Review of the existing maximum residue levels for meptyldinocap (DE-126) according to Article 12 of Regulation (EC) No 396/2005

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Abstract

According to Article 12 of Regulation (EC) No 396/2005, EFSA has reviewed the maximum residue levels (MRLs) currently established at European level for the pesticide active substance meptyldinocap (DE-126). To assess the occurrence of meptyldinocap residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Regulation (EC) No 1107/2009, Commission Regulation (EU) No 188/2011 and the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (including the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was missing. Hence, the consumer risk assessment is considered indicative only and some MRL proposals derived by EFSA still requires further consideration by risk managers.

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Summary

Meptyldinocap (DE-126) was approved on 1 April 2015 by means of Regulation (EU) No 1330/2014 in the framework of Regulation (EC) No 1107/2009 as amended by Commission Implementing Regulations (EU) No 540/2011 and 541/2011.

As the meptyldinocap was approved after the entry into force of Regulation (EC) No 396/2005 on 2 September 2008, the European Food Safety Authority (EFSA) is required to provide a reasoned opinion on the review of the existing maximum residue levels (MRLs) for that active substance in compliance with Article 12(1) of the aforementioned regulation.

As the basis for the MRL review, on 15 January 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 February 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State Spain to identify the critical GAPs in the format of a specific GAP overview file. Subsequently, Member States were requested to provide residue data supporting the critical GAPs, within a period of 1 month, by 17 May 2019. On the basis of all the data submitted by Member States and by the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked the rapporteur Member State (RMS) to complete the Pesticide Residues Overview File (PROfile) and to prepare a supporting evaluation report. The PROfile, evaluation report, and an updated GAP overview file were provided by the RMS to EFSA on 31 July 2019. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Based on the information provided by the RMS, Member States and the EURL, and taking into account the conclusions derived by EFSA in the framework of Regulation (EC) No 1107/2009, Commission Regulation (EU) No 188/2011, and the MRLs established by the Codex Alimentarius Commission, EFSA prepared in January 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for consultation via a written procedure. Comments received by 25 February were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of meptyldinocap (DE-126) in plants was investigated in primary and rotational crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as sum of meptyldinocap and 2,4-DNOP, expressed as meptyldinocap covering fruits and fruiting vegetables. The fate of the R and S and the E/Z-isomers of meptyldinocap was not addressed in previous studies, however in view of the large margin of safety in the exposure calculations, a possible impact of a preferential conversion of one isomeric form to another on the toxicity and consumer risk assessment will not be of concern for the authorised uses reported in the framework of this review. Specific residue definition could not be derived for rotational crops (data gap).

Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid matrices at the limit of quantification (LOQ) of 0.01 mg/kg. According to the EURLs a LOQ of 0.05 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials were considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation. Considering the general data gaps identified related to storage stability and the data gaps for a metabolism rotational crops study, MRLs for all commodities under assessment are tentative only.

Meptyldinocap is authorised for use on crops that might be fed to livestock. Dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The highest chronic exposure represented 1% of the acceptable daily intake (ADI) (DE child) and the highest acute exposure amounted to 35% of the acute reference dose (ARfD) (melons) (EU).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for meptyldinocap (CXL). Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 1% of the ADI (DE child) and the highest acute exposure amounted to 35% of the ARfD (melons).
Background

Regulation (EC) No 396/2005¹ (hereinafter referred to as ‘the Regulation’) establishes the rules governing the setting and the review of pesticide maximum residue levels (MRLs) at European level. Article 12(1) of that Regulation stipulates that the European Food Safety Authority (EFSA) shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC² a reasoned opinion on the review of the existing MRLs for that active substance. As meptyldinocap (DE-126) was approved on 1 April 2015 by means of Regulation (EU) No 1330/2014³ in the framework of Regulation (EC) No 1107/2009⁴ as amended by Commission Implementing Regulations (EU) No 540/2011⁵ and 541/2011⁶, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Regulation (EC) No 1107/2009 and Commission Regulation (EU) No 188/2011⁷, meptyldinocap was evaluated by the United Kingdom, designated as rapporteur Member State (RMS). Subsequently, a peer review on the initial evaluation of the RMS was conducted by EFSA, leading to the conclusions as set out in the EFSA scientific output (EFSA, 2014). According to the provisions of the approval Regulation, confirmatory information was requested, among others, as regards, the possible impact of any preferential degradation and/or conversion of the mixture of isomers on the worker risk assessment, the consumer risk assessment and the environment, to be submitted two years after the adoption of specific guidance by the Commission.

According to the legal provisions, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC repealed by Regulation (EC) No 1107/2009. It should be noted, however, that, in the framework of Regulation (EC) No 1107/2009, only a few representative uses were evaluated, whereas MRLs set out in Regulation (EC) No 396/2005 should accommodate all uses authorised within the European Union (EU) and uses authorised in third countries that have a significant impact on international trade. The information included in the assessment report prepared under Regulation (EC) No 1107/2009 is therefore insufficient for the assessment of all existing MRLs for a given active substance.

To gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities;
- the analytical methods for enforcement of the proposed MRLs.

As the basis for the MRL review, on 15 January 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 15 February 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format

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¹ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1–16.
² Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1–32. Repealed by Regulation (EC) No 1107/2009.
³ Commission Implementing Regulation (EU) No 1330/2014 of 15 December 2014 approving the active substance meptyldinocap, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011. OJ L 359, 16.12.2014, p. 85–89.
⁴ 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.
⁵ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1–186.
⁶ Commission Implementing Regulation (EU) No 541/2011 of 1 June 2011 amending Implementing Regulation (EU) No 540/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 187–188.
⁷ Commission Regulation (EU) No 188/2011 of 25 February 2011 laying down detailed rules for the implementation of Council Directive 91/414/EEC as regards the procedure for the assessment of active substances which were not on the market 2 years after the date of notification of that Directive. OJ No L 53, 26.2.2011, p. 51–55.
of specific GAP forms. In the framework of this consultation, 16 Member States provided feedback on their national authorisations of meptyldinocap. Based on the GAP data submitted, the designated RMS Spain was asked to identify the critical GAPs to be further considered in the assessment, in the format of a specific GAP overview file. Subsequently, in a second step, Member States were requested to provide residue data supporting the critical GAPs by 17 May 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked Spain to complete the PROF ile and to prepare a supporting evaluation report. The PROF ile and the supporting evaluation report, together with an updated GAP overview file, were submitted to EFSA on 31 July 2019. Subsequently, EFSA performed the completeness check of these documents with the RMS. The outcome of this exercise including the clarifications provided by the RMS, if any, was compiled in the completeness check report.

Considering all the available information and taking into account the MRLs established by the Codex Alimentarius Commission (CAC) (i.e. codex maximum residue limit; CXLs), EFSA prepared in January 2020 a draft reasoned opinion, which was circulated to Member States and EURLs for commenting via a written procedure. All comments received by 25 February were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Spain, 2019), taking into account also the information provided by Member States during the collection of data, and the EURL report on analytical methods (EURL, 2019) are considered as main supporting documents to this reasoned opinion and, thus, made publicly available.

In addition, further supporting documents to this reasoned opinion are the completeness check report (EFSA, 2020a) and the Member States consultation report (EFSA, 2020b). These reports are developed to address all issues raised in the course of the review, from the initial completeness check to the reasoned opinion. Furthermore, the exposure calculations for all crops reported in the framework of this review performed using the EFSA Pesticide Residues Intake Model (PRIMo) and the PROF ile as well as the GAP overview file listing all authorised uses are key supporting documents and made publicly available as background documents to this reasoned opinion. A screenshot of the report sheet of the PRIMo is presented in Appendix C.

Terms of Reference

According to Article 12 of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

The active substance and its use pattern

Meptyldinocap is the ISO common name for the mixture of 75-100% (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl crotonate and 25% to 0% (RS)-2-(1-methylheptyl)-4,6-dinitrophenyl isocrotonate (IUPAC). Meptyldinocap contains R/S and E/Z stereo centres.

