STATEMENT

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Statement on the dietary risk assessment for the proposed temporary maximum residue level for chlormequat in oyster mushrooms

European Food Safety Authority (EFSA)

Abstract

The European Commission requested EFSA to provide a statement in the framework of Article 43 of Regulation (EC) No 396/2005 on the dietary risk assessment for the proposed temporary maximum residue levels (MRLs) (6 and 7 mg/kg) for chlormequat in cultivated oyster mushrooms. The MRL proposals were derived by the evaluating Member State (EMS) Germany. Chlormequat residues can be found in mushrooms due to cross-contamination from cereal straw lawfully treated with chlormequat chloride which is used as cultivation substrate. EFSA concluded that the exposure to residue levels at the proposed MRLs is unlikely to pose a risk to consumers' health. However, EFSA recommended to take appropriate risk management actions to avoid contamination of cultivated oyster mushrooms and other fungi cultivated on straw.

Keywords: chlormequat chloride, cultivated fungi, pesticide, MRL, consumer risk assessment

Requestor: European Commission

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Summary

In the framework of Article 43 of Regulation (EC) No 396/2005, the European Commission requested European Food Safety Authority (EFSA) to carry out a dietary exposure and a consumer risk assessment for two temporary maximum residue levels (MRLs) for chlormequat in cultivated oyster mushrooms proposed by the evaluating member state (EMS) Germany. The proposed temporary MRL should accommodate for residues of chlormequat chloride in cultivated oyster fungi exceeding the current legal limit established at European level due to cross-contamination from cereal straw which was lawfully treated with chlormequat. EFSA was not requested to assess the methodology used to derive the proposed MRLs and the appropriateness of the MRL proposals. Thus, EFSA focussed this statement on the dietary risk assessment related to the exposure to oyster mushrooms containing residues at the level of the proposed temporary MRLs.

The consumer exposure assessment was performed with the revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo) using the MRL options proposed by Germany as input value. In the absence of specific data, the consumption data for cultivated fungi were used.

EFSA concluded that both MRL options proposed by Germany are unlikely to pose a risk to consumers' health. However, the consumer risk assessment is affected by non-standard uncertainties and EFSA recommended to generate further studies to increase the robustness of the risk assessment; furthermore, EFSA compiled a number of recommendations to be considered by risk managers.

The risk management MRL options for cultivated fungi are summarised in the table below.

Code[(a)]	Commodity	Existing EU t-MRL (mg/kg)	Proposed EU t-MRL (mg/kg)	Comment/justification
Enforcement residue definition: Chlormequat (sum of chlormequat and its salts, expressed as chlormequat chloride)				
0280010	Cultivated fungi (including oyster mushrooms)	0.9[(ft)]	Oyster mushrooms (0280010-008) 6 or 7 (further risk management consideration)	Germany proposed to increase the existing temporary MRL for oyster mushrooms based on monitoring data In a comprehensive chronic risk assessment, which covers the authorised EU uses of chlormequat, the Codex MRLs taken over in the EU legislation and the proposed temporary MRLs for mushrooms, the estimated chronic exposure did not exceed the ADI. Thus, a long-term consumer risk was found to be unlikely EFSA calculated different scenarios for the acute risk assessment, using the proposed temporary MRLs derived for oyster mushrooms. Assuming that the unit-to-unit variability is lower in cultivated mushrooms grown on straw which contains residues of chlormequat chloride than in crops treated directly, an acute consumer health risk is not expected Considering that according to the EU food classification, oyster mushrooms are listed under the crop code for cultivated fungi, risk managers have to decide whether the proposed temporary MRLs should apply only for oyster mushrooms or for the whole group of cultivated fungi, although for other cultivated fungi the existing MRL might be sufficient. The results of the risk assessment performed by EFSA cover all types of cultivated fungi, since specific consumption data for oyster mushrooms are not available

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(ft): Monitoring shows that cross-contamination of untreated cultivated fungi may occur with straw lawfully treated with chlormequat. 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 13 April 2021, or, if that information is not submitted by that date, the lack of it.

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1. Introduction and background information

Chlormequat is an active substance that was approved for being used in plant protection products on 1 December 2009 under Regulation (EC) No 1107/2009[1] by Commission Directive 2010/2/EU[2]; the approval was restricted to the use on cereals and on non-edible crops.

Chlormequat belongs to the class of quaternary ammonium compounds with the ISO common name for 2-chloroethyltrimethylammonium (IUPAC). For plant protection product formulations, the chloride salt (2-chloroethyltrimethylammonium chloride) is usually used.

The chemical structure of the active substance and its salt is reported in Appendix C.

EFSA finalised the MRL review under Article 12 of Regulation (EC) No 396/2005[3] of this active substance on 7 March 2016 (EFSA, 2016). The maximum residue levels (MRLs) for chlormequat are established in Annexes II of Regulation (EC) No 396/2005.

The presence of chlormequat chloride residues in cultivated fungi is resulting from residues in straw which is used as cultivation substrate for different species of mushrooms. Thus, residues in cultivated fungi are considered a cross-contamination from residues in cereal straw lawfully treated with chlormequat.

The MRL for cultivated fungi is currently set as a temporary MRL at the level of 0.9 mg/kg (Regulation (EU) No 2017/693[4]), implementing an EFSA recommendation derived in the framework of the Article 12 MRL review. In its reasoned opinion under Article 12, EFSA derived five different MRL proposals for cultivated fungi for consideration by risk managers, using different scientific approaches to calculate MRLs based on data of national control programmes (official monitoring data) covering the period of 2011 to 2014. Risk managers decided to implement the MRL proposal that was calculated as the 99th percentile of the available monitoring data.

Mushroom growers submitted monitoring data showing that residues in oyster mushrooms (*Pleurotus ostreatus*) occur at higher levels than the current temporary MRL of 0.9 mg/kg applicable for cultivated fungi. Germany submitted additional monitoring data from official controls performed specifically on oyster mushrooms, which confirmed the findings of the mushroom growers.

