Evaluation of confirmatory data following the Article 12 MRL review for diquat

European Food Safety Authority (EFSA), Giulia Bellisai, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Irene Castellan, Lucien Ferreira, German Giner, Luna Greco, Samira Jarrah, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Silvia Ruocco, Miguel Santos, Alessia Pia Scarlato, Anne Theobald and Alessia Verani

Abstract

The applicant Syngenta Crop Protection AG submitted a request to the competent national authority in Sweden to evaluate the confirmatory data that were identified for diquat in the framework of the MRL review under Article 12 of Regulation (EC) No 396/2005 as not available. The applicant provided sufficient data to address the data gaps related to plant metabolism studies and analytical methods for plant and animal products. The data gap requesting further studies to investigate the nature of residues of diquat and its metabolite TOPPS in processed products was not sufficiently addressed. Considering the new studies submitted under the current application and considering that the EU uses for diquat had to be withdrawn following a decision on non-approval, EFSA proposed the lowering of the existing MRLs to the appropriate limit of quantifications for the commodities under assessment. In addition, EFSA proposed to perform a more comprehensive review of the existing MRLs that were not subject to the current assessment, taking into account the findings and conclusions of the peer review, the consequences of the non-approval decision and the revisions of Codex MRLs.

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Correspondence: pesticides.mrl@efsa.europa.eu
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Summary

In 2015, when the European Food Safety Authority (EFSA) reviewed the existing Maximum Residue Levels (MRLs) for diquat according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) a confirmatory method and an independent laboratory validation (ILV) for enforcement of diquat in commodities of plant (1a) and animal (1b) origin;
2) a fully validated analytical method for enforcement of diquat in hops (dried);
3) representative studies investigating the metabolism of diquat in two additional crop groups different from cereals;
4) toxicological data on the major plant metabolite TOPPS;
5) additional residues trials supporting authorisations and/or further clarifications on authorisations in tree nuts and olives for oil production (conducted with appropriate limits of quantification (LOQs));
6) where diquat is applied as a crop desiccant, residue trials analysing the residues in compliance with the proposed risk assessment residue definition;
7) a processing study simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) addressing the nature of diquat and TOPPS residues in processed commodities.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 2016/1002, including footnotes related to data gaps number 1 (a confirmatory method and an ILV for enforcement of diquat in commodities of plant (1a) and animal (1b) origin), data gap number 2 (a fully validated analytical method for enforcement of diquat in hops (dried)) and data gap number 3 (representative studies investigating the metabolism of diquat in two additional crop groups different from cereals) were sufficiently addressed by noting that this information was provided and assessed already during the renewal assessment. Hence, the respective footnotes can be removed.

The analytical methods for plant and animal products were found to be sufficiently validated; the methods allow to quantify the residues of diquat with an LOQ of 0.01 mg/kg in high water content, dry/starch, high oil content, high acidic content plant commodities, in plant commodities difficult to analyse (dried hops) and in animal matrices. For milk, the method was validated for an LOQ of 0.005 mg/kg.

Based on the finding of the new metabolism studies, EFSA concluded that the enforcement residue definition for plants can remain as proposed in the MRL review. The residue definition for risk assessment for plants (desiccant uses only) should be revised into two separate residue definitions: ‘diquat’ and ‘TOPPS’ were proposed. However, it is noted that for TOPPS data gap exists regarding the hazard characterisation and the toxicological reference values.
Data gap number 7 (requesting a standard hydrolysis study investigating the nature of diquat and TOPPS under representative hydrolytic conditions in processed commodities) was not addressed. Therefore, the residue definition for processed products is still open.

For a number of crops, EFSA proposes to consider the lowering of the existing MRL to the appropriate LOQ, taking into account the LOQs of the validated analytical methods submitted in response to data gap number 1a and considering the fact the previously authorised EU uses for these crops had to be withdrawn following the decision on non-approval of the active substance diquat.

Similarly, for animal products, the lowering of the existing EU MRLs is proposed, taking into account the LOQ of the analytical methods submitted in response to data gap number 1b, the fact that residues are no longer expected in feed items grown in the EU and that the Codex MRLs for the animal products concerned are set at the LOQ of 0.001mg/kg (for milk) and 0.01 mg/kg for products of animal origin.

The revision of the current residue definitions for animal products proposed in the framework of the peer review and the resulting needs for new analytical methods as well as the impact on the acceptability of Codex MRLs set for animal products should be considered in a separate assessment for which a specific mandate to EFSA should be discussed.

Following the assessment of confirmatory data, EFSA derived MRL proposals as summarised in the table below. For these MRL proposals, EFSA concluded that according to the calculations performed according to the internationally agreed methodology, the existing and proposed EU MRLs for the commodities under consideration will not result in consumer intake exceeding the acute reference dose (ARfD) or the acceptable daily intake (ADI) for parent diquat.

Overall, the risk assessment is indicative and affected by non-standard uncertainties related to the lack of data on diquat metabolite TOPPS and the fact that the data gap for processed products is still open. An additional source of uncertainty for animal products is the fact that information on the expected residue levels of the metabolites proposed to be included in the residue definition for risk assessment (i.e. diquat monopyridone and diquat dipyridone) and on the toxicological profile of these metabolites are currently not available.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|---------------------------|
| 0151010 | Table Grapes | 0.01* | 0.01* | The existing EU MRL was derived for an SEU GAP for weed control, which in the meantime has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the current LOQ. |
| 0151020 | Wine grapes | 0.01* | 0.01* | See table grapes (0151010). |
| 0270010 | Asparagus | 0.01* | 0.01* | The existing EU MRL was derived for an NEU GAP for weed control, which in the meantime has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the current LOQ. |
| 0300040 | Lupins/lupini beans | 0.2 | 0.01* | The existing EU MRL was derived for an NEU GAP for preharvest crop desiccant, which in the meantime has |
The existing EU MRL was derived from an MRL in place at the time of the MRL review. The MRL proposal derived in the MRL review based on an NEU desiccant use was not taken over in the EU legislation, due to deficiencies of the data set. All EU uses in oilseeds became obsolete in the meantime following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop.

The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed.

EFSA recommends lowering the MRL to the LOQ.

| Code(a) | Commodity       | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|---------|-----------------|-----------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0401010 | Linseeds        | 5               | 0.01*        | The existing EU MRL was derived from an MRL in place at the time of the MRL review. The MRL proposal derived in the MRL review based on an NEU desiccant use was not taken over in the EU legislation, due to deficiencies of the data set. All EU uses in oilseeds became obsolete in the meantime following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends lowering the MRL to the LOQ. |
| 0401030 | Poppy seeds     | 0.1             | 0.01*        | See linseeds (0401010).                                                                                                                                     |
| 0401040 | Sesame seeds    | 0.1             | 0.01*        | See linseeds (0401010).                                                                                                                                 |
| 0401080 | Mustard seeds   | 0.5             | 0.01*        | See linseeds (0401010).                                                                                                                                 |
| 0401120 | Borage seeds    | 0.1             | 0.01*        | See linseeds (0401010).                                                                                                                                 |
| 0401140 | Hemp seeds      | 0.5             | 0.01*        | See linseeds (0401010).                                                                                                                                 |
| 0700000 | HOPS            | 0.01*           | 0.01*        | The existing MRLs reflect the previously authorised NEU GAP. In the meantime, the GAP has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the LOQ. |
| 1011010 | Muscle of Swine | 0.05* (fat 2)   | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.05* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for meat (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL. Considering that diquat is not fat soluble, the Codex MRL for meat can be taken over in the EU for muscle without modification. |
| 1012010 | Bovine          |                 |              |                                                                                                                                                           |
| 1013010 | Sheep           |                 |              |                                                                                                                                                           |
| 1014010 | Goat            |                 |              |                                                                                                                                                           |
| 1015010 | Equine          |                 |              |                                                                                                                                                           |
| 1017010 | Other farmed terrestrial animals | | |                                                                                                                                                           |
| 1011020 | Fat of Swine    | 0.05* (fat 2)   | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. A Codex Alimentarius CXL was not in place in 2015 for fat tissues. |
| 1012020 | Bovine          |                 |              |                                                                                                                                                           |
| 1013020 | Sheep           |                 |              |                                                                                                                                                           |
| 1014020 | Sheep           |                 |              |                                                                                                                                                           |
| Code  | Commodity                          | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                 |
|-------|------------------------------------|-----------------|--------------|------------------------------------------------------------------------------------------|
| 1015020 1017020 | Goat Equine Other farmed terrestrial animals |                  |              | The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for fat (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL. |
| 1011030 1012030 1013030 1014030 1015030 1017030 | Liver of Swine Bovine Sheep Goat Equine Other farmed terrestrial animals | 0.05* (ft 2) | 0.01* See swine muscle (1011010) |
|         |                                    |                  |              | In 2019, the Codex MRL for edible offal (from mammals other than marine mammals), which also applies to liver, was lowered to the LOQ of 0.01 mg/kg. |
| 1011040 1012040 1013040 1014040 1015040 1017040 | Kidney of Swine Bovine Sheep Goat Equine Other farmed terrestrial animals | 0.05* (ft 2) | 0.01* See swine muscle (1011010) |
|         |                                    |                  |              | In 2019, the Codex MRL for edible offal (from mammals other than marine mammals), which also applies to kidney, was lowered to the LOQ of 0.01 mg/kg. |
| 1011050 1012050 1013050 1014050 1015050 1017050 | Edible offals (other than liver and kidney) of Swine Bovine Sheep Goat Equine Other farmed terrestrial animals | 0.05* (ft 2) | 0.01* See swine muscle (1011010) |
|         |                                    |                  |              | In 2019, the Codex MRL for edible offal (from mammals other than marine mammals), which also applies to other edible offals, was lowered to the LOQ of 0.01 mg/kg. |
| 1011990 1012990 1013990 1014990 1015990 1017990 | Others Swine Bovine Sheep Goat Equine Other farmed terrestrial animals | 0.05* (ft 2) | 0.01* See swine muscle (1011010) |
| 1016010 | Poultry: muscle                     | 0.05* (ft 2)    | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.05* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. |
| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|---------------------------|
| 1016020 | Poultry: fat | 0.05* (ft 2) | 0.01* | Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for meat (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL. Considering that diquat is not fat soluble, the Codex MRL for meat can be taken over in the EU for muscle without modification. |
| 1016030 | Poultry: liver | 0.05* (ft 2) | 0.01* | See poultry muscle (1016010) In 2019, the Codex MRL for liver, which also applies to liver, was lowered to the LOQ of 0.01 mg/kg. |
| 1016040 | Poultry: kidney | 0.05* (ft 2) | 0.01* | See poultry muscle (1016010) In 2019, the Codex MRL for kidney, which also applies to kidney, was lowered to the LOQ of 0.01 mg/kg. |
| 1016050 | Poultry: Edible offals (other than liver and kidney) | 0.05* (ft 2) | 0.01* | See poultry muscle (1016010) In 2019, the Codex MRL for edible offal was lowered to the LOQ of 0.01 mg/kg. |
| 1016990 | Poultry: others | 0.05* (ft 2) | 0.01* | See poultry muscle (1016010) |
| 1020000 | Milk of Cattle | 0.01* (ft 2) | 0.005* | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.01* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.005 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.005 mg/kg should be considered. The current Codex MRLs for milk (set for the same residue definition) which was established in 2019 were set at the LOQ of 0.001 mg/kg. |
| 1030010 | Birds eggs: Chicken | 0.05* (ft 2) | 0.01* | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.05* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for... |
Additional recommendation:

EFSA recommends a more comprehensive review of the existing MRLs that were not subject to the current assessment of confirmatory data, taking into account the following aspects:

- For all commodities for which the current EU MRLs were based on previously authorised EU uses, the EU uses had to be withdrawn following the non-approval decision. Hence, the EU MRLs should be lowered to the appropriate LOQ, or where relevant, to an alternative fall-back MRL, e.g. reflecting acceptable Codex MRLs.
- Since the MRL review in 2015, some of the Codex MRLs implemented in the EU legislation have been withdrawn (e.g. CXL for oats (2 mg/kg), lentils (dry) (0.2 mg/kg), soya beans (0.3 mg/kg)) or replaced by new Codex MRLs (e.g. CXL for dry peas). Thus, these EU MRLs based on outdated Codex MRLs should be reconsidered as well.
- In the framework of the peer review, a revision of the residue definitions for plant desiccant uses and animal products was proposed. EFSA recommends assessing the implications of the proposed new residue definitions on analytical methods as well as the impact on the acceptability of Codex MRLs set for animal products.

Hence, a more comprehensive review of the existing EU MRLs would be appropriate. In the current assessment, EFSA derived MRL proposals for those commodities that had to be assessed in the context of confirmatory data requested in the MRL review. For all other commodities not covered by the current assessment, a separate assessment to review the existing EU MRLs needs to be performed, for which a specific mandate under Art. 43 of Regulation (EC) No 396/2005 should be submitted to EFSA.
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**Assessment**

The review of existing maximum residue levels (MRLs) for the active substance diquat according to Article 12 of Regulation (EC) No 396/2005\(^1\) (MRL review) has been performed in 2015 (EFSA, 2015a). European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The list of good agricultural practices (GAPs) assessed in the framework of the MRL review for which confirmatory data were requested is listed for transparency in Appendix A.

Following the review of existing MRLs, the legal limits have been modified by Commission Regulation (EU) No 2016/1002\(^2\), including footnotes for tentative MRLs that specified the type of information that was identified as missing. Any party having an interest in maintaining the proposed tentative MRL was requested to address the confirmatory data by 24 June 2018.

Parallel to the MRL review, diquat was also evaluated for the renewal of approval in the framework of Regulation (EC) No 1107/2009\(^3\) and in the context of Commission Regulation (EU) No 1141/2010\(^4\) with the United Kingdom designated as rapporteur Member State (RMS). The representative uses evaluated were as desiccant on potato, oilseed rape, sunflower, pulses and as herbicide on apple, citrus, pome fruit, stone fruit, tree nut, olive, grapevine, tomato, potato, carrot, chicory, sugar beet, onion. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA and in 2015 the EFSA conclusion was published (EFSA, 2015b). Following discussions in the Standing Committee on Plants, Animals, Food and Feed, a decision was taken to not renew the approval of diquat (Commission Implementing Regulation (EU) 2018/1532)\(^5\).

As a consequence, the EU uses of plant protection products containing diquat had to be withdrawn by 4 May 2019 (period of grace according to Article 46 of Regulation (EC) No 1107/2009 expired on 4 February 2020). Hence, all GAPs for which the MRLs have been derived in 2015, including the GAPs listed in Appendix A, are no longer authorised in the EU.

In June 2018, in accordance with the specific provisions set out in the working document (European Commission, 2020), the applicant, Syngenta Crop Protection AG submitted an application to the competent national authority in Sweden (rapporteur Member State, RMS) to evaluate the confirmatory data identified as missing during the MRL review. To address the data gaps identified in the MRL review (EFSA, 2015a), which are listed individually in the summary section, the applicant resubmitted the following studies that were also provided in the context of the renewal assessment:

- A validated high-performance liquid chromatography (HPLC-MS/MS) method for analyses of diquat ion in all plant commodities including difficult matrices (hops) which was already evaluated during the peer review.
- A validated HPLC-MS/MS method for analyses of diquat ion in animal commodities which was already evaluated during the peer review.
- Additional metabolism studies on tomato (representative for weed control) and on potato and oilseed rape (representative for desiccant uses); these studies were also previously evaluated during the peer review.
- In addition, the applicant provided residue trials for a range of crops for uses of diquat assessed in the MRL review.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 2 August 2021 (Sweden, 2021). EFSA assessed the

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1. Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
2. Commission Regulation (EU) 2016/1002 of 17 June 2016 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 AMT, diquat, dodine, glufosinate and tritosulfuron in or on certain products. OJ L 167, 24.6.2016, p. 1–45.
3. 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.
4. Commission Regulation (EU) No 1141/2010 of 7 December 2010 laying down the procedure for the renewal of the inclusion of a second group of active substances in Annex I to Directive 91/414/EEC and establishing the list of those substances. OJ L 322, 8.12.2010, p. 10–19.
5. Commission Implementing Regulation (EU) 2018/1532 of 12 October 2018 concerning the non-renewal of approval of the active substance diquat, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. OJ L 257, 15.10.2018, p. 10–12.
application as requested by the European Commission in accordance with Article 10 of Regulation (EC) No 396/2005.

Considering the new situation for EU authorisations which had to be withdrawn with a maximum period of grace by 4 February 2020, some of the data gaps related to the EU uses implemented in the MRL legislation became obsolete. EFSA therefore focused in this assessment on the generic data gaps on analytical methods required for MRL enforcement, on the metabolism studies in view of deriving residue definitions and on the data gap on the nature of residues in processed commodities (standard hydrolysis studies), which are relevant for deriving residue definitions for processed products.

EFSA based its assessment on the evaluation report submitted by the RMS (Sweden, 2021), the reasoned opinion on the MRL review according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2015a) and additional assessments of diquat performed after the MRL review (EFSA, 2015b).

For this application, the data requirements established in Regulation (EU) No 544/20116 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Commission Regulation (EU) No 2016/1002 are applicable. The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20117.

An updated list of end points relevant for the confirmatory data assessment, including the end points of relevant studies assessed previously and the confirmatory data evaluated in this application, is presented in Appendix B.

The evaluation report submitted by the RMS (Sweden, 2021) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. Residues in plants

1.1. Nature of residues and methods of analysis in plants

1.1.1. Nature of residues in primary crops

In the MRL review, a data gap (data gap number 3) was identified, requesting representative studies investigating the metabolism of diquat in two additional crop groups different from cereals. EFSA considered this necessary to fully address the metabolism of diquat as a crop desiccant in plants (EFSA, 2015a).

In the context of the renewal assessment, new metabolism studies in potato and oilseed rape representing desiccant uses were submitted and considered as acceptable (EFSA, 2015b). In addition, a fruit metabolism study on tomato for the herbicide use of diquat was provided (EFSA, 2015b). Details on the design of the studies are presented in Appendix B.1.1.1.

For the use of diquat as a desiccant in potatoes and oilseed rape, diquat was the major compound of the total radioactive residues with up to 79% of the total radioactive residue (TRR) in potato flesh and 60% TRR in oilseed rapeseed. Metabolite TOPPS was found at significant proportions rapeseed (10% TRR – 0.075 mg/kg), but was not detected in potato tuber (EFSA, 2015b).

EFSA concluded that the data gap 3 identified in the framework of the MRL review was addressed by the studies assessed in the renewal process. The impact on the residue definitions for plant products is discussed in Section 1.1.6.

1.1.2. Nature of residues in rotational crops

No confirmatory data were requested in the MRL review and therefore not relevant for the current assessment.

1.1.3. Nature of residues in processed commodities

In the MRL review, a data gap (data gap number 7) was identified related to the nature of residues in processed products. A processing study was therefore requested to investigate the degradation of diquat

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6 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.

7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127-175.
and TOPPS under hydrolytic conditions representative for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) (EFSA, 2015a).

In the framework of the renewal process, the applicant provided a scientific position paper to demonstrate that diquat and TOPPS are stable under conditions of processing. This information was, however, not considered as sufficient, and therefore, a data gap was identified in the EFSA conclusion (EFSA, 2015b). New data were not provided in the frame of this assessment.

EFSA confirms the previous conclusion that the nature of diquat and TOPPS residues expected in processed products is not sufficiently addressed.

1.1.4. Methods of analysis in plants

In the MRL review, a data gap (data gap number 1a) for a confirmatory method and an ILV for enforcement of diquat in commodities of plant origin was identified.

In addition, EFSA noted a data gap (number 2) requesting a validated analytical method for enforcement of diquat specifically in hops.

To address these two data gaps, the applicant resubmitted the analytical methods which were already assessed by EFSA in the renewal of approval assessment (EFSA, 2015b). Details on these methods and the validation data are presented in Appendix B.1.1.1.

In short, the HPLC-MS/MS method was found to be sufficiently validated and allows to quantify residues of diquat with an LOQ of 0.01 mg/kg in high water content, dry/starch, high oil content and high acidic content plant commodities and in commodities difficult to analyse (dried hops). A confirmatory method (fully validated second mass transition) and interlaboratory validation (ILV) were also provided.