The chemical structure of the active substance and its main metabolites are reported in Appendix F.

As various studies have been conducted with dinocap (DNOPC), it should be noted that the applicant stated and demonstrated that meptyldinocap is approximately 22% of dinocap (EFSA, 2014). Considering that (a) dinocap is not authorised in the EU at the time of this review and (b) separate EU MRLs are set for dinocap, the uses of dinocap were not considered in the framework of this assessment.

The EU MRLs for meptyldinocap are established in Annexes IIIA of Regulation (EC) No 396/2005. CXLs for meptyldinocap were also established by the CAC. An overview of the MRL changes that occurs since the entry into force of the Regulation mentioned above is provided below (Table 1).
For the purpose of this MRL review, all the uses of meptyldinocap currently authorised within the EU as submitted by the Member States during the GAP collection, have been reported by the RMS in the GAP overview file. The critical GAPs identified in the GAP overview file were then summarised in the PROFile and considered in the assessment. The details of the authorised critical GAP for meptyldinocap are given in Appendix A. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Spain, 2019);
- the draft assessment report (DAR) and its addenda prepared under Council Directive 91/414/EEC (The United Kingdom, 2006, 2013);
- the conclusion on the peer review of the pesticide risk assessment of the active substance DE-126 (EFSA, 2014);
- the Joint Meeting on Pesticide residues (JMPR) Evaluation report (FAO, 2010).

The assessment is performed in accordance with the legal provisions of the uniform principles for evaluation and authorisation of plant protection products as set out in Commission Regulation (EU) No 546/2011 and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (European Commission, 1997a-g, 2000, 2010a,b, 2017; OECD, 2011, 2013).

More detailed information on the available data and on the conclusions derived by EFSA can be retrieved from the list of end points reported in Appendix B.

### 1. Residues in plants

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

##### 1.1.1. Nature of residues in primary crops

The metabolism of meptyldinocap was investigated after foliar treatment using meptyldinocap in apples and fruiting vegetables (cucumber and squash) and 2,6-DNOPC (isomer of dinocap) in apples, covering the group of fruits and fruiting vegetables (The United Kingdom, 2006, 2013; EFSA, 2014). All studies were assessed in the framework of the peer-review of meptyldinocap, no additional studies were provided under the current review. Meptyldinocap and 2,6-DNOPC were radiolabelled in the phenyl ring of the molecule. In all studies the route of metabolism is to metabolite 2,4-DNOP and then to minor polar compounds.

The fate of the R and S and the E/Z isomers of meptyldinocap was not addressed in previous studies. EFSA notes that in view of the large margin of safety in the exposure calculations, a possible impact of a preferential conversion of one isomeric form to another on the toxicity and consumer risk assessment will not be of concern for the authorised uses reported in the framework of this review.

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(a): Commission Regulation (EU) No 441/2012 of 24 May 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenthrin, bifenazate, biphenthrin, boscalid, cadusafos, chlorantraniliprole, chlorothalonil, clothianidin, cyproconazole, deltamethrin, dicamba, difenoconazole, dinocap, etoxazole, fenpyroximate, fludioxonil, glyphosate, metalaxyl-M, meptyldinocap, novaluron, thiamethoxam, and triazophos in or on certain products Text with EEA relevance OJ L 135, 25.5.2012, p. 4-56.

8 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.
1.1.2. Nature of residues in rotational crops

Meptyldinocap is authorised on crops that may be grown in rotation (strawberries, cucumbers, courgettes, melons, watermelons). The field DT$_{90}$ (arrow sandy loam) reported in the soil degradation studies evaluated in the framework of the peer review was 122 days (EFSA, 2014). For the metabolite 2,4-DNOP, the DT$_{90}$ values were lower than 100 days (5.7–93.3 days) in all soil types tested.

There were no studies investigating the nature of residues in rotational crops available in this review. In the framework of the peer-review of dinocap, a metabolism study on rotational crops was submitted (beans, oats and turnips) but has been regarded as not valid (Austria, 2000; EFSA, 2011a). However, considering the persistence of the parent and phenol metabolite (2,4-DNOP), only 10% of the initial concentration of the parent is expected in the soil after 122 days, and thus potentially be taken up by succeeded crops. However, this conclusion should be confirmed by studies investigating the uptake and nature of residues in rotational crops (data gap). These studies are also required as to conclude whether the metabolism and distribution of meptyldinocap in rotational crops is similar to the metabolic pathway observed in primary crops.

Additionally, during the peer review, the soil metabolites X103317 and X12335709 were identified in the aerobic degradation study however their degradation rate in soil was not investigated. In addition, for these metabolites sufficient toxicological information is not available. Due to these uncertainties the relevance of these metabolites in rotational crops cannot be excluded and their investigation in rotational crops might also be required depending on the results of the soil degradation studies.

In the meanwhile, Member States granting authorisations for meptyldinocap should take the appropriate risk mitigation measures in order to avoid the presence of significant residues in rotational crops.

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of meptyldinocap in processed commodities available for this review. In grapes, strawberries and melons residues were above 0.1 mg/kg; however, since the total theoretical maximum daily intake is below 10% of the acceptable daily intake (ADI), the investigation of the nature of residues in processed commodities is not required.

1.1.4. Methods of analysis in plants

During the peer-review an analytical method based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) was considered sufficiently validated in high water, high acid, high oil and dry matrices with a limit of quantification (LOQ) of 0.01 mg/kg for meptyldinocap and the phenol metabolite (2,4-DNOP). This primary method is supported by an independent laboratory validation (ILV). An additional method (DFG-S19) validated only for meptyldinocap and supported by an ILV was also available in high water, high acid and dry matrices with a LOQ of 0.05 mg/kg.

Additionally, an analytical method validated by the EU Reference Laboratories is available for the monitoring of meptyldinocap. According to the EURLs, for meptyldinocap and metabolite 2,4-DNOP, an LOQ of 0.005 mg/kg in high water, high acid, high oil and dry commodities is achievable by using the QuEChERS method followed by post-extraction alkaline hydrolysis in routine analyses (EURL, 2019). However, full validation data were not available. Due to the unknown percentage of labs using this method, the applicability of the method cannot be justified.

1.1.5. Stability of residues in plants

The storage stability of dinocap (which contains ca. 22% meptyldinocap) was investigated in the framework of the peer review (EFSA, 2014) and a new study with meptyldinocap was submitted under this review (Spain, 2019). The storage stability of dinocap and meptyldinocap was investigated in apples (high water content commodity) and grapes (high acid content commodity) (EFSA, 2014; Spain, 2019).

For dinocap, during the peer review the available studies demonstrated storage stability for a period of 3 months in apples and 12 months in grapes (EFSA, 2014). The new study reported by RMS during this Art. 12 review demonstrates the storage stability of meptyldinocap for a period of 24 months in apples and 6 months in grapes when stored at $-20^\circ$C (Spain, 2019), therefore, an acceptable storage period for the whole group of high water and high acid commodities of 24 and 6 months, respectively can be proposed.
Since part of the residue trials samples in grapes and strawberries were stored for a period of 6.5–11.5 months, which is longer than the storage stability period demonstrated in the studies (6 months) a possible decrease in recoveries to values lower than 70% has therefore to be considered and these trials are not considered acceptable. These trials were used in the calculations on a tentative basis. For cucumbers/courgettes and melons the storage period of the residue trial samples is covered by the storage stability studies in high water commodities for meptyldinocap. However, no studies were available to address the storage stability of 2,4-DNOP in high water and high acid commodities, therefore a data gap is also observed.

1.1.6. Proposed residue definitions

The metabolism of meptyldinocap was investigated in fruits and fruiting vegetables (apple, cucumbers, squash) and was found similar in all crops assessed. The metabolism in rotational crops and the fate of the R and S and the E/Z isomers of meptyldinocap was not addressed in previous studies.

