-Mo)
Sum of mepiquat and its salts, expressed as mepiquat chloride

Plant residue definition for risk assessment (RD-RA)
Sum of mepiquat and its salts, expressed as mepiquat chloride

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)
Matrices with high water content, high oil content, high acid content and high starch matrices; HPLC–MS/MS, LOQ 0.05 mg/kg
Confirmatory method available
ILV available
(EFSA, 2008)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category                        | Commodity                        | T (°C) | Stability period | Compounds covered | Comment/source     |
|-----------------------------------|---------------------------------|----------------------------------|--------|------------------|-------------------|-------------------|
|                                    | High water content              | Wheat forage                     | –18    | 24               | Months            | Parent            | EFSA (2008)       |
|                                    | High water content              | Cotton forage                    | –15    | 25               | Months            | Parent            | Greece (2017)     |
|                                    | High oil content                | Cotton seed, Cotton seed (delinted) | –15    | 25               | Months            | Parent            | Greece (2017)     |
|                                    | Dry/high starch                 | Wheat grain                       | –18    | 24               | Months            | Parent            | EFSA (2008)       |
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/indoor(\text{a}) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR(\text{b}) (mg/kg) | STMR(\text{c}) (mg/kg) | CF(\text{d}) |
|-----------|--------------------------|---------------------------------------------------------------|----------------|------------------------|---------------------|------------------------|---------|
| Cotton (emergency use, 1 × 0.075 kg/ha, BBCH 69) | SEU | 0.41, 1.89, 3.19 | **Option 1:** Only three trials were considered as independent according to the legal data requirements. Since cotton is a major crop in southern Europe, five additional residue trials compliant with the SEU GAP are therefore required to derive a MRL in cotton seeds. No MRL proposal is derived  | No proposal | – | – | – |
| | | 0.41, 0.88, 0.99, 1.51, 1.89, 1.91, 2.02, 3.19 | **Option 2:** Based on the three independent residue trials submitted, EFSA calculated an MRL using the OECD calculator | 8 | 3.19 | 1.9 | 1 |
| | | | **Option 3:** The trials were performed in the same geographical area; thus, they are not considered as fully independent. Only three of these trials are independent. A MRL proposal was derived on the basis of all trials, considering that the increased number of residue trials compared to option 2 may give a more robust MRL proposal. EFSA calculated an MRL using the OECD calculator | 5 | 3.19 | 1.70 | 1 |

MRL: maximum residue level; GAP: good agricultural practice; OECD: Organisation for Economic Co-operation and Development.

(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?

- Residues not expected

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

- Not triggered

B.1.2.3. Processing factors

| Processed commodity       | Number of valid studies\(^{(a)}\) | Processing factor (PF) | Comment/source |
|---------------------------|----------------------------------|------------------------|----------------|
|                           |                                  | Individual values      | Mean PF\(^{(c)}\) | CF\(_{P}\)\(^{(b)}\) |
| Cotton delinted seed      | 2                                | 1.1; 1.4               | 1.2             | 1.0             | Greece (2017) |
| Cotton hulls              | 2                                | 0.2; 0.3               | 0.3             | 1.0             | Greece (2017) |
| Cotton meal               | 2                                | 1.7; 2.1               | 1.9             | 1.0             | Greece (2017) |
| Cotton crude oil          | 2                                | < 0.1; < 0.1           | < 0.1           | 1.0             | Greece (2017) |
| Cotton refined oil        | 2                                | < 0.1; < 0.1           | < 0.1           | 1.0             | Greece (2017) |

\(^{(a)}\): 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; median of the individual conversion factors for each processing residues trial.
\(^{(c)}\): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

B.2. Residues in livestock

Scenario 1: Calculation with the contribution of mepiquat chloride residues in cotton seed/meal.