EFSA concluded that the data gaps number 1a and 2 were sufficiently addressed. The requirements of the new guidance on extraction efficiency (European Commission, 2017) which is not applicable for the current assessment were partially addressed and further investigation would be desirable.

1.1.5. Stability of residues in plants

No confirmatory data were requested in the MRL review, and therefore, this section is not relevant for the current assessment.

1.1.6. Proposed residue definitions

In the framework of the MRL review (EFSA, 2015a), the following residue definitions were derived for unprocessed plant commodities:

- Residue definition for enforcement: sum of diquat and its salts expressed as diquat (for cereals only; tentative for all other commodities of plant origin).
- Residue definition for risk assessment (tentative): sum of diquat, its salts and TOPPS expressed as diquat (a tentative conversion factor of 1.5 from enforcement to risk assessment for cereals only).

In Regulation (EC) No 396/2005, the following general enforcement residue definition has been implemented for all plant commodities:

- Diquat (sum of diquat and its salts, expressed as diquat).

In the framework of the renewal assessment of diquat (EFSA, 2015b), additional metabolism studies were assessed which were also resubmitted for the current assessment to address data gap number 3 (see also Section 1.1.1). Based on the comprehensive data package on plant metabolism studies representative for weed control in fruit crops and desiccant use in root crops, cereals and pulses/oilseeds, the following residue definitions were proposed:

- Residue definition for enforcement: diquat (all plant crops, desiccant and herbicide uses).
- Residue definition for risk assessment:
  - Herbicide uses: diquat,
  - Desiccant uses: two separate residue definitions were proposed, i.e.
    - diquat and
    - TOPPS
For TOPPS, EFSA noted that the data were insufficient to conclude on the toxicological profile (EFSA, 2015b). For processed commodities, the peer review concluded that the residue definition is ‘open’ as standard hydrolysis studies investigating the nature of residues formed from diquat and TOPPS in processed products after pasteurisation, boiling/brewing/baking and sterilisation were not available (EFSA, 2015b). Since no new data/information was presented in the current application, a final recommendation on the residue definition for processed products cannot be derived.

For rotational crops, according to the MRL review, a specific residue definition for rotational crops was not required (EFSA, 2015a). This conclusion was also confirmed during the renewal assessment (EFSA, 2015b).

Considering the new metabolism studies that were requested as confirmatory data and taking in account the conclusions derived in the framework of the peer review, where these studies were also assessed, EFSA recommends modifying the existing residue definitions for risk assessment for plant products as proposed in the peer review. The different wording for the residue definition for enforcement is considered a minor editorial discrepancy which does not have an impact on the levels of the established MRLs.

The revision of the risk assessment residue definition would also trigger the setting of toxicological reference values for TOPPS and the generation of residue data for this metabolite. As long as this information is not available, the risk assessments for this separate residue definition covering TOPPS cannot be performed (see also Section 3).

1.2. Magnitude of residues in plants

Not relevant for the current assessment; regulatory footnotes requesting additional residue trials were not included in the MRL regulation implementing the MRL proposals derived in the framework of the MRL review (Commission Regulation (EU) No 2016/1002).

For reasons of completeness, it is mentioned that the applicant submitted residue trials where diquat was used for weed control in apple and citrus; where diquat was used pre-emergence as a herbicide (carrots, onion, tomato, pepper, cauliflower, head cabbage, beans with pods, oilseed rape, sugar beet); for inter-row uses as a shielded application to weeds (strawberries, grapes, tomato, cucumber, kale, kohlrabi); for sucker control on grapevines and for desiccant uses in potatoes, dry beans, sunflower seeds, oilseed rape, soya beans and hops; these trials were assessed in the evaluation report (Sweden, 2021).

The samples derived from these trials were analysed for diquat; residue concentrations for TOPPS were not measured (Sweden, 2021).

Since all EU uses, including the uses of diquat for weed control and desiccant uses had to be withdrawn following the non-approval decisions, these residue trials are not relevant and are therefore not assessed by EFSA.

EFSA recommends that in general for all commodities for which the current EU MRLs were based on previously authorised EU uses, and which had to be withdrawn following the non-approval decision, the existing EU MRLs should be lowered to the appropriate LOQ, or where relevant, to an alternative fall-back MRL, e.g. reflecting acceptable Codex MRLs. In the framework of the current assessment which focussed for crops for which confirmatory data were requested, EFSA derived MRL recommendations for lowering the existing MRL for lupins, linseeds, poppy seeds, sesame seeds, mustard seeds, borage seeds and hemp seeds to the LOQ.

Furthermore, it is noted that since the MRL review, some of the Codex MRLs have been withdrawn (e.g. Codex maximum residue limit (CXL) for oats (2 mg/kg), lentils (dry) (0.2 mg/kg), soya beans (0.3 mg/kg)) or were replaced by new Codex MRLs (e.g. CXL for dry peas). Thus, the EU MRLs based on outdated Codex MRLs should be reconsidered as well. Hence, a more comprehensive review of the existing EU MRLs would be appropriate which goes beyond the scope of the assessment of confirmatory data. For all other commodities not covered by the current assessment, a separate assessment to review the existing EU MRLs needs to be performed, for which a specific mandate under Art. 43 of Regulation (EC) No 396/2005 should be submitted to EFSA.

2. Residues in livestock

In the MRL regulation implementing the MRL proposals derived in the framework of the MRL review (Commission Regulation (EU) 2016/1002), only one data gap related to animal products was
implemented, i.e. data gap number 1b, requesting the submission of confirmatory analytical methods and an ILV for the enforcement residue definition derived for animal products (i.e. diquat and its salts, expressed as diquat).

The applicant resubmitted an enforcement method which allows to quantify residues of diquat in animal matrices; this study was assessed previously in the framework of the peer review (EFSA, 2015b). Details on the validation of the analytical method are presented in Appendix B.2.1.1. The LC-MS/MS method was found to be sufficiently validated with an LOQ of 0.005 mg/kg for animal commodities (milk, muscle, fat, liver, kidney and eggs) for diquat. The confirmatory method and the interlaboratory validation (ILV) were considered acceptable (EFSA, 2015b).

EFSA concluded that the data gap 1b identified in the framework of the MRL review was addressed.

2.1. Nature and magnitude of residues in livestock

No additional data gaps other than the data gap on analytical methods were identified in the MRL review regarding the MRLs for livestock. However, EFSA noted that the conclusions derived in the framework of the peer review (EFSA, 2015b) and the subsequent decision on non-approval have an impact on the residue definitions and the residue levels for animal products. Hence, the EFSA conclusion would trigger a further review of the existing MRLs for animal products.

A brief outline of the situation is given in the subsequent paragraphs, including recommendations on modifications of MRLs for animal products that could be implemented in the EU legislation without a comprehensive new MRL review.

2.1.1. Revision of the residue definitions derived in the peer review

In the framework of the peer review (EFSA, 2015b), the residue definitions were reconsidered and the experts proposed the following residue definitions which are different compared to the residue definitions derived in the MRL review\(^8\):

- Residue definition for enforcement:
  - Poultry commodities: diquat.
  - Ruminant commodities: diquat dipyridone.

- Residue definition for risk assessment (all animal matrices):
  - diquat, diquat monopyridone and diquat dipyridone. Whether residues of the two metabolites can be expressed as diquat is pending a conclusion on the toxicological properties of diquat monopyridone and diquat dipyridone.

A further risk management discussion is recommended whether the revised enforcement residue definition derived in 2015 in the peer review for animal products (EFSA, 2015b) should be implemented in the MRL legislation. If this is agreed, analytical methods to quantify diquat dipyridone in the relevant matrices should be developed. As long as these methods are not available, it might be more appropriate to maintain the enforcement residue definition unchanged.

2.1.2. Magnitude of residues in livestock

In the framework of the MRL review, the dietary burden was calculated for dairy ruminants, meat ruminants, poultry and pigs considering the EU uses notified in 2015 to EFSA. Import tolerances for uses in third countries were not requested. The EU dietary burden calculation was the basis for deriving MRL proposals for certain products of animal origin (EFSA, 2015a).

Considering that the EU authorisations for the crops used in the dietary burden calculation have been withdrawn due to the decision of non-approval of diquat, the EU dietary burden calculation for European livestock had to be revised. Currently, livestock is no longer exposed to residues via feed produced in the EU. This new situation would allow to lower the EU MRLs for animal products to the appropriate LOQ.

It is also noted that Codex MRLs for animal products have been lowered in 2019 to the LOQ of 0.01 mg/kg for edible offal (mammalian), eggs, mammalian fats (except milk fat), meat (from mammals other than marine mammals), poultry fat, poultry meat, poultry (edible offal) and to the

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\(^8\) The residue definition for enforcement and risk assessment in livestock matrices was proposed as ‘diquat and its salts expressed as diquat’ (EFSA, 2015a).
LOQ of 0.001 mg/kg for milks (FAO, 2014, 2019). For animal products, where the previously established EU MRLs were derived from Codex MRLs, these revised Codex MRLs should therefore also be taken over in the EU legislation.

Overall, EFSA proposes to maintain the existing enforcement residue definition for all animal products as ‘diquat and its salts, expressed as diquat’ and to lower all existing EU MRLs for animal products to the LOQ achievable with the analytical methods (see Appendix B.2.1.1), i.e. to 0.005 mg/kg for milk and to 0.01 mg/kg for all other animal matrices.

3. **Consumer risk assessment**

In the framework of the MRL review, a comprehensive long-term exposure assessment was performed for diquat, taking into account the uses authorised in 2015 at EU level and the acceptable CXLs in place at that time (EFSA, 2015a).

EFSA now updated the previous risk assessment EU/Codex scenario 2 (including demonstrated safe EU MRL proposals and demonstrated safe CXLs (presented in Appendix B5 of EFSA, 2015a), using the following assumptions:

- Plant products for which the existing EU MRL was derived from a previously authorised EU use, for which the authorisation had to be withdrawn due to the non-approval decision, were not considered in the exposure assessment, assuming a zero-residue situation. It is noted that for none of these crops, a fall-back Codex MRL is in place that was previously accepted by the EU (no EU reservation).
- For plant products where the existing EU MRL is based on a CXL, the intake calculation was performed using the median residue value (STMR) derived by Joint FAO/WHO Meeting on Pesticide Residues (JMPR); however, for those crops where JMPR derived MRLs at the LOQ and where the STMR/HR derived by JMPR was 0 mg/kg, EFSA calculated conservatively using the LOQ as input value for the risk assessment.
- Commodities for which no EU uses or Codex MRLs exist were not considered in the intake calculation assuming a no residue situation (refined calculation mode in PRIMo).
- Codex MRLs of plant commodities implemented in the EU legislation which are obsolete, because the CXL has been withdrawn or modified, were still kept in the intake calculation. EFSA recommends to reassess the Codex MRLs in view of their acceptability at EU level, taking into account the decisions taken on the possible modification of residue definitions (see also Sections 1.1.6 and 2.1.1) in a separate assessment.
- For animal products, the intake calculations were conservatively performed using the proposed MRL (all at the LOQ of 0.01 mg/kg, except for milk where an MRL proposal at the LOQ of 0.005 mg/kg was derived).

The risk assessment is affected by the following additional non-standard uncertainties and limitations:

- The risk assessment for plant products was restricted to the residue definition of parent diquat; since information on the toxicological profile of TOPPS and on the magnitude of TOPPS (separate risk assessment residue definition for desiccant uses in crops) is not available. This deficiency is only relevant for Codex MRLs above the LOQ derived from desiccant uses which were implemented in the EU legislation.
- For animal products, the risk assessment could not take into account the proposed new residue definition derived in the peer review (i.e. diquat, diquat monopyridone and diquat dipyridone). Information on the expected residue levels of the metabolites diquat monopyridone and diquat dipyridone in animal products and the toxicological profile of these metabolites are currently not available.

Overall, the risk assessment is indicative.

For the indicative risk assessment of diquat, EFSA used the toxicological reference values (acceptable daily intake (ADI) and acute reference dose (ARfD)) for diquat derived in the framework of the renewal process (EFSA, 2015b). The calculations were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019), refined calculation mode.

The long-term exposure related to the crops under assessment accounted for maximum 97% of the ADI NL toddler diet with main contributors: rapeseeds (23%), oat (19%) and milk (15%).

The short-term exposure did not indicate a consumer risk for diquat; highest exposure among the commodities concerned was calculated for potatoes (92% of the ARfD).
4. Conclusion and Recommendations

To address data gaps identified in the framework of the MRL review (EFSA, 2015a) implemented in the MRL Regulation (EU) 2016/1002, the applicant submitted data in June 2018. EFSA notes that considering the new situation for EU authorisations which had to be withdrawn with a maximum period of grace by 4 February 2020, some of the data gaps related to the EU uses implemented in the MRL legislation became obsolete. EFSA therefore focused in this assessment on the generic data gaps on analytical methods required for MRL enforcement, on the metabolism studies in view of deriving residue definitions and on the data gap on the nature of residues in processed commodities (standard hydrolysis studies), which are relevant for deriving residue definitions for processed products.

Overall, EFSA concluded that data gap number 1 (a confirmatory method and an ILV for enforcement of diquat in commodities of plant (1a) and animal (1b) origin), data gap number 2 (a fully validated analytical method for enforcement of diquat in hops (dried)) and data gap number 3 (representative studies investigating the metabolism of diquat in two additional crop groups different from cereals) were sufficiently addressed.

Data gap number 7 (a processing study simulating representative hydrolytic conditions for pasteurisation (20 min at 90°C, pH 4), boiling/brewing/baking (60 min at 100°C, pH 5) and sterilisation (20 min at 120°C, pH 6) addressing the nature of diquat and TOPPS residues in processed commodities) was not sufficiently addressed.

Taking into account the findings of the new metabolism studies (data gap number 3), EFSA proposes to revise the residue definition for risk assessment in plant products as proposed in the peer review.

For a number of plant commodities, EFSA proposes to consider the lowering of the existing MRL to the appropriate LOQ, taking into account the LOQs of the validated analytical methods submitted in response to data gap number 1a and 2 and considering the fact that the previously authorised EU uses for these crops had to be withdrawn following the decision on non-approval of the a.s. diquat.

Similarly, for animal products, the lowering of the existing EU MRLs is proposed, taking into account the LOQ of the analytical methods submitted in response to data gap number 1b, the fact that residues are no longer expected in feed items grown in the EU and that the Codex MRLs for the animal products concerned are set at the LOQs of 0.001 mg/kg (for milk) and 0.01 mg/kg for products of animal origin, respectively.

The revision of the current residue definitions for animal products proposed in the framework of the peer review and the resulting needs for new analytical methods as well as the impact on the acceptability of Codex MRLs set for animal products should be considered in a separate assessment for which a specific mandate to EFSA should be discussed.

EFSA also recommends that under this specific mandate, a detailed review of all of the currently implemented Codex MRLs should be performed, noting that in the last years, some Codex MRLs implemented in the EU have been revised at Codex level.

EFSA concluded that based on the indicative calculations performed for diquat according to the internationally agreed methodology, the proposed EU MRLs will not result in consumer intake exceeding the ARFD or the ADI. The risk assessment is based on several assumptions and affected by the non-standard uncertainties and limitations.

The overview of the assessment of confirmatory data and the recommended MRL modifications are summarised in Appendix B.4.

References

EFSA (European Food Safety Authority), 2015a. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for diquat according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2015;13 (1):3972, 69 pp. https://doi.org/10.2903/j.efsa.2015.3972
EFSA (European Food Safety Authority), 2015b. Conclusion on the peer review of the pesticide risk assessment of the active substance diquat. EFSA Journal 2015;13(11):4308, 127 pp. https://doi.org/10.2903/j.efsa.2015.4308
EFSA (European Food Safety Authority), Anastassiadou M, Brancato A, Carrasco Cabrera L, Ferreira L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Pedersen R, Raczyk M, Reich H, Ruocco S, Sacchi A, Santos M, Stanek A, Tarazona J, Theobald A and Verani A, 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1 (update of EFSA PRIMo revision 3). EFSA Supporting Publication 2019;EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605
EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

European Commission, 2001. Review report for the active substance diquat. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 12 December 2000 in view of the inclusion of diquat in Annex I of Council. Directive 91/414/EEC. SANCO/1688/VI/97-Final, 22 March 2001.

European Commission, 2017. Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods. SANTE 2017/10632, Rev. 3, 22 November 2017.

European Commission, 2020. Commission working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs finalised in the Standing Committee on Plants, Animals. Food and Feed at its meeting on 18 February 2020. SANTE/E4/VW 10235/2016 - Rev. 4, 6 pp., Brussels, 18 February 2020.

FAO (Food and Agriculture Organization of the United Nations), 2014. Diquat. In: Pesticide residues in food – 2013. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 220, 725 pp.

FAO (Food and Agriculture Organization of the United Nations), 2019. Diquat. In: Pesticide residues in food – 2018. Evaluations, Part I, Residues. FAO Plant Production and Protection Paper No. 235. Rome. 1664 pp.

Sweden, 2021. Evaluation report on the modification of confirmatory data following review of the active substance diquat according to Article 12 of Regulation (EC) No 396/2005. July 2021, 236 pp.

**Abbreviations**

- **a.s.** active substance (here: diquat)
- **ADI** acceptable daily intake
- **AR** applied radioactivity
- **ARfD** acute reference dose
- **BBCH** growth stages of mono- and dicotyledonous plants
- **Bw** body weight
- **CAC** Codex Alimentarius Commission
- **CAS** Chemical Abstract Service
- **CCPR** Codex Committee on Pesticide Residues
- **CEN** European Committee for Standardisation (Comité Européen de Normalisation)
- **CF** conversion factor for enforcement to risk assessment residue definition
- **CXL** Codex maximum residue limit
- **DAT** days after treatment
- **Eq** residue expressed as a.s. equivalent
- **FAO** Food and Agriculture Organization of the United Nations
- **GAP** Good Agricultural Practice
- **GC** gas chromatography
- **GC-ECD** gas chromatography with electron capture detector
- **HPLC** high-performance liquid chromatography
- **HPLC-MS** high-performance liquid chromatography with mass spectrometry
- **HPLC-MS/MS** high-performance liquid chromatography with tandem mass spectrometry
- **HPLC-UVD** high-performance liquid chromatography with ultra-violet detector
- **HR** highest residue
- **IEEDI** international estimated daily intake
- **IESTI** international estimated short-term intake
- **ILV** independent laboratory validation
- **IPCS** International Programme of Chemical Safety
- **ISO** International Organisation for Standardisation
- **IUPAC** International Union of Pure and Applied Chemistry
- **JMPR** Joint FAO/WHO Meeting on Pesticide Residues
- **Koc** organic carbon adsorption coefficient
- **LC** liquid chromatography
- **LOQ** limit of quantification
- **MRL** maximum residue level
- **MS** Member States
- **MS** mass spectrometry detector
- **MS/MS** tandem mass spectrometry detector
- **NEU** northern Europe
OECD  Organisation for Economic Co-operation and Development  
PBI  plant back interval  
PHI  preharvest interval  
$P_{ow}$  partition coefficient between n-octanol and water  
PRIMo  (EFSA) Pesticide Residues Intake Model  
RA  risk assessment  
RAC  raw agricultural commodity  
RD  residue definition  
RMS  rapporteur Member State  
SANCO  Directorate-General for Health and Consumers  
SEU  southern Europe  
SL  soluble concentrate  
STMR  supervised trials median residue  
TRR  total radioactive residue  
UV  ultraviolet (detector)  
WHO  World Health Organization
Appendix A – EU GAPs assessed in the MRL review for which data gaps were identified (EFSA, 2015a)

It is highlighted that following the non-approval decision of diquat all these uses had to be withdrawn.

| Crop and/or situation | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-----------------------------------|-------------|-------------|---------------------------------|
|                       | Type(b) | Conc. a.s. (g/L) | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (days) min-max | kg a.s./hl min-max | Water (L/ha) min-max | Rate min-max | Unit | PHI (days)(d) | Remarks |
| **Critical outdoor GAPs for Northern Europe** |
| Asparagus | F Weeds | SL | 200 | Foliar treatment – spraying | 0-39 | 1 | | | | | 0.20-0.40 | kg a.s./ha | n.a. |
| Lupins | FR, UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 4 |
| Linseed | FR, UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Poppy seed | UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Sesame seed | UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Sunflower seed | UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Rape seed | BE, CZ, SE, UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Mustard seed | UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Borage | UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 7 |
| Hempseed | UK | F Desiccant | SL | 200 | Foliar treatment – spraying | 1 | | 0.60 | kg a.s./ha | 5 |
| Hops | DE | F Desiccant | SL | 200 | Foliar treatment – spraying | 38 | 1 | 1.00 | kg a.s./ha | 14 |
### Critical outdoor GAPs for Southern Europe

| Crop and/or situation | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------|-------------|-------------------------------|------------|---------|
| **Table grapes**      | IT          | F           | Weeds                         | SL         | 200     | Soil treatment – general (see also comment field) | 1-3 | 0.66-1.00 kg a.s./ha | n.a. | IT states use is on ‘vines’. EL has same GAP except only one application. |
| **Wine grapes**       | IT          | F           | Weeds                         | SL         | 200     | Soil treatment – general (see also comment field) | 1-3 | 0.66-1.00 kg a.s./ha | n.a. |

**MRL:** maximum residue level; **GAP:** Good Agricultural Practice; **NEU:** northern European Union; **SEU:** southern European Union; **MS:** Member State; **a.s.:** active substance; **SL:** soluble concentrate; **n.a.:** not applicable.

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

(b): CropLife International Technical Monograph no 2, 7th Edition. Revised March 2017. Catalogue of pesticide formulation types and international coding system.

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

(d): PHI: minimum preharvest interval.
Appendix B – List of end points

B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|-----------------------------------|-------------|---------|----------------|----------------|---------------|
| Fruit crops                       | Tomatoes    | Foliar spray (F/G); 1 × 200 µg/plant | 0, 1, 2, 4, 5, 6, 8 | Radiolabelled diquat: label position not reported, foliar spray outdoor/field and indoor applications (EFSA, 2015a) |
|                                  | Tomatoes    | Bare soil (pre-emergence) (G); 1 × 1,032 kg a.s./ha | 112 | [2,2',6,6'-14C]-diquat dibromide (EFSA, 2015b; Sweden, 2021) |
| Root crops                        | Potatoes    | Foliar spray (F); 1 × 1,68 kg a.s./ha | Tubers: 14 | Radiolabelled diquat: label position not reported, foliar spray outdoor/field and indoor applications (EFSA, 2015a) |
|                                  | Potatoes    | Foliar spray (F); 1 × 0.969 kg a.s./ha | Tubers: 10, 20 | [2,2',6,6'-14C]-diquat dibromide (EFSA, 2015b; Sweden, 2021) |
| Leafy crops                       | –           | –       | –              | –              | Not investigated. |
| Cereals/ grass                    | Barley, oats | Foliar spray (F); 1 × 0.3; 0.6; 1.1 kg a.s./ha | Grain and straw: 7, 14 | Radiolabelled diquat: label position not reported, foliar spray outdoor/field and indoor applications (EFSA, 2015a) |
|                                  | Wheat       | Foliar spray (F); 1 × 10.2 kg a.s./ha | Grain, straw and chaff: 7 | Radiolabelled diquat: label position not reported, foliar spray outdoor/field and indoor applications (EFSA, 2015a) |
|                                  | Maize       | Foliar spray (F/G); 1 × 200 µg/plant | 0, 1, 2, 4, 5, 6, 8 | Radiolabelled diquat: label position not reported, foliar spray outdoor/field and indoor applications (EFSA, 2015a) |
| Pulses/oilseeds                  | Oilseed rape | Foliar spray (F); 1 × 0.3; 0.6; 1.2 kg a.s./ha | Seeds: 7 whole plant: 14 | Radiolabelled diquat: label position not reported, foliar spray outdoor/field and indoor applications (EFSA, 2015a) |
|                                  | Oilseed rape | Foliar spray (F); 1 × 0.575 kg a.s./ha | Seeds: 5 | [2,2',6,6'-14C]-diquat dibromide (EFSA, 2015b; Sweden, 2021) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                     | Carrots     | Bare soil (G); 1.1 kg a.s./ha | 30, 120, 365 | Carrots were peeled. Root and leaves sampled (EFSA, 2015a) |
| Leafy crops                          | Lettuce     | Bare soil (G); 1.1 kg a.s./ha | 30, 120, 365 | EFSA (2015a) |
| Cereal (small grain)                 | Wheat       | Bare soil (G); 1.1 kg a.s./ha | 30, 120, 365 | Straw, chaff and grain sampled 2015a |
**Processed commodities (hydrolysis study)**

| Conditions                        | Stable? | Comment/Source                                                                                                                                 |
|-----------------------------------|---------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Pasteurisation (20 min, 90°C, pH 4) | Inconclusive | The MRL review concluded that significant diquat residue levels are expected when diquat is used as a crop desiccant (in potatoes, sweet potatoes, pulses (dry), oilseeds, cereals and hops (dried)) and that a hydrolysis study is therefore not required. However, the nature of diquat and TOPPS under standard hydrolytic conditions needs to be investigated (data gap (number 7)) (EFSA, 2015a). This data gap still open. |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Inconclusive |                                                                                                                                               |
| Sterilisation (20 min, 120°C, pH 6) | Inconclusive |                                                                                                                                               |

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**Can a general residue definition be proposed for primary crops?**

- **Yes**
  - Plant groups covered: Cereals, root & tuber vegetables and pulses/oilseeds (desiccant use); fruit crops (weed control) (EFSA, 2015a,b).

**Rotational crop and primary crop metabolism similar?**

- **Not triggered**
  - No residues in rotational crops upon single application at target rate; not investigated for repeated long-term use (EFSA, 2015a,b).

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

- **Inconclusive**
  - Open, nature of residues in processed commodities not investigated (EFSA, 2015a,b).

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

- **Primary crops:**
  - Sum of diquat and its salts, expressed as diquat (EFSA, 2015a; Reg. (EU) 2016/1002);
  - Diquat (EFSA, 2015b)

- **Rotational crops:**
  - A specific residue definition is not required for rotational crops (EFSA, 2015a);
  - No residues in rotational crops upon single application at target rate; not investigated for repeated long-term use (EFSA, 2015b)

- **Processed commodities:**
  - Open (data gap (number 7) on diquat and TOPPS under standard hydrolytic conditions) (EFSA, 2015a,b)

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

- **Primary crops:**
  - Sum of diquat, its salts and TOPPS, expressed as diquat (EFSA, 2015a), confirmed in the current assessment
  - Peer-review (EFSA, 2015b):
  - Herbicide uses: Diquat
  - Desiccant uses: Diquat; TOPPS.
B.1.1.2. Stability of residues in plants

Not relevant in the framework of the confirmatory data assessment.

See List of End Points in EFSA (2015b).

B.1.2. Magnitude of residues in plants

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

Not relevant in the framework of the confirmatory data assessment (see Section 1.2).

B.1.2.2. Residues in rotational crops

No residues in rotational crops upon single application at target rate; not investigated for repeated long-term use (EFSA, 2015b).

Processed commodities:

- Open (data gap (number 7) on diquat and TOPPS under standard hydrolytic conditions) (EFSA, 2015a,b)

Rotational crops:

- A specific residue definition is not required for rotational crops (EFSA, 2015a);
- No residues in rotational crops upon single application at target rate; not investigated for repeated long-term use (EFSA, 2015b)

RD 1) and 2) to be considered separately (insufficient data to conclude on the toxicological profile of TOPPS).

Rotational crops:

- A specific residue definition is not required for rotational crops (EFSA, 2015a);
- No residues in rotational crops upon single application at target rate; not investigated for repeated long-term use (EFSA, 2015b)

Processed commodities:

- Open (data gap (number 7) on diquat and TOPPS under standard hydrolytic conditions) (EFSA, 2015a,b)

Rotational crops:

- A specific residue definition is not required for rotational crops (EFSA, 2015a);
- No residues in rotational crops upon single application at target rate; not investigated for repeated long-term use (EFSA, 2015b)

Processed commodities:

- Open (data gap (number 7) on diquat and TOPPS under standard hydrolytic conditions) (EFSA, 2015a,b)

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

| Matrices with high water content, high oil content, high acid content, dry matrices and difficult to analyse matrices (e.g. dried hops): HPLC-MS/MS; LOQ 0.01 mg/kg. Confirmatory method and ILV available (EFSA, 2015b; Sweden, 2021). |

DAT: days after treatment; a.s.: active substance; MRL: maximum residue level; LOQ: limit of quantification; HPLC-MS/MS: high performance liquid chromatography with tandem mass spectrometry; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

Not relevant in the framework of the confirmatory data assessment. See List of End Points in EFSA (2015b).

B.1.2. Magnitude of residues in plants

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

Not relevant in the framework of the confirmatory data assessment (see Section 1.2).

B.1.2.2. Residues in rotational crops

Residues in rotational and succeeding crops expected based on confined rotational crop study?

Not triggered

The MRL review concluded that a specific residue definition is not required for rotational crops and that no significant levels (<0.01 mg/kg) in the edible parts of the rotated crops are expected if diquat is applied according to the uses reported (EFSA, 2015a).

Residues in rotational and succeeding crops expected based on field rotational crop study?

Not triggered

- MRL: maximum residue level.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the confirmatory data assessment.
B.2. Residues in livestock

B.2.1. Nature of residues and methods of analysis in livestock

B.2.1.1. Metabolism studies, methods of analysis and residue definitions in livestock

| Livestock (available studies) | Animal          | Dose (mg/kg bw day) | Duration (days) | Comment/Source                                                                 |
|-------------------------------|-----------------|----------------------|-----------------|-------------------------------------------------------------------------------|
| Laying hen                    | 0.25–0.32       | 5                    | Label position not reported; number of animals not reported; daily sampling of eggs and excreta, tissues at sacrifice 7 h after last dosing (EFSA, 2015a). |
| Laying hen                    | 2.4             | 4                    | Label position not reported; three animals; daily sampling of eggs and excreta, tissues at sacrifice 19 h after last dosing (EFSA, 2015a). |
| Lactating ruminants           | 1.1             | 7                    | Label position not reported; one animal; daily sampling of milk and excreta, tissues at sacrifice 4 h after last dosing (EFSA, 2015a). |
| Pig                           | Not investigated.|                     |                  |                                                                                |
| Fish                          | Not investigated.|                     |                  |                                                                                |

B.2.1.2. Stability of residues in livestock

Not relevant in the framework of the confirmatory data assessment. No information available.
| Time needed to reach a plateau concentration in milk and eggs (days) | Milk: >7 days | EFSA (2015b) |
| --- | --- | --- |
| Metabolism in rat and ruminant similar | Eggs: inconclusive | EFSA (2015b) |
| Inconclusive | EFSA (2015b) |
| Can a general residue definition be proposed for animals? | No | EFSA (2015b) |
| Animal residue definition for monitoring (RD-Mo) | Sum of diquat and its salt expressed as diquat (EFSA, 2015a), (Reg. (EU) 2016/1002) | |
| RD proposed in peer review (not implemented in EU legislation): | Ruminant tissues and milk: Diquat dipyridone (EFSA, 2015b) | |
| Poultry tissues and eggs: Diquat (EFSA, 2015b) | |
| Animal residue definition for risk assessment (RD-RA) | Sum of diquat and its salts expressed as diquat (EFSA, 2015a) | |
| RD proposed in peer review: | Diquat, diquat monopyridone and diquat dipyridone; whether residues of the two metabolites can be expressed as diquat is pending a conclusion on the toxicological properties of diquat monopyridone and diquat dipyridone (EFSA, 2015b). | |
| Fat soluble residues | No | |
| Methods of analysis for monitoring of residues (analytical technique, matrix, LOQs) | MRL review (EFSA, 2015a): | |
| • HPLC-UVD method for diquat; sufficiently validated at the LOQ of 0.05mg/kg in muscle, liver, kidney and fat; at the LOQ of 0.01 mg/kg in milk; | | |
| • GLC-ECD method validated at the LOQ of 0.01 mg/kg for diquat in eggs; however, a confirmatory method and ILV was missing for other livestock matrices. | | |
| Peer review (EFSA, 2015b; Sweden, 2021): | LC-MS/MS (method GRM012.02A) for determination of diquat*; LOQ of 0.005 mg/kg (milk, muscle, fat, liver, kidney, blood and eggs) for diquat; ILV and confirmatory methods acceptable. | |

bw: body weight; d: day; HPLC-UVD: high performance liquid chromatography with ultra-violet detector; LOQ: limit of quantification; GC-ECD: gas chromatography with electron capture detector; ILV: independent laboratory validation; LC-MS/MS: liquid chromatography with tandem mass spectrometry.
## B.3. Consumer risk assessment

| Code | Commodity       | Existing MRL (b) | Proposed MRL | Conclusion/recommendation |
|------|-----------------|------------------|--------------|---------------------------|
| 0151010 | Table Grapes | 0.01* | 0.01* | The existing EU MRL was derived for an SEU GAP for weed control, which in the meantime has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the current LOQ. |
| 0151020 | Wine grapes | 0.01* | 0.01* | See table grapes (0151010). |
| 0270010 | Asparagus | 0.01* | 0.01* | The existing EU MRL was derived for an NEU GAP for weed control, which in the meantime has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the current LOQ. |
| 0300040 | Lupins/lupini beans | 0.2 | 0.01* | The existing EU MRL was derived for an NEU GAP for preharvest crop desiccant, which in the meantime has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the current LOQ. |

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**ARfD:** acute reference dose; **bw:** body weight; **IESTI:** international estimated short-term intake; **PRIMo:** (EFSA) Pesticide Residues Intake Model; **ADI:** acceptable daily intake; **IEDI:** international estimated daily intake; **MRL:** maximum residue level.
| Code(a) | Commodity       | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                                                                                                                                                                                                                 |
|--------|-----------------|-----------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0401010| Linseeds        | 5               | 0.01*        | The existing EU MRL was derived from an MRL in place at the time of the MRL review. The MRL proposal derived in the MRL review based on an NEU desiccant use was not taken over in the EU legislation, due to deficiencies of the data set. All EU uses in oilseeds became obsolete in the meantime following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends lowering the MRL to the LOQ. |
| 0401030| Poppy seeds     | 0.1             | 0.01*        | See linseeds (0401010).                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0401040| Sesame seeds    | 0.1             | 0.01*        | See linseeds (0401010).                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0401080| Mustard seeds   | 0.5             | 0.01*        | See linseeds (0401010).                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0401120| Borage seeds    | 0.1             | 0.01*        | See linseeds (0401010).                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0401140| Hemp seeds      | 0.5             | 0.01*        | See linseeds (0401010).                                                                                                                                                                                                                                                                                                                                                                                                  |
| 0700000| HOPS            | 0.01*           | 0.01*        | The existing MRLs reflect the previously authorised NEU GAP. In the meantime, the GAP has become obsolete following the non-approval decision and the withdrawal of the national authorisations for diquat. Uses in third countries have not been reported. A Codex MRL is not in place for this crop. The data gap concerning the analytical method and the metabolism study has been addressed; the data gap regarding the processing study has not been addressed. EFSA recommends maintaining the MRL at the LOQ. |
| 1011010| Muscle of Swine | 0.05* (ft 2)    | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.05* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for meat (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL. Considering that diquat is not fat soluble, the Codex MRL for meat can be taken over in the EU for muscle without modification. |
| 1012010| Tissue of Bovine| 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1013010| Tissue of Sheep | 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1014010| Tissue of Goat  | 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1015010| Tissue of Equine| 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1017010| Other farmed terrestrial animals | 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1011020| Fat of Swine    | 0.05* (ft 2)    | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. A Codex Alimentarius CXL was not in place in 2015 for fat tissues.                                                                                                                                                                                                                                             |
| 1012020| Tissue of Bovine| 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1013020| Tissue of Sheep | 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| 1014020| Tissue of Goat  | 0.05* (ft 2)    | 0.01*        |                                                                                                                                                                                                                                                                                                                                                       |
| Code(a) | Commodity                      | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|--------|-------------------------------|----------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1015020| Goat                          |                |              | The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for fat (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL. |
| 1017020| Equine Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1011030| Liver of Swine                | 0.05* (ft 2)   | 0.01*        | See swine muscle (1011010)                                                                                                                                 |
| 1012030| Bovine                       |                |              | In 2019, the Codex MRL for edible offal (from mammals other than marine mammals), which also applies to liver, was lowered to the LOQ of 0.01 mg/kg. |
| 1013030| Sheep                         |                |              |                                                                                                                                                            |
| 1014030| Goat                          |                |              |                                                                                                                                                            |
| 1015030| Equine Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1017030| Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1011040| Kidney of Swine               | 0.05* (ft 2)   | 0.01*        | See swine muscle (1011010)                                                                                                                                 |
| 1012040| Bovine                       |                |              | In 2019, the Codex MRL for edible offal (from mammals other than marine mammals), which also applies to kidney, was lowered to the LOQ of 0.01 mg/kg. |
| 1013040| Sheep                         |                |              |                                                                                                                                                            |
| 1014040| Goat                          |                |              |                                                                                                                                                            |
| 1015040| Equine Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1017040| Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1011050| Edible offals (other than liver and kidney) of Swine | 0.05* (ft 2)   | 0.01*        | See swine muscle (1011010)                                                                                                                                 |
| 1012050| Bovine                       |                |              | In 2019, the Codex MRL for edible offal (from mammals other than marine mammals), which also applies to other edible offals, was lowered to the LOQ of 0.01 mg/kg. |
| 1013050| Sheep                         |                |              |                                                                                                                                                            |
| 1014050| Goat                          |                |              |                                                                                                                                                            |
| 1015050| Equine Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1017050| Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1011990| Others                        | 0.05* (ft 2)   | 0.01*        | See swine muscle (1011010)                                                                                                                                 |
| 1012990| Swine                         |                |              |                                                                                                                                                            |
| 1013990| Bovine                       |                |              |                                                                                                                                                            |
| 1014990| Sheep                         |                |              |                                                                                                                                                            |
| 1015990| Goat                          |                |              |                                                                                                                                                            |
| 1017990| Equine Other farmed terrestrial animals |                |              |                                                                                                                                                            |
| 1016010| Poultry: muscle               | 0.05* (ft 2)   | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.05* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. |

(a) Code of the addendum to Appendix B of the Codex MRL. (b) MRL based on the Codex residue definition.
| Code(a) | Commodity                  | Existing MRL(b) | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|--------|----------------------------|----------------|--------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1016020 | Poultry: fat               | 0.05* (ft 2)   | 0.01*        | Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for meat (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL. Considering that diquat is not fat soluble, the Codex MRL for meat can be taken over in the EU for muscle without modification. |
| 1016030 | Poultry: liver             | 0.05* (ft 2)   | 0.01*        | See poultry muscle (1016010) In 2019, the Codex MRL for liver, which also applies to liver, was lowered to the LOQ of 0.01 mg/kg.                                |
| 1016040 | Poultry: kidney            | 0.05* (ft 2)   | 0.01*        | See poultry muscle (1016010) In 2019, the Codex MRL for kidney, which also applies to kidney, was lowered to the LOQ of 0.01 mg/kg.                             |
| 1016050 | Poultry: Edible offals (other than liver and kidney) | 0.05* (ft 2)   | 0.01*        | See poultry muscle (1016010) In 2019, the Codex MRL for edible offal was lowered to the LOQ of 0.01 mg/kg.                                                  |
| 1016990 | Poultry: others            | 0.05* (ft 2)   | 0.01*        | See poultry muscle (1016010)                                                                                                                                 |
| 1020000 | Milk of Cattle             | 0.01* (ft 2)   | 0.005*       | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.01* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.005 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.005 mg/kg should be considered. The current Codex MRLs for milk (set for the same residue definition) which was established in 2019 were set at the LOQ of 0.001 mg/kg. |
| 1020010 | Milk of Sheep              |                |              |                                                                                                                                                            |
| 1020020 | Milk of Goat               |                |              |                                                                                                                                                            |
| 1020030 | Milk of Others             |                |              |                                                                                                                                                            |
| 1030010 | Birds eggs: Chicken        | 0.05* (ft 2)   | 0.01*        | The existing EU MRL was based on the dietary burden of livestock, exposed to residues in feed reflecting the EU authorised uses in 2015. The Codex MRL in 2015 was set at the same level (0.05* mg/kg). The data gap concerning a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin has |
been addressed. The enforcement method for the current residue definition is sufficiently validated at an LOQ for 0.01 mg/kg. Considering the withdrawal of EU uses in feed, the lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered. The current Codex MRLs for eggs (set for the same residue definition) which was established in 2019 are identical with the proposed new MRL.

Considering the withdrawal of EU uses in feed, the dietary burden is expected to be below the trigger value and was not recalculated. The requested confirmatory data (a confirmatory method and an ILV for enforcement of diquat in commodities of animal origin) are addressed. The lowering of the existing MRL to the LOQ of 0.01 mg/kg should be considered.

The current Codex MRLs for meat, fat, edible offals of mammals other than marine mammals and poultry (set for the same residue definition) which were established in 2019, is identical with the proposed new MRL.

Additional recommendation:
EFSA recommends a more comprehensive review of the existing MRLs that were not subject to the current assessment of confirmatory data, taking into account the following aspects:

- For all commodities for which the current EU MRLs were based on previously authorised EU uses, the EU uses had to be withdrawn following the non-approval decision. Hence, the EU MRLs should be lowered to the appropriate LOQ, or where relevant, to an alternative fall-back MRL, e.g. reflecting acceptable Codex MRLs.
- Since the MRL review in 2015, some of the Codex MRLs implemented in the EU legislation have been withdrawn (e.g. CXL for oats (2 mg/kg), lentils (dry) (0.2 mg/kg), soya beans (0.3 mg/kg)) or replaced by new Codex MRLs (e.g. CXL for dry peas). Thus, these EU MRLs based on outdated Codex MRLs should be reconsidered as well.
- In the framework of the peer review, a revision of the residue definitions for plant desiccant uses and animal products was proposed. EFSA recommends assessing the implications of the proposed new residue definitions on analytical methods as well as the impact on the acceptability of Codex MRLs set for animal products.
Hence, a more comprehensive review of the existing EU MRLs would be appropriate. In the current assessment, EFSA derived MRL proposals for those commodities that had to be assessed in the context of confirmatory data requested in the MRL review. For all other commodities not covered by the current assessment, a separate assessment to review the existing EU MRLs needs to be performed, for which a specific mandate under Art. 43 of Regulation (EC) No 396/2005 should be submitted to EFSA.
Appendix C – Pesticide Residue Intake Model (PRIMo)

**Diquat**

### Toxicological reference values

| Source of ADI | EU Regulation | Year of evaluation |
|---------------|---------------|--------------------|
| EU | 2018/1532 | 2018/1532 |

#### Input values

- **ADI (mg/kg bw per day):**
  - Source of ADI: Toxicological reference values
  - Details – chronic risk assessment/children

- **ARfD (mg/kg bw):**
  - Source of ARfD: Toxicological reference values
  - Details – acute risk assessment/adults

#### LOQs (mg/kg)

- Range from: 0.005 to 0.05

#### Details – acute risk

- **LOQs (mg/kg):**
  - Range from: 0.005 to 0.05

#### Details – chronic risk

- **LOQs (mg/kg):**
  - Range from: 0.005 to 0.05

**Refined calculation mode**

**Chronic risk assessment:** JMPR methodology (IEDI/TMDI)

- **Conclusion:**
  - The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
  - The long-term intake of residues of Diquat is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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### Evaluation of confirmatory data for diquat to address data gaps identified in the MRL review

**Preparation of confirmatory data for diquat**

- **European Food Safety Authority**
  - EU Regulation 2018/1532

**Evaluation of confirmatory data for diquat to address data gaps identified in the MRL review**

### Calculated exposure

| Commodity/MS group of commodities | Exposure to residue (µg/kg) | Chronic risk assessment: JMPR methodology (IEDI/TMDI) | No of diets exceeding the ADI: --- |
|-----------------------------------|---------------------------|--------------------------------------------------------|-----------------------------------|
| **Milk: Cattle**                  |                           |                                                        |                                   |
| **Rapeseeds/canola seeds**       |                           |                                                        |                                   |
| **Oat**                           |                           |                                                        |                                   |
| **Potatoes**                      |                           |                                                        |                                   |

**Input values**

- **LOQs (mg/kg):**
  - Range from: 0.005 to 0.05

**Supplementary results – chronic risk assessment**

- **Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

**Details – acute risk assessment/children**

- **Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

**Details – acute risk assessment/adults**

- **Chronic risk assessment: JMPR methodology (IEDI/TMDI)**

**Conclusion:**

- The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
- The long-term intake of residues of Diquat is unlikely to present a public health concern.

**DISCLAIMER:** Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

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### Unprocessed Commodities

| 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) |
|-----------------------|------------------------|--------------------------|---------------------|-----------------------|------------------------|--------------------------|---------------------|
| 92%                   | Potatoes               | 0.1/0.06                 | 9.2                 | 18%                   | Potatoes               | 0.1/0.06                 | 1.8                 |
| 28%                   | Pears                  | 0.02/0.02                | 2.8                 | 13%                   | Oat                    | 0.2/0.2                  | 1.3                 |
| 27%                   | Oranges                | 0.02/0.02                | 2.7                 | 6%                    | Oranges                | 0.02/0.02                | 0.61                |
| 22%                   | Oat                    | 0/2/2                    | 2.2                 | 6%                    | Pears                  | 0.02/0.02                | 0.61                |
| 22%                   | Apples                 | 0.02/0.02                | 2.2                 | 6%                    | Apples                 | 0.02/0.02                | 0.56                |
| 19%                   | Bananas                | 0.02/0.02                | 1.9                 | 5%                    | Strawberries           | 0.05/0.05                | 0.47                |
| 19%                   | Peaches                | 0.02/0.02                | 1.9                 | 4%                    | Kaki/Japanese persimmons | 0.02/0.02            | 0.44                |
| 16%                   | Grapefruits            | 0.03/0.02                | 1.6                 | 4%                    | Bananas                | 0.02/0.02                | 0.42                |
| 12%                   | Mandarins              | 0.02/0.02                | 1.2                 | 4%                    | Peaches                | 0.02/0.02                | 0.37                |
| 9%                    | Kaki/Japanese persimmons | 0.02/0.02            | 0.93                | 4%                    | Mandarins              | 0.02/0.02                | 0.36                |
| 9%                    | Beans                  | 0.2/0.05                 | 0.91                | 4%                    | Grapefruits            | 0.02/0.02                | 0.36                |
| 8%                    | Plums                  | 0.02/0.02                | 0.84                | 4%                    | Plums                  | 0.02/0.02                | 0.36                |
| 8%                    | Strawberries           | 0.05/0.05                | 0.82                | 3%                    | Beans                  | 0.2/0.05                 | 0.33                |
| 7%                    | Apples                 | 0.02/0.02                | 0.70                | 3%                    | Lentils                | 0.02/0.05                | 0.31                |
| 7%                    | Lemons                 | 0.02/0.02                | 0.69                | 3%                    | Quinoos                | 0.02/0.02                | 0.30                |

### Processed Commodities

| 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) |
|-----------------------|--------------------------------|--------------------------|---------------------|-----------------------|--------------------------------|--------------------------|---------------------|
| 73%                   | Oat/boiled                     | 2/2/2                    | 7.3                 | 30%                   | Oat/boiled                     | 2/2/2                    | 3.0                 |
| 60%                   | Oat/milling (flakes)           | 2/2/2                    | 6.0                 | 7%                    | Apples/juice                   | 0.2/0.02                 | 0.67                |
| 56%                   | Potatoes/fried                 | 0.1/0.06                 | 5.6                 | 5%                    | Coffee beans/extraction        | 0.2/0.02                 | 0.48                |
| 30%                   | Potatoes/dried (flakes)        | 0.1/0.23                 | 3.0                 | 4%                    | Potatoes/other                 | 0.1/0.05                 | 0.42                |
| 11%                   | Apples/juice                   | 0.02/0.02                | 1.1                 | 4%                    | Beans/canned                   | 0.2/0.05                 | 0.36                |
| 11%                   | Oranges/juice                  | 0.02/0.02                | 1.1                 | 3%                    | Oranges/juice                  | 0.02/0.02                | 0.30                |
| 7%                    | Pears/juice                    | 0.02/0.02                | 0.65                | 3%                    | Potatoes/dried (flakes)        | 0.1/0.23                 | 0.29                |
| 5%                    | Peaches/canned                 | 0.02/0.02                | 0.52                | 2%                    | Grapefruits/juice              | 0.02/0.02                | 0.22                |
| 4%                    | Lents/boiled                   | 0.02/0.05                | 0.40                | 2%                    | Peaches/canned                 | 0.02/0.02                | 0.16                |
| 4%                    | Peas/canned                    | 0.3/0.02                 | 0.36                | 1%                    | Peas/canned                    | 0.3/0.02                 | 0.13                |
| 3%                    | Peaches/juice                  | 0.02/0.02                | 0.33                | 0.8%                  | Tomatoes/sauce/pure             | 0.01/0.01                | 0.08                |
| 3%                    | Sunflower seeds/cots           | 0.9/0.22                 | 0.26                | 0.3%                  | Quinoos/jam                    | 0.02/0.02                | 0.03                |
| 2%                    | Tomatoes/juice                 | 0.01/0.01                | 0.19                | 0.2%                  | Okra, lady’s fingers/boiled    | 0.01/0.01                | 0.02                |
| 2%                    | Coffee beans/extraction        | 0.02/0.02                | 0.19                |                       |                                  |                          |                     |

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Diquat is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.
## Appendix D – Input values for the exposure calculations

### D.1. Consumer risk assessment

| Code   | Commodity               | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment | Input value (mg/kg) | Comment | Acute risk assessment | Input value (mg/kg) | Comment |
|--------|-------------------------|------------------------|--------------------|-------------------------|---------------------|---------|------------------------|---------------------|---------|
| 110010 | Grapefruits             | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 110020 | Oranges                 | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 110030 | Lemons                  | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 110040 | Limes                   | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 110050 | Mandarins               | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 110990 | Other citrus fruits     | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 120030 | Cashew nuts             | 0.02 (b)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 130010 | Apples                  | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 130020 | Pears                   | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 130030 | Quinces                 | 0.02 (d)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 130040 | Medlar                  | 0.02 (e)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 130050 | Loquats/Japanese medlars | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 130990 | Other pome fruit        | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 140010 | Apricots                | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 140020 | Cherries (sweet)        | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 140030 | Peaches                 | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 140040 | Plums                   | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 140990 | Other stone fruit       | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 152000 | Strawberries            | 0.05 (d)               | Reg. (EU) 2016/1002 |                         | 0.05                | MRL     | 0.05                   | MRL                 |         |
| 154070 | Azarole/Mediterranean medlar | 0.02 (d) | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 161040 | Kumquats                | 0.02 (e)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 161060 | Kaki/Japanese persimmons | 0.02 (d)            | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 163020 | Bananas                 | 0.02 (a)               | Reg. (EU) 2016/1002 |                         | 0.02                | MRL     | 0.02                   | MRL                 |         |
| 211000 | Potatoes                | 0.1                    | Reg. (EU) 2016/1002 |                         | 0.05                | STMR-RAC| 0.06                  | HR-RAC              |         |
| 231010 | Tomatoes                | 0.01*                  | Reg. (EU) 2016/1002 |                         | 0.01*               | LOQ     | 0.01*                  | LOQ                 |         |
| 231020 | Sweet peppers/bell peppers | 0.01*                | Reg. (EU) 2016/1002 |                         | 0.01*               | LOQ     | 0.01*                  | LOQ                 |         |
| 231030 | Aubergines/egg plants   | 0.01*                  | Reg. (EU) 2016/1002 |                         | 0.01*               | LOQ     | 0.01*                  | LOQ                 |         |
| 231040 | Okra/lady’s fingers     | 0.01*                  | Reg. (EU) 2016/1002 |                         | 0.01*               | LOQ     | 0.01*                  | LOQ                 |         |
| 300010 | Beans                   | 0.2 (d)                | Reg. (EU) 2016/1002 |                         | 0.05                | STMR-RAC| 0.05                  | STMR-RAC            |         |
| 300020 | Lentils (dry)           | 0.2 (d)                | Reg. (EU) 2016/1002 |                         | 0.05                | STMR-RAC| 0.05                  | STMR-RAC            |         |
| 300030 | Peas                    | 0.3 (d)                | Reg. (EU) 2016/1002 |                         | 0.05                | STMR-RAC| 0.05                  | STMR-RAC            |         |
| 401050 | Sunflower seeds         | 0.9                    | Reg. (EU) 2016/1002 |                         | 0.11                | STMR-RAC| 0.11                  | STMR-RAC            |         |
| 401060 | Rapeseeds/canola seeds  | 1.5                    | Reg. (EU) 2016/1002 |                         | 0.49                | STMR-RAC| 0.49                  | STMR-RAC            |         |
| 401070 | Soya beans              | 0.3 (e)                | Reg. (EU) 2016/1002 |                         | 0.03                | STMR-RAC| 0.03                  | STMR-RAC            |         |
| 500050 | Oat                     | 2 (e)                  | Reg. (EU) 2016/1002 |                         | 2                   | MRL     | 2                     | MRL                 |         |
| 620000 | Coffee beans            | 0.02*                  | Reg. (EU) 2016/1002 |                         | 0.02*               | LOQ     | 0.02*                  | LOQ                 |         |
| Code     | Commodity                  | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|----------|----------------------------|------------------------|--------------------|-------------------------|-----------------------|
|          |                            |                        |                    | Input value (mg/kg)     | Comment (mg/kg)       |
|          |                            |                        |                    | Comment                 |                       |
| 1011010  | Swine: Muscle/meat         | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1011020  | Swine: Fat tissue          | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1011030  | Swine: Liver               | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1011040  | Swine: Kidney              | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1011050  | Swine: Edible offals       | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
|          | (other than liver and kidney) |                    |                    |                         |                       |
| 1011990  | Swine: Other products      | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1012010  | Bovine: Muscle/meat        | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1012020  | Bovine: Fat tissue         | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1012030  | Bovine: Liver              | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1012040  | Bovine: Kidney             | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1012050  | Bovine: Edible offals      | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
|          | (other than liver and kidney) |                    |                    |                         |                       |
| 1012990  | Bovine: Other products     | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1013010  | Sheep: Muscle/meat         | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1013020  | Sheep: Fat tissue          | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1013030  | Sheep: Liver               | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1013040  | Sheep: Kidney              | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1013050  | Sheep: Edible offals       | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
|          | (other than liver and kidney) |                    |                    |                         |                       |
| 1013990  | Sheep: other products      | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1014010  | Goat: Muscle/meat          | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1014020  | Goat: Fat tissue           | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1014030  | Goat: Liver                | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1014040  | Goat: Kidney               | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1014050  | Goat: Edible offals        | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
|          | (other than liver and kidney) |                    |                    |                         |                       |
| 1014990  | Goat: other products       | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1015010  | Equine: Muscle/meat        | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1015020  | Equine: Fat tissue         | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1015030  | Equine: Liver              | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1015040  | Equine: Kidney             | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| 1015050  | Equine: Edible offals      | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
|          | (other than liver and kidney) |                    |                    |                         |                       |
| 1015990  | Equine: Other products     | 0.01*                  | FAO (2019)/proposed| 0.01*                   | LOQ                   |
| Code       | Commodity                                      | Existing/proposed MRL | Source/type of MRL | Chronic risk assessment | Acute risk assessment |
|------------|------------------------------------------------|-----------------------|--------------------|-------------------------|-----------------------|
|            |                                                |                       |                    | Input value (mg/kg)   | Comment | Input value (mg/kg) | Comment |
|            |                                                |                       |                    | Comment                |          | Comment           |         |
| 1016010    | Poultry: Muscle/meat                           | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1016020    | Poultry: Fat tissue                            | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1016030    | Poultry: Liver                                 | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1016040    | Poultry: Kidney                                | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1016050    | Poultry: Edible offals (other than liver and kidney) | 0.01*               | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1016990    | Poultry: Other products                       | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      |                   |         |
| 1017010    | Other farmed animals: Muscle/meat              | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1017020    | Other farmed animals: Fat tissue               | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1017030    | Other farmed animals: Liver                    | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1017040    | Other farmed animals: Kidney                   | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1017050    | Other farmed animals: Edible offals (other than liver and kidney) | 0.01*               | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1017990    | Other farmed animals: Other products           | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      |                   |         |
| 1020010    | Milk: Cattle                                   | 0.005*                | Proposed           | 0.005*                 | LOQ      | 0.005*            | LOQ     |
| 1020020    | Milk: Sheep                                    | 0.005*                | Proposed           | 0.005*                 | LOQ      | 0.005*            | LOQ     |
| 1020030    | Milk: Goat                                     | 0.005*                | Proposed           | 0.005*                 | LOQ      | 0.005*            | LOQ     |
| 1020040    | Milk: Horse                                    | 0.005*                | Proposed           | 0.005*                 | LOQ      | 0.005*            | LOQ     |
| 1020990    | Milk: Others                                   | 0.005*                | Proposed           | 0.005*                 | LOQ      | 0.005*            | LOQ     |
| 1030010    | Eggs: Chicken                                  | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1030020    | Eggs: Duck                                     | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1030030    | Eggs: Goose                                    | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1030040    | Eggs: Quail                                    | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1030990    | Eggs: Others                                   | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      |                   |         |
| 1050000    | Amphibians and reptiles                        | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1060000    | Terrestrial invertebrate animals               | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |
| 1070000    | Wild terrestrial vertebrate animals            | 0.01*                 | FAO (2019)/proposed | 0.01*                  | LOQ      | 0.01*             | LOQ     |

Other crops/commodities: Not applicable

MRL: maximum residue level; STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity; LOQ: limit of quantification; Proposed: indicates an MRL proposal suggested by EFSA. (a): It is to be noted that the current EU MRL for citrus fruits, pome fruits, stone fruits including azarole, kumquats, kaki and bananas are based on a Codex MRL set in 2013; these CXLs were labelled with an asterisk, hence being an LOQ of 0.02* mg/kg. In the EU legislation, the CXLs are not labelled with an asterisk.

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(b): For the group of tree nuts which is also based on a CXL set in 2013, it is to be noted that a CXL of 0.02* mg/kg is in place for cashew nuts only and not for the other commodities of this group.
(c): For strawberries, a CXL of 0.05 mg/kg was labelled with an asterisk indicating that the CXL is set at the LOQ of 0.05* mg/kg. In the EU legislation, the CXL was not labelled with an asterisk.
(d): For some pulses, Codex MRLs in place in 2015 when the MRL review was performed have been withdrawn in 2019 and/or were replaced by new CXLs for which the EU expressed a reservation.
(e): For oats and soya beans, the CXL implemented in the EU legislation has been withdrawn meanwhile.
**Appendix E – Used compound codes**

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------|-------------------------------------------------|---------------------------------|
| **Diquat**<sup>(a)</sup> (cation) | 6,7-dihydrodipyrido[1,2-a:2',1'-c]pyrazine-5,8-dium c1cccc2c3ccc[n+]3CC[n+]12 SYJFEGQWDCRVNX-UHFFFAOYSA-N | ![Structural formula of Diquat](image) |
| **TOPPS**<sup>(b)</sup> (R32245) | 1-oxo-1,2,3,4-tetrahydropyrido[1,2-a]pyrazin-5-ium O=C1NCC[n+]2cccccl2 LCIXSCGVFW2KB-UHFFFAOYSA-O | ![Structural formula of TOPPS](image) |
| **Diquat monopyridone**<sup>(b)</sup> (SYN546442) | 4-oxo-3,4,6,7-tetrahydrodipyrido[1,2-a:2',1'-c] pyrazinediium O=C1CC=CC=2c3c[cc[n+]3CC]+1 = 2 QOBWZBDCECCSHB-UHFFFAOYSA-N | ![Structural formula of Diquat monopyridone](image) |
| **Diquat dipyrinone**<sup>(b)</sup> (R30740) | 4,9-dioxo-3,4,6,7,9,10-hexahydrodipyrido[1,2-a:2',1'-c] pyrazinediium O=C2CC=CC=1C=3C=CC(=O)[N+]3CC[N+]12 SAAJNWLCADGOAV-UHFFFAOYSA-N | ![Structural formula of Diquat dipyrinone](image) |

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

(a): The metabolite name in bold is the name used in the conclusion.
(b): ACD/Name 2021.1.3 ACD/Labs 2021.1.3 (File Version N15E41, Build 123232, 07 July 2021).
(c): ACD/ChemSketch 2021.1.3 ACD/Labs 2021.1.3 (File Version C25H41, Build 123835, 28 August 2021).