As the meptyldinocap and its metabolite (2,4-DNOP) were found to be sufficient markers in fruits and fruiting vegetables, the residue definition for enforcement and risk assessment is proposed as meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap) covering fruits and fruiting vegetables.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in all four main plant matrices (high water, high acid, high oil and dry) is available (EFSA, 2014).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of meptyldinocap residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Spain, 2019) as well as the residue trials evaluated in the framework of the peer review (The United Kingdom, 2006, 2013; EFSA, 2014).

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (European Commission, 2017).

For all commodities, the available residue trials are sufficient to derive tentative MRL and risk assessment values taking note of the following considerations:

- All residue trial samples considered in this framework were not stored in compliance with the conditions for which storage stability of residues was demonstrated. For part of the residue trial samples of grapes and strawberries, the storage period of meptyldinocap is not covered by the available storage stability study (6 months). In addition, for all commodities, the stability of metabolite 2,4-DNOP was not investigated.

1.2.2. Magnitude of residues in rotational crops

Studies investigating the magnitude of residues in rotational crops were not available in this review. Pending the investigation of the nature of residues since the DT_{90} of meptyldinocap is above 100 days (122 days), additional field rotational crops trials covering the most critical GAP currently authorised on fruiting vegetables (strawberries, cucurbits, courgettes, melons and watermelons) and covering the calculated PEC_{soil total} may be required.

1.2.3. Magnitude of residues in processed commodities

The effect of industrial processing and/or household preparation was assessed on studies conducted on strawberries (Spain, 2019). An overview of all available processing studies is available in Appendix B.1.2.3. Tentative processing factors (not fully supported by data) could be derived for canned strawberries and jam.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.
1.2.4. Proposed MRLs

The available data are considered sufficient to derive tentative MRL proposals as well as risk assessment values for the authorised uses reported in this Art. 12 review. Additional storage stability data covering the storage period of residue field trials samples for meptyldinocap and 2,4-DNOP are required. It is further noted that investigations of the impact of a possible preferential metabolism/degradation of the different isomers of meptyldinocap in plants, processing commodities and animals is not required based on the authorised uses. In case future uses of meptyldinocap would lead to a higher consumer exposure, further information might be required.

Specific MRLs for rotational crops are not needed, provided that Member States will take adequate risk mitigation measures in order to avoid significant residues to occur in rotational crops.

2. Residues in livestock

Meptyldinocap is authorised for use on apples that might be fed to livestock. Livestock dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance (OECD, 2013), which has now also been agreed upon at European level. The input values for all relevant commodities are summarised in Appendix D. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg dry matter (DM), further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

3. Consumer risk assessment

In the framework of this review, only the uses of meptyldinocap reported by the RMS in Appendix A were considered; however, the use of meptyldinocap was previously also assessed by the JMPR (FAO, 2010). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. To facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs.

3.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, EFSA, 2019a). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where a tentative MRL could be derived by EFSA in the framework of this review, input values were derived according to the internationally agreed methodologies (FAO, 2009). All input values included in the exposure calculations are summarised in Appendix D.

The exposure values calculated were compared with the toxicological reference values for meptyldinocap, derived by EFSA (2014). The highest chronic exposure was calculated for DE child representing 1% of the ADI and the highest acute exposure was calculated for melons, representing 35% of the acute reference dose (ARfD). Although uncertainties remain due to the data gaps identified in the previous sections, this indicative exposure calculation did not indicate a risk to consumer's health.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of the isomer ratios due to plant metabolism. Considering, however, that toxicological studies have been carried out with meptyldinocap (EFSA, 2014), a change of isomer ratios in the residue might, in the worst-case situation, lead to a triplication of the toxicological burden of the residue. Since the exposure calculations represent only 1% of the ADI and 35% of the ARfD, EFSA notes that in view of the large margin of safety in the exposure calculations the potential change of isomer ratios in the final residue will not be of concern for the authorised uses reported in the framework of this review. In case future uses of meptyldinocap would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

3.2. Consumer risk assessment with consideration of the existing CXLs

To include the CXLs in the calculations of the consumer exposure, CXLs were compared with the EU MRL proposals in compliance with Appendix E and all data relevant to the consumer exposure
assessment have been collected from JMPR evaluations. An overview of the input values used for this exposure calculation is also provided in Appendix D.

Chronic and acute exposure calculations were also performed using revision 3.1 of the EFSA PRIMo and the exposure values calculated were compared with the toxicological reference values derived for meptyldinocap. The highest chronic exposure was calculated for DE child, representing 1% of the ADI, and the highest acute exposure was calculated for melons, representing 35% of the ARfD. Based on these calculations, EFSA concludes that the CXLs are not expected to be of concern for European consumers.

Conclusions

The metabolism of meptyldinocap (DE-126) in plants was investigated in primary crops. According to the results of the metabolism studies, the residue definition for enforcement and risk assessment can be proposed as sum of meptyldinocap and 2,4-DNOP, expressed as meptyldinocap for fruits and fruiting vegetables. The fate of the R and S and the E/Z isomers of meptyldinocap was not addressed in the previous studies however in view of the large margin of safety in the exposure calculations, a possible impact of a preferential conversion of one isomeric form to another on the toxicity and consumer risk assessment will not be of concern for the authorised uses reported in the framework of this review. Specific residue definition could not be derived for rotational crops.

Fully validated analytical methods are available for the enforcement of the proposed residue definition in high water and high acid matrices at the LOQ of 0.01 mg/kg. According to the EURLs, a LOQ of 0.05 mg/kg is achievable by using the QuEChERS method in routine analyses.

Available residue trials were considered sufficient to derive tentative MRL proposals as well as risk assessment values for all commodities under evaluation. Considering the general data gaps identified related to storage stability and the data gaps for a metabolism rotational crops study, MRLs for all commodities under assessment are tentative only.

Meptyldinocap is authorised for use on crops that might be fed to livestock. Dietary burden calculations were therefore performed for different groups of livestock according to OECD guidance. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is unnecessary.

Chronic and acute consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 3.1 of the EFSA PRIMo. The highest chronic exposure represented 1% of the ADI (DE child) and the highest acute exposure amounted to 35% of the ARfD (melons) (EU).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for meptyldinocap (CXL). Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 1% of the ADI (DE child) and the highest acute exposure amounted to 35% of the ARfD (melons).

Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 2). None of the MRL values listed in the table are recommended for inclusion in Annex II to the Regulation as they are not sufficiently supported by data. In particular, all tentative MRLs need to be confirmed by the following data:

- a representative study investigating the nature of residues in rotational crops. Further investigation of the soil metabolites X103317 and X12335709 in rotational crops might also be required depending on the results of the soil degradation studies.
- a storage stability study for metabolite 2,4-DNOP in high water and high acid commodities, covering the storage period of the residue field trials (this data gap is not applicable to the MRLs finally proposed for cucumbers and courgettes which are based on the CXLs).
- additional southern European Union (SEU) and northern European Union (NEU) GAP-compliant residue trials on grapes. Storage of samples should be covered by the acceptable storage period for high acid commodities.
- additional SEU and indoor GAP-compliant residue trials in strawberries. Storage of samples should be covered by the acceptable storage period for high acid commodities.
If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

**Table 2:** Summary table

| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment |
|-------------|--------------------|-------------------------|----------------------|----------------------------------|---------|
| 130010      | Apples             | 0.05*                   | –                    | 0.01*                            | Further consideration needed (a) |
| 151010      | Table grapes       | 1                       | 0.2                  | 0.2                              | Further consideration needed (b) |
| 151020      | Wine grapes        | 1                       | 0.2                  | 0.2                              | Further consideration needed (b) |
| 152000      | Strawberries       | 3                       | 0.3                  | 0.3                              | Further consideration needed (b) |
| 232010      | Cucumbers          | 0.1                     | 0.07                 | 0.07                             | Recommended (c) |
| 232030      | Courgettes         | 0.1                     | 0.07                 | 0.07                             | Recommended (c) |
| 233010      | Melons             | 0.5                     | 0.5                  | 0.5                              | Further consideration needed (b) |
| 233030      | Watermelons        | 0.1                     | –                    | 0.5                              | Further consideration needed (d) |
| –           | Other commodities of plant and/or animal origin | See Reg. 441/2012 | – | – | Further consideration needed (d) |

