REASONED OPINION OF EFSA

Modification of the existing MRL for chlormequat in pears

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-741)

Issued on 05 February 2009

SUMMARY

According to Article 6(3) of Regulation (EC) No 396/2005, The Netherlands compiled an application to set a temporary MRL of 0.1 mg/kg for chlormequat in pears until 31 July 2014 in order to accommodate for carry over of chlormequat residues due to uses formerly authorized in pear trees. The subsequent evaluation report, drafted by The Netherlands as well, was forwarded to EFSA on 07 October 2008 according to Article 9 of the Regulation.

Based on the evaluation report and the supporting dossier submitted by The Netherlands, EFSA derives the following conclusions regarding the application.

Metabolism of chlormequat in pears was not investigated. However, carry over of chlormequat in pear orchards is caused by the slow degradation of the parent compound in pear trees and the accumulation of unchanged chlormequat in the stem. Other significant metabolites are therefore not expected and further data are not required. An analytical method for enforcement of chlormequat in pears is also available.

Supervised residues field trials are reported where levels of chlormequat in pears have been monitored over a period of 9-10 years following the revocation of chlormequat authorizations in pears. Residue levels in pears sampled in 2007 were found to be below the LOQ of 0.05 mg/kg. In addition, both targeted and untargeted monitoring data collected between 1999 and 2008 were provided. Based on these data it is demonstrated that for the harvest of 2009 chlormequat levels in untargeted pear samples will be below the LOQ in more than 95% of the cases while chlormequat levels in targeted pear samples are expected to be below the LOQ in less than 95% of the cases. It is therefore concluded that a temporary MRL of 0.1 mg/kg until 31 July 2014 might be required on the condition that from a risk management point of view the MRL is expected to accommodate both targeted and untargeted pear samples. If the MRL is only expected to cover residue levels in untargeted samples, the setting of a temporary MRL for chlormequat in pears is no longer necessary.

The possible occurrence of chlormequat residues in rotational crops was not investigated because pear trees are perennial, meaning that they are not grown in rotation with other crops.

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1 For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for chlormequat in pears. EFSA Scientific Report (2009) 232, 1-34
Residues in commodities of animal origin were not assessed neither considering that pears and its by-products are usually not fed to livestock.

Finally, chronic intake calculations were performed considering the MRL of 0.1 mg/kg proposed by The Netherlands for chlormequat in pears as well as all existing MRLs for the active substance. The calculations are based on revision 2 of the EFSA PRIMo and no chronic intake concerns are identified for all available European diets. An acute intake calculation was also undertaken for the MRL of 0.1 mg/kg in pears and no acute intake concern was identified.

Key words: chlormequat, pears, MRL application, Regulation (EC) No 396/2005, quaternary ammonium plant growth regulators
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BACKGROUND
Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

In particular, The Netherlands, hereafter referred to as the Evaluating Member State (EMS), compiled an application to modify the existing MRL for the active substance chlormequat in pears. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 07 October 2008. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2008-741 and the following subject:

Chlormequat (Chloride) - Application to modify the existing MRL for chlormequat in pears from 0.2 mg/kg to 0.1 mg/kg. From 31 July 2009 the LOQ of 0.05* mg/kg should apply; Request for the lowering of current tMRL of 0.2 mg/kg to 0.1 mg/kg and extension of this tMRL until 31 July 2014.

After reception of the evaluation report EFSA proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE
According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application. Particular attention shall be given to the requirements set out in that Article.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion is 07 January 2009.
THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Chlormequat is the ISO common name for 2-chloroethyltrimethylammonium (IUPAC).

\[
\text{Cl} \quad \text{CH}_2 \quad \text{CH}_2 \quad \text{N}^+ \quad \text{CH}_3
\]

Chlormequat belongs to the class of quaternary ammonium plant growth regulators. It is usually applied as a chloride salt. Chlormequat inhibits cell elongation, which results in a sturdier plant by shortening and strengthening the stem. It may also be used to increase the flowering and/or fruit setting. It mainly acts by inhibiting the gibberellin biosynthesis.

Chlormequat was evaluated in the framework of Directive 91/414/EEC as a stage 3 active substance with The United Kingdom being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process include a single foliar application on winter and spring wheat, winter and spring barley, triticale, durum wheat, spelt wheat, rye and oats from growth stage of BBCH 30 up to growth stage of BBCH 49, in all EU countries. The peer review for this active substance resulted in a decision on inclusion of the active substance in Annex I of the Directive, which was taken on 23 January 2009 in the Standing Committee on the Food Chain and the Animal Health but not yet published by a directive.