| Relevant groups     | Dietary burden expressed in mg/kg bw per day | mg/kg DM | Most critical diet\(^{(a)}\) | Most critical commodity\(^{(b)}\) | Trigger exceeded (yes/no) mg/kg bw |
|---------------------|---------------------------------------------|---------|-----------------------------|---------------------------------|----------------------------------|
|                     | Median | Maximum | Median | Maximum |                      |                                    |                                    |
| Cattle (all diets)  | 0.287  | 0.477   | 7.54  | 12.49  | Dairy cattle         | Rye                               | Straw                             | Yes                               |
| Cattle (dairy only) | 0.287  | 0.477   | 7.46  | 12.41  | Dairy cattle         | Rye                               | Straw                             | Yes                               |
| Sheep (all diets)   | 0.600  | 1.021   | 14.12 | 24.03  | Lamb                | Rye                               | Straw                             | Yes                               |
| Sheep (ewe only)    | 0.466  | 0.796   | 13.97 | 23.88  | Ram/Ewe             | Rye                               | Straw                             | Yes                               |
| Swine (all diets)   | 0.047  | 0.047   | 1.58  | 1.58   | Swine (finishing)    | Wheat                             | Milled byproducts                  | Yes                               |
| Poultry (all diets) | 0.290  | 0.460   | 4.24  | 6.72   | Poultry layer        | Wheat                             | Straw                             | Yes                               |
| Poultry (layer only)| 0.290  | 0.460   | 4.24  | 6.72   | Poultry layer        | Wheat                             | Straw                             | Yes                               |
Scenario 2: Calculation without the contribution of mepiquat chloride residues in cotton seed/meal.

| Relevant groups | Dietary burden expressed in | Most critical diet<sup>(a)</sup> | Most critical commodity<sup>(b)</sup> | Trigger exceeded (yes/no) | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum | mg/kg bw |
|-----------------|-----------------------------|-------------------------------|---------------------------------|--------------------------|-----------------|--------|--------|--------|--------|--------|
| Cattle (all diets) | 0.287 0.477 | 7.54 12.49 | Dairy cattle | Rye Straw Yes | 0.004 |
| Cattle (dairy only) | 0.287 0.477 | 7.46 12.41 | Dairy cattle | Rye Straw Yes | 0.004 |
| Sheep (all diets) | 0.600 1.021 | 14.12 24.03 | Lamb | Rye Straw Yes | 0.004 |
| Sheep (ewe only) | 0.466 0.796 | 13.97 23.88 | Ram/Ewe | Rye Straw Yes | 0.004 |
| Swine (all diets) | 0.047 0.047 | 1.58 1.58 | Swine (finishing) | Wheat Milled bypds | 0.004 |
| Poultry (all diets) | 0.290 0.460 | 4.24 6.72 | Poultry layer | Wheat Straw Yes | 0.004 |
| Poultry (layer only) | 0.290 0.460 | 4.24 6.72 | Poultry layer | Wheat Straw Yes | 0.004 |

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

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal | Dose (mg/kg bw per day) | Duration (days) | Comment/source |
|-------------------------------|--------|-------------------------|----------------|----------------|
| Laying hen | 18 | 6 | 360 N rate EFSA (2015) |
| Lactating goat | 19 | 5 | 15 N rate/meat ruminants 40 N rate/dairy ruminants EFSA (2015) |
Time needed to reach a plateau concentration in milk and eggs (days)

| Commodity | Value | Unit | Reference |
|-----------|-------|------|-----------|
| Milk      | 3     | days | EFSA (2008) |
| Eggs      | no plateau reached during the study (6 days) but the feeding study indicated that plateau was reached after 10 days | EFSA (2008) |

Metabolism in rat and ruminant similar

| Can a general residue definition be proposed for animals? | Yes |
|----------------------------------------------------------|-----|
| Animal residue definition for monitoring (RD-Mo) | Sum of mepiquat and its salts, expressed as mepiquat chloride |
| Animal residue definition for risk assessment (RD-RA) | Sum of mepiquat, 4-hydroxy-mepiquat and their salts, expressed as mepiquat chloride |

Fat soluble residues

| Can a general residue definition be proposed for animals? | No |
|----------------------------------------------------------|----|

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

| Methods of analysis | HPLC–MS/MS; LOQ: 0.05 mg/kg (as mepiquat chloride). Validated in kidney and liver (EFSA, 2008), and in milk, eggs and meat (EFSA, 2013) |

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/source |
|------------------------------------|--------|-----------|--------|-----------------|------------------|----------------|
|                                    | Cow    | Tissues (muscle, fat, liver, kidney) | –18°C  | 26 Months | Mepiquat chloride | EFSA (2008) |
|                                    | Cow    | Milk      | –18°C  | 26 Months | Mepiquat chloride | EFSA (2008) |
|                                    | Hen    | Muscle    | –18°C  | 26 Months | Mepiquat chloride | EFSA (2008) |
|                                    | Hen    | Egg       | –18°C  | 26 Months | Mepiquat chloride | EFSA (2008) |
|                                    | Cow    | Liver     | –18°C  | 26 Months | 4-hydroxy-mepiquat | EFSA (2008) |
|                                    | Cow    | Milk      | –18°C  | 26 Months | 4-hydroxy-mepiquat | EFSA (2008) |

B.2.2. Magnitude of residues in livestock

No modification of the MRLs is needed.
B.3. Consumer risk assessment

| ARfD | 0.3 mg/kg bw (EFSA, 2008) |
|------|--------------------------|
| Highest IESTI, according to EFSA PRIMo | Cotton seed: < 0.01% of ARfD |
| Assumptions made for the calculations | The calculation is based on the temporary MRL proposal of 8 mg/kg only for the crop under consideration (STMR: 1.9 mg/kg) |

| ADI | 0.2 mg/kg bw per day (EFSA, 2008) |
|------|-------------------------------|
| Highest IEDI, according to EFSA PRIMo | 3.1% of ADI (Danish child) Cotton seed: < 0.01% of ADI (Dutch child) |
| Assumptions made for the calculations | The calculation is based on the median residue levels in the raw agricultural commodities. The contribution of commodities where no GAP was reported in the framework of the MRL review and subsequent Art 10 MRL setting 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 |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 401090  | Cotton seed | 0.05* | No MRL proposal | **Option 1:** Only three trials were considered as independent according to the legal data requirements. Since cotton is a major crop in southern Europe five additional residue trials compliant with the SEU GAP are therefore required to derive a MRL in cotton seed. No MRL proposal is derived |
| 8 (temporary) | | | | **Option 2:** Considering that the emergency authorisation on this crop is granted for a limited period of time (120 days), the proposal for the temporary MRL is based on the three independent GAP-compliant residue trials on cotton seed. A consumer health concern is unlikely with regard to mepiquat chloride residues in cotton seed related to the GAP-compliant supervised field trials |
| 5 (temporary) | | | | **Option 3:** Although only three residue trials can be considered as independent, the proposal for the temporary MRL is based on the submitted eight residue trials considering that the emergency authorisation on this crop is granted for a limited period of time (120 days). A consumer health concern is unlikely |

MRL: maximum residue level; SEU: southern Europe; GAP: good agricultural practice. 
*: 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)

### Mepiquat

**Status of the active substance:** Code no.  
**LOQ (mg/kg bw):** Proposed LOQ  
**ADI (mg/kg bw per day):** 0.2  
**ARfD (mg/kg bw):** 0.3  
**Source of ADI:** EFSA  
**Source of ARfD:** EFSA  
**Year of evaluation:** 2008

