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REASONED OPINION

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Modification of the temporary maximum residue levels for mepiquat in cultivated fungi and oyster mushrooms

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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 Finland to modify the temporary maximum residue level (MRL) to a permanent MRL for the active substance mepiquat in cultivated fungi (with a specific MRL for oyster mushrooms). The data submitted in support of the request (monitoring data from food business operators) are not sufficient to derive permanent MRL proposals. The assessment of these data, complemented by an analysis of the most recent monitoring data available from EU monitoring programmes, supports the conclusion that the existing *t*-MRL for cultivated fungi is still sufficient to account for the residue uptake in cultivated mushrooms other than oyster mushrooms. It was also noted that lower *t*-MRLs could be derived based on the assessment of the most recent monitoring data. A risk management decision is still needed on whether to maintain the existing *t*-MRL value. Regarding oyster mushrooms, EFSA derived different options for risk managers to eventually update the values of the temporary MRLs based on the most recent monitoring data from food business operators. Adequate analytical methods for enforcement are available to control the residues of mepiquat (expressed as mepiquat chloride) in the 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 cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat according to the current agricultural practices is unlikely to present a risk to consumer health.

KEYWORDS

consumer risk assessment, cultivated fungi, Mepiquat chloride, MRL, oyster mushrooms, pesticide

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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 set permanent maximum residue levels (MRLs) for mepiquat in cultivated fungi (except oyster mushrooms) (0.1 mg/kg) and in oyster mushrooms (3 mg/kg), on the basis of commercial monitoring data. These MRLs are intended to account for mepiquat residues which may result from the cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat according to the current agricultural practices.

The application, alongside the dossier containing the supporting data in IUCLID format, was submitted through the European Food Safety Authority (EFSA) Central Submission System on 19 December 2022. The appointed EMS assessed the dossier and declared its admissibility on 3 May 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 21 June 2023 to 12 July 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the 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 7 September 2023. The EMS proposed to modify the existing temporary MRL for mepiquat in cultivated fungi (except oyster mushrooms) from 0.09 mg/kg to 0.1, 0.07 or 0.06 mg/kg, and to modify the temporary MRL for oyster mushrooms from 0.7 mg/kg to 3, 2 or 1.5 mg/kg. However, the EMS did not support the request of the applicant to set these MRLs on a permanent basis.

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

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

The metabolism of 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 in primary and rotational crops 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]).

The current MRLs are 0.09 mg/kg for cultivated mushrooms (except oyster mushrooms) and 0.7 mg/kg for cultivated oyster mushrooms. These MRLs are temporary and in the framework of the present application, the setting of a permanent MRL for cultivated mushrooms and for oyster mushrooms was requested based on the submission of a more recent monitoring data from food business operators (FBO). According to the Regulation (EC) No 396/2005 however, only temporary MRL (*t*-MRL) can be set on the basis of monitoring data. Therefore, the setting of permanent MRLs is not supported.

In order to update this assessment of the magnitude of mepiquat residues in cultivated mushrooms, EFSA assessed the newly submitted FBO monitoring data (2018–2022) and took into account the most recent monitoring data submitted to EFSA in the framework of the official national control programmes (2018–2022).

Regarding cultivated fungi other than oyster mushrooms, it is concluded that the existing temporary MRL of 0.09 mg/kg is still expected to provide a compliance level of at least 98% (non-compliance rate ≤ 2%). Thus, the proposal by the applicant to raise the existing *t*-MRL from 0.09 to 0.1 mg/kg for cultivated fungi does not seem to be justified. It was also noted that lower t-MRLs (in the range 0.04–0.08 mg/kg) could be derived based on the assessment of the most recent monitoring data. EFSA did not propose specific change of the existing t-MRL value, but a risk management decision is still needed on whether to maintain it at the current level.

Regarding oyster mushrooms, the most recent monitoring data (specific on oyster mushrooms) from official national control programmes indicate a compliance rate of 100% (0% MRL exceedance) for the existing temporary MRL of 0.7 mg/kg over the last 4 years. However, based on an updated calculation with more recent monitoring data provided by food business operators, there are indications that the existing temporary MRL of 0.7 mg/kg may lead to a non-compliance rate of 7%. Based on this updated assessment, the option of setting a higher MRL for oyster mushrooms might be considered by risk managers. EFSA reported different MRL options (1 or 3 mg/kg) based on updated percentiles 95th, 97.5th, 99th, 99.5th and by the 95th percentile of the data population at the 95% confidence level. The MRL options and the percentiles derived by EFSA are reported in the summary Tables 1 and 2.

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. Independently from the MRL value eventually set by risk managers based on the present assessment, it was concluded, based on a worst case exposure assessment using the median and highest values derived from FBO data obtained on oyster mushrooms, that the short-term and long-term intake of residues resulting from the cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat according to the current agricultural practices is unlikely to present a risk to consumer health.

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

TABLE 1 Overview of the statistical indicators supporting different MRL options for cultivated mushrooms other than oyster mushrooms and for oyster mushrooms base on various dataset.

		Updated assessment (including new data from present assessment)		Previous assessment data (EFSA, 2019c)	
	Percentiles[a]	FBO data 2011–2022	EU monitoring 2018–2022	FBO data 2011–2019	EU monitoring 2014–2017
Cultivated mushrooms other than oyster mushrooms	P95	0.060	0.04	0.066	0.065
	P97.5	0.079	0.05	0.079	0.070
	P99	0.144	0.061	0.092	0.146
	P99.5	0.230	0.078	0.170	n.r.
	P95/95 UCL[b]	0.066	0.05	0.079	0.065
	% of samples exceeding *t*-MRL (0.09 mg/kg)	2%	0.32%	2%	2%
Oyster mushrooms	P95	0.910	0.021	0.878	n.a.
	P97.5	2.500	0.042	2.843	n.a.
	P99	2.843	0.063	2.948	n.a.
	P99.5	2.948	0.23[b]	2.948	n.a.
	P95/95 UCL[b]	2.948	0.052	2.948	n.a.
	% of samples exceeding *t*-MRL (0.7 mg/kg)	7%	0%	5%	n.a.

Abbreviations: FBO, food business operators; n.a., not available; n.r., not reported.

[a]Percentiles and upper confidence level were calculated using SAS® software.

[b]Upper confidence level.

TABLE 2 MRL summary table.

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)				
0280010	Cultivated fungi (except oyster mushrooms)	0.09[ft]	No change (Risk management consideration)	The applicant's proposal to set permanent MRL is not supported An updated assessment of the available monitoring data (from food business operators and from EU monitoring programmes) indicate that the existing temporary MRL of 0.09 mg/kg provides a compliance level of minimum 98% (non-compliance rate ≤ 2%) and is thus sufficient to account for the residue uptake in cultivated mushrooms. The proposal of the applicant to raise the *t*-MRL to 0.1 mg/kg is thus not properly justified It was noted that lower *t*-MRLs (in the range 0.04–0.08 mg/kg) could be derived based on the assessment of the most recent monitoring data. EFSA did not propose specific change of the existing *t*-MRL value but a risk management decision is still needed on whether to maintain it at the current level Risk for consumers unlikely regardless of the temporary MRL option
0280010–008	Oyster mushrooms	0.7	No change or 1 mg/kg or 3 mg/kg (Risk management consideration)	The applicant's proposal to set permanent MRL in oyster mushrooms is not supported The new EU monitoring data specific to oyster mushrooms (2018–2022) do not indicate non-compliance issue over the period 2018–2022 with the current *t*-MRL However, an updated assessment of the available monitoring data from food business operators indicates that the existing temporary MRL of 0.7 mg/kg may lead to a non-compliance rate of 7% Based on an updated assessment of the available monitoring data from food business operators, a higher *t*-MRL of 1 mg/kg could be set based on Percentile 95th. Furthermore, a *t*-MRL of 3 mg/kg would be supported by Percentiles 97.5th, 99th, 99.5th and by the 95th percentile of the data population at the 95% confidence level Risk for consumers unlikely regardless of the temporary MRL option

Abbreviations: EU, European Union; MRL, maximum residue level; *t*-MRL, temporary maximum residue level.

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

[ft]The following MRL applies to oyster mushrooms: 0.7 mg/kg. Monitoring data show that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with mepiquat. 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. (Reg. (EU) 2021/2202).

ASSESSMENT

The European Food Safety Authority (EFSA) received an application to modify the existing temporary maximum residue level (MRL) for mepiquat in cultivated fungi. 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 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). 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 EFSA (EFSA, 2008). Mepiquat was approved[2] for the use as a plant growth regulator on 1 March 2009. The process of renewal of the first approval of the active substance is currently ongoing.

The EU MRLs for mepiquat are established in Annexes II and IIIA of Regulation (EC) No 396/2005.[3] The review of the 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 several reasoned opinions on the modification of the MRLs for mepiquat, including the reasoned opinions on the setting of temporary MRLs for mepiquat in cultivated fungi (EFSA, 2016) and in oyster mushrooms (EFSA, 2019c). The proposals from these reasoned opinions have been considered in recent MRL regulations.[4] Codex MRLs are not set for mepiquat.