**Enforcement residue definition:** meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap)

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment |
|-------------|-----------|-------------------------|----------------------|----------------------------------|---------|
| 130010      | Apples    | 0.05*                   | –                    | 0.01*                            | Further consideration needed (a) |
| 151010      | Table grapes | 1                       | 0.2                  | 0.2                              | Further consideration needed (b) |
| 151020      | Wine grapes | 1                       | 0.2                  | 0.2                              | Further consideration needed (b) |
| 152000      | Strawberries | 3                       | 0.3                  | 0.3                              | Further consideration needed (b) |
| 232010      | Cucumbers  | 0.1                     | 0.07                 | 0.07                             | Recommended (c) |
| 232030      | Courgettes | 0.1                     | 0.07                 | 0.07                             | Recommended (c) |
| 233010      | Melons     | 0.5                     | 0.5                  | 0.5                              | Further consideration needed (b) |
| 233030      | Watermelons | 0.1                     | –                    | 0.5                              | Further consideration needed (d) |
| –           | Other commodities of plant and/or animal origin | See Reg. 441/2012 | – | – | Further consideration needed (d) |

**MRL:** maximum residue level; **CXL:** codex maximum residue limit.

*:* Indicates that the MRL is set at the limit of quantification.

(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).

(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).

(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).

(d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).

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**Abbreviations**

a.i. active ingredient  
a.s. active substance  
ADI acceptable daily intake  
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  
CF conversion factor for enforcement residue definition to risk assessment residue definition  
CXL codex maximum residue limit  
DAR draft assessment report  
DAT days after treatment
| Abbreviation | Full Form |
|--------------|-----------|
| DB           | dietary burden |
| DM           | dry matter |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| EC           | emulsifiable concentrate |
| EURLs        | European Union Reference Laboratories for Pesticide Residues (former CRLs) |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| InChiKey     | International Chemical Identifier Key. |
| ISO          | International Organisation for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| JMPR         | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| LC–MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOQ          | limit of quantification |
| Mo           | monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| NEDI         | national estimated daily intake |
| NEU          | northern European Union |
| NESTI        | national estimated short-term intake |
| NTMDI        | national theoretical maximum daily intake |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PF           | processing factor |
| PHI          | preharvest interval |
| P<sub>ow</sub> | partition coefficient between n-octanol and water |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| STMR         | supervised trials median residue |
| TMDI         | theoretical maximum daily intake |
| WHO          | World Health Organization |
Appendix A – Summary of authorised uses considered for the review of MRLs

A.1. Authorised outdoor uses in northern EU

| Crop and/or situation | MS or country | F G or I | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|---------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |               |         |                                   | Type(b) | Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Water L/ha min-max | Rate and unit | | |
| Table grapes          | SI, AT        | F       | Powdery mildew                    | EC        | 350 g/L    | Foliar treatment – spraying   | 13–81      | 4  | 7           | – | –                 | 210 g a.i./ha | 21               | AT Method: Air assisted sprayer low-high volume; Restriction: max. two applications after flowering |
| Wine grapes           | SI, AT        | F       | Powdery mildew                    | EC        | 350 g/L    | Foliar treatment – spraying   | 13–81      | 4  | 7           | – | –                 | 210 g a.i./ha | 21               | AT Method: Air assisted sprayer low-high volume; Restriction: max. two applications after flowering |

MRL: maximum residue level; a.s.: active substance; MS: Member State; EC: emulsifiable concentrate; a.i.: active ingredient.

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

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.

(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.
### A.2. Authorised outdoor uses in southern EU

| Crop and/or situation | MS or country | F or G | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|---------------|--------|-----------------------------------|-------------|------------|-------------------------------|------------|---------|
| Apples                | IT            | F      | Powdery Mildew                    | EC 350 g/L  | Foliar treatment – spraying   | 10–60          | 3        | 7       | 210 g a.i./ha | n.a.   |
| Table grapes          | PT, IT, EL, ES| F      | Powdery Mildew                    | EC 350 g/L  | Foliar treatment – spraying   | 13–81          | 4        | –       | 210 g a.i./ha | 21 PT:BBCH 71–81 |
| Wine grapes           | PT, IT, EL, ES| F      | Powdery Mildew                    | EC 350 g/L  | Foliar treatment – spraying   | 13–81          | 4        | –       | 210 g a.i./ha | 21 PT:BBCH 71–81 |
| Strawberries          | HR, ES, IT    | F      | Powdery Mildew, Sphaerotheca maculatis | EC 350 g/L  | Foliar treatment – spraying   | 3              | –        | –       | 210 g a.i./ha | 3–     |
| Cucumbers             | HR, ES, IT    | F      | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC 350 g/L  | Foliar treatment – spraying   | 15–85          | 3        | –       | 210 g a.i./ha | 3–     |
| Courgettes            | HR, ES, IT    | F      | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC 350 g/L  | Foliar treatment – spraying   | 15–85          | 3        | –       | 210 g a.i./ha | 3–     |
| Crop and/or situation | MS or country | Pests or Group of pests controlled | Preparation | Method kind | Range of growth stages & season (c) | Number min-max | Interval between application (min) | a.s./hL min-max | Water L/ha min-max | Rate and unit | PHI (days) (d) | Remarks |
|-----------------------|--------------|----------------------------------|-------------|-------------|----------------------------------|----------------|----------------------------------|----------------|-----------------|----------------|----------------|---------|
| Melons HR, ES, IT     | F            | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC          | Foliar treatment – spraying | 15-85 | 3 | – | – | – | 210 g a.i./ha | 3 |
| Watermelons HR, ES, IT| F            | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC          | Foliar treatment – spraying | 15-85 | 3 | – | – | – | 210 g a.i./ha | 3 |

MRL: maximum residue level; a.s.: active substance; MS: Member State; EC: emulsifiable concentrate; a.i.: active ingredient.
(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).
(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide.
(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.
# A.3. Authorised indoor uses in EU

| Crop and/or situation | MS or country | F G or T(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|-----------------------------------|-------------|-------------|-----------------------------|--------------|---------|
| Strawberries HR, ES, IT | I | Powdery Mildew, Sphaerotheca maculatis | EC 350 g/L | Foliar treatment – spraying | 15-85 | 3 | – | 210 g a.i./ha | 3 ES: Manual spray with lance |
| Cucumbers HR, ES, IT | I | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC 350 g/L | Foliar treatment – spraying | 15-85 | 3 | – | 210 g a.i./ha | 3 ES: Manual spray with lance |
| Courgettes HR, ES, IT | I | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC 350 g/L | Foliar treatment – spraying | 15-85 | 3 | – | 210 g a.i./ha | 3 ES: Manual spray with lance |
| Melons HR, ES, IT | I | Powdery Mildew, Erysiphe cichoracearum, Sphaerotheca fuliginea i Podosphaera xanthii | EC 350 g/L | Foliar treatment – spraying | 15-85 | 3 | – | 210 g a.i./ha | 3 ES: Manual spray with lance |
| Crop and/or situation | MS or country | F G or I(a) | Pests or Group of pests controlled | Preparation Type(b) | Concentration Conc. a.s. | Method kind | Range of growth stages & season(c) | Number min-max | Interval between application (min) | Application rate per treatment a.s./hL | Water L/ha | Rate and unit | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|------------------------------------|---------------------|--------------------------|-------------|-----------------------------------|----------------|----------------------------------|----------------------------------------|-----------|--------------|--------------|---------|
| Watermelons           | HR, IT        | I           | Powdery Mildew, *Erysiphe cichoracearum*, *Sphaerotheca fuliginea* i *Podosphaera xanthii* | EC                  | 350 g/L                  | Foliar treatment – spraying | 15–85              | 3                              | –                          | –                 | 210 g a.i./ha | 3            | –           |