In accordance with Article 6(3) of Regulation (EC) No 396/2005, Germany as the evaluating Member State (EMS), submitted an application to modify the existing MRL for chlormequat in oyster mushrooms. 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 22 March 2019. Based on the monitoring data provided by the mushroom growers, Germany proposed two options for modifying the existing MRL for oyster mushrooms:

- 6 mg/kg (95th percentile of all sample results)
- 7 mg/kg (95th percentile of positive findings only, i.e. results greater than the limit of quantification (LOQ)).

2. Terms of Reference as provided by the European Commission

On 12 April 2019, EFSA received a request from the European Commission to carry out a dietary exposure and a consumer risk assessment for the two MRL options of 6 and 7 mg/kg, respectively, as presented in the Evaluation Report prepared by Germany and to deliver a Scientific Statement according to Article 43 of Regulation (EC) No 396/2005 on the safety for consumers in relation to the two options.

The deadline to deliver the statement was agreed to be 25 April 2019.

EFSA accepted the mandate and included it in the EFSA Register of Questions with the reference number EFSA-Q-2019-00255.

[1] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.

[2] Commission Directive 2010/2/EU of 27 January 2010 amending Council Directive 91/414/EEC as regards an extension of the use of the active substance chlormequat. OJ L 24, 28.1.2010, p. 11–13.

[3] Regulation (EC) No 396/2005 of the European 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) 2017/693 of 7 April 2017 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bitertanol, chlormequat and tebufenpyrad in or on certain products. OJ L 101, 13.4.2017, p. 1–34.

2.1. Interpretation of the Terms of Reference

As requested in the mandate, EFSA focussed this statement on the dietary risk assessment for the two MRL proposals derived by Germany (2019). EFSA did not assess the methodology used to derive the proposed MRLs and the appropriateness of the MRL proposals.

This document is not a stand-alone document and should be read alongside with the evaluation report submitted by the EMS (Germany, 2019) and the exposure calculations using EFSA Pesticide Residues Intake Model (PRIMo) model; both documents are made publicly available as background documents.

3. Temporary MRLs proposed by the EMS

3.1. Monitoring data on oyster fungi

The EMS Germany compiled monitoring data (n = 308) on chlormequat chloride residues in oyster mushrooms (*P. ostreatus*) from different sources (Germany, 2019):

- 168 samples analysed under the national German control programmes (2001–2018);
- 138 samples from food business operators (2001 to beginning 2019);
- Two samples of oyster mushrooms from the EFSA monitoring database compiling national monitoring data reported to EFSA under Article 31 of Regulation (EC) No 396/2005 (2014, 2017).

The samples originated from different countries, mainly European Union (EU) Member States. The 82.5% of the samples (n = 254) contained residues of chlormequat chloride at or above the LOQ of the analytical method applied, with the highest value of 16.4 mg/kg chlormequat chloride.

Monitoring data (n = 117) on other species of the genus Pleurotus (i.e *P. eryngii*, *P. citrinopileatus*) and on the mushroom shiitake (*Lentinula edodes*) showed a lower percentage of positive findings (23.9%), none of them exceeding the existing t-MRL of 0.9 mg/kg (Germany, 2019). Thus, the data give an indication that the levels and the frequency of chlormequat chloride residues differ among the mushroom varieties.

3.2. MRL estimation

Germany pooled the sample results on oyster mushrooms to derive MRL proposals according to the methodology recommended by the Food and Agriculture Organization (FAO) of the United Nations for the setting of MRLs in spices and extraneous MRLs (FAO, 2016).

The EMS Germany proposed two MRL options for risk management consideration (Germany, 2019):

- The MRL proposal of 6 mg/kg (MRL option 1) was derived calculating the 95th percentile of all sample results;
- The MRL proposal of 7 mg/kg (MRL option 2) was derived by calculating the 95th percentile of the subset of data (254 samples) with residues greater than the LOQ.

As outlined in Section 2.1, EFSA did not verify the calculated temporary MRLs derived by the EMS.

4. Consumer risk assessment

The consumer exposure assessment was performed using the revision 3.1 of the EFSA PRIMo. This dietary exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2018a). The input values used for the dietary exposure calculation are summarised in Appendix B. The assumptions for the chronic and the acute risk assessment and the results are presented below.

4.1. Chronic (long-term) risk assessment

EFSA estimated the chronic dietary exposure for residues of chlormequat chloride, taking into account the expected residues in food products assessed in the framework of the MRL review (supervised trials median residues (STMRs) for barley grain, oats grain and the mean residue concentration of monitoring data for pears, EFSA, 2016); in addition, the STMR values related to

Codex MRLs which were recently implemented in the EU MRL legislation[5] were included in the exposure assessment.

The EFSA PRIMo revision 3.1 contains consumption data for cultivated fungi (mean consumption) for 30 diets ranging from 0.011 g/kg body weight (bw) to 0.2367 g/kg bw (Irish adults). The consumption data cover all types of fungi classified under the food code 0280010 (Annex I of regulation (EC) number 396/2005) (see Table 1). Specific consumption data for oyster mushrooms (*P. ostreatus*) are not available. As input values for cultivated fungi, EFSA used the proposed MRLs derived by Germany (scenario 1: MRL proposal 6 mg/kg, scenario 2: MRL proposal of 7 mg/kg).

Table 1: EU food classification for cultivated fungi (code 0280010 of Annex I of Regulation (EC) No 396/2005)

Common name	Scientific name
Common mushrooms/button mushrooms/champignons mushrooms	*Agaricus bisporus*
Corn smuts/Mexican truffles	*Ustilago maydis*
Enokitake/winter mushrooms	*Flammulina velutipes*
Fusarium venenatum	*Fusarium venenatum*
Horse mushrooms	*Agaricus arvensis*
Jew's ears/hirneola	*Auricularia auricula-judae*
Nameko	*Pholiota nameko*
Oyster mushrooms	*Pleurotus ostreatus*
Paddy straw mushroom	*Volvariella volvacea*
Pom-pom blancs/lion's mane mushrooms/monkeyhead mushrooms	*Hericium erinaceus*
Shiitake	*Lentinula edodes*
Shimeji/bunashimeji/beach mushrooms	*Hypsizygus tessulatus:* syn: *H. marmoreus*
Snow mushrooms/white jelly mushrooms	*Tremella fuciformis*
Wood blewits/pied bleus	*Clytocibe nuda;* syn: *Lepista nuda*
Other cultivated fungi	
Other species of genus Pleurotus, not elsewhere mentioned	

The estimated dietary exposure derived for the different diets included in the EFSA PRIMo revision 3.1 was compared with the toxicological reference value (acceptable daily intake (ADI) value of 0.04 mg/kg body weight per day) derived for chlormequat chloride during the EU pesticides peer review (European Commission, 2009).