#### Chronic risk assessment – refined calculations

| Commodity/group of commodities | MS Diet | TMDI (range) in % of ADI | 3rd contributor to MS diet (in % of ADI) | pTMRLs at LOQ (in % of ADI) |
|--------------------------------|---------|--------------------------|-----------------------------------------|-----------------------------|
| **Highest calculated TMDI values in % of ADI** | **Highest contributor to MS diet** | **2nd contributor to MS diet** | **3rd contributor to MS diet** | **Commodity** | **Group of commodities** |
| 3.1 DK child | 1.7 Wheat | 1.3 Rye | 0.1 Oats | 0.1 Data |
| 2.7 WHO Cluster diet B | 2.6 Wheat | 0.1 barley | 0.0 Fish, Fish Products |
| 2.2 WHO cluster diet D | 2.0 Wheat | 0.1 Rye | 0.1 Barley |
| 2.0 IT child/toddler | 2.0 Wheat | 0.0 Barley | 0.0 Cultivated fungi |
| 1.7 WHO cluster diet E | 1.2 Wheat | 0.3 Barley | 0.1 Rye |
| 1.6 WHO Cluster diet F | 1.1 Wheat | 0.2 Rye | 0.2 Barley |
| 1.6 DE child | 1.2 Wheat | 0.2 Rye | 0.1 Oats |
| 1.5 NL child | 1.4 Wheat | 0.1 Rye | 0.0 Oats |
| 1.4 ES child | 1.3 Wheat | 0.0 Birds' eggs | 0.0 Barley |
| 1.2 IT adult | 1.2 Wheat | 0.0 Barley | 0.0 Cultivated fungi |
| 1.2 IE adult | 0.7 Wheat | 0.4 Barley | 0.1 Oats |
| 1.2 PT General population | 1.2 Wheat | 0.0 Rye | 0.0 Barley |
| 1.2 UK Toddler | 1.2 Wheat | 0.0 Birds' eggs | 0.0 Oats |
| 1.1 SE general population 90th percentile | 1.0 Wheat | 0.1 Rye | 0.0 Birds' eggs |
| 1.1 WHO regional European diet | 0.9 Wheat | 0.1 barley | 0.0 Fish, Fish Products |
| 1.0 FR all population | 1.0 Wheat | 0.0 Birds' eggs | 0.0 Barley |
| 0.9 UK infant | 0.8 Wheat | 0.1 Oats | 0.0 Birds' eggs |
| 0.9 ES adult | 0.7 Wheat | 0.2 Barley | 0.0 Birds' eggs |
| 0.9 DK adult | 0.6 Wheat | 0.2 Oats | 0.0 Birds' eggs |
| 0.8 FR toddler | 0.8 Wheat | 0.0 Birds' eggs | 0.0 FRUIT (FRESH OR FROZEN) |
| 0.8 NL general | 0.6 Wheat | 0.1 Rye | 0.0 Rye |
| 0.7 LT adult | 0.3 Rye | 0.3 Wheat | 0.0 Oats |
| 0.7 UK vegetarian | 0.6 Wheat | 0.0 Oats | 0.0 Birds' eggs |
| 0.5 FI adult | 0.3 Wheat | 0.2 Rye | 0.0 Oats |
| 0.5 UK Adult | 0.5 Wheat | 0.0 Barley | 0.0 Birds' eggs |
| 0.3 FR infant | 0.3 Wheat | 0.0 Birds' eggs | 0.0 FRUIT (FRESH OR FROZEN) |
| 0.0 PL general population | 0.0 Cultivated fungi | 0.0 Birds' eggs | 0.0 FRUIT (FRESH OR FROZEN) |

#### Conclusion:

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

The acute risk assessment is based on the ARID. 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 ARID.

| Commodity          | pTMRL/threshold MRL (mg/kg) | Highest % of ARIDADI | IESTI 1 | ***) | IESTI 2 | **) |
|--------------------|-----------------------------|----------------------|---------|-----|---------|-----|
| **Processed commodities** |
| Wheat flour       | 0.6 / -                     | 2.4                  | 0.6 / - |     |         |     |
| Bread/pizza       | 0.6 / -                     | 0.8                  | 0.8     |     |         |     |

**No of commodities for which ARIDADI is exceeded (IESTI 1):**

**No of commodities for which ARIDADI is exceeded (IESTI 2):**

**Conclusion:**

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

No exceedance of the ARIDADI was identified for any unprocessed commodity.

No exceedance of the ARIDADI was also identified for processed commodities.

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**No exceedance of the ARIDADI was identified for any unprocessed commodity.**

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**pTMRL: provisional temporary MRL.**

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

D.1. Livestock dietary burden calculations

| Feed commodity                        | Median dietary burden | Maximum dietary burden |
|---------------------------------------|-----------------------|------------------------|
|                                       | Input value (mg/kg)   | Comment                | Input value (mg/kg)   | Comment                |
| Cotton undelinted seed                | 1.9 STMR              | 1.9 STMR               |
| Cotton seed meal                      | 3.6 STMR × PF (1.9)   | 3.6 STMR × PF (1.9)    |
| Wheat and rye grain                   | 0.6 STMR (EFSA, 2015) | 0.6 STMR (EFSA, 2015) |
| Barley and oat grain                  | 0.7 STMR (EFSA, 2015) | 0.7 STMR (EFSA, 2015) |
| Wheat and rye straw                   | 28.3 STMR (EFSA, 2015) | 50.1 HR (EFSA, 2015)   |
| Barley and oat straw                  | 2.3 STMR (EFSA, 2015) | 5.9 HR (EFSA, 2015)    |
| Barley brewer’s grain (dried)         | 2.31 STMR × default PF (3.3) | 2.31 STMR × default PF (3.3) |
| Wheat distiller’s grain (dried)       | 1.98 STMR × default PF (3.3) | 1.98 STMR × default PF (3.3) |
| Wheat gluten meal                     | 1.08 STMR × default PF (1.8) | 1.08 STMR × default PF (1.8) |
| Wheat milled by-products              | 2.1 STMR × PF (3.5) (EFSA, 2015) | 2.1 STMR × PF (3.5) (EFSA, 2015) |

**Risk assessment residue definition:** sum of mepiquat and its salts, expressed as mepiquat chloride

| STMR: supervised trials median residue; HR: highest residue; PF: processing factor. |

D.2. Consumer risk assessment

| Commodity                        | Chronic risk assessment | Acute risk assessment |
|----------------------------------|-------------------------|-----------------------|
|                                  | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Cotton seed                      | 1.9 STMR                | 1.9 STMR              |
| Barley and oats grain            | 0.7 STMR (EFSA, 2015)   | Acute risk assessment undertaken only with regard to cotton seed |
| Wheat and rye grain              | 0.6 STMR (EFSA, 2015)   |                       |
| Cultivated fungi                 | 0.013 STMR (EFSA, 2016) |                       |

**Risk assessment residue definition for commodities of plant origin:** sum of mepiquat and their salts, expressed as mepiquat chloride

| Swine meat                       | 0.05* 0.8 × STMR_{muscle} + 0.2 × STMR_{fat} (EFSA, 2015) | Acute risk assessment undertaken only with regard to cotton seed |
| Swine fat                        | 0.05* STMR (EFSA, 2015)                                    |
| Swine liver                      | 0.09 STMR_{muscle} × CF (EFSA, 2015)                        |
| Swine kidney                     | 0.05* STMR (EFSA, 2015)                                    |
| Ruminant meat                    | 0.06 0.8 × STMR_{muscle} + 0.2 × STMR_{fat} (EFSA, 2015)   |
| Ruminant fat                     | 0.05 STMR (EFSA, 2015)                                    |
| Ruminant liver                   | 0.41 STMR_{muscle} × CF (EFSA, 2015)                       |
| Ruminant kidney                  | 0.30 STMR (EFSA, 2015)                                    |
| Poultry meat                     | 0.05* 0.9 × STMR_{muscle} + 0.1 × STMR_{fat} (EFSA, 2015)  |
| Poultry fat                      | 0.05* STMR (EFSA, 2015)                                    |
| Commodity         | Chronic risk assessment | Acute risk assessment |
|-------------------|-------------------------|-----------------------|
|                   | Input value (mg/kg)     | Comment               |
| Poultry liver     | 0.05*                   | STMR (EFSA, 2015)     |
| Ruminant milk     | 0.05*                   | STMR (EFSA, 2015)     |
| Birds’ eggs       | 0.05*                   | STMR (EFSA, 2015)     |

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor for enforcement to risk assessment residue definition.

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

| Code/trivial name        | Chemical name/SMILES notation<sup>(a)</sup>                                                                 | Structural formula<sup>(a)</sup> |
|-------------------------|---------------------------------------------------------------------------------------------------------------|----------------------------------|
| 4-hydroxy mepiquat-chloride | 4-hydroxy-1,1-dimethylpiperidinium chloride <br>\([\text{C}]^+\text{[N]}^+\text{[C]}\text{CCC(O)CC}1\) | ![Structural formula](attachment:formula_1.png) |
| mepiquat                | 1,1-dimethylpiperidinium <br>\([\text{C}]^+\text{[N]}^+\text{[C]}\text{CCCCC}1\)                    | ![Structural formula](attachment:formula_2.png) |
| mepiquat chloride       | 1,1-dimethylpiperidinium chloride <br>\([\text{C}]^+\text{[N]}^+\text{[C]}\text{CCCCC}1\)           | ![Structural formula](attachment:formula_3.png) |

SMILES: simplified molecular-input line-entry system.

<sup>(a)</sup>: (ACD/ChemSketch, Advanced Chemistry Development, Inc., ACD/Labs Release: 12.00 Product version: 12.00 (Build 29305, 25 Nov 2008)).