EC MRLs for chlormequat in animal and plant commodities, including cereals, have been set for the first time in 1996, which were revised in 2000 by Directive 2000/42/EC. As a result of this revision, the MRL for chlormequat in pears was set at the analytical limit of quantification (LOQ) of 0.05 mg/kg because the use of chlormequat in pears was no longer authorised. This MRL however did not consider the carry over of chlormequat residues due to the previously authorised uses in pear trees. Chlormequat has the ability to accumulate in pear trees resulting in chlormequat residues in the pears several years after application. In order to address this contamination, the MRL was temporarily increased to 0.5 mg/kg in 2001. As the contamination level decreased over the years, the temporary MRL in pears was lowered on several occasions. The last modification of the MRL dates from 2008 where the MRL was set at 0.2 mg/kg until 31 July 2009. This value was transferred to Regulation (EC) No 396/2005 without any modification.

According to the current legislation for chlormequat in pears the LOQ of 0.05 mg/kg will apply as from 01 August 2009. The Netherlands is however of the opinion that based on the currently available monitoring data residue levels of chlormequat in pears will still exceed the LOQ after that date. An application to maintain a temporary MRL at 0.1 mg/kg until 31 July 2014 was therefore submitted. In support of the MRL application an evaluation report was prepared by The Netherlands.
ASSESSMENT

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

According to the EFSA conclusion on chlormequat (EFSA, 2009) adequate methods are available for enforcement of chlormequat, including its salts, in matrices with a high content of water, acid or oil as well as in dry commodities. The analytical method uses liquid chromatography with detection by double mass spectrometry. A LOQ of 0.5 mg/kg was derived for dry commodities, while a LOQ of 0.05 mg/kg was derived for the other commodity groups.

Considering that pears belong to the group of commodities with high water content, it is possible to enforce chlormequat in pears with a LOQ of 0.05 mg/kg.

1.2. Methods for enforcement of residues in food of animal origin

The availability of an analytical method for enforcement of residues in food of animal origin was not considered in the framework of this application. Pears and their by-products are usually not fed to animals and residues in animal commodities resulting from the reported contamination are therefore not expected.

2. Mammalian toxicology

The toxicological properties of chlormequat have been evaluated under Directive 91/414/EEC (EFSA, 2009) and reference values have been derived for chlormequat chloride. Considering that the residue definition for risk assessment is defined as chlormequat in the framework of this application, reference values are also recalculated to chlormequat based on the molecular weight of both compounds. The reference values are summarized in the table below.

Table 2-1. Overview of the toxicological reference values

<table>
<thead>
<tr>
<th>Source</th>
<th>Year</th>
<th>Value (mg/kg bw/d)</th>
<th>Study relied upon</th>
<th>Safety factor</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reference values expressed as chlormequat chloride</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADI</td>
<td>EFSA</td>
<td>2009</td>
<td>0.04</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-year dog study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARfD</td>
<td>EFSA</td>
<td>2009</td>
<td>0.09</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4-week dog study</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reference values expressed as chlormequat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADI</td>
<td>EFSA</td>
<td>2009</td>
<td>0.031</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1-year dog study</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARfD</td>
<td>EFSA</td>
<td>2009</td>
<td>0.070</td>
<td>100</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4-week dog study</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n.n.: not necessary
3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The metabolism of chlormequat chloride was investigated in wheat (EFSA, 2009). The main component in grain and straw at harvest was unmetabolised chlormequat. Considering that the available analytical methods determine the chlormequat cation the relevant residue for both enforcement and risk assessment was defined as chlormequat and its salts, expressed as chlormequat chloride. This residue definition is only applicable to cereals.

No metabolism studies are available for chlormequat in fruit crops and carry over of chlormequat residues was only monitored for the unchanged parent compound so far. However, the carry over seems to be caused by the slow degradation and subsequent accumulation of parent chlormequat in the stem of the trees (The Netherlands, 2008). Presence of other significant metabolites is therefore not expected. Also considering that the existing temporary MRL in pears is set for chlormequat, it is proposed to define the relevant residue as chlormequat in the framework of this application.

An analytical method is available for enforcement of the parent compound in pears (see also section 1.1).

3.1.1.2. Magnitude of residues

Currently, the use of chlormequat in pears is no longer authorised but a temporary MRL of 0.2 mg/kg applies in order to accommodate for carry over of chlormequat residues from uses formerly authorized in Belgium and in The Netherlands. This temporary MRL will expire on 01 August 2009, but according to The Netherlands (2008), levels of chlormequat in pears are still expected to exceed the LOQ of 0.05 mg/kg after that day. The Netherlands therefore propose to set a new temporary MRL of 0.1 mg/kg until 31 July 2014. In the Dutch evaluation report, different sources of information supporting this proposal are reported.