Results

In scenario 1 (considering the MRL proposal of 6 mg/kg for cultivated fungi), the estimated long-term dietary intake of chlormequat chloride was in the range of 2% to 48% of the ADI (maximum for Dutch toddlers). The contribution of cultivated fungi accounted for up to 3.6% of the ADI (Irish adults).

In scenario 2 (considering the MRL proposal of 7 mg/kg for cultivated fungi), the maximum long-term dietary intake of chlormequat chloride was not affected. Thus, the highest long-term exposure accounted for 48% of the ADI; the contribution of cultivated fungi was slightly higher, i.e. 4.14% of the ADI (Irish adults).

The chronic (long-term) risk assessment is affected by non-standard uncertainties related to the fact that the calculations were performed using the proposed MRLs for cultivated fungi instead of a STMR value derived from supervised field trials, which is expected to lead to an overestimation of the exposure. Furthermore, lacking specific consumption data for oyster mushrooms, the calculations were performed assuming that all fungi classified under the code for cultivated fungi contain residues at the proposed MRLs for oyster mushrooms, which is another assumption which is likely to overestimate the exposure.

[5] Commission Regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products. Official Journal L 96, 5.4.2019, p. 6–49.

4.2. Acute (short-term) risk assessment

The acute risk assessment was performed for cultivated fungi only. Lacking specific consumption data for oyster mushrooms, the exposure calculation was performed using the large portion (LP) derived for cultivated fungi (i.e. 8.44 g/kg bw for children (97.5th percentile for Belgian toddlers with a mean body weight of 17.8 kg) and 2.78 g/kg bw for adults (97.5th percentile for French adults with mean body weight of 66.4 kg)).

In the EFSA PRIMo revision 3.1, the unit weight for cultivated mushrooms was reported to be 25 g (unit weight edible portion and unit weight raw agricultural commodities). Thus, for the standard setting of PRIMo revision 3.1, the exposure calculations for cultivated fungi are performed according to international estimated short-term intake (IESTI) case 2a, using a variability default factor of 7. The EMS proposed to replace the default variability factor of 7, considering that the unit weight of oyster mushroom carpophorus is likely to be below 25 g (Mohamed et al., 2016) which would justify the use of a variability factor of 1. In addition, the EMS highlighted that the substrate on which oyster mushrooms are cultivated is likely to show a homogeneous residue distribution. A rather homogeneous product can be anticipated also from the inoculum (spawn) under the controlled moisture and temperature conditions. Thus, according to the EMS, the residues in individual oyster mushrooms are likely to be homogeneous (Germany, 2019).

EFSA agrees with the EMS to replace the default variability factor of 7 which is considered too conservative. EFSA calculated two scenarios, using variability factor of 3 and 1. The scenario using the variability factor of 3 was calculated, taking into account that average variability factors of 2.8 and 3.6 were obtained from supervised residue trials and from market surveys, respectively (EFSA PPR Panel, 2005).

The estimated acute dietary exposure derived for children and adults using variability factor of 3 and 1 was compared with the toxicological reference value (acute reference dose (ARfD) value of 0.09 mg/kg bw) derived for chlormequat chloride during the EU pesticides peer-review (European Commission, 2009).

Results

The results of the short-term risk assessment for the two MRL options for chlormequat in cultivated fungi is reported in Table 2.

Table 2: Results of the acute risk assessment for chlormequat in cultivated fungi, using non-standard variability factors of 1 and 3

Diet	Scenario 1 (6 mg/kg)		Scenario 2 (7 mg/kg)	
VF	**BE toddler**	**FR adults**	**BE toddler**	**FR adults**
1	56% ARfD	19% ARfD	66% ARfD	22% ARfD
3	75% ARfD	24% ARfD	88% ARfD	27% ARfD

The acute risk assessment is affected by the following non-standard uncertainties, which should be considered by risk managers:

- Specific consumption data for oyster mushrooms are not available. The LP for oyster mushrooms may be equal or lower to the LP included in the EFSA PRIMo calculation spreadsheet.
- Empirical data on the unit-to-unit variability of chlormequat chloride residues on individual mushrooms are not available. The replacement of the default variability factor of 7 with 3 and 1 is based on considerations that should be verified with empirical data. If a higher level of unit-to-unit variability occurs in reality, the exposure calculations might underestimate the actual exposure. If the unit-to-unit variability is leading to a variability factor of greater than 5.66 (scenario 1, using proposed MRL of 6 mg/kg) or greater than 4.14 (scenario 2, using proposed MRL of 7 mg/kg), the acute exposure would exceed the ARfD.
- There are indications that the unit weight of oyster mushrooms is lower than 25 g (Mohamed et al., 2016). Thus, exposure calculations using IESTI case 2a instead of IESTI case 1 is considered a conservative approach that may lead to an overestimation of the exposure.
- The exposure calculations for oyster mushrooms were performed with the proposed MRLs, instead of the highest residue (HR) of residue trials. Thus, the use of the MRL is a deviation of the internationally agreed methodology which usually would be considered as an

overestimation. However, taking into account that the temporary MRL proposals cover 95% of the monitoring data, the occurrence of higher residues than the proposed MRLs cannot be excluded. Thus, for these cases, the estimated acute dietary exposure of consumers might be higher than calculated by EFSA.

- Residues of chlormequat chloride in oyster mushrooms are resulting from the use of chlormequat in cereals, leading to significant residues in straw. Since for the monitoring data on oyster mushrooms, the corresponding residue levels in straw are not available, it is not possible to conclude whether the monitoring data reflect the worst-case situation, i.e. mushrooms cultivated on straw containing residues in accordance with the existing authorised uses for cereals. In the framework of the MRL review under Article 12, information on the expected residues in cereal straw were provided. For EU uses, the supervised residue trials showed that residues in straw may occur at levels up to 39 mg/kg (EFSA, 2016). Although the available monitoring data were sufficiently representative according to the EMS, it cannot be excluded that the available data overestimate the actual residues in oyster mushrooms, if straw used to cultivate fungi was treated with exaggerated dose rates compared to the authorised good agricultural practices. The monitoring data might also underestimate the situation, if the mushrooms were grown on straw that contained significantly lower residues than expected according to the authorised uses.