MRL: maximum residue level; a.s.: active substance; MS: Member State; EC: emulsifiable concentrate; a.i.: active ingredient.
## 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                       |             |         |                |                |                |
|                                   |             | Apple   | 1 × 1.96 kg a.i./ha | 0, 7, 14 and 21 | 14C-phenyl-labelled meptyldinocap (EFSA, 2014) |
|                                   |             | Apple   | 1 × 1.96 kg a.i./ha | 0, 7, 14 and 21 | 14C-phenyl-labelled 2,6-DNOPC (EFSA, 2014) |
|                                   |             | Cucumber| 1 × 0.56 kg a.i./ha | Whole plants: 0, 8, 21, 34, 48, 63 Fruits: 21 | 14C-phenyl-labelled meptyldinocap supplementary information only (EFSA, 2011a) |
|                                   |             | Squash  | 3 × 0.56 kg a.i./ha | Whole plants: 0, 7, 17, 25, 32, 40, 53, 66, 80 Fruits: 0, 7, 17 (before and after T2 and T3) | 14C-phenyl-labelled meptyldinocap supplementary information only (EFSA, 2011a) The 2nd and 3rd application were performed 7 and 17 days after the 1st application |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     |             | –       | –              | –         | No available studies were available and would be required (data gap) |
| Leafy crops                          |             | –       | –              | –         | No available studies were available and would be required (data gap) |
| Cereal (small grain)                 |             | –       | –              | –         | No available studies were available and would be required (data gap) |
| Other                                |             | –       | –              | –         | No available studies were available and would be required (data gap) |

| Processed commodities (hydrolysis study) | Conditions                  | Stable? | Comment/Source |
|------------------------------------------|-----------------------------|---------|----------------|
|                                          | Pasteurisation (20 min, 90°C, pH 4) | Not triggered | The total theoretical maximum daily intake is below 10% of the ADI |
|                                          | Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered | |
|                                          | Sterilisation (20 min, 120°C, pH 6) | Not triggered | |
|                                          | Other processing conditions | Not triggered | |
Can a general residue definition be proposed for primary crops? | Yes | Applicable only to fruits and fruiting vegetables  
Rotational crop and primary crop metabolism similar? | Inconclusive | RC studies were not available and would be required (data gap)  
Residue pattern in processed commodities similar to residue pattern in raw commodities? | Not applicable | Hydrolysis studies were not required.  
Plant residue definition for monitoring (RD-Mo) | Fruits and fruiting vegetables: meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap)  
Plant residue definition for risk assessment (RD-RA) | Fruits and fruiting vegetables: meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap)  
Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs) |  
1. Matrices with high water, high acid, high oil content and dry commodities:  
   Analytes: meptyldinocap and 2.4-DNOP  
   LC–MS/MS, LOQ 0.01 mg/kg, ILV available for dry and high water commodities  
   (UK, 2006, 2013; EFSA, 2014)  
2. DFG-S19  
   Matrices with high water, high acid content and dry  
   Analytes: meptyldinocap  
   LC–MS/MS, LOQ 0.05 mg/kg, ILV available  
   (UK, 2006, 2013; EFSA, 2014)  
3. An analytical method provided by the EURLs (EURL, 2019) show that meptyldinocap and metabolite 2,4-DNOP can be monitored in high water, high acid, high oil and dry commodities at a LOQ of 0.005 mg/kg by using the QuEChERS method followed by post-extraction alkaline hydrolysis. Full validation data, however, were not available.

(a): Spiked as meptyldinocap but measured as its corresp. phenol (2,4-DNOP), following alkaline hydrolysis. Validation trials were performed in cucumbers, grapes, wheat flour and peanut butter.  
(b): Validation data were available for only for 1 spiked level (0.005 mg/kg).  

a.i.: active ingredient; DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.
### B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category | Commodity | T (°C) | Stability period Value | Compounds covered | Comment/Source |
|------------------------------------|----------|-----------|--------|------------------------|-------------------|----------------|
|                                    | High water content | Apples | –20 | 3 Months | Dinocap (which contains ca. 22% meptyldinocap) | EFSA (2014) |
|                                    |          | Apples | –20 | 24 Months | Meptyldinocap | Spain (2019) |
|                                    | High oil content | –       | –     | – | – | – |
|                                    | High protein content | –       | –     | – | – | – |
|                                    | High starch content | –       | –     | – | – | – |
|                                    | High acid content | Grapes | –20 | 12 Months | Dinocap (which contains ca. 22% meptyldinocap) | EFSA (2014) |
|                                    |          | Grapes | –20 | 6 Months | Meptyldinocap | For grapes, the residue level declined by nearly 50% after 12 months storage and there is not a procedural recovery declined (Spain, 2019) |
|                                    | Processed products | –       | –     | – | – | – |
|                                    | Others   | –       | –     | – | – | – |
### B.1.2. Magnitude of residues in plants

#### B.1.2.1. Summary of residues data from the supervised residue trials – Primary crops

| Commodity       | Region/indoor | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR<sup>(b)</sup> (mg/kg) | STMR<sup>(c)</sup> (mg/kg) |
|-----------------|---------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------------------|--------------------------|
| RD-Mo and RD-RA: meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap) |               |                                                                  |                                                                               |                        |                          |                          |
| Apples          | SEU           | $4 \times < 0.01$                                                 | Residue trials on apples compliant with GAP (Spain, 2019)                        | 0.01* (tentative)      | 0.01                     | 0.01                     |
| Table and Wine grapes | NEU         | $3 \times < 0.025; 2 \times < 0.025; 0.03; 0.05; 0.08; 0.09; 0.12$ | According to Whitney-Mann comparability test data from SEU and NEU belong to the same population. Merged data set proposed to set the MRL (EFSA, 2014). The storage period of the samples in *bold* (199–248 days) is not covered by the storage stability studies (6 months) for meptyldinocap. These trials were used in the calculations on a tentative basis | 0.2 (tentative)       | 0.12                     | 0.025                    |
|                 | SEU           | $4 \times < 0.025; 3 \times < 0.025; 0.03; 0.06; 0.06; 0.1$       | Residue trials on strawberries compliant with GAP (Spain, 2019). The storage period of the samples in *bold* (307–348 days) is not covered by the storage stability studies (6 months) for meptyldinocap. These trials were used in the calculations on a tentative basis | 0.1 (tentative)      | 0.07                     | 0.03                     |
| Strawberries    | SEU           | $< 0.01; < 0.01; 0.02; 0.03; 0.03; 0.04; 0.04; 0.07$              | Residue trials on strawberries compliant with GAP (Spain, 2019). The storage period of the samples in *bold* (190–218 days) is not covered by the storage stability studies (6 months) for meptyldinocap. These trials were used in the calculations on a tentative basis | 0.3 (tentative)      | 0.13                     | 0.085                    |
| Indoor          | 0.03; 0.06; 0.07; 0.08; 0.09; 0.11; 0.12; 0.13 | Residue trials on strawberries compliant with GAP (Spain, 2019). The storage period of the samples in *bold* (190–218 days) is not covered by the storage stability studies (6 months) for meptyldinocap. These trials were used in the calculations on a tentative basis | 0.3 (tentative)      | 0.13                     | 0.085                    |
| Commodity                     | Region/indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) |
|------------------------------|------------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|--------------|--------------|
| Cucumbers, Courgettes        | SEU              | Cucumber: < 0.01; < 0.01; < 0.01; 0.015                          | Residue trials on cucumbers (4 trials) and courgettes (5 trials) compliant with GAP (Spain, 2019) | 0.03 (tentative)(d)    | 0.015        | 0.01         |
|                              | Indoor           | Courgettes: < 0.01; < 0.01; < 0.01; < 0.01; 0.01                | Residue trials on cucumbers (4 trials) and courgettes (4 trials) compliant with GAP (Spain, 2019) | 0.05 (tentative)(d)    | 0.04         | 0.025        |
| Melons, Watermelons          | SEU              | < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; < 0.01; 0.025; 0.04     | GAP compliant residue trials on melons (Spain, 2019). Extrapolated to watermelons | 0.02 (tentative)(d)    | 0.01         | 0.01         |
|                              | Indoor           | < 0.025; < 0.025; < 0.025; < 0.025; 0.025; 0.05; 0.28          | GAP compliant residue trials on melons (Spain, 2019). Extrapolated to watermelons | 0.5 (tentative)(d)     | 0.28         | 0.025        |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level.

