Modification of the existing maximum residue levels for mepiquat in various oilseeds and animal commodities

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Abstract
In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted a request to the competent national authority in France to modify the existing maximum residue levels (MRLs) for the active substance mepiquat in various oilseeds. The data submitted in support of the request were found to be sufficient to derive MRL proposals for rapeseeds, linseeds, mustard seeds, poppy seeds, gold of pleasure and sunflower seeds. Adequate analytical methods for enforcement are available to control the residues of mepiquat chloride in the plant and animal commodities under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of mepiquat chloride according to the reported agricultural practices is unlikely to present a risk to consumer health.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in France (evaluating Member State (EMS)) to modify the existing maximum residue levels (MRLs) for the active substance mepiquat in various oilseeds. 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 25 January 2018. To accommodate for the intended uses of mepiquat, the EMS proposed to raise the existing MRL for sunflower seeds, mustard seeds, linseeds, poppy seeds, gold of pleasure seeds, from the limit of quantification (LOQ) 0.05 mg/kg to 40 mg/kg, to raise the MRL for turnip rape, oil radish from the LOQ 0.05 mg/kg to 15 mg/kg and to raise the MRL for rapeseeds from 4 mg/kg to 15 mg/kg. Concerning animal commodities, the EMS proposed to raise the existing MRL for ruminant and equine liver from 0.5 mg/kg to 0.6 mg/kg, to raise the MRL for milk from 0.06 mg/kg to 0.15 mg/kg and for eggs from the LOQ 0.05 mg/kg 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 8 June 2018 the EMS submitted a revised evaluation report (France, 2017), which replaced the previously submitted evaluation report.

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

The metabolism of mepiquat was investigated in three different crop groups as well as in rotational crops.

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. EFSA concluded that for the current application the metabolism of mepiquat chloride is sufficiently addressed and the proposed residue definitions are applicable.

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

The available residue trials are sufficient to derive MRL proposals of 15 mg/kg for rapeseed for the intended use in northern EU Member States, 40 mg/kg for linseed, mustard seed, poppy seed, gold of pleasure and sunflower seed for intended uses in northern and southern Europe.

Specific studies investigating the magnitude of mepiquat chloride residues in processed commodities were evaluated in the framework of the MRL review and a subsequent EFSA reasoned opinion; robust processing factors were derived for rape seed and cotton seed (meal).

The occurrence of mepiquat residues in rotational crops was investigated in the framework of the European Union (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, provided that the active substance is used according to the proposed good agricultural practice (GAP).

As the crops under consideration and their by-products are used as feed products, a potential carry-over of residues into food of animal origin was assessed. The nature of mepiquat residues in livestock has been investigated during the EU pesticides peer review and the residue definition for enforcement was proposed as the sum of mepiquat and its salts, expressed as mepiquat chloride; for risk assessment the residue was defined as the sum of mepiquat, 4-hydroxymepiquat and their salts, expressed as mepiquat chloride. The available metabolism study allowed EFSA to derive a conversion factor of 1.7 from monitoring to risk assessment in ruminant liver. The intended uses lead to an increase in the livestock dietary burden for all species which triggers modifications of MRLs for certain animal commodities.

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 for mepiquat chloride.

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 7.5% of the ADI (WHO Cluster diet B). The contribution of mepiquat chloride residues in sunflower seeds and rapeseeds to the total consumer exposure were estimated to account for 4.6% and 1.1% of the ADI, respectively, while for the rest of the plant and animal commodities under consideration the contribution to the total exposure is below 1% of the ADI (WHO Cluster diet B).

No acute consumer risk was identified in relation to the MRLs proposed in the current assessment.

EFSA concluded that the proposed use of mepiquat chloride on rapeseeds, sunflower seeds, linseeds, mustard seeds, poppy seeds and gold of pleasure will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health.

EFSA proposes to amend the existing MRLs as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code (a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|----------|-----------|------------------------|-------------------------|-----------------------|
| 401060   | Rapeseeds (including turnip rape seeds and radish seeds) | 4 | 15 | The submitted data are sufficient to derive a MRL proposal for the intended NEU use. Risk for consumers unlikely. The MRL also applies to turnip rape and oil radish according to Annex I. of Reg. (EC) 396/2005. The footnote found in Reg. (EU) 2016/1015 can be deleted. Insufficient residue trials for SEU use. |
| 401010   | Linseeds   | 0.05* | 40 | The submitted data on sunflower seed are sufficient to derive a MRL proposal for minor oilseeds by extrapolation (NEU and SEU use). Risk for consumers unlikely. |
| 0401030  | Poppy seeds | 0.05* | 40 | The submitted data on sunflower seed are sufficient to derive a MRL proposal for minor oilseeds by extrapolation (NEU and SEU use). Risk for consumers unlikely. |
| 401080   | Mustard seeds | 0.05* | 40 | The submitted data on sunflower seed are sufficient to derive a MRL proposal for sunflower seed (NEU and SEU use). Risk for consumers unlikely. |
| 0401130  | Gold of pleasure | 0.05* | 40 | The submitted data on sunflower seed are sufficient to derive a MRL proposal for sunflower seed (NEU and SEU use). Risk for consumers unlikely. |
| 401050   | Sunflower seeds | 0.05* | 40 | MRL proposal based on livestock intake when considering the contribution of the new intended uses. Risk for consumers unlikely. |
| 1011030, 1011040 | Swine liver and kidney | 0.05* | 0.07 | MRL proposal based on livestock intake when considering the contribution of the new intended uses. Risk for consumers unlikely. |
| 1012010, 1015010 | Bovine and equine muscle | 0.09 | 0.06 | Based on the dietary burden calculation the existing MRL could be lowered. |
| 1012020, 1015020 | Bovine and equine fat | 0.06 | 0.05 | |
| 1012030, 1015030 | Bovine and equine liver | 0.5 | 0.3 | |
| 1012040, 1015040 | Bovine and equine kidney | 0.8 | 0.4 | |
| 1013040, 1014040 | Sheep and goat kidney | 0.8 | 0.7 | |
| 1013030, 1014030 | Sheep and goat liver | 0.5 | 0.6 | |
| 1020010, 1020040 | Bovine and equine milk | 0.06 | 0.07 | |
| 1020020, 1020030 | Sheep and goat milk | 0.06 | 0.15 | |
| 1030000 | Birds’ eggs | 0.05* | 0.07 | |

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

Abstract ................................................................................................................................................... 1  
Summary .................................................................................................................................................. 3  
Assessment ............................................................................................................................................. 6  
1. Residues in plants ........................................................................................................................ 7  
   1.1. Nature of residues and methods of analysis in plants .......................................................... 7  
   1.1.1. Nature of residues in primary crops ................................................................................. 7  
   1.1.2. Nature of residues in rotational crops .............................................................................. 7  
   1.1.3. Nature of residues in processed commodities ................................................................. 7  
   1.1.4. Methods of analysis in plants ............................................................................................ 7  
   1.1.5. Stability of residues in plants ............................................................................................ 7  
   1.1.6. Proposed residue definitions ............................................................................................... 7  
   1.2. Magnitude of residues in plants .............................................................................................. 8  
   1.2.1. Magnitude of residues in primary crops .......................................................................... 8  
   1.2.2. Magnitude of residues in rotational crops ....................................................................... 8  
   1.2.3. Magnitude of residues in processed commodities .......................................................... 9  
   1.2.4. Proposed MRLs ................................................................................................................ 9  
2. Residues in livestock ......................................................................................................................... 9  
   2.1. Nature of residues and methods of analysis in livestock .................................................... 9  
   2.2. Magnitude of residues in livestock ...................................................................................... 9  
3. Consumer risk assessment ............................................................................................................. 10  
4. Conclusion and Recommendations ............................................................................................... 10  
References ............................................................................................................................................... 10  
Abbreviations ........................................................................................................................................... 11  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs ............ 13  
Appendix B – List of end points ........................................................................................................... 16  
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................. 24  
Appendix D – Input values for the exposure calculations ............................................................... 26  
Appendix E – Used compound codes .............................................................................................. 28
Assessment

The detailed description of the intended uses of mepiquat which are the basis for the current maximum residue level (MRL) application is reported in Appendix A.

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

Mepiquat was evaluated in the framework of Directive 91/414/EEC\(^1\) with the United Kingdom designated as rapporteur Member State (RMS); as representative uses the use plant growth regulator in cereals for stem stabilisation was assessed. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2008). Mepiquat was approved\(^2\) for the use as plant growth regulator on 1 March 2009. The process of renewal of the first approval is currently ongoing.

The European Union (EU) MRLs for mepiquat are established in Annex II of Regulation (EC) No 396/2005\(^3\) for the residue definition which comprises the sum of mepiquat and its salts, expressed as mepiquat chloride. 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 the MRL legislation. After completion of the MRL review, EFSA has issued two reasoned opinion on the modification of MRLs for mepiquat. The proposals from these reasoned opinions have been considered in recent regulations\(^4\) on EU MRLs.

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in France (evaluating Member State (EMS)) to modify the existing MRLs for the active substance mepiquat in various oilseeds and animal commodities. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 25 January 2018. To accommodate for the intended uses of mepiquat chloride, the EMS proposed to raise the existing MRL for sunflower seeds from the limit of quantification (LOQ) 0.05 mg/kg to 50 mg/kg, to raise the MRL for mustard seeds, linseeds, poppy seeds, gold of pleasure seeds, turnip rape seeds, radish seeds from the LOQ 0.05 mg/kg to 15 mg/kg and to raise the MRL for rapeseeds from 4 mg/kg to 15 mg/kg. Concerning animal commodities, the EMS proposed to raise the existing MRL for ruminant and equine liver from 0.5 mg/kg to 0.6 mg/kg, to raise the MRL for milk from 0.06 mg/kg to 0.15 mg/kg and for eggs from the LOQ 0.05 mg/kg to 0.07 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (France, 2017), the draft assessment report (DAR) (and its 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 opinions on the review of the existing MRLs for mepiquat according to Article 12 of Regulation (EC) No 396/2005 and recent MRL assessments (EFSA, 2013, 2015, 2016, 2018).

For this application, the data requirements established in Regulation (EU) No 544/2011\(^5\) and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011\(^6\).

A selected list of end points of the studies assessed by EFSA in the framework of the this MRL application, including the end points of relevant studies assessed previously are 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. Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16. 3.2005, p. 1–16.
4. For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5. 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.
6. 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.
The evaluation report submitted by the EMS (France, 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.

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 residues in primary crops resulting from the use of mepiquat chloride 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 rapeseed was provided (EFSA, 2015). 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

The crops under consideration 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. A confined rotational crop study using wheat, radish and lettuce planted in soil treated with mepiquat chloride was assessed during the peer review (EFSA, 2008). The metabolism in the rotational crops was found to be more extensive than in primary crops. However, as relevant residue levels of metabolites are unlikely to occur in rotational crops, a specific residue definition for rotational crops was not deemed necessary (EFSA, 2015). The good agricultural practices (GAPs) assessed in the MRL review were more critical than the new intended uses, therefore this conclusion is still considered valid in the framework of the current application.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of mepiquat residues was also investigated in the framework of the peer review and it was demonstrated that mepiquat remained is 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 content and dry matrices at a LOQ of 0.05 mg/kg (LOQ expressed as mepiquat chloride) (EFSA, 2008). An analytical method using radiolabelled internal standard was provided with the current dossier. The method is sufficiently validated for the determination of mepiquat residues in high water-, high acid-, high oil content and dry commodities; the method allow quantification of residues at the LOQ of 0.01 mg/kg (expressed as mepiquat chloride) (France, 2017).

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 at −15°C in high oil (cotton seed) content commodities (EFSA, 2018).

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). This residue definition is also applicable to rotational crops and processed commodities.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

The GAPs for rapeseed, sunflower seed and minor oilseeds assessed in the reasoned opinion are reported in Appendix A.

The applicant submitted a total of 24 residue trials on rapeseed and 16 residue trials on sunflower seed conducted in northern and southern Europe in the growing seasons of 2014–2015. The samples were analysed in accordance with the residue definitions for enforcement and risk assessment. The analytical 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 have been demonstrated.

Rapeseeds, turnip rape seeds and radish seeds

In support of the intended use on rapeseed the applicant submitted 12 northern Europe (NEU) and 12 southern Europe (SEU) residue field trials performed in rapeseed. Four of the NEU and Four of the SEU trials were considered as replicates where two different formulations types (suspoemulsion (SE) and suspension concentrate (SC)) were tested on different plots on the same site. From the replicates, the highest residue values were selected to calculate the MRL proposal. In three SEU trials, oilseed rape received two spring treatments (intervals of 21–44 days) which is not in line with the intended use pattern. Thus, these three SEU trials were excluded from the assessment. Consequently, eight trials conducted in NEU and five trials conducted in SEU could be considered further in the assessment. As rapeseed is a major crop in both SEU and NEU, at least eight GAP-compliant residue trials are required for each zone to derive a MRL proposal. Therefore, the residue data allow to derive a MRL proposal of 15 mg/kg for rapeseed accommodating for the NEU use only.

Radish seeds (oil radish) and turnip rape are classified under oilseed rape (Part B of Regulation (EC) No 396/2005); considering that the GAP for these minor oilseeds is comparable with rapeseed, the residue trials in rapeseed are representative for these two minor crops. It is therefore proposed that for these crops the MRL proposal derived of rape seeds should be applied.

Sunflower seeds

In support of the intended use on sunflowers, the applicant submitted eight NEU and eight SEU residue field trials according to the GAP proposed for sunflowers (2 × 0.3 kg a.s./ha, 21 days interval between applications). One of the residue trials conducted in NEU has been excluded by the EMS due to the first application being too early (BBCH 16 instead of BBCH 31-59). EFSA is of the opinion that since the residue level observed in this trial is in the same range compared to residues measured in the GAP-compliant trials, the trial could be accepted. Based on these trials, a MRL proposal of 40 mg/kg was calculated.

In addition, four SEU and four NEU trials where the crop was treated only once (application rate of 1 × 0.3 kg a.s./ha) were submitted (see below).

Mustard seeds, linseeds, poppy seeds and gold of pleasure seeds

The intended GAP for the minor oilseeds foresees one application at 0.3 kg a.s./ha. The residue trials in sunflower seeds with one treatment are acceptable and compliant with the intended GAP on minor oilseeds under consideration. The statistical test (Mann-Whitney) shows that there is no significant difference between the magnitudes of residues found in NEU and SEU trials, therefore this data can be pooled to support a more robust MRL proposal. The residue data on sunflower seed allow to derive a MRL proposal of 40 mg/kg for linseed, mustard seed, poppy seed and gold of pleasure for the NEU and SEU use.

1.2.2. Magnitude of residues in rotational crops

Based on the available information on the magnitude of the residues, EFSA concluded that relevant residue levels are unlikely to occur in rotational crops provided that the compound is used according to proposed GAPs (see also Section 1.1.2).

7 Residue trials L130786, L140734, L140722.
1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of residues in processed commodities of rapeseed and cotton seeds were assessed in the framework of the peer review (EFSA, 2008) and during previous MRL assessments (EFSA, 2015, 2018), where more details can be found.

1.2.4. Proposed MRLs

The available data are considered sufficient to derive the following MRL proposals:

- 15 mg/kg for rapeseeds in NEU;
- 40 mg/kg for linseeds, mustard seeds, poppy seeds and gold of pleasure in NEU and SEU;
- 40 mg/kg for sunflower seeds NEU and SEU.

2. Residues in livestock

Rapeseeds, linseeds and sunflower seeds and their by-products can be used as livestock feed, and therefore a potential carry-over of residues resulting from the use of mepiquat chloride into food of animal origin has to be assessed.

It is noted that in the framework of the MRL review (EFSA, 2015) the livestock dietary burden calculation was performed according to a different calculation methodology. In this reasoned opinion, the livestock dietary burden was re-calculated using the OECD methodology (OECD, 2013), taking into account the intended uses in oilseeds and other crops used for feed purpose that may contain mepiquat residues. The calculated dietary burdens exceeded the trigger value of 0.1 mg/kg DM for all livestock species.

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 were considered as sufficiently validated (EFSA, 2015). Furthermore, additional methods of analysis have been provided with this dossier and are considered as sufficiently validated (France, 2017). Storage stability of mepiquat was demonstrated for a period of 26 months at –18°C in all commodities of animal origin (EFSA, 2008).

2.2. Magnitude of residues in livestock

Feeding studies investigating the magnitude of mepiquat chloride residues in lactating goats and laying hens reported in the framework of the peer review (EFSA, 2008) were used to derive MRL proposals and risk assessment values for animal commodities. According to the results of these studies, at the expected calculated dietary burden, the following existing MRLs for animal products have to be raised:

- 0.05* to 0.07 mg/kg for swine liver, swine kidney,
- 0.5 to 0.6 mg/kg for sheep and goat liver,
- 0.06 to 0.07 mg/kg for bovine and equine milk,
- 0.06 to 0.15 mg/kg for sheep and goat milk
- 0.05* to 0.07 mg/kg for birds’ eggs.

Based on the revised calculation, the lowering of the following existing MRLs would be appropriate:

- 0.09 to 0.06 mg/kg for bovine and equine muscle,
- 0.06 to 0.05 mg/kg for bovine and equine fat,
- 0.5 to 0.3 mg/kg for bovine and equine liver
- 0.8 to 0.4 mg/kg for bovine and equine kidney
- 0.8 to 0.7 mg/kg for sheep and goat kidney.
3. Consumer risk assessment

The toxicological profile of mepiquat chloride was assessed in the framework of the 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. EFSA performed a dietary risk assessment using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different subgroups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (FAO, 2016).

The long-term exposure was performed taking into account the STMR values derived for the crops assessed in this application. For the remaining commodities, the STMR values from previous EFSA assessments were used as input values. The estimated long-term dietary intake of mepiquat chloride was in the range of 0–7.5% of the ADI (WHO clustered diet B). The highest contribution to the total consumer exposure of mepiquat chloride residues were 4.6% of the ADI for sunflower seed, 1.1% of the ADI for rapeseed and < 1% of the ADI for minor oilseeds and animal commodities.

The acute exposure assessment was performed only with regard to the commodities under consideration assuming the consumption of a large portion of the food items as reported in the national food surveys and that these items contained residues at the highest level as observed in supervised field trials (EFSA, 2007). However as oilseeds are usually bulked, for these commodities the STMR values were used for the acute risk assessment. The calculated maximum exposure in percentage of the ARfD accounted for 12.8% for sunflower seed, 4.1% for linseed, 3.8% for poppy seed, 2.8% for milk, 1.4% for rapeseed, < 1% for bovine liver and < 1% for eggs.

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

4. Conclusion and Recommendations

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal for rapeseeds, linseeds, mustard seeds, poppy seeds, gold of pleasure and sunflower seeds. The livestock dietary burdens were reassessed according to the latest OECD methodology. The assessment outcome is driven by the existing uses while the new uses of mepiquat chloride on oilseeds do not have a significant impact on the estimated maximum livestock exposure. The new MRLs proposed for products of animal origin are mainly resulting from the assessment with the new methodology. This is highlighted for risk manager consideration.

The peer review of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, and therefore, the conclusions reported in this reasoned opinion should be taken as provisional and might need to be reconsidered in the light of the outcome of the peer review.

EFSA concluded that the proposed use of mepiquat on rapeseed, linseed, mustard seed, poppy seed, gold of pleasure and sunflower 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.4.

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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
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice

www.efsa.europa.eu/efsajournal 11 EFSA Journal 2018;16(7):5380
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
LC liquid chromatography
LOQ limit of quantification
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 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
SE suspo-emulsion
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median 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 | Pests or Group of pests controlled | Preparation | Application | PHI (days)\(^{(d)}\) | Remarks |
|-----------------------|--------------------------|------------------------------------|-------------|-------------|----------------------|---------|
| **Oilseed rape (rapeseed), winter** | NEU, SEU (AT, BE, CZ, DE, HU, NL, PL, RO, SK, SL, UK, FR, BG, HR) | Plant growth regulator | SC, 300 g/L | BBCH 13–20 | 1 | – | Autumn application Can be applied in tank mix with ammonium sulfate at 1.0 kg/ha |
| **Oilseed rape (rapeseed), winter** | NEU, SEU (AT, BE, CZ, DE, HU, NL, PL, RO, SK, SL, UK, FR, BG, HR) | Plant growth regulator | SC, 300 g/L | BBCH 13–20 | 2 | 14 | 100–400 | 150 g as/ha | – | Autumn – split application of 2 × 0.5 L/ha Can be applied in tank mix with ammonium sulfate at 0.5 kg/ha |
| **Oilseed rape (rapeseed), winter and summer** | NEU, SEU (AT, BE, CZ, DE, HU, NL, PL, RO, SK, SL, UK, FR, BG, HR) | Plant growth regulator | SC, 300 g/L | BBCH 21–59 | 1 | – | 100–400 | 300 g as/ha | – | Spring application Can be applied in tank mix with ammonium sulfate at 1.0 kg/ha |
| Crop and/or situation | NEU, SEU, MS or country | FG or I(a) | Pests or Group of pests controlled | Preparation | Type(b) | Conc. a.s. | Method kind | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Application rate per treatment | PHI (days)(d) | Remarks |
|----------------------|-------------------------|------------|-----------------------------------|-------------|---------|-----------|-------------|-------------|--------------------------------|----------------|-----------------------------|-------------------------------|--------------|---------|
| Oilseed rape (rapeseed), winter and summer | NEU, SEU (FR, BG, HR) | F | Plant growth regulator | SC | 300 g/L | SP | BBCH 21–59 | 2 | 14 | 100–400 | 150 | g a.s./ha | – | Spring – split application of 2 × 0.5 L/ha Can be applied in tank mix with ammonium sulfate at 0.5 kg/ha |
| Oilseed rape (rapeseed), winter | NEU, SEU (AT, BE, CZ, DE, HU, NL, PL, RO, SK, SL, UK, FR, BG, HR) | F | Plant growth regulator | SC | 300 g/L | SP | BBCH 13–20 + BBCH 21–59 | 2 | Interval defined by vegetation break over winter | 100–400 | 300 | g a.s./ha | – | Autumn and spring application Can be applied in tank mix with ammonium sulfate at 1.0 kg/ha |
| Sunflower | NEU, SEU (BG, CZ, HR, HU, RO, SK, SL) | F | Plant growth regulator | SE | 150 g/L | SP | BBCH 31–59 | 2 | 21 | 100–400 | 300 | g a.s./ha | – | Product can be applied in tank-mix ammonium sulphate at 0.75 kg/ha or a local water conditioner of comparable activity |
| Crop and/or situation | NEU, SEU, MS or country |
|-----------------------|-------------------------|
| Turnip rape seeds, mustard seeds, linseeds, poppy seeds, gold of pleasure seeds, radish seeds | NEU, SEU (AT, BE, CZ, DE, HU, NL, PL, RO, SK, SL, UK, FR, BG, HR) |

**Preparation**
- Type (b): SC
- Concentration (a.s.): 300 g/L
- Method kind: SP
- Range of growth stages & season (c): BBCH 21–59
- Number min–max: 1
- Interval between application (min): –
- Application rate per treatment (g a.s./hL min–max): 100–400
- Water L/ha min–max: 150–300
- Rate Unit: g as/ha

**Remarks**
- Minor uses, covered by the residue package of oilseed rape and sunflower. Can be applied in tank-mix with ammonium sulfate at 1.0 kg/ha (or a local water conditioner of comparable activity). Dose rate range from 0.6–1.0 l/ha

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**NEU**: northern European Union; **SEU**: southern European Union; **MS**: Member State; **a.s.**: active substance; **SC**: suspension concentrate.

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

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

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

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

#### B.1. Residues in plants

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

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

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

| Rotational crops (available studies) | 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 (hydrolysis study) | 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)    |
Can a general residue definition be proposed for primary crops?

Rotational crop and primary crop metabolism similar?

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

Plant residue definition for monitoring (RD-Mo)

Plant residue definition for risk assessment (RD-RA)

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

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Compounds covered | Comment/ Source |
|-----------------------------------|----------|-----------|--------|------------------------|-------------------|-----------------|
| High water content                | Wheat forage | –20 | 24 Months | Parent | EFSA (2008) |
| High water content                | Cotton forage | –15 | 25 Months | Parent | EFSA (2018) |
| High oil content                  | Cotton seed, cotton seed (delinted) | –15 | 25 Months | Parent | EFSA (2018) |
| Dry/High starch                   | Wheat grain | –20 | 24 Months | Parent | EFSA (2008) |

DAT: days after treatment; a.s.: active substance; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

The metabolic pattern depicted in rotational crops was found to be more extensive than in primary crops. However, as no relevant residues are expected in the succeeding crops, a specific residue definition is not necessary for rotational crops (EFSA, 2015).

Sum of mepiquat and its salts, expressed as mepiquat chloride

Sum of mepiquat and its salts, expressed as mepiquat chloride

Matrices with high water content, high oil content, high acid content and dry matrices: LC–MS/MS, LOQ 0.01 mg/kg (expressed as mepiquat-chloride). Confirmatory method available. ILV available (France, 2017)
### B.1.2. Magnitude of residues in plants

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

| Commodity | Region/Indoor<sup>(a)</sup> | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL<sup>(c)</sup> (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------|-----------------------------|---------------------------------------------------------------|-----------------|-----------------------------------|-----------------|-----------------|
| Rapeseeds (incl. turnip rape seeds and radish seeds) | NEU | 0.93, 2 × 3, 3.1, 4.2, 6.6, 5.1, 7.7 | Residue trials on rapeseed compliant with GAP | 15 | 7.7 | 3.65 |
| | SEU | 1.6; 2.4; 4.8; 5.2; 5.5 | Residue trials on rapeseed compliant with GAP. Number of trials not sufficient to derive an MRL proposal for rapeseeds (major crop) | – | – | – |
| Sunflower seeds | NEU | 4; 8.3; 9.2; 10<sup>(d)</sup>; 2 × 12; 15; 18 | NEU residue trials on sunflower compliant with GAP | 40 | 28 | 12.5 |
| | SEU | 5.7; 10; 13; 2 × 14; 18; 19; 28 | SEU residue trials on sunflower compliant with GAP | – | – | – |
| Linseeds, mustard seeds, poppy seeds and gold of pleasure seeds | NEU | 6.6; 2 × 11; 12 | Trials on sunflower seed performed with one application. Extrapolation from sunflower seed to minor oilseeds is considered acceptable | 40 | 24 | 11.5 |
| | SEU | 5; 12; 18; 24 | – | – | – |

MRL: maximum residue level; GAP: good agricultural practice.

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

<sup>(a)</sup>: 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.

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

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

<sup>(d)</sup>: Application conducted at BBCH 16 instead of BBCH 31-59 indicated in GAP. EFSA is of the opinion that since the residue level observed in this trial is in the same range compared to residues measured in the GAP-compliant trials, the trial could be accepted.
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

Processing studies submitted with the current application were evaluated during a previous EFSA assessment (EFSA, 2015, 2018).

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing factor (PF) | \(\text{CF}_{\text{P}}\)\(^{(b)}\) | Comment/Source |
|---------------------|---------------------------------|------------------------|-----------------|----------------|
| Sunflower meal      | 2                               | 1.1; 1.4               | 1.2             | 1.0            | EFSA (2018)     |
| Rape seed meal      | 4                               | 0.98; 1.39; 1.72; 2.24 | 1.6             | 1.0            | EFSA (2015)     |

\(^{(a)}\): 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

Dietary burden expressed in mg/kg bw per day mg/kg DM Median Maximum Median Maximum Dietary burden expressed in mg/kg bw per day mg/kg DM Median Maximum Median Maximum

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Dietary burden expressed in mg/kg DM Most critical subgroup\(^{(a)}\) | Most critical commodity\(^{(b)}\) | Trigger exceeded (Y/N) Max burden |
|-----------------------------|---------------------------------------------|-------------------------------------------------|---------------------------------|----------------------------------|
| Cattle (all)                | 0.381                                       | 12.09                                           | Dairy cattle                    | Rye straw                        | Yes                             |
| Cattle (dairy only)         | 0.381                                       | 9.90                                            | Dairy cattle                    | Rye straw                        | Yes                             |
| Sheep (all)                 | 0.780                                       | 18.36                                           | Lamb                            | Rye straw                        | Yes                             |
| Sheep (ewe only)            | 0.612                                       | 18.36                                           | Ram/Ewe                        | Rye straw                        | Yes                             |
| Swine (all)                 | 0.145                                       | 4.85                                            | Swine (finishing)               | flaxseed/linseed meal            | Yes                             |
| Poultry (all)               | 0.442                                       | 6.46                                            | Poultry layer                   | Wheat straw                      | Yes                             |
| Poultry (layer only)        | 0.442                                       | 6.46                                            | Poultry layer                   | Wheat straw                      | Yes                             |

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                       | EFSA (2008)     |
| Lactating goat               | 19         | 5                       | EFSA (2008)     |

Time needed to reach a plateau concentration in milk and eggs (days)

- Milk: after 3 days EFSA (2008)
- Eggs: no plateau was reached during the study (6 days), but feeding study indicated that a plateau was reached after 10 days EFSA (2008)

Metabolism in rat and ruminant similar

- Yes EFSA (2008)

Can a general residue definition be proposed for animals?

- Yes EFSA (2008)

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-hydroxymepiquat and their salts, expressed as mepiquat chloride

Fat soluble residues

- No EFSA (2008)

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

- HPLC-MS/MS: high-performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
  - HPLC–MS/MS, LOQ 0.01 mg/kg (expressed as mepiquat-chloride), validated in milk, meat, liver, egg and fat. Confirmatory method available. ILV available (France, 2017)

B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity             | T (°C) | Stability period Value | Compounds covered | Comment/Source |
|-------------------------------------|--------|-----------------------|--------|------------------------|-------------------|----------------|
| Cow                                 | Milk   | Tissues (muscle, fat, liver, kidney) | −18°C | 26 Months              | Mepiquat chloride | EFSA (2008)    |
| Cow                                 | Milk   | Milk                  | −18°C | 26 Months              | Mepiquat chloride | EFSA (2008)    |
| Hen                                 | Muscle | Muscle                | −18°C | 26 Months              | Mepiquat chloride | EFSA (2008)    |
| Hen                                 | Egg    | Egg                   | −18°C | 26 Months              | Mepiquat chloride | EFSA (2008)    |
| Cow                                 | Liver  | Liver                 | −18°C | 26 Months              | 4-hydroxy-mepiquat| EFSA (2008)    |
| Cow                                 | Milk   | Milk                  | −18°C | 26 Months              | 4-hydroxy-mepiquat| EFSA (2008)    |
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|------------------|---------------------------------------------|-----------------------|---------------------|------------------|
|                   | Mean  | Highest  | STMR (mg/kg) | HR (mg/kg) |                 |
| **Cattle (all)**  |       |          |              |            |                 |
| Closest feeding level 0.42 mg/kg bw; 0.7 N rate dairy cattle<sup>(a)</sup> |       |          |              |            |                 |
| Muscle            | 0.05  | 0.05     | 0.05         | 0.06       | **0.06**         | 1.0 |
| Fat               | 0.05  | 0.05     | 0.05         | 0.05       | **0.05**         | 1.0 |
| Liver             | 0.14  | 0.19     | 0.20         | 0.29       | **0.3**          | 1.7 |
| Kidney            | 0.15  | 0.20     | 0.22         | 0.40       | **0.4**          | 1.0 |
| **Cattle (dairy only)** |       |          |              |            |                 |
| Closest feeding level 0.42 mg/kg bw; 0.7 N rate dairy cattle<sup>(a)</sup> |       |          |              |            |                 |
| Milk<sup>(b)</sup> | 0.05  | 0.05     | 0.05         | 0.07       | **0.07**         | 1.0 |
| **Sheep (all)**   |       |          |              |            |                 |
| Closest feeding level 0.42 mg/kg bw; 0.3 N rate lamb<sup>(a)</sup> |       |          |              |            |                 |
| Muscle            | 0.05  | 0.05     | 0.06         | 0.08       | 0.09            | 1.0 |
| Fat               | 0.05  | 0.05     | 0.05         | 0.06       | **0.06**         | 1.0 |
| Liver             | 0.14  | 0.19     | 0.28         | 0.55       | **0.6**          | 1.7 |
| Kidney            | 0.15  | 0.20     | 0.36         | 0.65       | 0.7             | 1.0 |
| **Sheep (ewe only)** |       |          |              |            |                 |
| Closest feeding level 0.42 mg/kg bw; 0.4 N rate ewe<sup>(a)</sup> |       |          |              |            |                 |
| Milk<sup>(b)</sup> | 0.05  | 0.05     | 0.07         | 0.11       | **0.15**         | 1.0 |
| **Swine (all)**   |       |          |              |            |                 |
| Closest feeding level 0.42 mg/kg bw; 2.9 N rate finishing<sup>(a)</sup> |       |          |              |            |                 |
| Muscle            | 0.05  | 0.05     | 0.05         | 0.05       | **0.05**         | 1.0 |
| Fat               | 0.05  | 0.05     | 0.05         | 0.05       | **0.05**         | 1.0 |
| Liver             | 0.14  | 0.19     | 0.05         | 0.07       | **0.07**         | 1.7 |
| kidney            | 0.15  | 0.20     | 0.05         | 0.07       | **0.07**         | 1.0 |
| **Poultry (all)** |       |          |              |            |                 |
| Closest feeding level 0.44 mg/kg bw; 0.7 N rate layer<sup>(a)</sup> |       |          |              |            |                 |
| Muscle            | 0.05  | 0.05     | 0.05         | 0.05       | **0.05**         | 1.0 |
| Fat               | 0.05  | 0.05     | 0.05         | 0.05       | **0.05**         | 1.0 |
| Liver             | 0.05  | 0.05     | 0.05         | 0.05       | **0.05**         | 1.0 |
| **Poultry (layer only)** |       |          |              |            |                 |
| Closest feeding level 0.44 mg/kg bw; 0.7 N rate layer<sup>(a)</sup> |       |          |              |            |                 |
| Eggs              | 0.05  | 0.05     | 0.05         | 0.07       | **0.07**         | 1.0 |

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; bw: body weight; n.a. not applicable.

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

<sup>(a)</sup>: Closest feeding level and N dose rate related to the maximum dietary burden.

<sup>(b)</sup>: Highest residue level from day 1 to day 28 (daily mean of 3 cows).

<sup>(c)</sup>: Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
### B.3. Consumer risk assessment

**ARfD**

| Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|-------------------------|-------------------------|-----------------------|
| Sunflower seed | 0.3 mg/kg bw (EFSA, 2008) | 0.3 mg/kg bw (EFSA, 2008) | Sunflower seed: 12.8% of ARfD Linseed: 4.1% of ARfD Poppy seed: 3.8% of ARfD Milk: 2.9% of ARfD Rapeseed: 1.4% of ARfD Bovine liver: 1.3% of ARfD Other commodities: < 1% of ARfD |

**ADI**

| Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|------------|-------------------------|-------------------------|-----------------------|
| Sunflower seed | 0.2 mg/kg bw per day (EFSA, 2008) | 0.2 mg/kg bw per day (EFSA, 2008) | 7.5% ADI (WHO Cluster diet B) Contribution of crops assessed: Sunflower seed: 4.6% of ADI Rapeseed: 1.1% of ADI Minor oilseeds: < 1% of ADI Sheep and bovine liver: < 1% of ADI Milk: < 1% of ADI Eggs: < 1% of ADI |

**Assumptions made for the calculations**

Oilseeds are expected to be bulked, therefore the calculation is based on the supervised trial median residues (STMR) found in the crop commodities. For the animal commodities, the highest residues (HR) values multiplied by the relevant conversion factor were used.

### B.4. Recommended MRLs

| Code(s) | Commodity     | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|---------------|-------------------------|-------------------------|-----------------------|
| 401060  | Rapeseeds     | 4                       | 15                      | The submitted data are sufficient to derive a MRL proposal for the NEU use. Risk for consumers unlikely. The same MRL applies to turnip rape seeds (code 0401060-002) and radish seeds (code 0401060-001) according to Annex I of Reg. (EC) 396/2005. Insufficient residue trials for SEU use |
| 401010  | Linseeds      | 0.05*                   | 40                      | The submitted data on sunflower seed are sufficient to derive a MRL proposal for the NEU and SEU use on linseeds. Risk for consumers unlikely. |
| 040130  | Poppy seeds   | 0.05*                   | 40                      | The submitted data on sunflower seed are sufficient to derive a MRL proposal for sunflower seed (NEU and SEU use). Risk for consumers unlikely |
| 401080  | Mustard seeds | 0.05*                   | 40                      | The submitted data on sunflower seed are sufficient to derive a MRL proposal for sunflower seed (NEU and SEU use). Risk for consumers unlikely |
| 0401130 | Gold of pleasure | 0.05*               | 40                      | The submitted data on sunflower seed are sufficient to derive a MRL proposal for sunflower seed (NEU and SEU use). Risk for consumers unlikely |
| 401050  | Sunflower seeds | 0.05*                  | 40                      | The submitted data on sunflower seed are sufficient to derive a MRL proposal for sunflower seed (NEU and SEU use). Risk for consumers unlikely |

**Enforcement residue definition:** sum of mepiquat and its salts, expressed as mepiquat chloride
| Code<sup>(a)</sup> | Commodity          | ExistingEU MRL (mg/kg) | ProposedEU MRL (mg/kg) | Comment/justification                                                                 |
|-------------------|--------------------|------------------------|------------------------|---------------------------------------------------------------------------------------|
| 1011030           | Swine liver        | 0.05*                  | 0.07                   | MRL proposal based on livestock intake when considering the contribution of the new intended uses. Risk for consumers unlikely. |
| 1011040           | Swine kidney       | 0.05*                  | 0.07                   | Risk for consumers unlikely                                                             |
| 1012010, 1015010  | Bovine and equine muscle | 0.09                  | 0.06                   | The existing MRL could be lowered based on the dietary burden calculation                |
| 1012020, 1015020  | Bovine and equine fat | 0.06                  | 0.05                   | Risk for consumers unlikely                                                             |
| 1012030, 1015030  | Bovine and equine liver | 0.5                   | 0.3                    | Risk for consumers unlikely                                                             |
| 1012040, 1015040  | Bovine and equine kidney | 0.8                   | 0.4                    | Risk for consumers unlikely                                                             |
| 1013030, 1014030  | Sheep and goat liver | 0.5                   | 0.6                    | MRL proposal based on livestock intake when considering the contribution of the new intended uses. Risk for consumers unlikely. Risk manager consideration required. |
| 1013040, 1014040  | Sheep and goat kidney | 0.8                   | 0.7                    | The existing MRL could be lowered based on the dietary burden calculation                |
| 1020010, 1020040  | Cattle and equine milk | 0.06                  | 0.07                   | MRL proposal based on livestock intake when considering the contribution of the new intended uses. Risk for consumers unlikely. |
| 1020020, 1020030  | Sheep and goat milk | 0.06                  | 0.15                   | Risk for consumers unlikely                                                             |
| 1030000           | Birds’ eggs        | 0.05*                  | 0.07                   | Risk for consumers unlikely                                                             |

MRL: maximum residue level; NEU: northern Europe; 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)

## Mepiquat

### Toxicological end points

| LOQ (mg/kg bw) | Proposed LOQ |
|----------------|--------------|
| 0.05           |              |

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) |
|------------------------|-----------------|
| 0.2                    | 0.3             |

| Source of ADI | EFSA | Year of evaluation | 2008 |
|---------------|------|--------------------|------|
| Source of ARfD| EFSA |                     |      |

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity, the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

### Chronic risk assessment – refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI (minimum – maximum) |
|-------------------------------|---------------------------------------------|
| Sunflower seed                | 7.5 – 2.6                                  |
| Wheat                         | 2.5 – 1.0                                  |
| Sunflower seed                | 2.0 – 1.0                                  |
| Wheat                         | 1.2 – 1.0                                  |
| Linseed                       | 1.3 – 1.0                                  |
| Rye                           | 1.0 – 0.8                                  |
| Milk and milk products: Cattle| 0.1 – 0.0                                  |
| Sunflower seed                | 0.9 – 0.0                                  |
| Rye                           | 0.5 – 0.1                                  |
| Milk and milk products: Cattle| 0.4 – 0.3                                  |
| Sunflower seed                | 0.8 – 0.3                                  |
| Rye                           | 0.1 – 0.1                                  |
| Milk and milk products: Cattle| 0.2 – 0.0                                  |
| Sunflower seed                | 0.01 – 0.0                                 |
| Birds' eggs                   | 0.01 – 0.0                                 |

### 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.

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The acute risk assessment is based on the ARfD.

### No of critical MRLs for unprocessed commodities

For processed commodities, no exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

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

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

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

### 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 ARfD/ADI was identified for any unprocessed commodity.

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

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**Modification of existing MRLs for mepiquat in various oilseeds and animal commodities**

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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                |
| Risk assessment residue definition: sum of mepiquat and its salts, expressed as mepiquat chloride |
| Wheat and rye grain | 0.60 STMR (EFSA, 2015) | 0.60 STMR (EFSA, 2015) |
| Barley and oat grain | 0.73 STMR (EFSA, 2015) | 0.73 STMR (EFSA, 2015) |
| Wheat and rye straw | 28.3 STMR (EFSA, 2015) | 50.10 HR (EFSA, 2015) |
| Barley and oat straw | 2.34 STMR (EFSA, 2015) | 5.90 HR (EFSA, 2015) |
| Barley brewer’s grain (dried) | 0.78 STMR × PF (1.1) (EFSA, 2015) | 0.78 STMR × default PF (1.1) (EFSA, 2015) |
| Wheat distiller’s grain (dried) | 1.98 STMR (EFSA, 2015) × default PF (3.3) | 1.98 STMR (EFSA, 2015) × default PF (3.3) |
| Wheat gluten meal | 1.08 STMR (EFSA, 2015) × default PF (1.8) | 1.08 STMR (EFSA, 2015) × default PF (1.8) |
| Wheat milled by-products | 2.10 STMR (EFSA, 2015) × default PF (3.5) | 2.10 STMR (EFSA, 2015) × default PF (3.5) |
| Canola/rape seed meal | 5.84 STMR × PF (1.6, EFSA, 2015) | 5.84 STMR × PF (1.6, EFSA, 2015) |
| Cotton undelinted seed | 1.70 STMR (EFSA, 2018) | 1.70 STMR (EFSA, 2018) |
| Cotton meal | 3.23 STMR × PF (1.9, EFSA, 2018) | 3.23 STMR × PF (1.9, EFSA, 2018) |
| Sunflower meal | 23.75 STMR × PF (1.9, EFSA, 2018) | 23.75 STMR × PF (1.9, EFSA, 2018) |
| Flaxseed/linseed meal | 18.4 STMR × PF (1.6, EFSA, 2018) | 18.4 STMR × PF (1.6, EFSA, 2018) |
| Rape meal | 5.84 STMR × PF (1.6, EFSA, 2015) | 5.84 STMR × PF (1.6, EFSA, 2015) |

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               |
| Risk assessment residue definition for commodities of plant origin: sum of mepiquat and its salts, expressed as mepiquat chloride |
| Rapeseed | 3.65 STMR               | 3.65 STMR             |
| Linseed  | 11.5 STMR               | 11.5 STMR             |
| Mustard seed | 11.5 STMR              | 11.5 STMR             |
| Poppy seed | 11.5 STMR              | 11.5 STMR             |
| Gold of pleasure | 11.5 STMR           | 11.5 STMR             |
| Sunflower seed | 12.5 STMR             | 12.5 STMR             |
| Cotton seed | 1.7 STMR (EFSA et al., 2018) | Acute risk assessment undertaken only with regard to the crops under consideration |
| Barley and oats grain | 0.7 STMR (EFSA, 2015) |               |
| Wheat and rye grain | 0.6 STMR (EFSA, 2015) |               |
| Cultivated fungi | 0.013 STMR (EFSA, 2016) |               |

Risk assessment residue definition for commodities of animal origin: sum of mepiquat, 4-hydroxy mepiquat and their salts, expressed as mepiquat chloride

| Swine muscle | 0.05 STMR | 0.05 HR |
| Swine fat | 0.05 STMR | 0.05 HR |
| Swine liver | 0.08 STMR × CF (1.7) | 0.11 HR × CF (1.7) |
| Swine kidney | 0.05 STMR | 0.07 HR |
| Commodity                        | Chronic risk assessment | Acute risk assessment |
|---------------------------------|-------------------------|-----------------------|
|                                 | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
|---------------------------------|-------------------------|-----------------------|---------------------|-----------------------|
| Bovine and equine muscle        | 0.05                    | STMR                  | 0.06                | HR                    |
| Bovine and equine fat           | 0.05                    | STMR                  | 0.05                | HR                    |
| Bovine and equine liver         | 0.35                    | STMR \times CF (1.7) | 0.5                 | HR \times CF (1.7)    |
| Bovine and equine kidney        | 0.22                    | STMR                  | 0.4                 | HR                    |
| Sheep and goat muscle           | 0.06                    | STMR                  | 0.08                | HR                    |
| Sheep and goat fat              | 0.05                    | STMR                  | 0.06                | HR                    |
| Sheep and goat liver            | 0.48                    | STMR \times CF (1.7) | 0.94                | HR \times CF (1.7)    |
| Sheep and goat kidney           | 0.36                    | STMR                  | 0.65                | HR                    |
| Poultry muscle                  | 0.05                    | STMR                  | 0.05                | HR                    |
| Poultry fat                     | 0.05                    | STMR                  | 0.05                | HR                    |
| Poultry liver                   | 0.05                    | STMR                  | 0.05                | HR                    |
| Cattle and equine milk          | 0.05                    | STMR                  | 0.07                | HR                    |
| Sheep and goat milk             | 0.07                    | STMR                  | 0.11                | HR                    |
| Birds’ eggs                     | 0.05                    | STMR                  | 0.06                | HR                    |

STMR: supervised trials median residue; HR: highest residue; CF: conversion factor.
## Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|--------------------------------------------------|---------------------------------|
| 4-hydroxy mepiquat-chloride | 4-hydroxy-1,1-dimethylpiperidinium chloride  
[Cl-].C[N+]=1(C)CCC(O)CC1  
GDFMSGICPAHHIB-UHFFFAOYNA-M | ![Structural formula](image) |
| mepiquat | 1,1-dimethylpiperidinium  
C[N+]=1(C)CCCCC1  
NNCAWEWCFVZOGF-UHFFFAOYNA-N | ![Structural formula](image) |
| mepiquat chloride | 1,1-dimethylpiperidinium chloride  
[Cl-].C[N+]-1(C)CCCCC1  
VHOVSQVSAQANU-UHFFFAOYNA-M | ![Structural formula](image) |

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

<sup>(a)</sup>: ACD/Name 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

<sup>(b)</sup>: ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).