For further details on the exposure calculations, a screenshot of the Report sheet of the EFSA PRIMo for the different scenarios is presented in Appendix A.

5. Conclusion and recommendations

Based on the results of the different scenarios of the dietary risk assessment, EFSA concluded that the occurrence of residues of chlormequat chloride in oyster mushrooms at the level of the proposed temporary MRLs (6 and 7 mg/kg) is unlikely to pose a chronic and an acute intake risk. The risk assessment contains assumptions that lead to non-standard uncertainties. In order to increase the robustness of the risk assessment, the following data should be generated:

- Residue trials that allow a reliable prediction of the expected residues in oyster mushrooms cultivated on straw that contain residues at levels in accordance with the most critical authorised use of chlormequat in cereals;
- Studies investigating the unit-to-unit variability of chlormequat chloride residues in individual mushrooms to verify the assumptions used in the acute consumer risk assessment;
- Unit weight data for oyster mushrooms.

Considering that residues of chlormequat chloride in oyster mushrooms are resulting from the presence of residues in treated straw, EFSA recommends the following options to be considered by risk managers:

- According to the results of the EU coordinated monitoring programmes, chlormequat chloride residues are the most frequently found residues in cereal grains. Almost 50% of the wheat grain samples analysed in the EU coordinated monitoring programme (EUCP) in 2015 and approximately 35% of the rye grain samples analysed in EUCP 2016 contained quantifiable residues of chlormequat chloride (EFSA, 2017, 2018b). These data imply that also a high proportion of straw produced in the EU is likely to contain chlormequat residues. Thus, it would be desirable to derive a sound basis for setting MRLs for fungi cultivated on straw based on residue trials, instead of setting temporary MRLs based on monitoring data;
- As alternative option, the production of cultivated fungi could be restricted, allowing only the use of organically produced straw (chlormequat-free) as cultivation substrate;
- If reliable data on the transfer rate of residues from straw to mushrooms are generated as recommended under the first bullet point, chlormequat chloride residue limits for straw could be derived that would avoid contamination of cultivated fungi. Mushroom growers, under their responsibility as food business operators, could be requested to use for growing mushrooms only straw that complies with these limits for straw.

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Abbreviations

ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CCPR	Codex Committee on Pesticide Residues
CF	conversion factor for enforcement to risk assessment residue definition
EMS	evaluating Member State
EUCP	EU coordinated monitoring programme
FAO	Food and Agriculture Organization of the United Nations
HR	highest residue
IESTI	international estimated short-term intake
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
LP	large portion
MRL	maximum residue level
PRIMo	(EFSA) Pesticide Residues Intake Model
SANCO	Directorate-General for Health and Consumers
STMR	supervised trials median residue
WHO	World Health Organization

Appendix A – Pesticide Residue Intake Model (PRIMo)

Chronic risk assessment

- Scenario 1 (MRL of 6 mg/kg)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	0.09
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2008	Year of evaluation:	2008

Input values

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

Comments: DE-MRL proposal of 6 mg/kg for cultivated fungi based on monitring data on oyster fungi and VF of 1.

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	Expsoure (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)
	48%	NL toddler	19.05	23%	Milk: Cattle	12%	Wheat	6%	Rapeseeds/canola seeds	0.0%	48%
	42%	DK child	16.79	20%	Rye	13%	Wheat	5%	Milk: Cattle		42%
	27%	NL child	10.99	12%	Wheat	9%	Milk: Cattle	3%	Rapeseeds/canola seeds	0.0%	27%
	26%	DE child	10.53	12%	Wheat	8%	Milk: Cattle	3%	Rye	0.0%	26%
	26%	UK infant	10.21	15%	Milk: Cattle	8%	Wheat	2%	Oat		26%
	25%	FR child 3–15 yr	10.08	14%	Wheat	9%	Milk: Cattle	1%	Cultivated fungi	0.0%	25%
	24%	GEMS/Food G06	9.48	21%	Wheat	1.0%	Milk: Cattle	0.3%	Cotton seeds	0.0%	24%
	23%	FR toddler 2 3 yr	9.05	11%	Milk: Cattle	9%	Wheat	1.0%	Cultivated fungi	0.0%	23%
	22%	GEMS/Food G07	8.66	13%	Wheat	4%	Rapeseeds/canola seeds	2%	Milk: Cattle	0.0%	22%
	22%	GEMS/Food G08	8.63	12%	Wheat	2%	Rapeseeds/canola seeds	2%	Milk: Cattle	0.0%	22%
	21%	UK toddler	8.57	12%	Wheat	8%	Milk: Cattle	0.9%	Cultivated fungi		21%
	21%	GEMS/Food G15	8.30	13%	Wheat	3%	Milk: Cattle	1%	Rapeseeds/canola seeds	0.0%	21%
	20%	IT toddler	8.17	20%	Wheat	0.6%	Cultivated fungi	0.0%	Pears	0.0%	20%
	20%	RO general	7.98	15%	Wheat	4%	Milk: Cattle	0.1%	Swine: Muscle/meat		20%
	19%	ES child	7.63	13%	Wheat	5%	Milk: Cattle	0.3%	Cultivated fungi	0.0%	19%
	19%	SE general	7.42	9%	Wheat	5%	Milk: Cattle	3%	Cultivated fungi		19%
	18%	GEMS/Food G10	7.30	12%	Wheat	2%	Milk: Cattle	2%	Rapeseeds/canola seeds	0.1%	18%
	16%	GEMS/Food G11	6.49	11%	Wheat	3%	Milk: Cattle	1%	Barley	0.1%	16%
	15%	DE general	6.06	6%	Wheat	5%	Milk: Cattle	2%	Rye	0.0%	15%
	15%	DE women 14–50 yr	6.02	6%	Wheat	5%	Milk: Cattle	2%	Rye	0.0%	15%
	15%	IE adult	5.81	7%	Wheat	4%	Cultivated fungi	2%	Milk: Cattle	0.0%	15%
	13%	NL general	5.35	6%	Wheat	3%	Milk: Cattle	2%	Rapeseeds/canola seeds	0.0%	13%
	13%	IT adult	5.23	12%	Wheat	0.8%	Cultivated fungi	0.0%	Pears	0.0%	13%
	12%	PT general	4.99	12%	Wheat	0.5%	Rye	0.2%	Oat	0.0%	12%
	11%	FI 3 yr	4.49	4%	Oat	4%	Wheat	2%	Rye	0.0%	11%
	11%	ES adult	4.47	7%	Wheat	2%	Milk: Cattle	1.0%	Cultivated fungi	0.0%	11%
	10%	LT adult	3.98	4%	Rye	3%	Wheat	2%	Milk: Cattle		10%
	10%	UK vegetarian	3.91	6%	Wheat	2%	Cultivated fungi	1%	Milk: Cattle		10%
	10%	FR adult	3.89	7%	Wheat	2%	Milk: Cattle	0.8%	Cultivated fungi	0.0%	10%
	9%	FR infant	3.69	7%	Milk: Cattle	2%	Wheat	0.2%	Cultivated fungi	0.0%	9%
	8%	DK adult	3.30	3%	Wheat	2%	Milk: Cattle	2%	Rye		8%
	8%	FI 6 yr	3.30	3%	Wheat	2%	Oat	2%	Rye	0.0%	8%
	7%	UK adult	2.99	5%	Wheat	1%	Milk: Cattle	0.9%	Cultivated fungi	0.0%	7%
	5%	IE child	2.16	3%	Wheat	1%	Milk: Cattle	0.4%	Cultivated fungi		5%
	5%	FI adult	1.93	2%	Rye	1%	Oat	1.0%	Wheat	0.0%	5%
	2%	PL general	0.79	2%	Cultivated fungi	0.0%	Table grapes	0.0%	Pears	0.0%	2%

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

- Scenario 2 (MRL of 7 mg/kg)

European Food Safety Authority

EFSA PRIMo revision 3.1; 2019/03/19

Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride)

LOQs (mg/kg) range from:	0.01	to:	0.05
Toxicological reference values			
ADI (mg/kg bw per day):	0.04	ARfD (mg/kg bw):	0.09
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2008	Year of evaluation:	2008

Input values

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

Comments: DE-MRL proposal of 7 mg/kg for cultivated fungi based on monitring data on oyster fungi and VF of 1.

Refined calculation mode

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (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)
TMDI/NEDI/IEDI calculation (based on average food consumption)	48%	NL toddler	19.18	23%	Milk: Cattle	12%	Wheat	6%	Rapeseeds/canola seeds	0.0%	48%
	42%	DK child	16.84	20%	Rye	13%	Wheat	5%	Milk: Cattle		42%
	28%	NL child	11.06	12%	Wheat	9%	Milk: Cattle	3%	Rapeseeds/canola seeds	0.0%	28%
	27%	DE child	10.60	12%	Wheat	8%	Milk: Cattle	3%	Rye	0.0%	27%
	26%	UK infant	10.23	15%	Milk: Cattle	8%	Wheat	2%	Oat		26%
	25%	FR child 3 15 yr	10.15	14%	Wheat	9%	Milk: Cattle	1%	Cultivated fungi	0.0%	25%
	24%	GEMS/Food G06	9.48	21%	Wheat	1.0%	Milk: Cattle	0.3%	Cotton seeds	0.0%	24%
	23%	FR toddler 2 3 yr	9.11	11%	Milk: Cattle	9%	Wheat	1%	Cultivated fungi	0.0%	23%
	22%	GEMS/Food G07	8.66	13%	Wheat	4%	Rapeseeds/canola seeds	2%	Milk: Cattle	0.0%	22%
	22%	UK toddler	8.63	12%	Wheat	8%	Milk: Cattle	1%	Cultivated fungi		22%
	22%	GEMS/Food G08	8.63	12%	Wheat	2%	Rapeseeds/canola seeds	2%	Milk: Cattle	0.0%	22%
	21%	GEMS/Food G15	8.30	13%	Wheat	3%	Milk: Cattle	1%	Rapeseeds/canola seeds	0.0%	21%
	21%	IT toddler	8.21	20%	Wheat	0.7%	Cultivated fungi	0.0%	Pears	0.0%	21%
	20%	RO general	7.98	15%	Wheat	4%	Milk: Cattle	0.1%	Swine: Muscle/meat		20%
	19%	ES child	7.65	13%	Wheat	5%	Milk: Cattle	0.4%	Cultivated fungi	0.0%	19%
	19%	SE general	7.59	9%	Wheat	5%	Milk: Cattle	3%	Cultivated fungi		19%
	18%	GEMS/Food G10	7.30	12%	Wheat	2%	Milk: Cattle	2%	Rapeseeds/canola seeds	0.1%	18%
	16%	GEMS/Food G11	6.49	11%	Wheat	3%	Milk: Cattle	1%	Barley	0.1%	16%
	15%	DE general	6.09	6%	Wheat	5%	Milk: Cattle	2%	Rye	0.0%	15%
	15%	DE women 14-50 yr	6.06	6%	Wheat	5%	Milk: Cattle	2%	Rye	0.0%	15%
	15%	IE adult	6.05	7%	Wheat	4%	Cultivated fungi	2%	Milk: Cattle	0.0%	15%
	14%	NL general	5.42	6%	Wheat	3%	Milk: Cattle	2%	Rapeseeds/canola seeds	0.0%	14%
	13%	IT adult	5.28	12%	Wheat	0.9%	Cultivated fungi	0.0%	Pears	0.0%	13%
	12%	PT general	4.99	12%	Wheat	0.5%	Rye	0.2%	Oat	0.0%	12%
	11%	ES adult	4.53	7%	Wheat	2%	Milk: Cattle	1%	Cultivated fungi	0.0%	11%
	11%	FI 3 yr	4.50	4%	Oat	4%	Wheat	2%	Rye	0.0%	11%
	10%	UK vegetarian	4.04	6%	Wheat	2%	Cultivated fungi	1%	Milk: Cattle		10%
	10%	LT adult	4.01	4%	Rye	3%	Wheat	2%	Milk: Cattle		10%
	10%	FR adult	3.94	7%	Wheat	2%	Milk: Cattle	0.9%	Cultivated fungi	0.0%	10%
	9%	FR infant	3.71	7%	Milk: Cattle	2%	Wheat	0.2%	Cultivated fungi	0.0%	9%
	8%	DK adult	3.35	3%	Wheat	2%	Milk: Cattle	2%	Rye		8%
	8%	FI 6 yr	3.31	3%	Wheat	2%	Oat	2%	Rye	0.0%	8%
	8%	UK adult	3.05	5%	Wheat	1%	Milk: Cattle	1%	Cultivated fungi	0.0%	8%
	5%	IE child	2.19	3%	Wheat	1%	Milk: Cattle	0.4%	Cultivated fungi		5%
	5%	FI adult	1.94	2%	Rye	1%	Oat	1.0%	Wheat	0.0%	5%
	2%	PL general	0.92	2%	Cultivated fungi	0.0%	Table grapes	0.0%	Pears	0.0%	2%

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

Acute risk assessment

- Scenario 1 (MRL of 6 mg/kg, VF 1)

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):	---	**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)	Highest % of ARfD/ADI	Commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
56%	Cultivated fungi	6/6	51	19%	Cultivated fungi	6/6	17
21%	Milk: Cattle	0.5/0.15	19	11%	Wheat	7/1.19	10.0
19%	Wheat	7/1.19	17	8%	Rye	8/1.42	6.9
11%	Pears	0.07/0.07	9.7	7%	Milk: Cattle	0.5/0.15	6.0
10%	Rye	8/1.42	9.0	4%	Bovine: Edible offals (other	1.5/1.14	3.8
9%	Bovine: Edible offals (other	1.5/1.14	8.3	4%	Barley	3/0.68	3.3
5%	Bovine: Liver	1.5/0.54	4.4	3%	Swine: Edible offals (other	1.5/1.14	3.0
5%	Bovine: Kidney	1.5/1.14	4.3	3%	Milk: Goat	0.5/0.15	2.8
4%	Barley	3/0.68	3.8	3%	Swine: Kidney	1.5/1.14	2.5
4%	Table grapes	0.05/0.05	3.8	3%	Bovine: Kidney	1.5/1.14	2.4
4%	Milk: Goat	0.5/0.15	3.7	3%	Milk: Sheep	0.5/0.15	2.3
4%	Rapeseeds/canola seeds	7/2.65	3.7	2%	Bovine: Liver	1.5/0.54	2.2
4%	Oat	15/3.1	3.4	2%	Pears	0.07/0.07	2.1
4%	Swine: Edible offals (other	1.5/1.14	3.4	2%	Oat	15/3.1	2.0
2%	Swine: Kidney	1.5/1.14	1.4	2%	Table grapes	0.05/0.05	1.7

Expand/collapse list

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):	---	**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)	Highest % of ARfD/ADI	Processed commodities	MRL/input for RA (mg/kg)	Exposure (µg/kg bw)
35%	Cultivated fungi/fried	6/6	31	6%	Wheat/bread/pizza	7/1.19	5.2
16%	Wheat/milling (flour)	7/1.19	14	5%	Barley/beer	3/0.14	4.9
12%	Oat/boiled	15/3.1	11	5%	Oat/boiled	15/3.1	4.7
10%	Oat/milling (flakes)	15/3.1	9.3	5%	Wheat/pasta	7/1.19	4.5
7%	Wheat/milling (wholemeal)-b	7/1.19	6.6	5%	Wheat/bread (wholemeal)	7/1.19	4.1
6%	Rye/boiled	8/1.42	5.1	0.3%	Table grapes/raisins	0.05/0.24	0.30
6%	Rye/milling (wholemeal)-bak	8/1.42	5.0	#NUM!	#NUM!	#NUM!	#NUM!
3%	Barley/cooked	3/0.68	2.5	#NUM!	#NUM!	#NUM!	#NUM!
2%	Pears/juice	0.07/0.05	1.6	#NUM!	#NUM!	#NUM!	#NUM!
2%	Rapeseeds/oils	7/5.3	1.6	#NUM!	#NUM!	#NUM!	#NUM!
1%	Barley/milling (flour)	3/0.68	1.2	#NUM!	#NUM!	#NUM!	#NUM!
0.0%	Soyabeans/soya drink	0.01/0.01	0.04	#NUM!	#NUM!	#NUM!	#NUM!
0.0%	Soyabeans/boiled	0.01/0	0.01	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!	#NUM!

Expand/collapse list

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) is unlikely to present a public health risk.

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

- Scenario 2 (MRL of 7 mg/kg, VF 1)

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)
66%	Cultivated fungi	7/7	59
21%	Milk: Cattle	0.5/0.15	19
19%	Wheat	7/1.19	17
11%	Pears	0.07/0.07	9.7
10%	Rye	8/1.42	9.0
9%	Bovine: Edible offals (other	1.5/1.14	8.3
5%	Bovine: Liver	1.5/0.54	4.4
5%	Bovine: Kidney	1.5/1.14	4.3
4%	Barley	3/0.68	3.8
4%	Table grapes	0.05/0.05	3.8
4%	Milk: Goat	0.5/0.15	3.7
4%	Rapeseeds/canola seeds	7/2.65	3.7
4%	Oat	15/3.1	3.4
4%	Swine: Edible offals (other	1.5/1.14	3.4
2%	Swine: Kidney	1.5/1.14	1.4

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)
22%	Cultivated fungi	7/7	19
11%	Wheat	7/1.19	10.0
8%	Rye	8/1.42	6.9
7%	Milk: Cattle	0.5/0.15	6.0
4%	Bovine: Edible offals (other	1.5/1.14	3.8
4%	Barley	3/0.68	3.3
3%	Swine: Edible offals (other	1.5/1.14	3.0
3%	Milk: Goat	0.5/0.15	2.8
3%	Swine: Kidney	1.5/1.14	2.5
3%	Bovine: Kidney	1.5/1.14	2.4
3%	Milk: Sheep	0.5/0.15	2.3
2%	Bovine: Liver	1.5/0.54	2.2
2%	Pears	0.07/0.07	2.1
2%	Oat	15/3.1	2.0
2%	Table grapes	0.05/0.05	1.7

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)
41%	Cultivated fungi/fried	7/7	37
16%	Wheat/milling (flour)	7/1.19	14
12%	Oat/boiled	15/3.1	11
10%	Oat/milling (flakes)	15/3.1	9.3
7%	Wheat/milling (wholemeal)-b	7/1.19	6.6
6%	Rye/boiled	8/1.42	5.1
6%	Rye/milling (wholemeal)-bak	8/1.42	5.0
3%	Barley/cooked	3/0.68	2.5
2%	Pears/juice	0.07/0.05	1.6
2%	Rapeseeds/oils	7/5.3	1.6
1%	Barley/milling (flour)	3/0.68	1.2
0.0%	Soyabeans/soya drink	0.01/0.01	0.04
0.0%	Soyabeans/boiled	0.01/0	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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)
6%	Wheat/bread/pizza	7/1.19	5.2
5%	Barley/beer	3/0.14	4.9
5%	Oat/boiled	15/3.1	4.7
5%	Wheat/pasta	7/1.19	4.5
5%	Wheat/bread (wholemeal)	7/1.19	4.1
0.3%	Table grapes/raisins	0.05/0.24	0.30
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short–term intake of residues of Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) is unlikely to present a public health risk.

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

- Scenario 1 (MRL of 6 mg/kg, VF 3)

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

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)
75%	Cultivated fungi	6/6	68
21%	Milk: Cattle	0.5/0.15	19
19%	Wheat	7/1.19	17
11%	Pears	0.07/0.07	9.7
10%	Rye	8/1.42	9.0
9%	Bovine: Edible offals (other than liver and	1.5/1.14	8.3
5%	Bovine: Liver	1.5/0.54	4.4
5%	Bovine: Kidney	1.5/1.14	4.3
4%	Barley	3/0.68	3.8
4%	Table grapes	0.05/0.05	3.8
4%	Milk: Goat	0.5/0.15	3.7
4%	Rapeseeds/canola seeds	7/2.65	3.7
4%	Oat	15/3.1	3.4
4%	Swine: Edible offals (other than liver and kidney)	1.5/1.14	3.4
2%	Swine: Kidney	1.5/1.14	1.4

Expand/collapse list

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

IESTI

Highest % of ARfD/ADI	Commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
24%	Cultivated fungi	6/6	21
11%	Wheat	7/1.19	10.0
8%	Rye	8/1.42	6.9
7%	Milk: Cattle	0.5/0.15	6.0
4%	Bovine: Edible offals	1.5/1.14	3.8
4%	Barley	3/0.68	3.3
3%	Swine: Edible offals	1.5/1.14	3.0
3%	Milk: Goat	0.5/0.15	2.8
3%	Swine: Kidney	1.5/1.14	2.5
3%	Bovine: Kidney	1.5/1.14	2.4
3%	Milk: Sheep	0.5/0.15	2.3
2%	Bovine: Liver	1.5/0.54	2.2
2%	Pears	0.07/0.07	2.1
2%	Oat	15/3.1	2.0
2%	Table grapes	0.05/0.05	1.7

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)
35%	Cultivated fungi/fried	6/6	31
16%	Wheat/milling (flour)	7/1.19	14
12%	Oat/boiled	15/3.1	11
10%	Oat/milling (flakes)	15/3.1	9.3
7%	Wheat/milling (wholemeal)-baking	7/1.19	6.6
6%	Rye/boiled	8/1.42	5.1
6%	Rye/milling (wholemeal)-baking	8/1.42	5.0
3%	Barley/cooked	3/0.68	2.5
2%	Pears/juice	0.07/0.05	1.6
2%	Rapeseeds/oils	7/5.3	1.6
1%	Barley/milling (flour)	3/0.68	1.2
0.0%	Soyabeans/soya drink	0.01/0.01	0.04
0.0%	Soyabeans/boiled	0.01/0	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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

IESTI

Highest % of ARfD/ADI	Processed commodities	input for RA (mg/kg)	Exposure (µg/kg bw)
6%	Wheat/bread/pizza	7/1.19	5.2
5%	Barley/beer	3/0.14	4.9
5%	Oat/boiled	15/3.1	4.7
5%	Wheat/pasta	7/1.19	4.5
5%	Wheat/bread	7/1.19	4.1
0.3%	Table grapes/	0.05/0.24	0.30
#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short-term intake of residues of Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.

- Scenario 2 (MRL of 7 mg/kg, 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)
88%	Cultivated fungi	7/7	79
21%	Milk: Cattle	0.5/0.15	19
19%	Wheat	7/1.19	17
11%	Pears	0.07/0.07	9.7
10%	Rye	8/1.42	9.0
9%	Bovine: Edible offals (other	1.5/1.14	8.3
5%	Bovine: Liver	1.5/0.54	4.4
5%	Bovine: Kidney	1.5/1.14	4.3
4%	Barley	3/0.68	3.8
4%	Table grapes	0.05/0.05	3.8
4%	Milk: Goat	0.5/0.15	3.7
4%	Rapeseeds/canola seeds	7/2.65	3.7
4%	Oat	15/3.1	3.4
4%	Swine: Edible offals (other	1.5/1.14	3.4
2%	Swine: Kidney	1.5/1.14	1.4

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)
27%	Cultivated fungi	7/7	25
11%	Wheat	7/1.19	10.0
8%	Rye	8/1.42	6.9
7%	Milk: Cattle	0.5/0.15	6.0
4%	Bovine: Edible offals (other	1.5/1.14	3.8
4%	Barley	3/0.68	3.3
3%	Swine: Edible offals (other	1.5/1.14	3.0
3%	Milk: Goat	0.5/0.15	2.8
3%	Swine: Kidney	1.5/1.14	2.5
3%	Bovine: Kidney	1.5/1.14	2.4
3%	Milk: Sheep	0.5/0.15	2.3
2%	Bovine: Liver	1.5/0.54	2.2
2%	Pears	0.07/0.07	2.1
2%	Oat	15/3.1	2.0
2%	Table grapes	0.05/0.05	1.7

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)
41%	Cultivated fungi/fried	7/7	37
16%	Wheat/milling (flour)	7/1.19	14
12%	Oat/boiled	15/3.1	11
10%	Oat/milling (flakes)	15/3.1	9.3
7%	Wheat/milling (wholemeal)-b	7/1.19	6.6
6%	Rye/boiled	8/1.42	5.1
6%	Rye/milling (wholemeal)-bak	8/1.42	5.0
3%	Barley/cooked	3/0.68	2.5
2%	Pears/juice	0.07/0.05	1.6
2%	Rapeseeds/oils	7/5.3	1.6
1%	Barley/milling (flour)	3/0.68	1.2
0.0%	Soyabeans/soya drink	0.01/0.01	0.04
0.0%	Soyabeans/boiled	0.01/0	0.01
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

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)
6%	Wheat/bread/pizza	7/1.19	5.2
5%	Barley/beer	3/0.14	4.9
5%	Oat/boiled	15/3.1	4.7
5%	Wheat/pasta	7/1.19	4.5
5%	Wheat/bread (wholemeal)	7/1.19	4.1
0.3%	Table grapes/raisins	0.05/0.24	0.30
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
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#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!
#NUM!	#NUM!	#NUM!	#NUM!

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short–term intake of residues of Chlormequat (sum of chlormequat and its salts, expressed as chlormequat-chloride) is unlikely to present a public health risk.

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

Appendix B – Input values for the consumer risk assessment

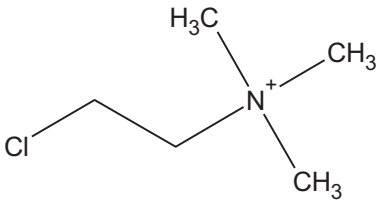
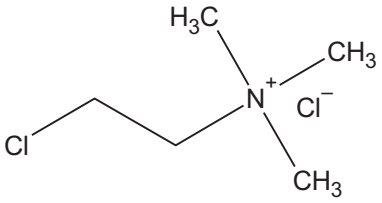
Commodity		Chronic risk assessment		Acute risk assessment	
		Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Pears		0.05	Mean, monitoring (EFSA, 2016)	Acute risk assessment only for crop under assessment	
Grapes		0.04	STMR × CF (FAO, 2017)[a]		
Cultivated fungi	Scenario 1	6	Proposed t-MRL (Germany, 2019)	6	Proposed t-MRL (Germany, 2019)
	Scenario 2	7	Proposed t-MRL (Germany, 2019)	7	Proposed t-MRL (Germany, 2019)
Rape seed		2.65	STMR × CF (FAO, 1994)[a]	Acute risk assessment only for crop under assessment	
Cotton seed		0.40	STMR × CF (FAO, 1994)[a]		
Barley grain		0.68	STMR (EFSA, 2016)		
Oats grain		3.10	STMR (EFSA, 2016)		
Rye grain		1.42	STMR × CF (FAO, 2017)[a]		
Wheat grain		1.19	STMR × CF (FAO, 2017)[a]		
Swine, meat		0.05	STMR × CF (FAO, 2017)[a]		
Swine, fat		0.05	STMR × CF (FAO, 2017)[a]		
Swine, liver		0.11	STMR × CF (FAO, 2017)[a]		
Swine, kidney		0.44	STMR × CF (FAO, 2017)[a]		
Swine, edible offal		0.44	STMR × CF (FAO, 2017)[a]		
Ruminant, meat		0.05	STMR × CF (FAO, 2017)[a]		
Ruminant, fat		0.05	STMR × CF (FAO, 2017)[a]		
Ruminant, liver		0.11	STMR × CF (FAO, 2017)[a]		
Ruminant, kidney		0.44	STMR × CF (FAO, 2017)[a]		
Ruminant, edible offal		0.44	STMR × CF (FAO, 2017)[a]		
Poultry, meat		0.05	STMR × CF (FAO, 2017)[a]		
Poultry, fat		0.05	STMR × CF (FAO, 2017)[a]		
Poultry, liver		0.05	STMR × CF (FAO, 2017)[a]		
Poultry, kidney		0.05	STMR × CF (FAO, 2017)[a]		
Poultry, edible offal		0.05	STMR × CF (FAO, 2017)[a]		
OFA, meat		0.05	STMR × CF (FAO, 2017)[a]		
OFA, fat		0.05	STMR × CF (FAO, 2017)[a]		
OFA, liver		0.11	STMR × CF (FAO, 2017)[a]		
OFA, kidney		0.44	STMR × CF (FAO, 2017)[a]		
OFA, edible offal		0.44	STMR × CF (FAO, 2017)[a]		
Milks		0.15	STMR × CF (FAO, 2017)[a]		
Birds Eggs		0.05	STMR × CF (FAO, 2017)[a]		
Wild terrestrial vertebrates		0.30	MRL in Regulation (EU) 2019/552[b]		

OFA: other farmed animals.

(a): The STMR values of the Codex MRL implemented in the EU legislation were converted to chlormequat chloride applying a molecular weight conversion factor of 1.29.

(b): Commission Regulation (EU) 2019/552 of 4 April 2019 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for azoxystrobin, bicyclopyrone, chlormequat, cyprodinil, difenoconazole, fenpropimorph, fenpyroximate, fluopyram, fosetyl, isoprothiolane, isopyrazam, oxamyl, prothioconazole, spinetoram, trifloxystrobin and triflumezopyrim in or on certain products. OJ L 96, 5.4.2019, p. 6–49.

Appendix C – Used compound codes

Code/trivial name[a]	IUPAC name/SMILES notation/ InChiKey[b]	Structural formula[c]
Chlormequat (cation)	(2-chloroethyl)trimethylammonium C[N+](C)(C)CCCl JUZXDNPBRPUIOR-UHFFFAOYSA-N	
Chlormequat chloride	(2-chloroethyl)trimethylammonium chloride [Cl−].C[N+](C)(C)CCCl UHZZMRAGKVHANO-UHFFFAOYSA-M	

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 Dec 2014).
(c): ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 Dec 2014).