Five field trials are reported where levels of chlormequat in pears have been monitored over a period of 9-10 years following the revocation of chlormequat authorizations in pears. The pears investigated originate from orchards with a known history of chlormequat treatments. Two of these trials were not continued after 2005 and do not provide any information regarding the decline of residues over the last few years. The three other trials indicate a fast breakdown of residues during the first years followed by a slower degradation over the last years. In 2007 the wood and the roots of the contaminated trees were also sampled and average chlormequat levels of 7.2 mg/kg and 48 mg/kg were found, respectively. According to the Netherlands, this means that theoretically chlormequat might still be translocated to the fruits. Nevertheless, residue levels in the pears harvested in 2007 were found to be below the LOQ of 0.05 mg/kg. Significant translocation from the trunks to the fruits is therefore not expected in practice.

In addition, The Netherlands provided the official Belgian and Dutch monitoring data for chlormequat in pears (Appendix A and B) after untargeted sampling. In order to predict the
expected residue levels for the harvest of 2009, both data sets were pooled and sorted by year of harvest, assuming that the harvest of pears starts on the 1st of August that year and that harvested pears might be present on the market until 31st of July the following year (see Table 3-1). Pear samples originating from third countries were not included as chlormequat used to be authorized in Belgium and in The Netherlands. Data for the harvest of 2003 were not included as well due to the limited number of samples.

Table 3-1. Summary of the official monitoring data combined for Belgium and the Netherlands (untargeted).

<table>
<thead>
<tr>
<th>Year of harvest</th>
<th>Total number of samples</th>
<th>≤0.05 mg/kg</th>
<th>0.06-0.10 mg/kg</th>
<th>0.11-0.20 mg/kg</th>
<th>0.21-0.50 mg/kg</th>
<th>Highest residue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2004</td>
<td>51</td>
<td>42</td>
<td>5</td>
<td>4</td>
<td>0</td>
<td>0.19</td>
</tr>
<tr>
<td>2005</td>
<td>27</td>
<td>19</td>
<td>6</td>
<td>2</td>
<td>0</td>
<td>0.14</td>
</tr>
<tr>
<td>2006</td>
<td>109</td>
<td>100</td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>0.41</td>
</tr>
<tr>
<td>2007</td>
<td>54</td>
<td>49</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0.13</td>
</tr>
</tbody>
</table>

Considering that MRLs based on monitoring data are usually calculated as the 95th percentile of a residue population, the 95th percentiles for each year of harvest were calculated and plotted in a graph (see Figure 3-1). A steady decline of chlormequat residues over the years is observed and, assuming an exponential degradation curve, it can be predicted that in 2009 the 95th percentile of the chlormequat levels will be below the LOQ of 0.05 mg/kg. This means that for the harvest of 2009 chlormequat levels in untargeted pear samples will be below the LOQ in more than 95 % of the cases.

Figure 3-1. Decline of residues based on the official monitoring data combined for Belgium and the Netherlands (untargeted), including an exponential trend line for the 95th percentiles ($y = 5E+233e^{-0.2695x}$, $R^2 = 0.9605$).
The Netherlands also reported monitoring data compiled by the Dutch Fruit Growers Organization (Appendix C). These monitoring data are targeted because only fruit growers with a known history of chlormequat use were selected. Pears of these growers were then sampled and analyzed on a yearly basis. As for the untargeted monitoring data, the decline of residues over the years was investigated by sorting the data for each year of harvest and by calculated the 95th percentiles. Data collected before 2000 were however not included in order to emphasize the degradation of chlormequat over the last years.

Table 3-2. Summary of the monitoring data collected by the Dutch Fruit Growers Organization (targeted).

<table>
<thead>
<tr>
<th>Year of harvest</th>
<th>Total number of samples</th>
<th>( \leq 0.05 ) mg/kg</th>
<th>0.06-0.10 mg/kg</th>
<th>0.11-0.20 mg/kg</th>
<th>0.21-0.50 mg/kg</th>
<th>&gt;0.50 mg/kg</th>
<th>Highest residue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000</td>
<td>49</td>
<td>1</td>
<td>8</td>
<td>15</td>
<td>21</td>
<td>4</td>
<td>0.95</td>
</tr>
<tr>
<td>2001</td>
<td>59</td>
<td>8</td>
<td>14</td>
<td>15</td>
<td>19</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>2002</td>
<td>69</td>
<td>19</td>
<td>20</td>
<td>19</td>
<td>11</td>
<td>0</td>
<td>0.5</td>
</tr>
<tr>
<td>2003</td>
<td>63</td>
<td>33</td>
<td>22</td>
<td>5</td>
<td>3</td>
<td>0</td>
<td>0.32</td>
</tr>
<tr>
<td>2004</td>
<td>63</td>
<td>47</td>
<td>11</td>
<td>4</td>
<td>1</td>
<td>0</td>
<td>0.24</td>
</tr>
<tr>
<td>2005</td>
<td>51</td>
<td>37</td>
<td>11</td>
<td>1</td>
<td>2</td>
<td>0</td>
<td>0.27</td>
</tr>
<tr>
<td>2006</td>
<td>50</td>
<td>36</td>
<td>7</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0.22</td>
</tr>
<tr>
<td>2007</td>
<td>48</td>
<td>39</td>
<td>7</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0.18</td>
</tr>
<tr>
<td>2008</td>
<td>46</td>
<td>39</td>
<td>3</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0.17</td>
</tr>
</tbody>
</table>

Figure 3-2 demonstrates that the 95th percentiles for targeted monitoring data are generally higher than for the untargeted data (see also Figure 3-1). Also the decline of residues is less consistent, in particular over the last three years, and a reliable degradation curve cannot be predicted. It is therefore not excluded that for the harvest of 2009 more than 5% of the targeted samples will exceed the LOQ of 0.05 mg/kg.

Comparing the data for targeted and untargeted sampling, it is concluded that a temporary MRL of 0.1 mg/kg until 31 July 2014 might be required on the condition that from a risk management point of view the MRL is expected to accommodate both targeted and untargeted pear samples. If the MRL is only expected to cover residue levels in untargeted samples, the setting of a temporary MRL for chlormequat in pears is no longer necessary.

3.1.1.3. Effect of industrial processing and/or household preparation

Exposure of consumers to chlormequat residues through the consumption of pears represents less than 10% of the ADI. Further investigation of residues in processed commodities is therefore not required.
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Figure 3-2. Decline of based on the monitoring data collected by the Dutch Fruit Growers Organization (targeted), including an exponential trend line for the 95th percentiles \( y = 8E+206e^{-0.2386x}, R^2 = 0.7993 \).

3.1.2. Rotational crops

Considering that the MRL application under consideration is resulting from a contamination and that pear trees are perennial, occurrence of chlormequat residues in rotational crops are not further considered in this framework.

3.2. Nature and magnitude of residues in livestock

Occurrence of chlormequat residues in food of animal origin was not further considered in the framework of this application. Pears and their by-products are usually not fed to animals and residues in animal commodities resulting from the reported contamination are therefore not expected.

4. Consumer risk assessment

As explained under section 3.1.1.2, the acceptance of the temporary MRL proposed by The Netherlands (2008) for chlormequat in pears will mainly depend on the risk management decision to base the MRL on targeted or untargeted monitoring data. In order to facilitate this decision, chronic intake calculations using revision 2 of the EFSA PRIMo were carried out considering the existing MRLs for chlormequat (Appendix D) as well as the temporary MRL of 0.1 mg/kg proposed by The Netherlands. Considering that the proposed MRL of 0.1 mg/kg is based on predictions rather than actual data and that EFSA has no data on the registered uses for all remaining commodities, the MRLs instead of the SMTRs were used as the input data for the intake calculations. This approach is expected to overestimate real exposure to
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chlormequat residues because the residue definitions for enforcement and risk assessment are expected to be the same.

An acute intake calculation was also carried out for the proposed MRL of 0.1 mg/kg in pears, using revision 2 of the EFSA PRIMo as well. Considering that the proposed MRL is based on predictions rather than actual data, the MRL is used in the intake calculations instead of the HR.

As the existing MRLs are set for chlormequat, the reference values expressed as chlormequat were used both for chronic and acute intake calculations.

Detailed results of the chronic and acute intake calculations are reported in Appendix E to this document. Intake calculations for all European diets result in a chronic exposure not higher than 76.6% of the ADI and contribution of pears to this exposure is very minor (less than 0.2% of the ADI). Acute exposure to chlormequat through consumption of pears with residues at the proposed level of 0.1 mg/kg amounts to 13.0% of the ARfD.
CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(3) of Regulation (EC) No 396/2005, The Netherlands compiled an application to set a temporary MRL of 0.1 mg/kg for chlormequat in pears until 31 July 2014 in order to accommodate for carry over of chlormequat residues due to uses formerly authorized in pear trees. The subsequent evaluation report, drafted by The Netherlands as well, was forwarded to EFSA on 07 October 2008 according to Article 9 of the Regulation.

Based on the evaluation report and the supporting dossier submitted by The Netherlands, EFSA derives the following conclusions regarding the application.

Metabolism of chlormequat in pears was not investigated. However, carry over of chlormequat in pear orchards is caused by the slow degradation of the parent compound in pear trees and the accumulation of unchanged chlormequat in the stem. Other significant metabolites are therefore not expected and further data are not required. An analytical method for enforcement of chlormequat in pears is also available.

Supervised residues field trials are reported where levels of chlormequat in pears have been monitored over a period of 9-10 years following the revocation of chlormequat authorizations in pears. Residue levels in pears sampled in 2007 were found to be below the LOQ of 0.05 mg/kg. In addition, both targeted and untargeted monitoring data collected between 1999 and 2008 were provided. Based on these data it is demonstrated that for the harvest of 2009 chlormequat levels in untargeted pear samples will be below the LOQ in more than 95 % of the cases while chlormequat levels in targeted pear samples are expected to be below the LOQ in less than 95% of the cases. It is therefore concluded that a temporary MRL of 0.1 mg/kg until 31 July 2014 might be required on the condition that from a risk management point of view the MRL is expected to accommodate both targeted and untargeted pear samples. If the MRL is only expected to cover residue levels in untargeted samples, the setting of a temporary MRL for chlormequat in pears is no longer necessary.

The possible occurrence of chlormequat residues in rotational crops was not investigated because pear trees are perennial, meaning that they are not grown in rotation with other crops. Residues in commodities of animal origin were not assessed neither considering that pears and its by-products are usually not fed to livestock.

Finally, chronic intake calculations were performed considering the MRL of 0.1 mg/kg proposed by The Netherlands for chlormequat in pears as well as all existing MRLs for the active substance. The calculations are based on revision 2 of the EFSA PRIMO and no chronic intake concerns are identified for all available European diets. An acute intake calculation was also undertaken for the MRL of 0.1 mg/kg in pears and no acute intake concern was identified.
REFERENCES

APPENDICES
Appendix A – Official monitoring data from Belgium
Appendix B – Official monitoring data from The Netherlands
Appendix C – Monitoring data collected by the Dutch Fruit Growers Organization
Appendix D – List of existing EC MRLs
Appendix E – Pesticide Residues Intake Model (PRIMo)
**APPENDIX A – OFFICIAL MONITORING DATA FROM BELGIUM**

<table>
<thead>
<tr>
<th>Sample code</th>
<th>Commodity</th>
<th>Sampling date</th>
<th>Active substance</th>
<th>Result</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>3259060022</td>
<td>Pears</td>
<td>07/04/2006</td>
<td>Chlorméquat</td>
<td>&lt;LOQ (0,05)</td>
<td>BE</td>
</tr>
<tr>
<td>1077060026</td>
<td>Pears</td>
<td>11/04/2006</td>
<td>Chlorméquat</td>
<td>&lt;LOQ (0,05)</td>
<td>BE</td>
</tr>
<tr>
<td>1077060027</td>
<td>Pears</td>
<td>11/04/2006</td>
<td>Chlorméquat</td>
<td>&lt;LOQ (0,05)</td>
<td>BE</td>
</tr>
<tr>
<td>1077060028</td>
<td>Pears</td>
<td>11/04/2006</td>
<td>Chlorméquat</td>
<td>&lt;LOQ (0,05)</td>
<td>BE</td>
</tr>
<tr>
<td>1077060025</td>
<td>Pears</td>
<td>11/04/2006</td>
<td>Chlorméquat</td>
<td>0,13</td>
<td>BE</td>
</tr>
<tr>
<td>2429060009</td>
<td>Pears</td>
<td>08/05/2006</td>
<td>Chlorméquat</td>
<td>&lt;LOQ (0,05)</td>
<td>BE</td>
</tr>
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APPENDIX B – OFFICIAL MONITORING DATA FROM THE NETHERLANDS

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Modification of the existing MRL for chlormequat in pears

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## APPENDIX D – LIST OF EXISTING EC MRLS

Pesticides - Web Version - EU MRLs (File created on 02/02/2009 15:12)

<table>
<thead>
<tr>
<th>Code number</th>
<th>Groups and examples of individual products to which the MRLs apply (a)</th>
<th>Chlormequat</th>
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<tr>
<td>110000</td>
<td>1, FRUIT FRESH OR FROZEN; NUTS</td>
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<tr>
<td>110000 (i)</td>
<td>Citrus fruit</td>
<td>0.05*</td>
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<tr>
<td>110010</td>
<td>Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)</td>
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</tr>
<tr>
<td>110020</td>
<td>Oranges (Bergamot, bitter orange, chinotto and other hybrids)</td>
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</tr>
<tr>
<td>110030</td>
<td>Lemons (Citron, lemon)</td>
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</tr>
<tr>
<td>110050</td>
<td>Mandarinis (Clementine, tangerine and other hybrids)</td>
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<tr>
<td>110990</td>
<td>Others</td>
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</tr>
<tr>
<td>120000</td>
<td>(ii) Tree nuts (shelled or unshelled)</td>
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<tr>
<td>120010</td>
<td>Almonds</td>
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<tr>
<td>120020</td>
<td>Brazil nuts</td>
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<tr>
<td>120030</td>
<td>Cashew nuts</td>
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<tr>
<td>120040</td>
<td>Chestnuts</td>
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</tr>
<tr>
<td>120050</td>
<td>Coconuts</td>
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</tr>
<tr>
<td>120060</td>
<td>Hazelnuts (Filbert)</td>
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</tr>
<tr>
<td>120070</td>
<td>Macadamia</td>
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</tr>
<tr>
<td>120080</td>
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<td>(iii) Pome fruit</td>
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<tr>
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<td>Pears (Oriental pear)</td>
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<td>Quinces</td>
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<td>Apricots</td>
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<td>Cherries (sweet cherries, sour cherries)</td>
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<tr>
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<td>Peaches (Nectarines and similar hybrids)</td>
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<tr>
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<td>Plums (Damson, greengage, mirabelle)</td>
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<td>140990</td>
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<td>150000</td>
<td>(v) Berries &amp; small fruit</td>
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<tr>
<td>151000</td>
<td>(a) Table and wine grapes</td>
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<tr>
<td>151010</td>
<td>Table grapes</td>
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</tr>
<tr>
<td>151020</td>
<td>Wine grapes</td>
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<tr>
<td>152000</td>
<td>(b) Strawberries</td>
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<tr>
<td>153000</td>
<td>(c) Cane fruit</td>
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<tr>
<td>153010</td>
<td>Blackberries, Dewberries, Loganberries, Boysenberries, and cloudberry</td>
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<td>153020</td>
<td>Raspberries (Wineberries)</td>
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<tr>
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<td>(d) Other small fruit &amp; berries</td>
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<td>Blueberries (Bilberries, cowberries (red bilberries))</td>
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<td>Currants (red, black and white)</td>
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<td>Gooseberries (Including hybrids with other ribes species)</td>
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<td>Rose hips</td>
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<td>Mulberries (arbutus berry)</td>
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<td>Azarole (mediteranean mediar)</td>
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<td>Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)</td>
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<td>154990</td>
<td>Others</td>
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<tr>
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<td>(vi) Miscellaneous fruit</td>
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<td>Figs</td>
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<td>Table olives</td>
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<td>Kumquats (Marumi kumquats, nagami kumquats)</td>
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<td>Carambola (Bilimbi)</td>
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<td>Persimmon</td>
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<td>Jambolan (java plum)</td>
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<td>Others</td>
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<tr>
<td>162000</td>
<td>(b) Inedible peel, small</td>
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<td>162010</td>
<td>Kiwi</td>
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<tr>
<td>162020</td>
<td>Lychee (Litchi) (Pulasan, rambutan (hairy litchi))</td>
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<td>162030</td>
<td>Passion fruit</td>
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<td>Prickly pear (cactus fruit)</td>
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<td>Star apple</td>
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<td>American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)</td>
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<td>162990</td>
<td>Others</td>
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<td>163000</td>
<td>(c) Inedible peel, large</td>
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<td>163010</td>
<td>Avocados</td>
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Modification of the existing MRL for chlormequat in pears


### 1. FRUITS

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<tr>
<td>163020</td>
<td>Bananas (Dwarf banana, plantain, apple banana)</td>
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<td>163030</td>
<td>Mangoes</td>
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<td>Papaya</td>
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<td>Pomegranate</td>
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<td>Cherimoya (Custard apple, sugar apple (sweetsoap), llama and other medium sized Annonaceae)</td>
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<td>163070</td>
<td>Guava</td>
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<td>163080</td>
<td>Pineapples</td>
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<td>163090</td>
<td>Bread fruit (Jackfruit)</td>
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<td>Durian</td>
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<td>163110</td>
<td>Soursop (guanabana)</td>
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<td>Others</td>
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### 2. VEGETABLES FRESH OR FROZEN

#### (i) Root and tuber vegetables

- 210000 | (a) Potatoes                                     | 0.05*|

#### (b) Tropical root and tuber vegetables

- 212000 | Cassava (Dasheen, eddoe (Japanese taro), tannia) | 0.05*|
- 212020 | Sweet potatoes                                   | 0.05*|
- 212030 | Yams (Potato bean (yam bean), Mexican yam bean) | 0.05*|
- 212040 | Arrowroot                                        | 0.05*|
- 212990 | Others                                           | 0.05*|

#### (c) Other root and tuber vegetables except sugar beet

- 213000 | Beetroot                                         | 0.05*|
- 213020 | Carrots                                          | 0.05*|
- 213030 | Celeriac                                         | 0.05*|
- 213040 | Horseradish                                      | 0.05*|
- 213050 | Jerusalem artichokes                             | 0.05*|
- 213060 | Parsnips                                         | 0.05*|
- 213070 | Parsley root                                     | 0.05*|
- 213080 | Radishes (Black radish, Japanese radish, small radish and similar varieties) Salsify (Schorzoner, Spanish salsify (Spanish oysterplant)) | 0.05*|
- 213090 | Others                                           | 0.05*|
- 213100 | Swedes                                           | 0.05*|
- 213110 | Turnips                                          | 0.05*|
- 213990 | Others                                           | 0.05*|

### (ii) Bulb vegetables

- 220000 | Garlic                                           | 0.05*|
- 220010 | Garlic Onions (Silverskin onions)                | 0.05*|
- 220020 | Shallots                                         | 0.05*|
- 220040 | Spring onions (Welsh onion and similar varieties) | 0.05*|
- 220990 | Others                                           | 0.05*|

### (iii) Fruit ing vegetables

- 230000 | (a) Solanaceae                                   | 0.05*|
- 231000 | Tomatoes (Cherry tomatoes, )                      | 0.05*|

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Modification of the existing MRL for chlormequat in pears

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<th>MRL</th>
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<td>251070</td>
<td>Red mustard Leaves and sprouts of Brassica spp (Mizuna)</td>
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<td>251080</td>
<td>Others</td>
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<tr>
<td>251990</td>
<td>(b) Spinach &amp; similar leaves</td>
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<tr>
<td>252000</td>
<td>(c) Vine leaves (grape leaves)</td>
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<tr>
<td>252010</td>
<td>Spinach (New Zealand spinach, turnip greens (turnip tops))</td>
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<tr>
<td>252020</td>
<td>Purslane (Winter purslane (miners s lettuce), garden purslane, common purslane, sorrel, glassworth)</td>
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<td>252030</td>
<td>Beet leaves (chard) (Leaves of beetroot)</td>
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<td>252990</td>
<td>Others</td>
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<tr>
<td>253000</td>
<td>(d) Water cress</td>
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<td>(e) Witloof</td>
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<td>(f) Herbs</td>
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<td>Chervil</td>
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<td>Chives</td>
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<td>256030</td>
<td>Celery leaves (fennel leaves, Caraway leaves, lovage, angelica, sweet cisel and other Apiaceae)</td>
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<td>256040</td>
<td>Parsley</td>
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<td>Sage (Winter savory, summer savory, )</td>
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<td>256060</td>
<td>Rosemary</td>
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<td>Thyme (marjoram, oregano)</td>
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<tr>
<td>256080</td>
<td>Basil (Balm leaves, mint, peppermint)</td>
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<td>Bay leaves (laurel)</td>
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<td>256100</td>
<td>Tarragon (Hyssop)</td>
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<tr>
<td>256990</td>
<td>Others</td>
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<tr>
<td>260000</td>
<td>(v) Legume vegetables (fresh)</td>
<td>0.05*</td>
</tr>
<tr>
<td>260100</td>
<td>Beans (with pods) (Green bean, snap bean, scarlet runner bean, slicing bean, yardlong beans)</td>
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<tr>
<td>260101</td>
<td>Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)</td>
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<tr>
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<td>Peas (with pods) (Mangetout (sugar peas))</td>
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<tr>
<td>260400</td>
<td>Peas (without pods) (Garden pea, green pea, chickpea)</td>
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<tr>
<td>260500</td>
<td>Lentils</td>
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<td>260990</td>
<td>Others</td>
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<tr>
<td>270000</td>
<td>(vii) Stem vegetables (fresh)</td>
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<tr>
<td>270010</td>
<td>Asparagus</td>
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<td>Cardoons</td>
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<tr>
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### Modification of the existing MRL for chlormequat in pears

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#### 6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA

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APPENDIX E – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)
### Chlormequat

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#### Toxicological end points

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#### Chronic risk assessment - refined calculations

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<th>Commodity / group of commodities in % of ADI</th>
<th>2nd contributor to MS diet</th>
<th>Commodity / group of commodities in % of ADI</th>
<th>3rd contributor to MS diet</th>
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<td>WHO regional European diet</td>
<td>Wheat</td>
<td>2.7</td>
<td>Rape seed</td>
<td>2.2</td>
<td>Cultivated fungi</td>
<td>3.4</td>
</tr>
<tr>
<td>29.7</td>
<td>PT General population</td>
<td>Wheat</td>
<td>0.9</td>
<td>Rye</td>
<td>0.9</td>
<td>Potatoes</td>
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</tr>
<tr>
<td>29.7</td>
<td>IT adult</td>
<td>Wheat</td>
<td>1.8</td>
<td>Cultivated fungi</td>
<td>0.2</td>
<td>Tomatoes</td>
<td>1.2</td>
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<tr>
<td>27.3</td>
<td>SE general population 90th percentile</td>
<td>Wheat</td>
<td>2.0</td>
<td>Milk and cream,</td>
<td>1.9</td>
<td>Rye</td>
<td>4.6</td>
</tr>
<tr>
<td>27.2</td>
<td>FR toddler</td>
<td>Wheat</td>
<td>6.4</td>
<td>Milk and cream,</td>
<td>0.8</td>
<td>Potatoes</td>
<td>10.1</td>
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<tr>
<td>24.0</td>
<td>FR all population</td>
<td>Wheat</td>
<td>0.6</td>
<td>Wine grapes</td>
<td>0.4</td>
<td>Milk and cream,</td>
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</tr>
<tr>
<td>23.3</td>
<td>ES adult</td>
<td>Wheat</td>
<td>3.2</td>
<td>Barley</td>
<td>2.1</td>
<td>Cultivated fungi</td>
<td>2.4</td>
</tr>
<tr>
<td>23.0</td>
<td>DK adult</td>
<td>Wheat</td>
<td>4.4</td>
<td>Rye</td>
<td>1.9</td>
<td>Oats</td>
<td>2.2</td>
</tr>
<tr>
<td>22.8</td>
<td>NL general</td>
<td>Wheat</td>
<td>2.6</td>
<td>Cultivated fungi</td>
<td>2.4</td>
<td>Barley</td>
<td>3.1</td>
</tr>
<tr>
<td>20.8</td>
<td>UK vegetarian</td>
<td>Wheat</td>
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<td>Cultivated fungi</td>
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<td>Oats</td>
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<td>17.8</td>
<td>LT adult</td>
<td>Wheat</td>
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<td>Wheat</td>
<td>1.5</td>
<td>Oats</td>
<td>2.2</td>
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<td>15.6</td>
<td>UK Adult</td>
<td>Wheat</td>
<td>2.0</td>
<td>Cultivated fungi</td>
<td>0.6</td>
<td>Sugar beet (root)</td>
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<tr>
<td>14.3</td>
<td>FI adult</td>
<td>Wheat</td>
<td>4.4</td>
<td>Rye</td>
<td>1.4</td>
<td>Oats</td>
<td>1.9</td>
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<tr>
<td>12.4</td>
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<td>Wheat</td>
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<td>Milk and cream,</td>
<td>0.7</td>
<td>Potatoes</td>
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<td>PL general population</td>
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<td>0.6</td>
<td>Potatoes</td>
<td>0.3</td>
<td>Apples</td>
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</tbody>
</table>

#### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs, were below the ADI. A long-term intake of residues of Chlormequat is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100% of the ARfD.

<table>
<thead>
<tr>
<th>Unprocessed commodities</th>
<th>No of commodities for which ARfD/ADI is exceeded (IFESTI 1);</th>
<th>No of commodities for which ARfD/ADI is exceeded (IFESTI 2);</th>
<th>No of commodities for which ARfD/ADI is exceeded (IFESTI 1);</th>
<th>No of commodities for which ARfD/ADI is exceeded (IFESTI 2);</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)</td>
<td>Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)</td>
<td>Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)</td>
<td>Highest % of ARfD/ADI Commodities pTMRL/threshold MRL (mg/kg)</td>
</tr>
<tr>
<td></td>
<td>13.0 Pears 0.1 / -</td>
<td>9.4 Pears 0.1 / -</td>
<td>3.1 Pears 0.1 / -</td>
<td>2.3 Pears 0.1 / -</td>
</tr>
</tbody>
</table>

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

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

Conclusion:

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

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

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

ADI  Acceptable Daily Intake
ARfD  Acute Reference Dose
BBCH  Federal Biological Research Centre for Agriculture and Forestry (Germany)
EC  European Community
EFSA  European Food Safety Authority
EMS  Evaluating Member State
EU  European Union
HR  Highest Residue
ISO  International Organization for Standardization
IUPAC  International Union of Pure and Applied Chemistry
LOQ  Limit Of Quantification
MRL  Maximum Residue Limit.
PRIMo  Pesticide Residues Intake Model
RMS  Rapporteur Member State
STMR  Supervised Trials Median Residue