In accordance with Article 6 of Regulation (EC) No 396/2005 and following the provisions set by the 'Transparency Regulation' (EU) 2019/1381,[5] the applicant BASF SE submitted on 19 December 2022 an application to set specific MRLs for all cultivated fungi, except oyster mushrooms and for oyster mushrooms specifically to the competent national authority in Finland, alongside the dossier containing the supporting data using the IUCLID format.

The appointed EMS Finland assessed the dossier and declared its admissibility on 3 May 2023. Subsequently, following the implementation of the EFSA's confidentiality decision, the non-confidential version of the dossier was published by EFSA, and a public consultation launched on the dossier. The consultation aimed to consult stakeholders and the public on the scientific data, studies and other information part of, or supporting, the submitted application, in order to identify whether other relevant scientific data or studies are available. The consultation run from 21 June 2023 to 12 July 2023. No additional data nor comments were submitted in the framework of the consultation.

At the end of the commenting period, the EMS proceeded drafting the evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the EFSA on 7 September 2023. The EMS proposed to modify the existing temporary MRL in cultivated fungi (except oyster mushrooms) from 0.09 mg/kg to 0.1, 0.07 or 0.06 mg/kg, and to modify the temporary MRL for oyster mushrooms from 0.7 mg/kg to 3, 2 or 1.5 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 and Article 16 of the MRL regulation.

EFSA based its assessment on the evaluation report submitted by the EMS (Finland, 2023), the 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 previous EFSA opinions on mepiquat (EFSA, 2016, 2018b, 2018c, 2018d, 2019b, 2019c), including the reasoned opinion on the MRL review according to Article 12 of Regulation No 396/2005 (EFSA, 2015).

For this application, the data requirements established in Regulation (EU) No 544/2011[6] and the guidance documents applicable at the date of submission of the IUCLID application are applicable (European Commission, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2010, 2020, 2021, 2022 ; OECD, 2011). 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.[7]

[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: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

[5]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, PE/41/2019/REV/1. OJ L 231, 6.9.2019, p. 1–28.

[6]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.

[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.

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 may need to be reconsidered in the light of the outcome of the peer review.

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, is presented in Appendix B.

The evaluation report submitted by the EMS (Finland, 2023) 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.[8]

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%–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 crop groups investigated, in accordance with the current guidelines, a general residue definition was derived by EFSA, which also covers cultivated fungi (EFSA, 2016).

In the previous assessment of temporary MRLs in oyster mushrooms, EFSA highlighted that investigation on the nature of residues in fungi would be desirable considering that the metabolism might be different in fungi growing as saprophytic organism (EFSA, 2019c). Such data have not been submitted so far.

1.1.2 | Nature of residues in rotational crops

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, the monitoring data have shown a significant uptake of mepiquat chloride from growing substrate (cereals straw) to cultivated mushrooms.

Rotational crop metabolism studies provide useful information on the uptake of mepiquat chloride from soil by plants. 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 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.

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, 2015).

1.1.4 | Analytical methods for enforcement purposes in plant commodities

Analytical methods using liquid chromatography–tandem mass spectrometry detector (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, 2019c).

Consequently, additional data are not required and have been submitted in the framework of the present application.

[8]Background documents to this reasoned opinion are published on OpenEFSA portal and are available at the following link: https://open.efsa.europa.eu/study-inventory/EFSA-Q-2023-00326

However, the Guideline Document on Extraction Efficiency (European Commission, 2022) states that for the applications for new MRLs under Art. 6 of Reg. (EC) No 396/2005, which are submitted after 23 November 2019, the extraction efficiency of analytical methods needs to be demonstrated in line with this document. For the present application, data to assess the extraction efficiency of the monitoring method and the data generation methods in high-water content matrices have not been submitted. Metabolism studies with high-water content matrix are not available to investigate the suitability of extraction procedures and there is also no information available which solvent systems have been used to generate monitoring data for mepiquat residues in mushrooms.

Thus, EFSA concludes that the extraction efficiency of the analytical methods applied for enforcement and data generation in high-water content matrices to which fungi belongs is not proven according to the requirements of the above guidance.

The EMS noted that the renewal process for mepiquat is currently ongoing and according to the most recent information reported in this framework, all the analytical methods (including the enforcement method mentioned above) use water or methanol-based extraction solvents. On the basis of the solubility data for mepiquat chloride and the extraction data from the crop metabolism studies, the EMS concluded that the extraction solvents used in the residue analytical methods are likely to extract incurred residues of mepiquat. Nevertheless, EFSA would recommend that all data on extraction efficiency which were submitted for all types of crops in the framework of this application are further considered and confirmed in the framework of the ongoing peer review for the renewal of approval of the active substance.

1.1.5 | Storage 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, 2015), 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 to the above-mentioned residue definition.

1.2 | Magnitude of residues in plants

MRLs on cultivated fungi are intended by the applicant to account for mepiquat residues which may result from the cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat according to the current agricultural practices.

In support of the last application for temporary maximum residue levels (*t*-MRLs) in mushrooms, the applicant submitted monitoring data on residues of mepiquat in cultivated mushrooms, including oyster mushrooms, as compiled by food business operators over the period of 2011–2019 (EFSA, 2019c). The samples were analysed in private laboratories. In support of the present MRL application, the applicant submitted an update of the monitoring data over the period of 2019–2022 as provided by food business operators (see Section 1.2.1.1).

In addition to these data, EFSA took into consideration the EU monitoring data on mepiquat chloride in cultivated fungi collected 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.

All residues were expressed as mepiquat chloride.

1.2.1 | Magnitude of residues in primary crops

1.2.1.1 | *Monitoring data from food business operators (FBO)*

Cultivated mushrooms other than oyster mushrooms

In the *t*-MRL assessment of 2019, a total of 306 samples analysed for mepiquat chloride were reported for mushroom varieties different than oyster. Samples dating from years 2011 to 2018 originated from the Netherlands, Poland, Belgium, Germany, France, Italy, Ireland, the United Kingdom and from Ireland/UK (EFSA, 2019c). Based on these data,

the percentage of MRL exceedance was of 2%, for the existing MRL of 0.09 mg/kg. Consequently, no change of the existing *t*-MRL was proposed (EFSA, 2019c).

In support of the present MRL application, more recent monitoring data from food business operators (FBO) from years 2019 to 2022 were submitted. For each result, the original laboratory report, accreditation of the laboratory and information of the analytical methods used were available. This dataset consists of 87 new samples originating from Belgium and the Netherlands (Finland, 2023).

The overview of the FBO monitoring data on mepiquat chloride concentrations found in the different datasets (old, new, overall) is presented in Appendix B.1.2.2 (a). In this Appendix, EFSA also reported the summary statistic, and the percentile estimates generally used to derive *t*-MRLs. All the statistics were performed using the upper bound approach, therefore considering the LOQ values for those samples where the residue concentrations were below LOQ. Histograms showing the distribution of mepiquat chloride concentrations found in the different datasets are also reported.

The recent data (2019–2022) do not show a significant change in the mepiquat chloride concentrations found in cultivated mushrooms compared to the previous assessment of 2019. Considering all the available samples from 2011 to 2022 ($n = 393$), the percentage of MRL exceedance remains 2%. On the basis of the exceedance rate observed in FBO data, the existing t-MRL seems to be sufficient to account for mepiquate residue uptake in cultivated fungi. The MRL options derived for cultivated fungi, in relation with the EMS proposal are discussed in detail in Section 1.2.4.

Cultivated oyster mushrooms

In the t-MRL assessment of 2019, a total of 74 samples analysed for mepiquat chloride were reported for oyster mushrooms (*Pleurotus ostreatus)*. Samples dating from years 2015 to 2019 originated from the Netherlands, Poland, Belgium, Germany, Hungary and from the United Kingdom (EFSA, 2019c). These data were used to derive different MRL options for oyster mushroom, acknowledging that levels and frequency of mepiquat chloride in oyster mushrooms was higher compared to other mushroom varieties. A *t*-MRL of 0.7 mg/kg was finally set in the Regulation for oyster mushrooms.

In support of the present MRL application, more recent monitoring data from FBO from years 2018 to 2022 were submitted. For each result, the original laboratory report, accreditation of the laboratory and information of the analytical methods used were available. This dataset consists of 27 new samples originating from Belgium and the Netherlands (Finland, 2023).

The overview of the monitoring data mepiquat chloride concentrations found in the different datasets (old, new, overall) is presented in Appendix B.1.2.2 (b). In this Appendix, EFSA also reported the summary statistic, and the percentile estimates generally used to derive t-MRLs. All the statistics were performed using the upper bound approach, therefore considering the LOQ values for those samples where the residue concentrations were below LOQ. Histograms showing the distribution of mepiquat chloride concentrations found in the different datasets are also reported.

The recent data (2018–2022) show higher average mepiquat chloride concentrations in oyster mushrooms compared to the previous assessment of 2019 (0.298 mg/kg compared to 0.222 mg/kg) and a higher percentage of MRL exceedance (11% compared to 5%). Considering data of all the available samples from 2015 to 2022 ($n = 101$), the MRL exceedance rate is 7%. This exceedance rate indicates that the existing t-MRL in oyster mushrooms might not be sufficient in all cases to account for mepiquat residue uptake in oyster mushrooms. The MRL options derived for cultivated fungi, in relation with the EMS proposal are discussed in detail in Section 1.2.4.

1.2.1.2 | *Monitoring data from for EU pesticide residue monitoring*

In the framework of Article 32 of Regulation (EC) No 396/2005 (official national control programmes), monitoring data were submitted to EFSA. For the present assessment, an extraction of these data was performed by EFSA to retrieve the results for mepiquat and mepiquant chloride in cultivated mushrooms.

In the reference period from 2014 to 2017 (reported as period 1), details on the mushroom variety analysed were not reported. However, in the period 2018 to 2022 (reported as period 2), the mushrooms varieties were reported and, monitoring data were separately available for oyster mushrooms.

The results for the reference period from 2014 to 2017 were already considered and reported in the previous assessment of the *t*-MRL for cultivated fungi. Based on 928 samples, 2% of non-compliance rate was observed, therefore the existing *t*-MRL of 0.09 mg/kg for cultivated fungi was maintained (EFSA, 2019c).

For the period 2018 to 2022 mepiquat and mepiquat chloride results in cultivated mushrooms and oyster mushrooms are available. The samples related to processed (dehydrated or canned) mushrooms were disregarded because only data on raw commodities are used to derive MRLs. For those samples where results were both reported as mepiquat and mepiquat chloride, EFSA retained only one value, the one expressed as mepiquat chloride. For those samples where results were reported as mepiquat, EFSA converted the values as mepiquat chloride using a factor of 1.3.[9] There were 15 samples for which the reported LOQ of the method was 10 mg/kg; considering that this is 1000 times higher than the existing LOQ of 0.01 mg/kg, these samples were disregarded. Consequently, a total of 2037 samples is available for the period 2018–2022, of which 92% originated from EU Member States and 7% from non-EU countries (for 1% of the samples the origin was unknown). A total of 166 samples were reported as oyster mushrooms, the rest ($n = 1871$) being other varieties of mushrooms (or unspecified varieties of mushrooms).

[9]The factor of 1.3 is derived from the ratio of the respective molecular weights of mepiquat chloride and mepiquat (149.66/114.21).

The summary statistic for period 1 (unspecified mushrooms varieties) and period 2 (oyster mushrooms and others cultivated mushrooms) are presented in Appendix B.1.2.2 (c). All the statistics were performed using the upper bound approach, therefore considering the LOQ values for those samples where the residue concentrations were below LOQ.

For cultivated mushrooms other than oyster mushrooms, a comparison of data between period 1 (2014–2017) and period 2 (2018–2022) indicates a decrease of 40% for the overall average mepiquat residue concentrations (0.025–0.015 mg/kg), a decrease of the percentage of quantified results (50% to 28%) and a decrease of the frequency of MRL exceedances (2% to 0.32%). Furthermore, when considering the mepiquat chloride results per year from 2014 to 2022, an overall decrease of all parameters is also observed: average residue concentration (0.036 to 0.013 mg/kg), max residue value (0.66 to 0.09 mg/kg), number MRL exceedances (8 to 1) (see Appendix B.1.2.2 (d) and Figure B.7). Consequently, there are indications that the existing *t*-MRL of 0.07 mg/kg is sufficient to account for mepiquat residues in cultivated fungi. The MRL options derived for cultivated fungi, in relation with the EMS proposal are discussed in detail in Section 1.2.4.

Regarding oyster mushrooms, the most recent specific monitoring data (2018–2022) show an absence of MRL exceedance for the period 2018–2022, indicating that the existing temporary MRL in oyster mushrooms sufficiently covers the uptake of mepiquat chloride residues. The MRL options derived for cultivated fungi, in relation with the EMS proposal are discussed in detail in Section 1.2.4.

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

The current MRLs for mepiquat chloride are 0.09 mg/kg for cultivated mushrooms and 0.7 mg/kg for oyster mushrooms. These MRLs are temporary, and their last assessment was done in 2019 (EFSA, 2019c). In the framework of the present application, the setting of a permanent MRL for cultivated mushrooms at a level of 0.1 mg/kg and for oyster mushrooms at a level of 3 mg/kg was requested based on the submission of more recent monitoring data from food business operators (FBO) (Finland, 2023).

According to the Regulation (EC) No 396/2005 however, only *t*-MRL can be set based on monitoring data. Therefore, the setting of permanent MRLs is not supported.

In order to estimate whether the existing temporary MRLs are sufficient to account for the uptake of mepiquat chloride residues in cultivated fungi and oyster mushrooms, EFSA assessed the newly submitted FBO monitoring data (2018–2022) and took into account with the most recent monitoring data submitted to EFSA in the framework of the official national control programmes (2018–2022).

In Appendix B.4.1, EFSA reported the statistical indicators that are generally used to derive MRLs from monitoring data using the methodologies developed by FAO (FAO, 2016) and the rate of MRL exceedance for each dataset (i.e. for cultivated mushrooms other than oyster mushrooms and for oyster mushrooms, for the previous assessment of 2019 and for the updated assessment). EFSA calculated the residue concentrations corresponding to 95th, 97.5th, 99th, 99.5th percentiles and the concentration corresponding to the 95th percentile of the data population at the 95% confidence level (approach laid down in Regulation (EU) No 283/2013[10]).

Cultivated mushrooms other than oyster mushrooms

The updated assessment of the FBO data indicate that the existing temporary MRL of 0.09 mg/kg provide a compliance level of 98% (non-compliance rate of 2%). Furthermore, according to the most recent EU monitoring data, the rate of MRL non-compliance was 0.32% of all samples tested over the last 4 years.

Therefore, the proposal of the applicant to raise the t-MRL to the value of 0.1 mg/kg does not seem to be justified.

Furthermore, it is noted that, based on the most recent EU monitoring data (2018–2022), lower t-MRLs (in the range 0.04–0.08 mg/kg) could be derived based on Percentiles 95th, 97.5th, 99th or 99.5th and on the 95th percentile of the data population at the 95% confidence level. Based the updated assessment of the FBO data, lower t-MRLs (in the range

[10]Regulation (EU) No 283/2013 - Part A - Section 6.7.2: *'In exceptional cases, when the conditions laid down in Article 16(1) to Regulation (EC) No 396/2005 are met, MRLs may be proposed on the basis of monitoring data. In such cases the proposal shall cover the 95th percentile of the data population at the 95% confidence level'.*

0.06–0.08 mg/kg) could be derived based on Percentiles 95th and 97.5th and on the 95th percentile of the data population at the 95% confidence level.

EFSA do not propose specific change of the existing t-MRL value, but a risk management decision will be needed on whether to maintain it at the current level.

Cultivated oyster mushrooms

The updated assessment of the FBO data indicate that the existing temporary MRL of 0.7 mg/kg may lead to a non-compliance rate of 7%. This is not confirmed by the most recent EU monitoring data (specific on oyster mushrooms) from official national control programmes, which shows 100% of MRL compliance (0% exceedance) of samples taken over the last 4 years.

Based on an updated assessment of the available FBO monitoring data, the option of setting a higher MRL might be considered by risk managers. Based on Percentile 95th of the available FBO monitoring data (0.91 mg/kg), a new higher *t*-MRL of 1 mg/kg could be set. Based on the same dataset, the MRL of 3 mg/kg as requested by the applicant, would be supported by the Percentiles 97.5th, 99th, 99.5th and by the 95th percentile of the data population at the 95% confidence level.

In Section 3, EFSA assessed whether residues on cultivated fungi, resulting from the cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat, 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 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 bodyweight (bw) per day and an acute reference dose (ARfD) of 0.3 g/kg bw for mepiquat chloride (European Commission, 2008).

In the assessment of the temporary MRLs for cultivated fungi of 2019, EFSA performed a dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018a, 2019a) and the current toxicological reference values for mepiquat. In this previous assessment, long-term (chronic) and short-term (acute) exposure assessments were performed considering the monitoring data from food business operators on oyster mushrooms. The median residue value (0.087 mg/kg) was used for the chronic exposure assessment and the highest residue value (2.95 mg/kg) was used for the acute exposure assessment. As the PRIMo model does not contain specific consumption data for oyster mushrooms, the exposure calculations were performed using consumption data for cultivated fungi which cover all varieties of cultivated mushrooms (EFSA, 2019c).

Using the default variability factor of 7 or an adjusted variability factor of 3, no acute consumer risks were identified (17% and 11% of the ARfD, respectively). Regarding the chronic exposure, the estimated long-term dietary intake of mepiquat chloride was in the range of 0.1%–7% of the ADI, while the contribution of cultivated fungi accounted for up to 0.01% of the ADI (EFSA, 2019c).

Based on the updated FBO data submitted for the present MRL request, an updated median value was derived in the present opinion, based on the worst case data provided for oyster mushrooms. This median value (0.068 mg/kg) is lower than the median value derived in 2019. The maximum value of the updated FBO dataset, also derived from oyster mushrooms, is 2.95 mg/kg, and is therefore unchanged compared to the previous assessment of 2019. The most recent data from the EU monitoring programmes indicate lower median values (0.01 mg/kg) and maximum values (0.23 and 0.27 mg/kg) for both oyster mushrooms and other cultivated mushrooms.

Consequently, it is concluded that the data submitted in the present opinion and the updated monitoring data from the EU monitoring programmes do not trigger a modification of previous risk assessment performed for mepiquat in the framework of the last MRL assessment (EFSA, 2019c).

It can be concluded that the short-term and long-term intake of residues resulting from the cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat according to the current agricultural practices is unlikely to present a risk to consumer health. This conclusion may need to be reconsidered in the light of the outcome of the ongoing EU pesticides peer review for the renewal of approval of the active substance.

For convenience, the input values used in the exposure calculations performed in 2019, which are unchanged are summarised in Appendix D.1 and the detailed results of the long-term and short term exposures are presented in Appendix B.3. For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is also presented in Appendix C.

4 | CONCLUSION AND RECOMMENDATIONS

The data on the occurrence of mepiquat residues in mushrooms submitted in support of this MRL application are not sufficient to support the setting of permanent MRLs for cultivated mushrooms and for oyster mushrooms because according to the Regulation (EC) No 396/2005 only t-MRL can be set based with monitoring data.

EFSA assessed the newly submitted FBO monitoring data (2018–2022) and took into account the most recent monitoring data submitted to EFSA in the framework of the official national control programmes (2018–2022).

Regarding cultivated fungi other than oyster mushrooms, on the basis of data submitted by the FBO and considering monitoring data from official national control programmes, it is concluded that the existing temporary MRL of 0.09 mg/kg is still expected to provide a compliance level of at least 98% (non-compliance rate ≤ 2%). The proposal to raise the existing *t*-MRL from 0.09 to 0.1 mg/kg for cultivated fungi therefore does not seem to be justified. It was also noted that lower *t*-MRLs (in the range 0.04–0.08 mg/kg) could be derived based on the assessment of the most recent monitoring data. EFSA did not propose specific change of the existing *t*-MRL value but a risk management decision is still needed on whether to maintain it at the current level.

Regarding oyster mushrooms, the most recent monitoring data (specific on oyster mushrooms) from official national control programmes indicate a compliance rate of 100% (0% MRL exceedance) with the existing temporary MRL of 0.7 mg/kg for all samples taken over the last 4 years. However, based on an updated calculation with more recent monitoring data provided by food business operators, there are indications that the existing temporary MRL of 0.7 mg/kg may lead to a non-compliance rate of 7%. Based on this updated assessment, the option of setting a higher MRL for oyster mushrooms might be considered by risk managers. EFSA reported different MRL options (1 mg/kg or 3 mg/kg) based on updated percentiles 95th, 97.5th, 99th, 99.5th and by the 95th percentile of the data population at the 95% confidence level.

Independently from the MRL value eventually set by risk managers based on the present assessment, it can be concluded that the short-term and long-term intake of residues resulting from the cross-contamination of untreated cultivated fungi (including oyster mushrooms) from cereal straw lawfully treated with mepiquat according to the current agricultural practices is unlikely to present a risk to consumer health. This conclusion may need to be reconsidered in the light of the outcome of the ongoing EU pesticides peer review for the renewal of approval of the active substance.

The MRL recommendations and the calculated percentiles supporting the different MRL options are summarised in Appendix B.4.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
cGAP	critical GAP
CV	coefficient of variation (relative standard deviation)
DALA	days after last application
DAR	draft assessment report
DAT	days after treatment
DM	dry matter
EC	emulsifiable concentrate
EMS	evaluating Member State
EURL	EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO	Food and Agriculture Organization of the United Nations
GAP	Good Agricultural Practice
HR	highest residue
IEDI	international estimated daily intake
IESTI	international estimated short-term intake
ILV	independent laboratory validation
IPCS	International Programme of Chemical Safety
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
K_{oc}	organic carbon adsorption coefficient
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue level
MS	Member States
MS/MS	tandem mass spectrometry detector
MW	molecular weight
OECD	Organisation for Economic Co-operation and Development

PBI	plant back interval
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
STMR	supervised trials median residue
TRR	total radioactive residue
WHO	World Health Organization

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CONFLICT OF INTEREST

If you wish to access the declaration of interests of any expert contributing to an EFSA scientific assessment, please contact interestmanagement@efsa.europa.eu.

REQUESTOR

European Commission

QUESTION NUMBER

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APPENDIX A

Summary of the critical GAPs assessed in the framework of the MRL review for mepiquat for cereals, leading to residues in straw

The existing authorised EU GAPs on cereals, leading to residues in cereal straw and potential cross-contaminations in cultivated mushrooms, are considered as the triggering GAPs. There are no authorised/intended uses on mushrooms.

APPENDIX B

List of end points

B.1 | RESIDUES IN PLANTS

B.1.1 | Nature of residues and analytical methods for enforcement purposes in plant commodities

B.1.1.1 | Metabolism studies, analytical methods and residue definitions in plants

Primary crops (available studies)	Crop groups	Crop(s)	Application(s)	Sampling (DAT)	Comment/source
	Fruit crops	Grape	Foliar, 2 × 1.1 kg/ha	98	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
	Root crops	–	–	–	–
	Leafy crops	–	–	–	–
	Cereals/grass	Wheat	Foliar, 1 × 0.7 kg/ha	0, 8, 71	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
		Barley	Foliar, 1 × 0.91 kg/ha	16, 37, 52	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
	Pulses/oilseeds	Cotton	Foliar, 1 × 0.16 kg/ha	15, 67	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
		Oilseed rape	Foliar, 2 × 0.3 kg/ha	63	2,6^{14}C-mepiquat chloride (EFSA, 2015)
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	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
	Leafy crops	Lettuce	Bare soil, 0.7 kg a.s./ha	29, 120, 365	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
	Cereal (small grain)	Wheat	Bare soil, 0.7 kg a.s./ha	29, 120, 365	2,6^{14}C-mepiquat chloride (EFSA, 2008, 2015)
	Other	–	–	–	–
Processed commodities (hydrolysis study)	**Conditions**		**Stable?**		**Comment/Source**
	Pasteurisation (20 min, 90°C, pH 4)		Yes		EFSA (2008, 2015)
	Baking, brewing and boiling (60 min, 100°C, pH 5)		Yes		EFSA (2008, 2015)
	Sterilisation (20 min, 120°C, pH 6)		Yes		EFSA (2008, 2015)
	Other processing conditions		–		–

Can a general residue definition be proposed for primary crops?	Yes	EFSA (2015)
Rotational crop and primary crop metabolism similar?	Yes	EFSA (2015)
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Yes	EFSA (2015)
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).	

DAT: days after treatment; PBI: plant-back interval; a.s.: active substance; 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
				Value	Unit		
	High-water content	Wheat forage	–20	24	Months	Mepiquat	EFSA (2015)
	High-water content	–	–	–	–	–	–
	High-oil content	Cotton seed	–15	25	Months	Mepiquat	EFSA (2018b, 2018c)
	High-protein content	–	–	–	–	–	–
	Dry/high starch	Wheat grain	–20	24	Months	Mepiquat	EFSA (2015)
	High-acid content	–	–	–	–	–	–
	Processed products	–	–	–	–	–	–
	Others	Cotton forage	–15	25	Months	Mepiquat	EFSA (2018b, 2018c)

B.1.2 | Magnitude of residues in plants

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

Supervised trials assessing the residues levels in cultivated mushrooms as a result of cross-contaminations from cereal straw lawfully treated with mepiquat are not available.

B.1.2.2 | Summary of monitoring data on cultivated fungi

a) Food business operator's data on cultivated fungi other than oyster mushrooms

	Food business operators' data (merging all available data)	**New food business operators' data (Finland, 2023)**	**Food business operators' data (EFSA, 2019c)**
Variety	Mushrooms different than oyster mushrooms	Mushrooms different than oyster mushrooms	Mushrooms different than oyster mushrooms
No of samples	393	87	306
Year(s) of collection	2011–2022	2019 (Feb)–2022	2011–2018
No of samples ≥ LOQ (%samples ≥ LOQ)	223 (57%)	53 (61%)	170 (53%)
Mean (mg/kg)	0.023	0.014	0.025
Standard deviation (mg/kg)	0.024	0.024	0.024
Median (mg/kg)	0.013	0.010	0.013
Min (mg/kg)	0.005	0.005	0.005
Max (mg/kg)	0.236	0.230	0.236
P90 (mg/kg)[a]	0.043	0.024	0.052
P95 (mg/kg)[a]	0.060	0.031	0.066
P97.5 (mg/kg)[a]	0.079	0.037	0.079
P99 (mg/kg)[a]	0.144	0.230[b]	0.092
P99.5 (mg/kg)[a]	0.230	0.230[b]	0.170
P95/95 UCL (upper confidence level)[a]	0.066	0.230[b]	0.079
No of samples > current MRL (0.09 mg/kg)	8	1	7
% of samples > current MRL (0.09 mg/kg)	2%	1%	2%
Distribution	**See Figure B.1**	**See Figure B.2**	**See Figure B.3**

Abbreviations: LOQ, limit of quantification; MRL, maximum residue limit.