*: Indicates that the MRL is proposed at the limit of quantification.

Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.

(b): Highest residue. The highest residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(c): Supervised trials median residue. The median residue for risk assessment (RA) refers to the whole commodity and not to the edible portion.

(d): MRL is tentative because the storage period of the samples is not covered by the available storage stability studies for 2,4-DNOP. A data gap was set.

(e): MRL is tentative because the storage period of part of the samples is not covered by the available storage stability studies for meptyldinocap and 2,4-DNOP. A data gap was set.

B.1.2.2. Residues in rotational crops

a) Overall summary

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

- Inconclusive

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

- Inconclusive

Taking into account the persistence of meptyldinocap and 2,4-DNOP only 10% of the initial concentration of the parent compound is expected in the soil after 122 days. Pending the elucidation of the metabolic pattern of meptyldinocap in rotational crops, investigation of the fate of the soil metabolites X103317 and X12335709 may be required.
B.1.2.3. Processing factors

| Processed commodity | Number of valid studies\(^{(a)}\) | Processing Factor (PF) | Comment/Source |
|---------------------|---------------------------------|------------------------|----------------|
|                     |                                 | Individual values | Median PF\(^{(b)}\) |               |
| Strawberry, jam     | 2                               | < 0.4; 0.5          | 0.5             | Tentative\(^{(c)}\) |
| Strawberry, canned  | 2                               | 0.7; 0.8           | 0.8             | Tentative\(^{(c)}\) |

PF: Processing factor (=Residue level in processed commodity expressed according to RD-Mo/Residue level in raw commodity expressed according to RD-Mo).

\(^{(a)}\): Studies with residues in the RAC at or close to the LOQ were disregarded (unless concentration may occur).

\(^{(b)}\): Median of the individual conversion factors for each processing residues trial.

\(^{(c)}\): A tentative PF is derived based on a limited data set.

B.2. Residues in livestock

| Relevant groups (subgroups) | Dietary burden expressed in | Most critical subgroup\(^{(a)}\) | Most critical commodity\(^{(b)}\) | Trigger exceeded\((Y/N)\) | Comments |
|-----------------------------|----------------------------|--------------------------------|---------------------------------|---------------------------|----------|
|                             | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum | Cattle (beef) | Barley, straw | N | – |
| Cattle (all)                | 0.001            | 0.02     | 0.02   |         |        |         |               |               |   |    |
| Cattle (dairy only)         | 0.001            | 0.02     | 0.02   |         |        |         |               |               |   |    |
| Sheep (all)                 | 0.001            | 0.03     | 0.03   |         |        |         | Sheep (lamb)  | Barley, straw | N | – |
| Sheep (ewe only)            | 0.001            | 0.03     | 0.03   |         |        |         | Sheep (ram/ewe)| Barley, straw | N | – |
| Swine (all)                 | n.r.             | n.r.     | n.r.   |         | n.r.   | n.r.    |               |               | N | – |
| Poultry (all)               | n.r.             | n.r.     | n.r.   |         | n.r.   | n.r.    |               |               | N | – |
| Poultry (layer only)        | n.r.             | n.r.     | n.r.   |         | n.r.   | n.r.    |               |               | N | – |
| Fish                        | –                | –        | –      | –       | –      | –       |               |               | – | Not assessed |

bw: body weight; DM: dry matter; Nr: not relevant since exposure to the most critical diet was not reported/applicable.

\(^{(a)}\): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.

\(^{(b)}\): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
## 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 per day) | Duration (days) | Comment/Source                  |
|------------------------------|------------|-------------------------|-----------------|----------------------------------|
| Laying hen                   | –          | –                       | –               | Not available and not triggered  |
| Lactating ruminants          | –          | –                       | –               | Not available and not triggered  |
| Pig                          | –          | –                       | –               | Not available and not triggered  |
| Fish                         | –          | –                       | –               | Not available and not triggered  |

- Time needed to reach a plateau concentration in milk and eggs (days): Milk: – Not applicable, Eggs: – Not applicable
- Metabolism in rat and ruminant similar: Inconclusive
- Can a general residue definition be proposed for animals?: Inconclusive
- Animal residue definition for monitoring (RD-Mo): Inconclusive
- Animal residue definition for risk assessment (RD-RA): Inconclusive
- Fat soluble residues: Yes, Log P<sub>o/w</sub> = 6.55 (EFSA, 2014)
- Methods of analysis for monitoring of residues (analytical technique, matrix groups, LOQs): Not available and not applicable

**bw:** body weight; P<sub>o/w</sub>: partition coefficient between n-octanol and water.

### B.2.1.2. Stability of residues in livestock

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|------------------------------------|--------|-----------|--------|------------------|-------------------|----------------|
|                                    | –      | –         | –      | –                | –                 | –              |

No studies available and not required
### B.2.2. Magnitude of residues in livestock

#### B.2.2.1. Summary of the residue data from livestock feeding studies

| Animal commodity   | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | MRL proposal (mg/kg) | CF<sup>(c)</sup> |
|--------------------|-----------------------------------------------|--------------------------------------------|---------------------|-----------------|
|                    | Mean  | Highest | STMR<sub>st</sub><sup>(a)</sup> (mg/kg) | HR<sub>st</sub><sup>(b)</sup> (mg/kg) |                  |
| Cattle (all)       | –     | –       | –                             | –                  |                  |
| Cattle (dairy only)| –     | –       | –                             | –                  |                  |
| Milk               | –     | –       | –                             | –                  |                  |
| Sheep (all)        | –     | –       | –                             | –                  |                  |
| Sheep (ewe only)   | –     | –       | –                             | –                  |                  |
| Swine (all)        | –     | –       | –                             | –                  |                  |
| Poultry (all)      | –     | –       | –                             | –                  |                  |
| Poultry (layer only)| –  | –       | –                             | –                  |                  |

* The need for MRL is not triggered for this group of livestock.

* Indicates that the MRL is proposed at the limit of quantification.

MRL: maximum residue level; n.a.: not applicable; n.r.: not reported.

(a): Median residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the median dietary burden.

(b): Highest residues expressed according to the residue definition for monitoring, recalculated at the 1N rate for the maximum dietary burden.

(c): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
### B.3. Consumer risk assessment

#### B.3.1. Consumer risk assessment without consideration of the existing CXLs

| ARfD                  | 0.12 mg/kg bw (EFSA, 2014) |
|-----------------------|----------------------------|
| Highest IESTI, according to EFSA PRIMo (rev.3.1) | Scenario EU (with risk mitigation measures): |
|                       | Melon: 35% of ARfD          |
|                       | Watermelon: 29% of ARfD     |
|                       | Table grapes: 7% of ARfD    |
| NESTI (% ARfD)        | Not assessed in this review |
| Assumptions made for the calculations | Scenario EU (with risk mitigation measures): |
|                       | The calculation is based on the highest residue levels expected in raw agricultural commodities assuming no residues from rotational crops. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |
| ADI                   | 0.016 mg/kg bw per day (EFSA, 2014) |
| TMDI according to EFSA PRIMo | Not assessed in this review |
| NTMDI, according to (to be specified) | Not assessed in this review |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) | Scenario EU (with risk mitigation measures): |
|                       | 1% ADI (DE child)           |
|                       | Contribution of crops assessed:   |
|                       | Apples: 0.8%                  |
|                       | Strawberries: 0.3%            |
|                       | Table grapes: 0.2%            |
| NEDI (% ADI)          | Not assessed in this review   |
| Assumptions made for the calculations | Scenario EU (with risk mitigation measures): |
|                       | The calculation is based on the median residue levels expected in raw agricultural commodities assuming no residues from rotational crops. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation |

Consumer exposure assessment through drinking water resulting from groundwater metabolite(s) according to SANCO/221/2000 rev.10 Final (25/02/2003)

| Metabolite(s)       | Not assessed in this review |
|---------------------|-----------------------------|
| ADI (mg/kg bw per day) | Not assessed in this review |
| Intake of groundwater metabolites (% ADI) | Not assessed in this review |
### B.3.2. Consumer risk assessment with consideration of the existing CXLs

| Parameter                                      | Value                                         |
|------------------------------------------------|-----------------------------------------------|
| **ARfD**                                       | 0.12 mg/kg bw (EFSA, 2014)                    |
| Highest IESTI, according to EFSA PRIMo (rev.3.1) |                                               |
| **NESTI (%) ARfD**                             | Not assessed in this review                   |
| Assumptions made for the calculations          |                                               |
| **ADI**                                        | 0.016 mg/kg bw per day (EFSA, 2014)           |
| TMDI according to EFSA PRIMo                   | Not assessed in this review                   |
| NTMDI, according to (to be specified)          | Not assessed in this review                   |
| Highest IEDI, according to EFSA PRIMo (rev.3.1) |                                               |
| **NEDI (%) ADI**                               | Not assessed in this review                   |
| Assumptions made for the calculations          |                                               |

#### Scenario CX1 (with risk mitigation measures):
- Melon: 35% of ARfD
- Watermelon: 29% of ARfD
- Table grapes: 7% of ARfD

#### Scenario CX1 (with risk mitigation measures):
- For those commodities having a CXL higher that the EU MRL proposal, highest residue levels applied in the EU scenario were replaced by the highest residue levels derived by JMPR assuming no residues from rotational crops

**ARfD:** acute reference dose; **bw:** body weight; **NESTI:** national estimated short-term intake; **PRIMo:** (EFSA) Pesticide Residues Intake Model; **IESTI:** international estimated short-term intake; **ADI:** acceptable daily intake; **bw:** body weight; **NEDI:** national estimated daily intake; **PRIMo:** (EFSA) Pesticide Residues Intake Model; MDI: theoretical maximum daily intake; **NTMDI:** national theoretical maximum daily intake; **CXL:** codex maximum residue limit.
### B.4. Proposed MRLs

**Table B.1: Summary table**

| Code number | Commodity          | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review MRL (mg/kg) | Comment                                      |
|-------------|--------------------|-------------------------|----------------------|----------------------------------|-----------------------------------------------|
| 130010      | Apples             | 0.05*                   | –                    | 0.01*                            | Further consideration needed<sup>(a)</sup>    |
| 151010      | Table grapes       | 1                       | 0.2                  | 0.2                              | Further consideration needed<sup>(b)</sup>    |
| 151020      | Wine grapes        | 1                       | 0.2                  | 0.2                              | Further consideration needed<sup>(b)</sup>    |
| 152000      | Strawberries       | 3                       | 0.3                  | 0.3                              | Further consideration needed<sup>(b)</sup>    |
| 232010      | Cucumbers          | 0.1                     | 0.07                 | 0.07                             | Recommended<sup>(c)</sup>                     |
| 232030      | Courgettes         | 0.1                     | 0.07                 | 0.07                             | Recommended<sup>(c)</sup>                     |
| 233010      | Melons             | 0.5                     | 0.5                  | 0.5                              | Further consideration needed<sup>(c)</sup>    |
| 233030      | Watermelons        | 0.1                     | –                    | 0.5                              | Further consideration needed<sup>(d)</sup>    |
| –           | Other commodities of plant and/or animal origin | See Reg. 441/2012 | – | – | Further consideration needed<sup>(d)</sup> |

**Enforcement residue definition:** meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap)

- **MRL:** maximum residue level; **CXL:** codex maximum residue limit.
- *: Indicates that the MRL is set at the limit of quantification.
- (a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); no CXL is available (combination F-I in Appendix E).
- (b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified (assuming the existing residue definition); existing CXL is covered by the tentative MRL (combination F-III in Appendix E).
- (c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination F-VII in Appendix E).
- (d): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix E).
### Meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP)

| Commodity | Highest contributor to MS diet | 2nd contributor to MS diet | 3rd contributor to MS diet | MRLs set at EU LOQs (mg/kg) Range from: to: |
|-----------|-------------------------------|---------------------------|---------------------------|---------------------------------------------|
| 1% DE, child | 0.02 0.7% 0.5% | 0.02 0.0% 0.0% | 0.02 0.0% 0.0% | 0.02 0.0% 0.0% |
| 1% NL, child | 0.02 0.7% 0.5% | 0.02 0.0% 0.0% | 0.02 0.0% 0.0% | 0.02 0.0% 0.0% |
| 0.6% GEMS/Food G06 | 0.01 0.2% 0.1% | 0.01 0.0% 0.0% | 0.01 0.0% 0.0% | 0.01 0.0% 0.0% |
| 0.6% DK, child | 0.00 0.3% 0.1% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% IE, adult | 0.00 0.2% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% FR, adult | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.6% PT, general | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.5% FI, 3-yr | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% DE, women 14-50 yr | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% GEMS/Food G07 | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% FR, child 3-15 yr | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% GEMS/Food G06 | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% GEMS/Food G15 | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% OE, general | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% GEMS/Food G11 | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% FI, 6-yr | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.4% FR, toddler 2 yr | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.3% OK, adult | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.3% GEMS/Food G10 | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.3% NL, general | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.3% UK, toddler | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.3% FR, infant | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.3% UK, vegetation | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% UK, adult | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% SE, general | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% FI, adult | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% UK, infant | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% PS, general | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% ES, adult | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% LT, adult | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% IT, toddler | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% ES, child | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.2% IT, child | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% | 0.00 0.0% 0.0% |
| 0.0% IE, child | 0.01 0.0% 0.0% | 0.01 0.0% 0.0% | 0.01 0.0% 0.0% | 0.01 0.0% 0.0% |

**Conclusion:**
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Meptyldinocap (sum of 2,4-DNOPC and 2,4-DNOP expressed as meptyldinocap) is unlikely to present a public health concern.
The acute risk assessment is based on the ARID.
The calculation is based on the large portion of the most critical consumer group.

## Acute risk assessment/children

### Details - acute risk assessment/children

### Details - acute risk assessment/adults/general population

The acute risk assessment is based on the ARID.

## Show results for all crops

### Results for children

| Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|--------------------------|---------------------|----------------------|
| 35% Melons  | 0.5/0.28                 | 42                  | Watermelons 0.5/0.28 |
| 29% Watermelons | 0.5/0.28              | 34                  | Melons 0.5/0.28 |
| 7% Table grapes | 0.3/0.12                 | 8.6                 | Table grapes 0.3/0.12 |
| 2% Cucumbers | 0.07/0.04                 | 2.6                 | Wine grapes 0.3/0.12 |
| 2% Strawberries | 0.3/0.13                 | 2.1                 | Strawberries 0.3/0.13 |
| 2% Courgettes | 0.07/0.04                  | 1.9                 | Cucumbers 0.07/0.04 |
| 0.9% Wine grapes | 0.3/0.12                  | 1.1                 | Courgettes 0.07/0.04 |
| 0.9% Apples | 0.01/0.01                 | 1.1                 | Apples 0.01/0.01 |

### Results for adults

| Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) | Highest % of ARfD/ADI |
|-------------|--------------------------|---------------------|----------------------|
| 1% Courgettes/boiled | 0.07/0.04               | 1.4                 | Wine grapes/wine 0.2/0.12 |
| 0.9% Wine grapes/juice | 0.3/0.12                | 1.1                 | Courgettes/boiled 0.07/0.04 |
| 0.5% Apples/juice | 0.01/0.01/0.01           | 0.54                | Table grapes/stains 0.2/0.56 |
| #NUM! #NUM! #NUM! | #NUM! #NUM! #NUM!        | #NUM! #NUM! #NUM!   | #NUM! #NUM! #NUM!   |
| #NUM! #NUM! #NUM! | #NUM! #NUM! #NUM!        | #NUM! #NUM! #NUM!   | #NUM! #NUM! #NUM!   |
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### Details - acute risk assessment/adults

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

## Conclusion:

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

A short-term intake of residues of Meptyldinocap (sum of 2,4-DINOPC and 2,4-DINDP expressed as meptyldinocap) is unlikely to present a public health risk.

For processed commodities, no exceedance of the ARID was identified.
Meptyldinocap

**LOQs (mg/kg)** range from: 0.01 to: 0.01

**ADI (mg/kg bw per day):** 0.016

**ARfD (mg/kg bw):** 0.12

**Source of ADI:** EFSA

**Source of ARfD:** EFSA

**Year of evaluation:** 2014

**No of diets exceeding the ADI:** ---

### Calculated exposure (% of ADI)

| Commodity/group of commodities | Exposure resulting from | 
|---------------------------------|-------------------------|
| Table grapes                   | 1%                      |
| Strawberries                   | 1%                      |
| Table grapes                   | 0.7%                    |
| Strawberries                   | 0.7%                    |
| Melons                         | 0.6%                    |
| Strawberries                   | 0.6%                    |
| Table grapes                   | 0.5%                    |
| Strawberries                   | 0.5%                    |
| Table grapes                   | 0.5%                    |
| Strawberries                   | 0.5%                    |
| Apples                         | 0.5%                    |
| Strawberries                   | 0.5%                    |
| Table grapes                   | 0.5%                    |
| Strawberries                   | 0.4%                    |
| Table grapes                   | 0.3%                    |
| Wine grapes                    | 0.3%                    |
| Strawberries                   | 0.2%                    |
| Table grapes                   | 0.2%                    |
| Wine grapes                    | 0.2%                    |
| Strawberries                   | 0.2%                    |
| Table grapes                   | 0.2%                    |
| Wine grapes                    | 0.2%                    |
| Strawberries                   | 0.2%                    |
| Table grapes                   | 0.2%                    |
| Wine grapes                    | 0.2%                    |
| Strawberries                   | 0.2%                    |
| Apples                         | 0.2%                    |
| Strawberries                   | 0.1%                    |
| Watermelons                    | 0.1%                    |
| Strawberries                   | 0.1%                    |
| Apples                         | 0.1%                    |
| Strawberries                   | 0.1%                    |
| Apples                         | 0.1%                    |
| Strawberries                   | 0.1%                    |
| Apples                         | 0.1%                    |
| Strawberries                   | 0.1%                    |
| Table grapes                   | 0.1%                    |
| Wine grapes                    | 0.1%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Table grapes                   | 0.0%                    |
| Wine grapes                    | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
| Apples                         | 0.0%                    |
| Strawberries                   | 0.0%                    |
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for Children

| Commodity            | MRL/Input (mg/kg) | Exposure (µg/kg bw) |
|----------------------|-------------------|---------------------|
| Melons               | 0.50/0.28         | 42                  |
| Watermelons          | 0.50/0.28         | 34                  |
| Table grapes         | 0.07/0.04         | 2.6                 |
| Strawberries         | 0.30/0.13         | 2.1                 |
| Courgettes           | 0.07/0.04         | 1.9                 |
| Wine grapes          | 0.20/0.12         | 1.1                 |
| Apples               | 0.01/0.01         | 1.1                 |

### Results for Adults

| Commodity            | MRL/Input (mg/kg) | Exposure (µg/kg bw) |
|----------------------|-------------------|---------------------|
| Melons               | 0.50/0.28         | 11                  |
| Watermelons          | 0.50/0.28         | 11                  |
| Table grapes         | 0.20/0.12         | 4.1                 |
| Wine grapes          | 0.20/0.12         | 2.8                 |
| Table grapes/wine    | 0.2/0.03          | 0.69                |
| Apples/juice         | 0.01/0.01         | 0.33                |

### Total Number of Commodities Exceeding the ARfD/ADI

- **No exceedance of the toxicological reference value was identified for any unprocessed commodity.**
- A short-term intake of residues of Meptyldinocap 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. Livestock dietary burden calculations

| Feed commodity       | Median dietary burden | Maximum dietary burden |  |
|----------------------|-----------------------|------------------------|---|
|                      | Input value (mg/kg)   | Comment                |   |
| Apple pomace, wet    | 0.01* STMR            | 0.01* STMR             |   |

*Risk assessment residue definition:* sum of meptyldinocap and 2,4-DNOP expressed as meptyldinocap

*: Indicates that the input value is proposed at the limit of quantification.

STMR: supervised trials median residue.

### D.2. Consumer risk assessment without consideration of the existing CXLs

| Commodity          | Chronic risk assessment | Acute risk assessment |  |
|--------------------|-------------------------|-----------------------|---|
|                    | Input value (mg/kg)     | Comment               |   |
|                    |                         |                       |   |
| Apples             | 0.01* STMR (tentative)  | 0.01* HR (tentative)  |   |
| Table grapes       | 0.025 STMR (tentative)  | 0.12 HR (tentative)   |   |
| Wine grapes        | 0.025 STMR (tentative)  | 0.12 HR (tentative)   |   |
| Strawberries       | 0.085 STMR (tentative)  | 0.13 HR (tentative)   |   |
| Cucumbers          | 0.025 STMR (tentative)  | 0.04 HR (tentative)   |   |
| Courgettes         | 0.025 STMR (tentative)  | 0.04 HR (tentative)   |   |
| Melons             | 0.025 STMR (tentative)  | 0.28 HR (tentative)   |   |
| Watermelons        | 0.025 STMR (tentative)  | 0.28 HR (tentative)   |   |

*STMR: supervised trials median residue; HR: highest residue.*

### D.3. Consumer risk assessment with consideration of the existing CXLs

| Commodity          | Chronic risk assessment | Acute risk assessment |  |
|--------------------|-------------------------|-----------------------|---|
|                    | Input value (mg/kg)     | Comment               |   |
|                    |                         |                       |   |
| Apples             | 0.01* STMR (tentative)  | 0.01* HR (tentative)  |   |
| Table grapes       | 0.025 STMR (tentative)  | 0.12 HR (tentative)   |   |
| Wine grapes        | 0.025 STMR (tentative)  | 0.12 HR (tentative)   |   |
| Strawberries       | 0.085 STMR (tentative)  | 0.13 HR (tentative)   |   |
| Cucumbers          | 0.02 STMR (CXL)         | 0.04 HR (CXL)         |   |
| Courgettes         | 0.02 STMR (CXL)         | 0.04 HR (CXL)         |   |
| Melons             | 0.025 STMR (tentative)  | 0.28 HR (tentative)   |   |
| Watermelons        | 0.025 STMR (tentative)  | 0.28 HR (tentative)   |   |

*STMR: supervised trials median residue; HR: highest residue; CXL: codex maximum residue limit.*
Appendix E – Decision tree for deriving MRL recommendations

Evaluation of the GAPs and available residues data at EU level

- GAP or DB > 0.1 mg/kg DM in EU?
- IS RD-RA derived for this commodity?
- MRL And RA derived in Section 2?
- MRL fully supported by data?

Consumer risk assessment for GAPs evaluated at EU level – EU scenarios

- Not considered for the RA.
- Current EU MRL is included in the RA.
- Tentative median/ highest values are included in the RA.
- Median/highest values are included in the RA.
- Risk identified?
- Fall-back MRL available?
- Fall-back MRL available?

Recommendations resulting from EU authorisations and import tolerances

- Specific LOQ or default MRL?
- Specific LOQ or default MRL?
- Maintain current EU MRL?
- Establish tentative EU MRL?
- Specific LOQ or default MRL?
- Specific LOQ or default MRL?

Comparison with CXLs
## