Modification of the temporary maximum residue level for mepiquat in oyster mushrooms

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, Finland, hereafter referred to as the evaluating Member State (EMS), received an application from BASF SE to modify the temporary maximum residue level (MRL) for the active substance mepiquat in cultivated fungi based on monitoring data. Mepiquat residues in mushrooms do not result from the use of the active substance on mushrooms, but from the uptake of residues via the growth substrate composed of cereal straw that has been treated with mepiquat. Based on a total of 74 samples on oyster mushrooms, three different MRL proposals were derived. A risk management decision is required, considering the acceptable non-compliance rate, in order to decide which temporary MRL is the most appropriate to cover the presence of mepiquat chloride residues in oyster mushrooms. The exposure to residues of mepiquat chloride at the levels observed in the monitoring data on cultivated oyster mushrooms, which were the basis for deriving the MRL proposals, is unlikely to present a risk to consumer health.

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Keywords: mepiquat chloride, cultivated fungi, oyster mushrooms, pesticide, MRL, consumer risk assessment

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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 Finland (evaluating Member State, EMS) to modify the existing temporary maximum residue level (MRL) for the active substance mepiquat in cultivated fungi based on monitoring data. Mepiquat residues in mushrooms do not result from the use of the active substance on mushrooms, but from the uptake of residues via the growth substrate composed of cereal straw that has been treated with mepiquat. 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 11 March 2019. The EMS proposed to set a specific temporary MRL of 0.7 mg/kg for oyster mushrooms by including a footnote to the commodity ‘cultivated fungi’ classified in the MRL food classification under code ‘0280010’; for other cultivated fungi, except oyster mushrooms, the existing temporary MRL of 0.09 mg/kg should be maintained.

The metabolism of mepiquat following foliar application in primary crops has been investigated in three different crop groups; furthermore, studies on the metabolic behaviour in rotational crops which were grown in soil treated with mepiquat are available. Overall, mepiquat chloride was the major residue and therefore a general plant residue definition for enforcement and risk assessment was proposed in the framework of the MRL review which covers ‘the sum of mepiquat and its salts, expressed as mepiquat chloride’. These residue definitions for enforcement and risk assessment are also applicable to cultivated fungi.

Sufficiently validated analytical methods are available to quantify residues of mepiquat chloride in fungi at or above 0.01 mg/kg (limit of quantification (LOQ)).

According to the data provided by the applicant, residues of mepiquat chloride are more likely to occur in oyster mushrooms (Pleurotus ostreatus) compared to other genera, such as Agaricus spp., since the cultivation substrate for this variety consists almost exclusively of cereal straw. Therefore, oyster mushroom was considered the worst-case for residue contamination.

In support of the MRL application, the applicant provided monitoring data on oyster mushrooms provided by food business operators which cover the period from 2015 until 2019. Based on the results of 74 samples on oyster mushrooms and in line with the methodology developed by the Food and Agriculture Organization of the United Nations (FAO) for the setting of extraneous MRLs (EMRL), different MRL proposals were derived.

Monitoring data on 928 samples of cultivated fungi submitted to EFSA in the framework of Article 32 of Regulation (EC) No 396/2005 (official national control programmes), which cover the period from 2014 to 2017, confirmed that the existing MRL of 0.09 mg/kg is sufficient for cultivated fungi other than oyster mushrooms.

The results from an experimental study conducted with oyster mushrooms grown in the presence of a known concentration of residues of mepiquat chloride in wheat straw were submitted. For the transfer from straw to oyster mushrooms, an indicative median transfer factor of 1.2 was calculated. In order to derive a robust transfer factor, additional studies would be required. However, this study gives an indication that significantly higher residues compared to those observed in monitoring data might be expected for oyster mushrooms, taking into account that in the supervised field trials on cereals the median residue concentration of mepiquat chloride in straw was 4.2 mg/kg, with maximum results up to 50 mg/kg, resulting in median and highest residue concentrations in oyster mushrooms of 5 and 60 mg/kg, respectively.

The toxicological profile of mepiquat was assessed in the framework of the EU pesticides peer review 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 g/kg bw for mepiquat chloride.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) using the median and highest residue value observed in the monitoring data (74 samples) on oyster mushrooms for the chronic and the acute exposure, respectively. In the absence of specific consumption data for oyster mushrooms, the consumption data for cultivated fungi which cover all varieties of cultivated mushrooms were used. Based on the results of the consumer risk assessment, EFSA concluded that the exposure to residues of mepiquat chloride at the levels observed in the monitoring data on cultivated oyster mushrooms is unlikely to present a risk to consumer health. The consumer risk assessment is affected by non-standard uncertainties. EFSA recommended to generate further data to derive definitive MRLs for mepiquat in oyster mushrooms and increase the robustness of the dietary risk assessment.
The peer review of the renewal of the approval of mepiquat in accordance with Regulation (EC) No 1107/2009 is ongoing and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the peer review.

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

| Code\(^{(a)}\) | Commodity | Existing EU tMRL (mg/kg) | Proposed EU tMRL (mg/kg) | Comment/justification |
|--------------|-----------|-------------------------|-------------------------|-----------------------|
| 0280010      | Cultivated fungi (including oyster mushrooms, 0280010-008) | 0.09 (ft) | Oyster mushrooms (0280010-80) 0.7 or 0.9 or 3 (further risk management considerations required) | MRL proposals from monitoring data (74 samples) on oyster mushrooms, taking into account the FAO approach for setting of EMRLs. The EMRL approach at the 97.5th percentile, the 99th percentile and the binomial probability (95th percentile/at the 95% confidence level) calculations lead to the same MRL proposal of 3 mg/kg. The 95th percentile estimation leads to similar MRL proposals of 0.9 mg/kg or 0.7 mg/kg (when excluding extreme values). Risk for consumers unlikely, regardless of the temporary MRL (tMRL) option. A risk management decision is required to decide which tMRL is the most appropriate, considering the non-compliance rate, to cover the presence of mepiquat residue in oyster mushrooms. Monitoring data confirmed that the current tMRL of 0.09 mg/kg might be sufficient for fungi different than oyster mushrooms (2% non-compliance rate). |

MRL: maximum residue level; EMRL: extraneous MRL.
\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
\(^{(ft)}\): Recent monitoring data show that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with mepiquat. This cross-contamination may not be fully avoidable in all cases. When reviewing the MRL, the Commission will take into account the information, if it is submitted by 31 December 2022, or if that information is not submitted by that date, the lack of it (Regulation (EU) 2019/50).
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Assessment

The use of mepiquat is authorised for cereals, leading to residues in cereal straw. The presence of mepiquat chloride in cultivated fungi is resulting from residues in cereal straw, which is used as a substrate to cultivate mushrooms.

Mepiquat belongs to the class of quaternary ammonium compounds with the ISO common name for 1,1-dimethylpiperidinium (IUPAC). For plant protection product formulations, the variant mepiquat chloride is used as an active ingredient. The chemical structure of the active substance, its salt and its main metabolite is reported in Appendix E.

Mepiquat was evaluated in the framework of Directive 91/414/EEC1 with the United Kingdom designated as rapporteur Member State (RMS). The representative use assessed was the use as a plant growth regulator in cereals for stem stabilisation. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by the European Food Safety Authority (EFSA, 2008). Mepiquat was approved2 for the use as a plant growth regulator on 1 March 2009. The process of renewal of the first approval is currently ongoing.

The European Union (EU) maximum residue levels (MRLs) for mepiquat are established in Annex II of Regulation (EC) No 396/20053. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2015) and the proposed modifications have been implemented in the MRL legislation. The MRL for cultivated fungi is currently set as a temporary MRL at the level of 0.09 mg/kg (Regulation (EU) No 2019/50)4, implementing an EFSA recommendation (EFSA, 2016).5 In 2018, EFSA has issued two reasoned opinions on the modification of MRLs for mepiquat in oilseeds and animal products. The proposals from these reasoned opinions have been considered in the EU MRL legislation.6

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF submitted an application to the competent national authority in Finland (evaluating Member State, EMS) to modify the existing temporary MRL for the active substance mepiquat in cultivated fungi, based on monitoring data. 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 11 March 2019. The EMS proposed to set a separate temporary MRL of 0.7 mg/kg for oyster mushrooms and to keep the existing temporary MRL of 0.09 mg/kg for other cultivated fungi.

EFSA based its assessment on the evaluation report submitted by the EMS (Finland, 2019) as well as the conclusions of the EU pesticides peer review and from previous EFSA opinions on mepiquat (EFSA, 2008, 2015, 2016, 2018b,c).

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 546/20117.

As the EU pesticides peer review for the renewal of approval of the active substance in accordance with Regulation (EC) No 1107/2009 is not yet finalised, 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.

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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, fluazifop, 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 Commission Regulation (EU) 2019/50 of 11 January 2019 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorantraniliprole, clomazone, cyclaniliprole, fenazaquin, fenpicoxamid, fluoxastrobins, lambda-cyhalothrin, mepiquat, onion oil, thiacloprid and valifenalate in or on certain products. C/2019/20.. OJ L 10, 14.1.2019, p. 8–59.
5 In its reasoned opinion, EFSA derived three different MRL proposals for cultivated fungi for consideration by risk managers. These different values were derived using the FAO approach to calculate extraneous MRLs (EMRL) or MRLs on spices based on data of national control programmes (official monitoring data) covering the period from 2011 to 2015. Risk managers decided to implement the MRL proposal that was derived calculating the 99th percentile of all samples results (FAO approach for EMRL).
6 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/ep-pesticides-database/public/?event=pesticide.residue.selection&language=EN
7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
A selected list of end points of the studies assessed by EFSA in the framework of this MRL application, including the end points of relevant studies assessed previously, are presented in Appendix B.

The evaluation report submitted by the EMS (Finland, 2019), the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) and the Excel tables reporting the results of the monitoring sampling and analyses (data from EU monitoring and business operators) provided in support of the application 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 mepiquat residues in primary crops following foliar applications of mepiquat chloride has been investigated in three crop groups (fruits, pulses/oilseeds and cereals/grass). These studies were assessed in the framework of the EU pesticide peer review and the MRL review of the active substance (EFSA, 2008, 2015). Limited metabolism was observed in all tested crops with mepiquat chloride representing the predominant component (72 to 90%) of the total radioactive residues (TRR).

Specific studies on the metabolism of mepiquat in mushrooms are not available. Since the metabolic profile of the active substance was seen to be similar in the three crops group investigated, in accordance with the current guidelines, a general residue definition was derived by EFSA, which also covers cultivated fungi (EFSA, 2016). Although not required according to the data requirements, it would be desirable to investigate the nature of residues in fungi, considering that the metabolism might be different in fungi growing as saprophytic organism.

1.1.2. Nature of residues in rotational crops

A confined rotational crop study using wheat, radish and lettuce planted in soil treated with mepiquat chloride was assessed during the EU pesticide peer review and the MRL review (EFSA, 2008, 2015). The accumulation of radioactivity in the plants indicated uptake of residues from the soil to wheat and radishes, but not in lettuce (where total residue was below limit of quantification (LOQ) at each plant-back interval (PBI)). The only compound identified was mepiquat chloride at levels below 0.01 mg/kg (except in wheat chaff, at 120 PBI). The remaining extractable radioactivity as well as the non-extractable radioactivity were concluded to be probably associated to metabolites (free, conjugated or incorporated into natural plant products) resulting from the fragmentation of the ring.

The residues of mepiquat in rotational crops are not of relevance for the assessment of the current application, as cultivated fungi are not grown in rotation with other plants. However, rotational crop metabolism studies provide useful information on the uptake of mepiquat chloride from soil by plants.

1.1.3. Nature of residues in processed commodities

The effect of processing on the nature of mepiquat residues was investigated in the framework of the EU pesticides peer review and it was demonstrated that mepiquat chloride 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

Analytical methods using liquid chromatography with tandem mass spectrometry (LC-MS/MS) detection were considered sufficiently validated for monitoring mepiquat chloride in plant commodities at or above the LOQ of 0.01 mg/kg (EFSA, 2018b). The reported LOQ is expressed as mepiquat chloride.

As mushrooms belong to the high-water content commodity group, EFSA confirms the previous conclusion that sufficiently validated analytical methods are available to control mepiquat chloride residues in cultivated fungi (EFSA, 2016).
1.1.5. Stability of residues in plants

Mepiquat chloride has been demonstrated to be stable for a period up to 24 months when stored at ≤ −20°C in high-water content matrices (EFSA, 2008), to which mushrooms belong.

1.1.6. Proposed residue definitions

Based on the results of the metabolism in primary and rotational crops and the hydrolysis studies, the following general residue definition for both monitoring and risk assessment in all plant commodities has been proposed in the framework of the MRL review (EFSA, 2015):

- Sum of mepiquat and its salts, expressed as mepiquat chloride

The residue definition for enforcement of mepiquat in Regulation (EC) No 396/2005 is identical as the above-mentioned residue definition.

1.2. Magnitude of residues in plants

In support of the MRL application, Finland assessed monitoring data on cultivated mushrooms, including oyster mushrooms, provided by food business operators (see Section 1.2.1.1). The samples were analysed in private laboratories. In addition, Finland assessed the data collected by EFSA in the framework of Article 32 of Regulation (EC) No 396/2005 (see Section 1.2.1.2). For these monitoring data, no information was available on condition and length of storage of the samples. However, the lack of this information was considered having a negligible impact, since samples from surveys are usually analysed within a few days after sampling (EFSA, 2016).

All residues were expressed as mepiquat chloride.8

Furthermore, the EMS assessed the results of an experimental study conducted with oyster mushrooms grown in the presence of a known concentration of residues of mepiquat chloride in wheat straw (see Section 1.2.1.3).

1.2.1. Magnitude of residues in primary crops

1.2.1.1. Monitoring data from food business operators

Cultivated Oyster mushrooms

The EMS compiled monitoring data (n = 74) on mepiquat chloride in oyster mushrooms (Pleurotus ostreatus) from two different sources:

- 64 samples provided by the Dutch Confederation of Agriculture and Horticulture (LTO) (2016, 2018, 2019);
- 10 samples provided by the European Mushroom Grower Group (GEPC) (201–2017).

The samples were originated from the Netherlands (55 samples), Poland (9 samples), Belgium (5), Germany (2 samples), Hungary (2 samples) and from the United Kingdom (1 sample). In 84% of the samples, mepiquat chloride was quantified (≥ LOQ). 45% of the samples showed residues higher than the existing MRL of 0.09 mg/kg. The highest residue value accounted for 2.95 mg/kg.

A histogram showing the distribution of mepiquat chloride residues found in these monitoring data, the overview of the monitoring sampling and the summary statistic to derive the MRL proposals according to the FAO methodology for extraneous MRLs (EMRL) and the approach outlined in Regulation (EU) 283/20139 are presented in Appendix B.

Cultivated mushrooms other than oyster mushrooms

The EMS compiled monitoring data (n = 306) from mushroom varieties different than oyster from two different sources:

- 301 samples provided by the GEPC (2011–2018)
- 5 samples provided by the LTO (2018–2019)

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8 For samples in which the results were reported as mepiquat equivalents, the results were recalculated to mepiquat chloride using the molecular conversion factor of 1.31.

9 Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ L 93, 3.4.2013, p. 1–84
The samples were originated from the Netherlands (80 samples), Poland (22 samples), Belgium (2 samples), Germany (37 samples), France (40 samples), Italy (4 samples), Ireland (40 samples), United Kingdom (62 sample) and from Ireland/UK (19 samples). This data package showed a much lower percentage of samples exceeding the current MRL of 0.09 mg/kg (2% MRL exceedance). The highest residue value accounted for 0.24 mg/kg. These data give an indication that levels and frequency of mepiquat chloride residues differ among the mushroom varieties and that oyster mushrooms can be considered as worst-case for residue contamination.

A histogram showing the distribution of the mepiquat chloride residues, the overview of data and the summary statistic are presented in Appendix B.

1.2.1.2. Monitoring data from EU pesticide residue monitoring

Cultivated mushrooms from unknown varieties

In the framework of Article 32 of Regulation (EC) No 396/2005 (official national control programmes), monitoring data were submitted to EFSA. Among these data, which covered the reference period from 2014 to 2017, mepiquat results in cultivated mushrooms are available for 928 samples; details on the mushroom variety analysed were not reported.

These samples originated from 15 EU Member States (869 samples) and from non-EU countries (31 samples); for 28 samples the origin was unknown. Overall, 50% of the samples contained quantifiable residues of mepiquat chloride; 2% of the samples exceeded the current MRL of 0.09 mg/kg. The highest residue value observed was 0.85 mg/kg. A histogram showing the distribution of the mepiquat chloride residues, the overview of data and the summary statistic are presented in Appendix B.

1.2.1.3. Transfer of mepiquat chloride residues from straw to oyster mushrooms

The applicant provided an experimental study investigating the uptake of mepiquat chloride residues in oyster mushrooms grown on wheat straw previously treated with mepiquat chloride. The study was performed with *P. ostreatus* (oyster mushrooms), since compared to other cultivated mushroom varieties, oyster mushrooms are expected to lead to the highest residues of mepiquat chloride, since this variety is usually grown on a substrate that contains a higher amount of straw. For oyster mushrooms, the substrate is constituted of 95% of straw, whereas the substrate of *Agaricus* mushrooms is only 15% of straw (Finland, 2019). Thus, the oyster mushrooms were considered to be the worst-case for residue transfer.

The wheat straw used in the experiment was obtained from a northern EU field trial on wheat treated with mepiquat chloride according to the authorised Good Agricultural Practice (GAP) for wheat (1 × 0.76 kg/ha at BBCH 49); the same GAP was assessed to derive the current MRL for wheat grain (see Appendix A). Residues of mepiquat chloride observed in wheat straw at harvest ranged from 12.7 to 31.9 mg/kg; the baled straw used as a substrate for the cultivation of oyster mushrooms contained 22.5 mg/kg of mepiquat chloride.

Oyster mushrooms were cultivated directly onto the treated baled straw. At maturity, fungi samples were collected (from three baled straw, three flushes per baled straw) and analysed for residues of mepiquat chloride. According to the EMS, the analytical method used to analyse the samples has been sufficiently validated and residue data were valid with regard to storage stability (Finland, 2019). The residue concentrations measured in oyster mushrooms ranged from 5.2 mg/kg to 44.3 mg/kg with a median residue concentration of 26.6 mg/kg. A median transfer factor of 1.2 was derived from three individual trials with 3 harvests, respectively.

In the supervised residue trials on cereals conducted according to the same GAP and assessed in the framework of the MRL review, residues of mepiquat chloride in wheat straw ranged from 2.64 to 50.1 mg/kg (STMR value 28.3 mg/kg) in the NEU. Additional results for wheat straw cultivated in SEU are available, ranging from 1.11 to 3.35 mg/kg (STMR value 1.83 mg/kg). For barley straw, the residues in NEU ranged from 1.1 mg/kg to 5.9 mg/kg (STMR value 2.34 mg/kg) and in SEU from 0.46 mg/kg to 3.35 mg/kg (STMR value 1.83 mg/kg) (EFSA, 2015).

Combining these results, the overall STMR and the HR for cereal straw was 4.2 mg/kg and 50.1 mg/kg for the NEU and 2.4 mg/kg and 7.8 mg/kg for the SEU.\(^{11}\) Taking into account the indicative median transfer factor derived from the experimental study provided by the applicant, the

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10 EFSA disregarded 22 samples from the dataset of 950 samples assessed by the EMS, because they were related to processed, dehydrated mushrooms.

11 EFSA did not merge NEU and SEU data sets since the results belong to different populations (U-test, 5%).
median and highest residue concentrations in oyster mushrooms are calculated to be 5 and 60 mg/kg, respectively. Based on the results of the supervised field trials on cereals assessed in the MRL review and the results of the transfer study described above, significantly higher residues compared to those observed in monitoring data might be expected in oyster mushrooms.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current assessment.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of mepiquat chloride residues in processed cultivated fungi have not been submitted and are not required, considering the low contribution of residues in this crop to the total calculated consumer exposure.

1.2.4. Proposed temporary MRLs

To derive MRL proposals from the available monitoring data in oyster mushrooms provided by food business operators, EFSA used the methodologies developed by FAO (2016). EFSA calculated four different MRL options, i.e. the residue concentration corresponding to 95th, 97.5th, 99th percentile and the concentration that covers the 95th percentile of the data population at the 95% confidence level (approach laid down in Regulation (EU) No 283/2013 and reported in European Commission (2018)). For sake of consistency, the method to estimate percentiles from monitoring data on cultivated fungi used in the previous EFSA opinion (EFSA, 2016; considering a data set of 524 samples) was the same as the one applied in the present opinion.12 The MRL of 0.7 mg/kg at the 95th percentile derived by the EMS excluding the extreme values might be an alternative option as it leads to a lower MRL value and the number of non-compliances is very low (5%). Since the consumer risk assessment to be carried out is unaffected by the choice, it is proposed to risk manager to decide which of these options should be considered for the modification of the existing temporary MRL in oyster mushrooms.

The calculated values were rounded to the class of MRL setting according to SANCO 16340/2010 (European Commission, 2010). The different MRL proposals expressed as mepiquat chloride are summarised below.

- 0.9 mg/kg 95th percentile (unrounded 0.878 mg/kg)
- 3 mg/kg 97.5th percentile (unrounded 2.843 mg/kg)
- 3 mg/kg 99th percentile (unrounded 2.948 mg/kg)
- 3 mg/kg 95th percentile at the 95% confidence level (unrounded 2.948 mg/kg)
- 0.7 mg/kg 95th percentile excluding extreme values (unrounded 0.673 mg/kg) (Finland, 2019).

The available data demonstrated that for oyster mushrooms, higher residues of mepiquat chloride are expected than in other mushrooms species. The monitoring data from national programmes (928 samples) confirmed the existing temporary MRL for cultivated fungi (2% non-compliance rate observed in monitoring data from EU pesticide residue monitoring). The monitoring data provided by food business operators on mushrooms other than oyster mushrooms gave similar result (2% non-compliance rate).

In Section 3, EFSA assessed whether residues on cultivated fungi are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant for the current assessment. Cultivated fungi are not used as feed items.

3. Consumer risk assessment

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMO). This exposure assessment model contains the relevant European food

12 The calculations were performed using SAS® software. Values <LOQ were considered as corresponding to the LOQ. EFSA estimated the percentiles (without interpolation between observed values) to ensure that at least (1-p) of the observations are equal or greater to this value. The EMS estimated percentiles excluding the extreme values; percentile estimates were fairly similar for the two larger datasets, but not exactly the same when number of observations was small (74 sample dataset).
consumption data for different subgroups of the EU population (EFSA, 2018a). Since the PRIMo model does not contain specific consumption data for oyster mushrooms, the exposure calculation was performed using consumption data for cultivated fungi which cover all varieties of cultivated mushrooms. The estimated exposure was compared with the toxicological reference values derived for mepiquat chloride during the EU pesticides peer-review (European Commission, 2008).

Long-term (chronic) dietary risk assessment

The most recent long-term exposure assessment performed by EFSA (2018c) was updated with the median residue value observed in the monitoring data on oyster mushrooms assessed in this MRL application. For the remaining commodities of plant and animal origin, the supervised trial median residues (expressed as mepiquat chloride) derived for the authorised uses of mepiquat were used as input values.

The estimated long-term dietary intake of mepiquat chloride was in the range of 0.1–7% of the ADI (maximum for Dutch toddlers). The contribution of cultivated fungi accounted for up to 0.01% of the ADI (Irish adults).

The chronic risk assessment is affected by non-standard uncertainties.

- Specific consumption data for oyster mushrooms (P. ostreatus) are not available. The calculations were performed assuming that the median residue found in oyster mushrooms is representative for all cultivated mushrooms, which is expected to lead to a light overestimation of the exposure.
- The calculation was performed using the median residue observed in monitoring data on oyster mushrooms provided by the food business operators instead of the STMR value derived from field residue trials.

Short-term (acute) dietary risk assessment

The acute exposure assessment was performed only with regard to the commodity under assessment, considering the highest residue value observed in the monitoring data on oyster mushrooms (data provided by food business operators). The default variability factor of 7 included in the PRIMo 3.1 model was used in the calculation (scenario 1). It is expected that for mushrooms a lower unit-to-unit variability might be appropriate. Therefore, a second scenario was calculated using a variability factor of 3 (scenario 2). In both scenarios, no acute consumer risk was identified for oyster mushrooms (17% and 11% of the ARfD, respectively, Belgian toddlers).

The acute risk assessment is affected by the following non-standard uncertainties:

- Specific consumption data for oyster mushrooms (P. ostreatus) are not available; the exposure calculations were performed using the large portion consumption data reported for all mushroom varieties.
- Information on the unit-to-unit variability expected in oyster mushrooms is not available.
- The calculation was performed using the highest residue concentration observed in the monitoring data on oyster mushrooms provided by the food business operators (i.e. 2.95 mg/kg). The transfer study (see Section 1.2.1.3) and the information from supervised residue trials in cereal straw give an indication that significantly higher residues might occur in oyster mushrooms (up to 60 mg/kg) when mepiquat is applied according to the critical GAP (cGAP) (EFSA, 2015). Therefore, it cannot be excluded that the short-term exposure may be higher than the exposure calculated from the submitted monitoring data.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C and the input values for the calculation in Appendix D.

4. Conclusion and Recommendations

Based on the results of a total of 74 samples on oyster mushrooms analysed by food business operators between 2015 and 2019, different MRL proposals were derived using the methodologies recommended by the FAO (2016). A risk management decision is required, considering the acceptable non-compliance rate, in order to decide which temporary MRL is appropriate.

EFSA concluded that the exposure to residues at the levels observed from the monitoring data collected on cultivated oyster mushrooms (data provided by food business operators) is unlikely to present a risk to consumer health.
In order to derive a definitive MRL for oyster mushrooms and to reduce the uncertainties of the dietary risk assessment, EFSA recommends the following:

- To perform residue trials that allow a reliable prediction of expected residues in oyster mushrooms cultivated on straw that contains residue concentrations of mepiquat chloride resulting from authorised uses of mepiquat in cereals;
- Alternatively, further studies to investigate the transfer of residues from straw to oyster mushrooms to derive a more robust transfer factor;
- Studies investigating the unit-to-unit variability of mepiquat chloride residues in individual mushrooms to reduce the uncertainties related to the acute risk assessment;
- Moreover, it would be desirable to investigate the nature of residues in fungi, considering that in fungi growing as saprophytic organism, metabolism might be different.

Furthermore, possible risk management restrictions might be discussed to reduce the occurrence of mepiquat chloride in cultivated mushrooms, such as restrictions to cultivate mushrooms in mepiquat-free straw (or, alternatively, to set a threshold residue limit for mepiquat chloride for straw used as substrate in mushroom cultivation), in order to avoid contamination of oyster mushrooms and other fungi cultivated in cereal straw.

The MRL recommendations are summarised in Appendix B.4.

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**Abbreviations**

| Abbreviation | Definition |
|--------------|------------|
| ADI          | acceptable daily intake |
| ARfD         | acute reference dose |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight |
| CF           | conversion factor for enforcement to risk assessment residue definition |
| cGAP         | critical GAP |
| DALA         | days after last application |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| EMRL         | extraneous MRL |
| EMS          | evaluating Member State |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| GEPC         | European Mushroom Grower Group |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| ILV          | independent laboratory validation |
| InChIKey     | International Chemical Identifier Key |
| ISO          | International Organisation for Standardisation |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC           | liquid chromatography |
| LOQ          | limit of quantification |
| LTO          | Dutch Confederation of Agriculture and Horticulture |
| MRL          | maximum residue level |
| MS           | Member States |
| MS/MS        | tandem mass spectrometry detector |
| NEU          | northern Europe |
| PBI          | plant-back interval |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| RA           | risk assessment |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | southern Europe |
| SL           | soluble concentrate |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TF           | transfer factor |
| TRR          | total radioactive residue |
| VF           | variability factor |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

Not relevant for mushrooms, since a direct treatment of cultivated fungi is not proposed.

**Critical GAPs assessed in the framework of the MRL review for mepiquat for cereals, leading to residues in straw (EFSA, 2015).**

| Crop       | Region | Outdoor/Indoor | MS                      | Pest controlled | Formulation | Content Conc. | Unit | Application                     | Growth stage From BBCH | Growth stage Until BBCH | No of appl. | Appl. rate | Unit | PHI or waiting period (days) | Comments (max. 250 characters) |
|------------|--------|----------------|--------------------------|------------------|-------------|---------------|------|-------------------------------|------------------------|-------------------------|-------------|------------|------|-----------------------------|---------------------------------|
| Barley     | NEU    | Outdoor        | BE, DE, UK, LU           | Stem stabilisation | SL          | 305           | g/L  | Foliar treatment – spraying   | 31                     | 49                      | 1            | 0.76      | kg/ha | n.a.                        |                                  |
| Oats       | NEU    | Outdoor        | FI                       | Stem stabilisation | SL          | 305           | g/L  | Foliar treatment – spraying   | 32                     | 39                      | 1            | 0.61      | kg/ha | n.a.                        |                                  |
| Rye        | NEU    | Outdoor        | BE, DE, SE, UK           | Stem stabilisation | SL          | 305           | g/L  | Foliar treatment – spraying   | 31                     | 49                      | 1            | 0.76      | kg/ha | n.a.                        |                                  |
| Wheat      | NEU    | Outdoor        | BE, DE, UK, FR           | Stem stabilisation | SL          | 305           | g/L  | Foliar treatment – spraying   | 31                     | 49                      | 1            | 0.76      | kg/ha | n.a.                        |                                  |
| Barley     | SEU    | Outdoor        | FR                       | Stem stabilisation | SL          | 305           | g/L  | Foliar treatment – spraying   | 32                     | 39                      | 1            | 0.76      | kg/ha | 52                          | Critical GAP is for winter barley. A less critical GAP is authorised on spring barley (1 × 0.46 kg/ha) |
| Oat        | SEU    | Outdoor        | FR                       | Stem stabilisation | SL          | 300           | g/L  | Foliar treatment – spraying   | 30                     | 39                      | 1            | 0.30      | kg/ha | n.a.                        |                                  |
| Wheat      | SEU    | Outdoor        | FR                       | Stem stabilisation | SL          | 305           | g/L  | Foliar treatment – spraying   | 31                     | 49                      | 1            | 0.76      | kg/ha | 56                          |                                  |

GAP: Good Agricultural Practice; MRL: maximum residue level; MS: Member State; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; SL: soluble concentrate; NEU: northern Europe; SEU: southern Europe.
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          | Crops     | Applications | Sampling | Comment/Source                                      |
|----------------------|-----------|--------------|----------|-----------------------------------------------------|
| Fruit crops          | Grape     | Foliar, 2 × 1.1 kg/ha | 98 DALA  | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)          |
| Cereals/grass        | Wheat     | Foliar, 1 × 0.7 kg/ha | 0, 8, 71 DAT | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
| Barley               | Foliar, 1 × 0.91 kg/ha | 16, 37, 52 DAT | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
| Pulses/oilseeds      | Cotton    | Foliar, 1 × 0.16 kg/ha | 15, 67 DAT | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
|                      | Oilseed rape | Foliar, 2 × 0.3 kg/ha | 63 DALA  | 2,6\(^14\)C-mepiquat chloride (EFSA, 2015)         |
| Rotational crops (available studies) | Crop groups | Crops | Application | PBI (DAT) | Comment/Source                                      |
| Root/tuber crops     | Radish    | Bare soil, 0.7 kg/ha | 29, 120, 365 | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
| Leafy crops          | Lettuce   | Bare soil, 0.7 kg/ha | 29, 120, 365 | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
| Cereal (small grain) | Wheat     | Bare soil, 0.7 kg/ha | 29, 120, 365 | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |

### Rotational crops (available studies)

| Crop groups          | Crops     | Application | PBI (DAT) | Comment/Source                                      |
|----------------------|-----------|--------------|-----------|-----------------------------------------------------|
| Root/tuber crops     | Radish    | Bare soil, 0.7 kg/ha | 29, 120, 365 | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
| Leafy crops          | Lettuce   | Bare soil, 0.7 kg/ha | 29, 120, 365 | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |
| Cereal (small grain) | Wheat     | Bare soil, 0.7 kg/ha | 29, 120, 365 | 2,6\(^14\)C-mepiquat chloride (EFSA, 2008)         |

### Processed commodity (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?

- Yes  
  EFSA (2008)

### Rotational crop and primary crop metabolism similar?

- Yes  
  EFSA (2008)

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

- Yes  
  EFSA (2008)

### Plant residue definition for monitoring (RD-Mo)

- Sum of mepiquat and its salts, expressed as mepiquat chloride (EFSA, 2015)

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

- Sum of mepiquat and its salts, expressed as mepiquat chloride (EFSA, 2015)

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

- 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 (EFSA, 2018b)

DALA: days after last application; DAT: days after treatment; 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

| Plant products (available studies) | Category                  | Commodity     | T (°C) | Stability period | Compounds covered | Comment/Source          |
|------------------------------------|---------------------------|---------------|--------|------------------|-------------------|-------------------------|
|                                    | High water content        | Wheat forage  | –20    | 24 Months        | Parent            | EFSA (2008)             |
|                                    | High oil content          | Cotton seed   | –15    | 25 Months        | Parent            | EFSA (2018b,c)          |
|                                    | High protein content      | –              | –      | –                | –                 | –                       |
|                                    | Dry/High starch           | Wheat grain    | –20    | 24 Months        | Parent            | EFSA (2008)             |
|                                    | High acid content         | –              | –      | –                | –                 | –                       |
|                                    | Processed products        | –              | –      | –                | –                 | –                       |
|                                    | Others                    | Cotton forage  | –15    | 25 Months        | Parent            | EFSA (2018b,c)          |
## B.1.2. Magnitude of residues in plants

### B.1.2.1. Summary of residues data from the experimental study

| Commodity | Region/Indoor\(^{(a)}\) | Individual residue levels observed (mg/kg) | Comments/Source | MRL | STMR | HR | Individual transfer factor (TF) \(^{(b)}\) | Median TF |
|-----------|-------------------------|-----------------------------------------|----------------|-----|------|----|--------------------------------|----------|
| Oyster mushrooms (Pleurotus ostreatus) | N/A | 1\(^{st}\) flush: 28.9; 24.7; 28.3 2\(^{nd}\) flush: 44.3; 20.1; 13.3 3\(^{rd}\) flush: 32.3; 26.6; 5.18 | Trials on oyster fungi cultivated on baled straw from spring wheat treated in the UK with mepiquat chloride at 1 x 0.76-0.77 kg/ha, BBCH 49\(^{(c)}\) PHI 63–78 days Mepiquat chloride in baled straw prior to fungi cultivation containing 22.5 mg/kg (Finland, 2019) The number of results is not sufficient to derive an MRL proposal Indicative STMR and HR values were derived, based on the 9 individual determinations | – | 26.6 | 44.3 | 1\(^{st}\) flush: 1.3; 1.1; 1.3 (median: 1.3) 2\(^{nd}\) flush: 2.0; 0.9; 0.6 (median 0.9) 3\(^{rd}\) flush: 1.4; 1.2; 0.2 (median 1.2) | 1.2 |

MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; BBCH: growth stages of mono- and dicotyledonous plants
\(^{(a)}\): 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.
\(^{(b)}\): Individual transfer factors (residue fungi/residue straw) at each harvest.
\(^{(c)}\): Critical NEU GAP for wheat assessed in the framework of the MRL review (EFSA, 2015).
## B.1.2.2. Summary of monitoring data on cultivated fungi

| Variety                          | EU monitoring data submitted to EFSA under Art. 32 of Reg. 396/2005 | Food business operators data |
|----------------------------------|---------------------------------------------------------------------|------------------------------|
|                                  | Not reported                                                        | Oyster mushrooms             | Mushrooms different than oyster mushrooms |
| No of samples                   | 928                                                                 | 74                           | 306             |
| Year of collection              | 2014–2017                                                           | 2015–2019 (Jan)              | 2011–2018       |
| No of samples ≥ LOQ (% of samples ≥ LOQ) | 460 (49.5%)                                                          | 62 (84%)                     | Not available(a) |
| Mean                            | 0.025 mg/kg                                                          | 0.222 mg/kg                  | 0.025 mg/kg     |
| Standard deviation              | 0.050 mg/kg                                                          | 0.048 mg/kg                  | 0.024 mg/kg     |
| Median                          | 0.013 mg/kg                                                          | 0.087 mg/kg                  | 0.013 mg/kg     |
| Min                              | 0.001 mg/kg                                                          | 0.005 mg/kg                  | 0.005 mg/kg     |
| Max                              | 0.845 mg/kg                                                          | 2.948 mg/kg                  | 0.236 mg/kg     |
| P90                             | 0.047 mg/kg                                                          | 0.420/0.411(b) mg/kg         | 0.052 mg/kg     |
| P95                             | 0.065 mg/kg                                                          | 0.878/0.673(b) mg/kg         | 0.066 mg/kg     |
| P97.5                           | 0.070 mg/kg                                                          | 2.843/1.248(b) mg/kg         | 0.079 mg/kg     |
| P99                             | 0.146 mg/kg                                                          | 2.948/2.871(b) mg/kg         | 0.092 mg/kg     |
| P95/95% UCL                     | 0.065 mg/kg                                                          | 2.948 mg/kg                  | 0.144 mg/kg     |
| No of samples > current MRL (0.09 mg/kg) | 18                                                                  | 33                           | 7               |
| % of samples > current MRL (0.09 mg/kg) | 2%                                                                  | 45%                          | 2%             |

P: percentile, UCL: upper confidence limit (upper bound); LOQ: limit of quantification; MRL: maximum residue level.
(a): The information, whether the reported residue concentrations exceeded the LOQ, was not provided.
(b): Percentiles calculated using SAS® software/Microsoft Excel. When using different methods, with or without interpolation between observed values, estimations are not the same when the number of observations is small.
Figure B.1: EU Monitoring data for mushrooms (EU official controls)

Figure B.2: Monitoring data for oyster mushrooms (food business operators)

Figure B.3: Monitoring data for mushrooms other than oyster mushrooms (food business operators)
B.1.2.3. Residues in rotational crops
Not relevant. Cultivated fungi are not grown in rotation.

B.1.2.4. Processing factors
No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock
Not relevant. Cultivated fungi are not used as feed item.

B.3. Consumer risk assessment

| ARfD                  | 0.3 mg/kg bw (European Commission, 2008) |
|-----------------------|------------------------------------------|
|                        | Cultivated fungi: 17% ARfD (BE toddlers) (scenario 1) |
|                        | 11% ARfD (BE toddlers) (scenario 2) |

Assumptions made for the calculations
PRIMo rev. 3.1
The calculation is based on the highest observed level from the monitoring data (74 samples) on raw mushrooms belonging to the species *P. ostreatus*.
The default variability factor (VF) of 7 was used in the calculation (scenario 1), which is considered a conservative approach leading to an overestimation of the exposure (EFSA, 2019a,b). An alternative calculation was performed using the VF of 3 (scenario 2).

| ADI                   | 0.2 mg/kg bw per day (European Commission, 2008) |
|-----------------------|------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 7% ADI (NL toddlers) |
|                        | Contribution of the crop assessed: |
|                        | Cultivated fungi: 0.01% of ADI (IE adult) |

Assumptions made for the calculations
PRIMo rev. 3.1
The calculation is based on the median observed value from the monitoring data (n = 74) on raw mushrooms belonging to the species *P. ostreatus*. For other commodities, the STMRs derived in previous EFSA assessments (EFSA, 2015, 2018b,c) were used as input values. Concentrations in liver of swine and ruminants were multiplied by a conversion factor for risk assessment of 1.7 derived from the metabolism study in ruminants (EFSA, 2015).
The contributions of commodities where no GAP was reported to EFSA in the framework of the MRL review or in succeeding MRL assessments were not included in the calculation.

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

| Code<sup>(a)</sup> | Commodity | Existing EU tMRL (mg/kg) | Proposed EU tMRL (mg/kg) | Comment/justification |
|-------------------|-----------|-------------------------|--------------------------|------------------------|
| 0280010           | Cultivated fungi (including oyster mushrooms, 0280010-008) | 0.09<sup>(ft)</sup> | Oyster mushrooms (0280010-80) 0.7 or 0.9 or 3 (further risk management considerations required) (ft) | MRL proposals from monitoring data (74 samples) on oyster mushrooms, taking into account the FAO approach for setting of EMRLs. The EMRL approach at the 97.5th percentile, the 99th percentile and the binomial probability (95th percentile/at the 95% confidence level) calculations lead to the same MRL proposal of 3 mg/kg. The 95th percentile estimation leads to similar MRL proposals of 0.9 mg/kg or 0.7 mg/kg (when excluding extreme values). Risk for consumers unlikely, regardless of the temporary MRL (tMRL) option. A risk management decision is required to decide which tMRL is the most appropriate, considering the non-compliance rate, to cover the presence of mepiquat residue in oyster mushrooms. Monitoring data confirmed that the current tMRL of 0.09 mg/kg might be sufficient for fungi different than oyster mushrooms (2% non-compliance rate) |

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**Enforcement residue definition:** Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)

MRL: maximum residue level; EMRL: extraneous MRL.

<sup>(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.  
<sup>(ft): Recent monitoring data show that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with mepiquat. This cross-contamination may not be fully avoidable in all cases. When reviewing the MRL, the Commission will take into account the information, if it is submitted by 31 December 2022, or, if that information is not submitted by that date, the lack of it (Regulation (EU) 2019/50).
Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)

| Toxicological reference values | ADI (mg/kg bw/day) | ARfD (mg/kg bw) |
|--------------------------------|--------------------|-----------------|
| LOQs (mg/kg) range from:       | 0.02               | 0.3             |
| Source of ADI: Source of ARfD: | EFSA PRIMo revision 3.1; 2019/03/19 | Year of evaluation: |

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Milk: Cattle                   | 7%                                | --                                           |
| Rapeseeds/canola seeds         | 6%                                | --                                           |
| Cotton seeds                   | 6%                                | --                                           |
| Swine: Muscle/meat             | 6%                                | --                                           |
| Milk: Cattle                   | 6%                                | --                                           |
| Rapeseeds/canola seeds         | 6%                                | --                                           |
| Rapeseeds/canola seeds         | 5%                                | --                                           |
| Swine: Muscle/meat             | 4%                                | --                                           |
| Milk: Cattle                   | 4%                                | --                                           |
| Rapeseeds/canola seeds         | 3%                                | --                                           |
| Rapeseeds/canola seeds         | 3%                                | --                                           |
| Rapeseeds/canola seeds         | 2%                                | --                                           |
| Cotton seeds                   | 2%                                | --                                           |
| Milk: Cattle                   | 2%                                | --                                           |
| Swine: Muscle/meat             | 1%                                | --                                           |
| Milk: Cattle                   | 1%                                | --                                           |
| Rapeseeds/canola seeds         | 1%                                | --                                           |
| Oat                            | 0.9%                              | --                                           |
| Milk: Cattle                   | 0.9%                              | --                                           |
| Oat                            | 0.8%                              | --                                           |
| Milk: Cattle                   | 0.7%                              | --                                           |
| Sunflower seeds                | 0.6%                              | --                                           |
| Barley                          | 0.5%                              | --                                           |
| Milk: Cattle                   | 0.5%                              | --                                           |
| Swine: Muscle/meat             | 0.5%                              | --                                           |
| Bovine: Muscle/meat            | 0.4%                              | --                                           |
| Milk: Cattle                   | 0.4%                              | --                                           |
| Bovine: Muscle/meat            | 0.3%                              | --                                           |
| Bovine: Muscle/meat            | 0.2%                              | --                                           |
| Poppy seeds                    | 0.1%                              | --                                           |

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health concern.

### Details – acute risk assessment

| Commodity/group of commodities | Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment |
|--------------------------------|--------------|-----------------------------------|-----------------------------------------------|
| Milk: Cattle                   |              |                                   |                                               |
| Swine: Muscle/meat             |              |                                   |                                               |
| Rapeseeds/canola seeds         |              |                                   |                                               |
| Cotton seeds                   |              |                                   |                                               |

**Conclusion:**

The long-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health concern.
Acute risk assessment

Scenario 1 (VF 7)

The acute risk assessment is based on the ARfD.

The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Highest % of ARfD | Commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD | Commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|------------------|-------------|--------------------------|---------------------|------------------|-------------|--------------------------|---------------------|
| 17%              | Cultivated fungi | 0.09/2.95                | 50                  | 5%              | Cultivated fungi | 0.09/2.95                | 15                  |
| 13%              | Sunflower seeds | 40/12.5                  | 40                  | 4%              | Sunflower seeds | 40/12.5                  | 13                  |
| 4%               | Linseeds       | 40/11.5                  | 12                  | 3%              | Popsy seeds    | 40/11.5                  | 8.1                 |
| 4%               | Mustard seeds  | 40/11.5                  | 12                  | 3%              | Mustard seeds  | 40/11.5                  | 8.1                 |
| 3%               | Wheat          | 30/6                     | 8.7                 | 2%              | Linseeds       | 40/11.5                  | 5.5                 |
| 2%               | Milk: Cattle   | 0.07/0.05                | 6.2                 | 2%              | Wheat          | 30/6                     | 5.0                 |
| 2%               | Rape seeds/turnips seeds | 15/3.65                | 5.0                 | 1%              | Barley         | 40/7.3                   | 3.5                 |
| 1%               | Barley         | 40/7.3                   | 4.1                 | 1.0%            | Rye            | 30/6                     | 2.9                 |
| 1%               | Bovine: Liver  | 0.5/0.46                 | 4.0                 | 0.9%            | Sheep: Liver   | 0.6/0.94                 | 2.6                 |
| 0.9%             | Milk: Goat     | 0.15/0.07                | 1.7                 | 0.6%            | Milk: Cattle   | 0.07/0.05                | 1.9                 |
| 0.5%             | Bovine: Kidney | 0.8/0.4                  | 1.5                 | 0.6%            | Rape seeds/turnips seeds | 15/3.65 | 1.9 |
| 0.3%             | Egg: Chicken   | 0.07/0.07                | 0.87                | 0.4%            | Milk: Goat     | 0.15/0.07                | 1.3                 |
| 0.3%             | Poultry: Muscle/meat | 0.05/0.05 | 0.85 | 0.4% | Milk: Sheep | 0.15/0.07 | 1.1 |
| 0.3%             | Oat            | 30/7.3                   | 0.81                | 0.3%            | Bovine: Kidney | 0.8/0.4                 | 0.84                |

### Results for adults

| Highest % of ARfD | Commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD | Commodities | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|------------------|-------------|--------------------------|---------------------|------------------|-------------|--------------------------|---------------------|
| 10%              | Sunflower seeds/oil | 40/25                  | 25                  | 2%              | Barley/bread | 40/16                   | 5.5                 |
| 5%               | Cultivated fungi/fried | 0.09/2.95          | 15                  | 0.9%            | Wheat/bread/pizza | 30/6 | 2.6 |
| 2%               | Wheat milling (flour) | 30/6                 | 7.3                 | 0.8%            | Wheat/pasta  | 30/6                    | 2.3                 |
| 1%               | Wheat milling (wholemeal)-baking | 30/6 | 3.3 | 0.7% | Wheat/bread (wholemeal) | 30/6 | 2.1 |
| 0.9%             | Oat/rolled    | 30/7.3                  | 2.6                 | 0.4%            | Oat/rolled   | 30/7.3                  | 1.1                 |
| 0.9%             | Barley/rolled | 40/7.3                  | 2.6                 |                  |              |                          |                     |
| 0.7%             | Oat/rolled    | 30/7.3                  | 2.2                 |                  |              |                          |                     |
| 0.7%             | Oat/rolled    | 30/7.35                 | 2.2                 |                  |              |                          |                     |
| 0.7%             | Barley/bread  | 40/7.3                  | 2.1                 |                  |              |                          |                     |
| 0.4%             | Barley/milling (flour) | 40/7.3          | 1.3                 |                  |              |                          |                     |

### Total number of commodities exceeding the ARfD/ADI in children and adult diets

**Unprocessed commodities**

**Processed commodities**

**Conclusion:**

No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARfD/ADI was identified.
### Scenario 2 (VF 3)

The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

#### Results for all crops

| Commodity                          | MRL/ADI | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------------------|---------|---------------------|-----------------------|
| Sunflower seeds                   | 40/17.2| 40                  | 4%                    |
| Linseeds                           | 40/11.5| 33                  | 3%                    |
| Mustard seeds                      | 40/11.5| 12                  | 2%                    |
| Wheat                              | 0.07/0.25| 0.07              | 2%                    |
| Rapeseeds/canola seeds             | 15/3.65| 33                  | 1%                    |
| Barley                             | 40.73  | 4.1                 | 1%                    |
| Rye                                | 35/6.8 | 3.8                 | 0.7%                  |
| Milk: Goat                         | 0.15/0.07| 0.15             | 0.6%                  |
| Bovine: Kidney                     | 0.8/0.4| 1.5                 | 0.6%                  |
| Eggs: Chicken                      | 0.07/0.07| 0.07             | 0.4%                  |
| Poultry: Muscle/meat               | 0.05/0.05| 0.05             | 0.3%                  |
| Oat                                | 3.07/3.2| 0.81               | 0.3%                  |

#### No exceedance of the toxicological reference value was identified for any unprocessed commodity.

A short-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health risk.

#### Results for children

| Commodity                          | MRL/ADI | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------------------|---------|---------------------|-----------------------|
| Sunflower seeds                   | 40/25  | 33                  | 3%                    |
| Cultivated fungi                   | 0.092/0.95| 0.092          | 3%                    |
| Linseeds                           | 40/11.5| 12                  | 3%                    |
| Mustard seeds                      | 40/11.5| 12                  | 2%                    |
| Wheat                              | 0.07/0.05| 0.07            | 2%                    |
| Barley                             | 40.73  | 4.1                 | 1%                    |
| Milk: Goat                         | 0.15/0.07| 0.15            | 0.6%                  |
| Bovine: Kidney                     | 0.8/0.4| 1.5                 | 0.6%                  |
| Eggs: Chicken                      | 0.07/0.07| 0.07             | 0.4%                  |
| Oat                                | 3.07/3.2| 0.81               | 0.3%                  |

#### No exceedance of the toxicological reference value was identified for any processed commodity.

A short-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health risk.

#### Results for adults

| Commodity                          | MRL/ADI | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|------------------------------------|---------|---------------------|-----------------------|
| Sunflower seeds                   | 40/17.2| 40                  | 4%                    |
| Cultivated fungi                   | 0.092/0.95| 0.092          | 3%                    |
| Linseeds                           | 40/11.5| 33                  | 3%                    |
| Mustard seeds                      | 40/11.5| 12                  | 3%                    |
| Wheat                              | 0.07/0.05| 0.07            | 2%                    |
| Barley                             | 40.73  | 4.1                 | 1%                    |
| Milk: Cattle                       | 0.15/0.05| 0.15            | 0.6%                  |
| Bovine: Liver                      | 0.8/0.4| 1.5                 | 0.6%                  |
| Eggs: Chicken                      | 0.07/0.07| 0.07             | 0.4%                  |
| Oat                                | 3.07/3.2| 0.81               | 0.3%                  |

#### No exceedance of the toxicological reference value was identified for any processed commodity.

A short-term intake of residues of Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride) is unlikely to present a public health risk.
## Appendix D – Input values for the dietary exposure calculations

### D.1. 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 | | | | |
| Cultivated fungi         | 0.087                   | Median residue concentration, monitoring data on oyster mushrooms | 2.95               | Highest residue concentration, monitoring data on oyster mushrooms |
| Linseed                  | 11.5                    | STMR (EFSA, 2018b,c)  |                      | Acute risk assessment focussed on the crop under consideration |
| Poppy seed               | 11.5                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Rapeseed                 | 3.65                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Sunflower seed           | 12.5                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Mustard seed             | 11.5                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Gold of pleasure         | 11.5                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Cotton seed(a)           | 1.70                    | STMR (EFSA, 2018c)    |                      |                      |
| Barley, oats grain       | 0.73                    | STMR (EFSA, 2015)     |                      |                      |
| Wheat, rye grain         | 0.60                    | STMR (EFSA, 2015)     |                      |                      |
| **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 (EFSA, 2018b,c)  |                      | Acute risk assessment focussed on the crop under consideration |
| Swine fat                | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Swine liver(b)           | 0.08                    | STMR × CF (EFSA, 2018b,c) |                      |                      |
| Swine kidney             | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Bovine and equine muscle | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Bovine, equine fat       | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Bovine, equine liver(b)  | 0.34                    | STMR × CF (EFSA, 2018b,c) |                      |                      |
| Bovine, equine kidney    | 0.22                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Sheep, goat muscle       | 0.06                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Sheep, goat fat          | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Sheep, goat liver(b)     | 0.48                    | STMR × CF (EFSA, 2018b,c) |                      |                      |
| Sheep, goat kidney       | 0.36                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Poultry muscle           | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Poultry fat              | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Poultry liver            | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Cattle, equine milk      | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Sheep, goat milk         | 0.07                    | STMR (EFSA, 2018b,c)  |                      |                      |
| Birds’ eggs              | 0.05                    | STMR (EFSA, 2018b,c)  |                      |                      |

STMR: supervised trials median residue; CF: conversion factor.

(a): MRL set as temporary, valid until 30 June 2021 in accordance with Article 18(4) of Regulation (EC) No 396/2005.

(b): Conversion factor from monitoring to risk assessment of 1.7 based on the metabolism study in ruminants (EFSA, 2015).
### Appendix E – Used compound codes

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

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

<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).