[a] Percentiles and upper confidence level were calculated using SAS® software.

[b] The calculated percentile coincides with the maximum value.

[c] The coverage of the confidence limit does not guarantee a confidence of 95% due to an insufficient number of values.

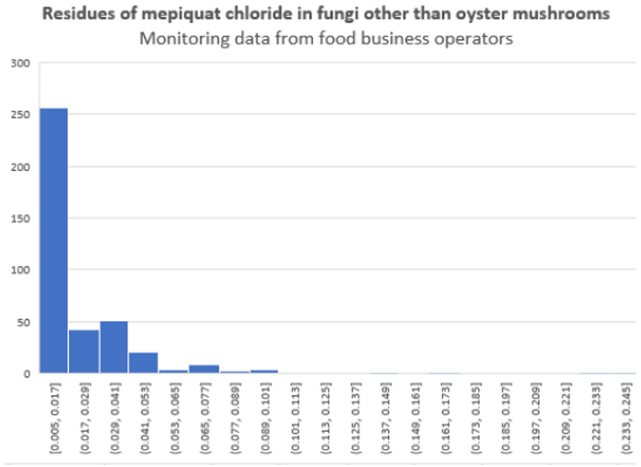


FIGURE B.1 Food business operators' monitoring data for mushrooms other than oyster mushrooms (all data since 2011).

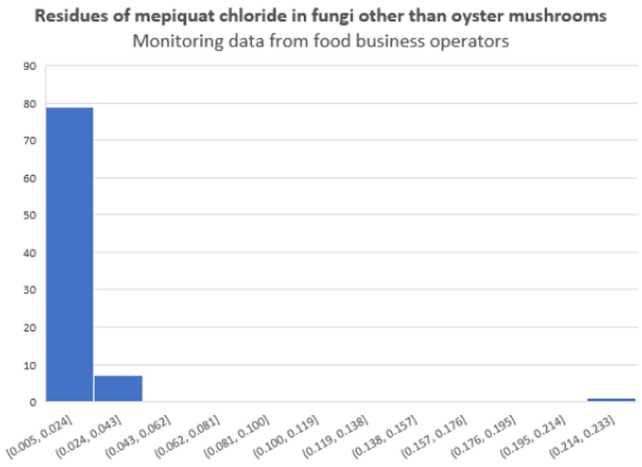


FIGURE B.2 Food business operators' monitoring data for mushrooms other than oyster mushrooms (new data since 2019).

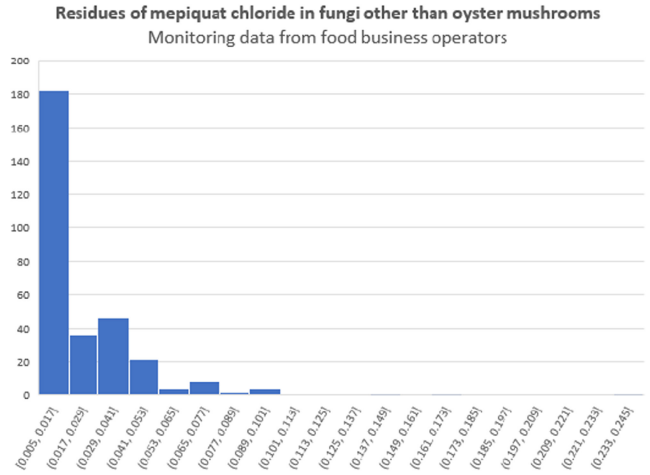


FIGURE B.3 Food business operators' monitoring data 2011–2018 for mushrooms other than oyster mushrooms (EFSA, 2019c).

b) Food business operator's data on oyster mushrooms

	Food business operators' data (merging all available data)	**New food business operators' data (Finland, 2023)**	**Food business operators' data (EFSA, 2019c)**
Variety	Oyster mushrooms	Oyster mushrooms	Oyster mushrooms
No of samples	101	27	74
Year(s) of collection	2015–2022	2018–2022	2015–2019 (Jan)
No of samples ≥ LOQ (%samples ≥ LOQ)	78 (77%)	16 (59%)	62 (84%)
Mean (mg/kg)	0.243	0.298	0.222
Standard deviation (mg/kg)	0.533	0.657	0.048
Median (mg/kg)	0.068	0.031	**0.087**
Min (mg/kg)	0.0005	0.005	0.005
Max (mg/kg)	2.948	2.500	**2.948**
P90 (mg/kg)[a]	0.550	1.300	0.420
P95 (mg/kg)[a]	0.910	2.200	0.878
P97.5 (mg/kg)[a]	2.500	2.500[b]	2.843
P99 (mg/kg)[a]	2.843	2.500[b]	2.948[b]
P99.5 (mg/kg)[a]	2.948[b]	2.500[b]	2.948[b]
P95/95 UCL (upper confidence level) (mg/kg)[a]	2.948[b]	Not estimated[c]	2.948[b]
No of samples > current MRL (0.7 mg/kg)	7	3	4
% of samples > current MRL (0.7 mg/kg)	7%	11%	5%
Distribution	**See Figure B.4**	**See Figure B.5**	**See Figure B.6**

Note: Values used in the consumer risk assessment are highlighted **in bold.**

Abbreviations: LOQ, limit of quantification; MRL, maximum residue limit.

[a]Percentiles and upper confidence level were calculated using SAS® software.

[b]The calculated percentile coincides with the maximum value.

[c]The coverage of the confidence limit does not guarantee a confidence of 95% due to an insufficient number of values.

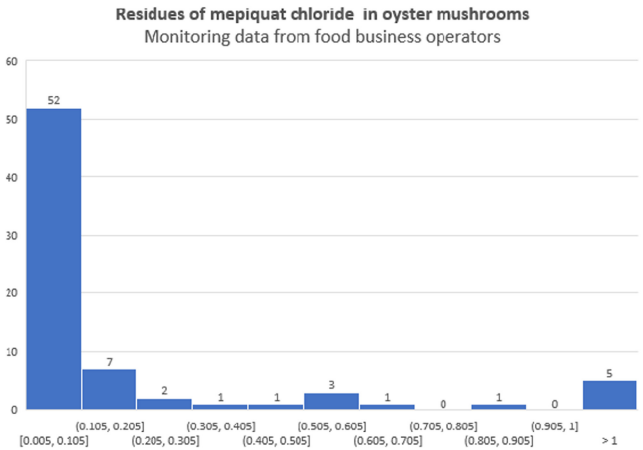


FIGURE B.4 Food business operators' monitoring data for oyster mushrooms (all data since 2015).

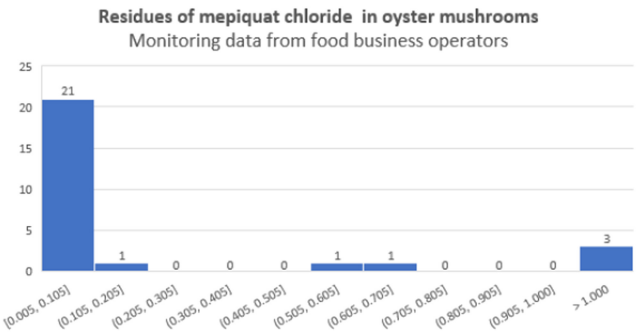


FIGURE B.5 Food business operators' monitoring data for oyster mushrooms (new data since 2019).

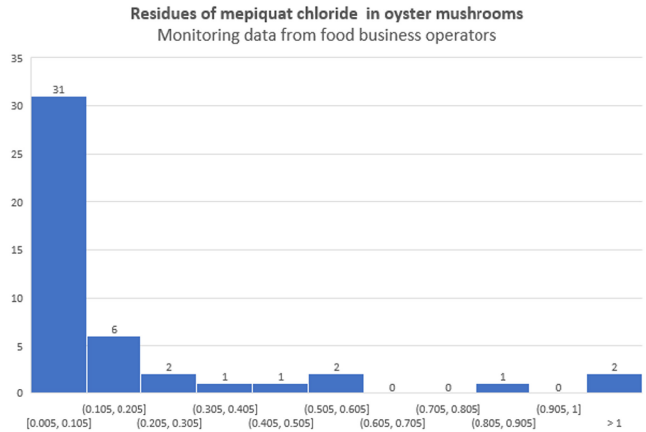


FIGURE B.6 Food business operators' monitoring data for oyster mushrooms 2015–2019 (EFSA, 2019c).

c) EU monitoring data submitted to EFSA under Art. 32 of Reg. (EC) No 396/2005

	Period 2	**Period 2**	**Period 1 (EFSA, 2019c)**
Variety	Mushrooms different than oyster mushrooms	Oyster mushrooms	Not reported (all varieties)
No of samples	1871	166	928
Year(s) of collection	2018–2022	2018–2022	2014–2017
No of samples ≥ LOQ (%samples ≥ LOQ)	515 (28%)	14 (8.4%)	460 (50%)
Mean (mg/kg)	0.015	0.012	0.025
Standard deviation (mg/kg)	0.016	0.019	0.050
Median (mg/kg)	0.01	0.01	0.013
Min (mg/kg)	0.003	0.005	0.001
Max (mg/kg)	0.27	0.23	0.845
P90 (mg/kg)[a]	0.022	0.013	0.047
P95 (mg/kg)[a]	0.04	0.021	0.065
P97.5 (mg/kg)[a]	0.05	0.042	0.070
P99 (mg/kg)[a]	0.061	0.063	0.146
P99.5 (mg/kg)[a]	0.078	0.23[b]	–
P95/95 UCL (upper confidence level) (mg/kg)[a]	0.05	0.052	0.065
No of samples > current MRL	6	0	18
% of samples > current MRL	0.32%	0%	2%

Abbreviations: LOQ, limit of quantification; MRL, maximum residue limit.

[a]Percentiles and upper confidence level were calculated using SAS® software.

[b]The calculated percentile coincides with the maximum value.

[c]The coverage of the confidence limit does not guarantee a confidence of 95% due to an insufficient number of values.

d) Yearly report of the EU monitoring data on cultivated fungi other than oyster mushrooms from 2014 to 2022

Year	Variety	Number of samples	Mean (mg/kg)	Standard deviation (mg/kg)	Max (mg/kg)	Number of samples with residues > current MRL
2014	Not reported	135	0.036	0.094	0.660	8
2015	Not reported	386	0.028	0.049	0.845	7
2016	Not reported	166	0.020	0.022	0.234	3
2017	Not reported	207	0.020	0.018	0.143	1
2018	Mushrooms different than oyster mushrooms	680	0.017	0.019	0.260	3
2019	Mushrooms different than oyster mushrooms	205	0.017	0.023	0.267	2
2020	Mushrooms different than oyster mushrooms	170	0.011	0.006	0.068	0
2021	Mushrooms different than oyster mushrooms	696	0.013	0.010	0.088	0
2022	Mushrooms different than oyster mushrooms	120	0.013	0.012	0.092	1
Total	–	2765	0.018	0.032	0.845	25

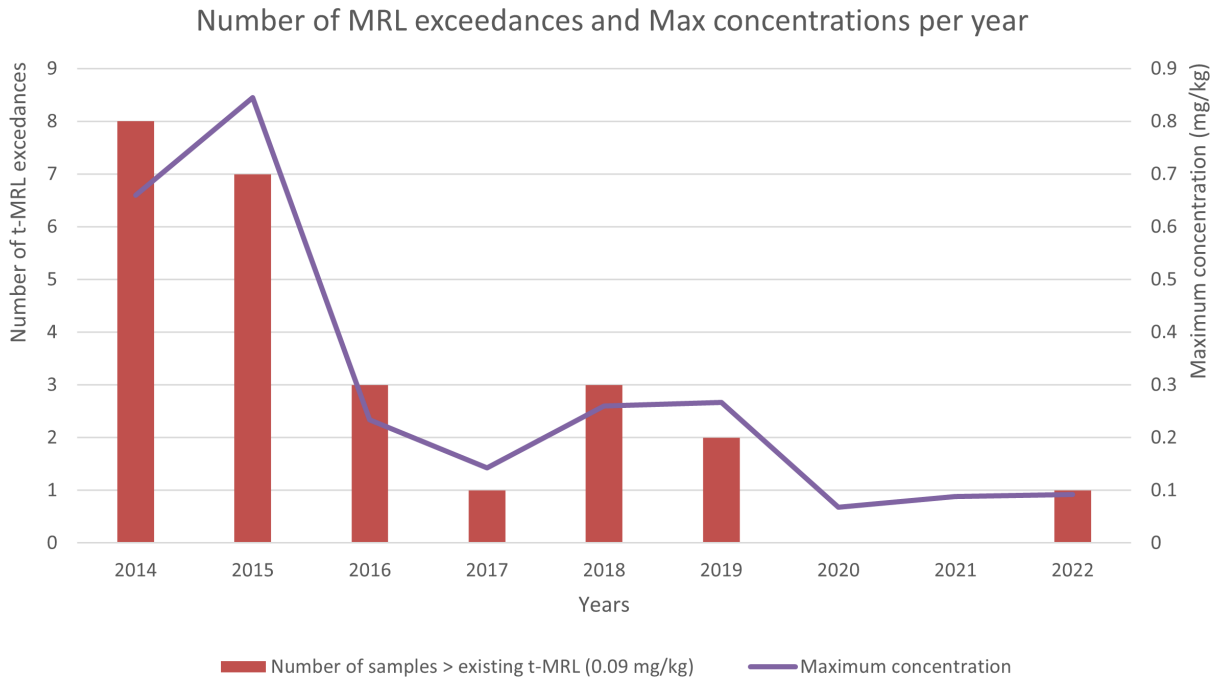


FIGURE B.7 EU monitoring data for cultivated fungi other than oyster mushrooms: Number of MRL exceedances and Maximum residue concentrations (mg/kg) per year since 2014.

B.1.2.3 | Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?	No	Mepiquat remain levels remain < 0.01 mg/kg in all edible commodities investigated. Therefore, significant levels of mepiquat are not expected in rotational crops (EFSA, 2015).
Residues in rotational and succeeding crops expected based on field rotational crop study?	Not triggered	Field rotational crop studies were not required and not reported (EFSA, 2015).

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)
Highest IESTI, according to EFSA PRIMo	Cultivated fungi: **Scenario 1:** 17% of ARfD (BE toddlers diet) **Scenario 2:** 11% of ARfD (BE toddlers diet)
Assumptions made for the calculations	The calculation is based on the highest observed level from the monitoring data from food business operators (101 samples) on raw mushrooms belonging to the species *Pleurotus ostreatus* (*i.e.*, oyster mushrooms). **Scenario 1:** The default variability factor (VF) of 7 was used in the calculation, which is considered a conservative approach leading to an overestimation of the exposure (EFSA, 2019a,b). **Scenario 2:** An alternative calculation was performed using the VF of 3. Calculations performed with PRIMo revision 3.1.

ADI	0.2 mg/kg bw per day (European Commission, 2008)
Highest IEDI, according to EFSA PRIMo	7% ADI (NL toddlers diet) Contribution of the crop assessed: Cultivated fungi: 0.01% of ADI (IE adults diet)
Assumptions made for the calculations	The calculation is based on the median observed value from the monitoring data from food business operators on raw mushrooms belonging to the species *Pleurotus ostreatus*. The median value derived in 2019 (based on 74 values; EFSA, 2019c) is still used for a conservative approach. For other commodities, the STMR values derived in previous EFSA assessments (EFSA, 2015, 2018b,c,d) 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. Calculations performed with PRIMo revision 3.1.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; STMR: supervised trials median residue.

B.4 | RECOMMENDED MRLS

B.4.1 | Overview of the statistical indicators supporting different MRL options for cultivated mushrooms other than oyster mushrooms and for oyster mushrooms based on various dataset

		Updated assessment (including new data from present assessment)		Previous assessment data (EFSA, 2019c)	
	Percentiles[a]	FBO data 2011–2022	EU monitoring 2018–2022	FBO data 2011–2019	EU monitoring 2014–2017
Cultivated mushrooms other than oyster mushrooms	P95	0.060	0.04	0.066	0.065
	P97.5	0.079	0.05	0.079	0.070
	P99	0.144	0.061	0.092	0.146
	P99.5	0.230	0.078	0.170	n.r.
	P95/95 UCL[b]	0.066	0.05	0.079	0.065
	% of samples exceeding *t*-MRL (0.09 mg/kg)	2%	0.32%	2%	2%
Oyster mushrooms	P95	0.910	0.021	0.878	n.a.
	P97.5	2.500	0.042	2.843	n.a.
	P99	2.843	0.063	2.948	n.a.
	P99.5	2.948	0.23[b]	2.948	n.a.
	P95/95 UCL[b]	2.948	0.052	2.948	n.a.
	% of samples exceeding *t*-MRL (0.7 mg/kg)	7%	0%	5%	n.a.

Abbreviations: FBO, food business operators; n.a., not available; n.r., not reported; *t*-MRL, temporary maximum residue level.

[a]Percentiles and upper confidence level were calculated using SAS® software.

[b]Upper confidence level.

B.4.2 | MRL summary table

Code[a]	Commodity	Existing EU MRL (mg/kg)	Proposed EU MRL (mg/kg)	Comment/justification
Enforcement residue definition: Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)				
0280010	Cultivated fungi (except oyster mushrooms)	0.09[ft]	No change (Risk management consideration)	The applicant's proposal to set permanent MRL is not supported An updated assessment of the available monitoring data (from food business operators and from EU monitoring programmes) indicate that the existing temporary MRL of 0.09 mg/kg provides a compliance level of minimum 98% (non-compliance rate ≤ 2%) and is thus sufficient to account for the residue uptake in cultivated mushrooms. The proposal of the applicant to raise the *t*-MRL to 0.1 mg/kg is thus not properly justified It was noted that lower *t*-MRLs (in the range 0.04–0.08 mg/kg) could be derived based on the assessment of the most recent monitoring data. EFSA did not propose specific change of the existing *t*-MRL value but a risk management decision is still needed on whether to maintain it at the current level. Risk for consumers unlikely regardless of the temporary MRL option
0280010–008	Oyster mushrooms	0.7	No change or 1 mg/kg or 3 mg/kg (Risk management consideration)	The applicant's proposal to set permanent MRL in oyster mushrooms is not supported The new EU monitoring data specific to oyster mushrooms (2018–2022) do not indicate non-compliance issue over the period 2018–2022 with the current *t*-MRL However, an updated assessment of the available monitoring data from food business operators indicates that the existing temporary MRL of 0.7 mg/kg may lead to a non-compliance rate of 7% Based on an updated assessment of the available monitoring data from food business operators, a higher *t*-MRL of 1 mg/kg could be set based on Percentile 95th. Furthermore, a *t*-MRL of 3 mg/kg would be supported by Percentiles 97.5th, 99th, 99.5th and by the 95th percentile of the data population at the 95% confidence level Risk for consumers unlikely regardless of the temporary MRL option

Abbreviations: EU, European Union; MRL, maximum residue level; *t*-MRL, temporary maximum residue level.

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

[ft]The following MRL applies to oyster mushrooms: 0.7 mg/kg. Monitoring data show that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with mepiquat. 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. (Reg. (EU) 2021/2202).

APPENDIX C

Pesticide Residue Intake Model (PRIMo)

- Chronic risk assessment

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Mepiquat (sum of mepiquat and its salts, expressed as mepiquat chloride)

LOQs (mg/kg) range from: 0.02 to: 0.10

Toxicological reference values

ADI (mg/kg bw per day):	0.2	ARfD (mg/kg bw):	0.3
Source of ADI:		Source of ARfD:	
Year of evaluation:		Year of evaluation:	

Input values

Details - chronic risk assessment | Supplementary results - chronic risk assessment | Details - acute risk assessment/children | Details - acute risk assessment/adults

Comments:

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

TMDI/NEDI/IEDI calculation (based on average food consumption)

Calculated exposure (% of ADI)	MS Diet	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity/ group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity/ group of commodities	Exposure resulting from: MRLs set at the LOQ (in % of ADI)	Exposure resulting from: commodities not under assessment (in % of ADI)
7%	NL toddler	13.59	2%	Sunflower seeds	2%	Rapeseeds/canola seeds	1%	Milk: Cattle		7%
6%	RO general	12.62	4%	Sunflower seeds	2%	Wheat	0.3%	Milk: Cattle		6%
6%	GEMS/Food G08	12.48	3%	Sunflower seeds	1%	Wheat	0.6%	Rapeseeds/canola seeds		6%
6%	GEMS/Food G15	12.25	3%	Sunflower seeds	1%	Wheat	0.4%	Rapeseeds/canola seeds		6%
6%	GEMS/Food G07	11.44	2%	Sunflower seeds	1%	Wheat	1.0%	Rapeseeds/canola seeds		6%
5%	NL child	10.87	2%	Sunflower seeds	1%	Wheat	0.8%	Rapeseeds/canola seeds		5%
4%	GEMS/Food G06	8.21	2%	Wheat	1%	Sunflower seeds	0.3%	Cotton seeds		4%
4%	DK child	8.14	2%	Rye	1%	Wheat	0.6%	Swine: Muscle/meat		4%
4%	FR child 3 15 yr	8.07	1%	Sunflower seeds	1%	Wheat	0.6%	Milk: Cattle		4%
4%	GEMS/Food G10	7.98	1%	Sunflower seeds	1%	Wheat	0.5%	Rapeseeds/canola seeds		4%
3%	IE adult	6.45	1%	Sunflower seeds	0.8%	Linseeds	0.7%	Wheat		3%
3%	PT general	6.08	2%	Sunflower seeds	1%	Wheat	0.0%	Rye		3%
3%	DE child	6.07	1%	Wheat	0.6%	Sunflower seeds	0.5%	Milk: Cattle		3%
3%	NL general	6.01	1%	Sunflower seeds	0.6%	Wheat	0.5%	Rapeseeds/canola seeds		3%
3%	FR toddler 2 3 yr	5.91	0.9%	Wheat	0.8%	Sunflower seeds	0.7%	Milk: Cattle		3%
3%	GEMS/Food G11	5.60	1%	Wheat	0.7%	Sunflower seeds	0.3%	Swine: Muscle/meat		3%
3%	ES child	5.58	1%	Wheat	0.7%	Sunflower seeds	0.3%	Milk: Cattle		3%
2%	IT toddler	4.21	2%	Wheat	0.1%	Sunflower seeds	0.0%	Barley		2%
2%	DE general	4.01	0.6%	Wheat	0.4%	Sunflower seeds	0.3%	Milk: Cattle		2%
2%	UK infant	3.88	1.0%	Milk: Cattle	0.8%	Wheat	0.1%	Oat		2%
2%	DE women 14-50 yr	3.85	0.6%	Wheat	0.4%	Sunflower seeds	0.3%	Milk: Cattle		2%
2%	ES adult	3.75	0.7%	Wheat	0.6%	Sunflower seeds	0.2%	Barley		2%
2%	UK toddler	3.58	1%	Wheat	0.5%	Milk: Cattle	0.0%	Bovine: Muscle/meat		2%
2%	FR adult	3.48	0.7%	Sunflower seeds	0.7%	Wheat	0.2%	Swine: Muscle/meat		2%
1%	SE general	3.00	1.0%	Wheat	0.3%	Milk: Cattle	0.1%	Bovine: Muscle/meat		1%
1%	LT adult	2.66	0.3%	Rye	0.3%	Wheat	0.3%	Sunflower seeds		1%
1%	IT adult	2.61	1%	Wheat	0.1%	Sunflower seeds	0.0%	Barley		1%
1.0%	FI 3 yr	1.99	0.4%	Wheat	0.2%	Oat	0.2%	Rye		1.0%
0.9%	FR infant	1.84	0.4%	Milk: Cattle	0.2%	Wheat	0.1%	Sunflower seeds		0.9%
0.9%	DK adult	1.78	0.3%	Wheat	0.2%	Swine: Muscle/meat	0.2%	Rye		0.9%
0.8%	FI 6 yr	1.52	0.3%	Wheat	0.2%	Rye	0.1%	Oat		0.8%
0.7%	UK vegetarian	1.48	0.6%	Wheat	0.1%	Milk: Cattle	0.0%	Oat		0.7%
0.6%	UK adult	1.27	0.5%	Wheat	0.1%	Milk: Cattle	0.0%	Bovine: Muscle/meat		0.6%
0.5%	IE child	1.00	0.3%	Wheat	0.1%	Milk: Cattle	0.0%	Swine: Muscle/meat		0.5%
0.5%	FI adult	0.91	0.2%	Rye	0.1%	Wheat	0.1%	Sunflower seeds		0.5%
0.1%	PL general	0.12	0.1%	Sunflower seeds	0.0%	Cultivated fungi	0.0%	Poppy seeds		0.1%

Conclusion:
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.

- Acute risk assessment – Scenario 1 (VF 7)

Acute risk assessment /children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
17%	Cultivated fungi	0.09/2.95	50
13%	Sunflower seeds	40/12.5	40
4%	Linseeds	40/11.5	12
4%	Mustard seeds	40/11.5	12
3%	Wheat	3/0.6	8.7
2%	Milk: Cattle	0.07/0.05	6.2
2%	Rapeseeds/canola seeds	15/3.65	5.0
1%	Barley	4/0.73	4.1
1%	Bovine: Liver	0.5/0.49	4.0
1%	Rye	3/0.6	3.8
0.6%	Milk: Goat	0.15/0.07	1.7
0.5%	Bovine: Kidney	0.8/0.4	1.5
0.3%	Eggs: Chicken	0.07/0.07	0.87
0.3%	Poultry: Muscle/meat	0.05/0.05	0.85
0.3%	Oat	3/0.73	0.81

Expand/collapse list

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
5%	Cultivated fungi	0.09/2.95	15
4%	Sunflower seeds	40/12.5	13
3%	Poppy seeds	40/11.5	8.1
3%	Mustard seeds	40/11.5	8.1
2%	Linseeds	40/11.5	5.5
2%	Wheat	3/0.6	5.0
1%	Barley	4/0.73	3.5
1.0%	Rye	3/0.6	2.9
0.9%	Sheep: Liver	0.6/0.94	2.6
0.7%	Bovine: Liver	0.5/0.49	2.0
0.6%	Milk: Cattle	0.07/0.05	1.9
0.6%	Rapeseeds/canola seeds	15/3.65	1.9
0.4%	Milk: Goat	0.15/0.07	1.3
0.4%	Milk: Sheep	0.15/0.07	1.1
0.3%	Bovine: Kidney	0.8/0.4	0.84

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Sunflower seeds/oils	40/25	29
5%	Cultivated fungi/fried	0.09/2.95	15
2%	Wheat/milling (flour)	3/0.6	7.3
1%	Wheat/milling (wholemeal)-baking	3/0.6	3.3
0.9%	Oat/boiled	3/0.73	2.6
0.9%	Barley/cooked	4/0.73	2.6
0.7%	Oat/milling (flakes)	3/0.73	2.2
0.7%	Rye/boiled	3/0.6	2.2
0.7%	Rapeseeds/oils	15/7.3	2.1
0.7%	Rye/milling (wholemeal)-baking	3/0.6	2.1
0.4%	Barley/milling (flour)	4/0.73	1.3

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Barley/beer	4/0.15	5.3
0.9%	Wheat/bread/pizza	3/0.6	2.6
0.8%	Wheat/pasta	3/0.6	2.3
0.7%	Wheat/bread (wholemeal)	3/0.6	2.1
0.4%	Oat/boiled	3/0.73	1.1

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.

- Acute risk assessment – Scenario 2 (VF 3)

Acute risk assessment/children	Acute risk assessment/adults/general population
Details - acute risk assessment/children	Details - acute risk assessment/adults

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

Show results for all crops

Unprocessed commodities

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
13%	Sunflower seeds	40/12.5	40
11%	Cultivated fungi	0.09/2.95	33
4%	Linseeds	40/11.5	12
4%	Mustard seeds	40/11.5	12
3%	Wheat	3/0.6	8.7
2%	Milk: Cattle	0.07/0.05	6.2
2%	Rapeseeds/canola seeds	15/3.65	5.0
1%	Barley	4/0.73	4.1
1%	Bovine: Liver	0.5/0.49	4.0
1%	Rye	3/0.6	3.8
0.6%	Milk: Goat	0.15/0.07	1.7
0.5%	Bovine: Kidney	0.8/0.4	1.5
0.3%	Eggs: Chicken	0.07/0.07	0.87
0.3%	Poultry: Muscle/meat	0.05/0.05	0.85
0.3%	Oat	3/0.73	0.81

Expand/collapse list

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
4%	Sunflower seeds	40/12.5	13
3%	Cultivated fungi	0.09/2.95	10
3%	Poppy seeds	40/11.5	8.1
3%	Mustard seeds	40/11.5	8.1
2%	Linseeds	40/11.5	5.5
2%	Wheat	3/0.6	5.0
1%	Barley	4/0.73	3.5
1.0%	Rye	3/0.6	2.9
0.9%	Sheep: Liver	0.6/0.94	2.6
0.7%	Bovine: Liver	0.5/0.49	2.0
0.6%	Milk: Cattle	0.07/0.05	1.9
0.6%	Rapeseeds/canola seeds	15/3.65	1.9
0.4%	Milk: Goat	0.15/0.07	1.3
0.4%	Milk: Sheep	0.15/0.07	1.1
0.3%	Bovine: Kidney	0.8/0.4	0.84

Processed commodities

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
10%	Sunflower seeds/oils	40/25	29
5%	Cultivated fungi/fried	0.09/2.95	15
2%	Wheat/milling (flour)	3/0.6	7.3
1%	Wheat/milling (wholemeal)-baking	3/0.6	3.3
0.9%	Oat/boiled	3/0.73	2.6
0.9%	Barley/cooked	4/0.73	2.6
0.7%	Oat/milling (flakes)	3/0.73	2.2
0.7%	Rye/boiled	3/0.6	2.2
0.7%	Rapeseeds/oils	15/7.3	2.1
0.7%	Rye/milling (wholemeal)-baking	3/0.6	2.1
0.4%	Barley/milling (flour)	4/0.73	1.3

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Barley/beer	4/0.15	5.3
0.9%	Wheat/bread/pizza	3/0.6	2.6
0.8%	Wheat/pasta	3/0.6	2.3
0.7%	Wheat/bread (wholemeal)	3/0.6	2.1
0.4%	Oat/boiled	3/0.73	1.1

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.

APPENDIX D

Input values for the exposure calculations

D.1 | CONSUMER RISK ASSESSMENT

Commodity	Existing/ proposed MRL (mg/kg)	Source	Chronic risk assessment		Acute risk assessment	
			Input value[a] (mg/kg)	Comment	Input value[a] (mg/kg)	Comment[b]
Risk assessment residue definition for commodities of plant origin: Sum of mepiquat and its salts, expressed as mepiquat chloride						
Cultivated fungi	0.09[c]	Existing MRL for cultivated fungi (EFSA, 2019c)	0.087[d]	Median residue concentration from FBO monitoring data on oyster mushrooms (see Appendix B.1.2.2 b)	2.95[e]	Highest residue concentration from FBO monitoring data on oyster mushrooms (see Appendix B.1.2.2 b)
Linseed	40	EFSA (2018c)	11.5	STMR	11.5	STMR
Poppy seed	40	EFSA (2018c)	11.5	STMR	11.5	STMR
Sunflower seed	40	EFSA (2018c)	12.5	STMR	12.5	STMR
Rapeseed	15	EFSA (2018c)	3.65	STMR	3.65	STMR
Mustard seed	40	EFSA (2018c)	11.5	STMR	11.5	STMR
Cotton seed	6	EFSA (2018d)	1.7	STMR	1.7	STMR
Gold of pleasure	40	EFSA (2018c)	11.5	STMR	11.5	STMR
Barley grain	4	EFSA (2015)	0.73	STMR	0.73	STMR
Oats grain	3	EFSA (2015)	0.73	STMR	0.73	STMR
Rye grain	3	EFSA (2015)	0.6	STMR	0.6	STMR
Wheat grain	3	EFSA (2015)	0.6	STMR	0.6	STMR
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	EFSA (2018d)	0.05	STMR	0.05	HR
Swine fat	0.05	EFSA (2018d)	0.05	STMR	0.05	HR
Swine liver[b]	0.07	EFSA (2018d)	0.08	STMR × CF[f]	0.12	HR × CF[f]
Swine kidney	0.07	EFSA (2018d)	0.05	STMR	0.07	HR
Bovine and equine muscle	0.09	EFSA (2018d)	0.05	STMR	0.06	HR
Bovine, equine fat	0.06	EFSA (2018d)	0.05	STMR	0.05	HR
Bovine, equine liver	0.5	EFSA (2018d)	0.34	STMR × CF[f]	0.49	HR × CF[f]
Bovine, equine kidney	0.8	EFSA (2018d)	0.22	STMR	0.4	HR
Sheep, goat muscle	0.09	EFSA (2018d)	0.06	STMR	0.08	HR
Sheep, goat fat	0.06	EFSA (2018d)	0.05	STMR	0.06	HR
Sheep, goat liver[b]	0.6	EFSA (2018d)	0.48	STMR × CF[f]	0.94	HR × CF[f]
Sheep, goat kidney	0.8	EFSA (2018d)	0.36	STMR	0.65	HR
Poultry muscle	0.05	EFSA (2018d)	0.05	STMR	0.05	HR
Poultry fat	0.05	EFSA (2018d)	0.05	STMR	0.05	HR
Poultry liver	0.05	EFSA (2018d)	0.05	STMR	0.05	HR
Cattle milk	0.07	EFSA (2018d)	0.05	STMR	0.05	STMR
Sheep, goat milk	0.15	EFSA (2018d)	0.07	STMR	0.07	STMR
Birds' eggs	0.07	EFSA (2018d)	0.05	STMR	0.07	HR

Abbreviations: CF, conversion factor; FBO, food business operators; HR, highest residue; STMR, supervised trials median residue.

[a]Figures in the table are rounded to two digits, but the calculations are normally performed with the actually calculated values (which may contain more digits). To reproduce the calculations, the unrounded values need to be used.

[b]Input values for the commodities which are not under consideration for the acute risk assessment are reported in grey.

[c]The current MRL of 0.09 mg/kg applies to all cultivated fungi other than oyster mushrooms. For oyster mushrooms the MRL of 0.7 mg/kg applies (Reg. (EU) 2021/976).

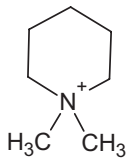
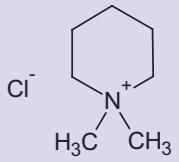
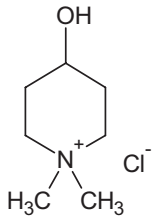
[d]The median value from FBO monitoring data derived in 2019 for oyster mushrooms is still considered as a worst case.

[e]The highest values from FBO monitoring data remains the same as in 2019, after consideration of the most updated FBO monitoring data.

[f]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[a]	Structural formula[b]
mepiquat	1,1-dimethylpiperidinium C[N+]1(C)CCCCC1 NNCAWEWCFVZOGF-UHFFFAOYNA-N	
mepiquat chloride	1,1-dimethylpiperidinium chloride [Cl-].C[N+]1(C)CCCCC1 VHOVSQVSAAQANU-UHFFFAOYNA-M	
4-hydroxy mepiquat chloride	4-hydroxy-1,1-dimethylpiperidin1-ium chloride [Cl-].C[N+]1(C)CCC(O)CC1 GDFMSGICPAHHIB-UHFFFAOYNA-M	

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

[a]ACD/Name 2020.2.1 ACD/Labs 2020 Release (File version N15E41, Build 116563, 15 June 2020).

[b]ACD/ChemSketch 2020.2.1 ACD/Labs 2020 Release (File version C25H41, Build 121153, 22 March 2021).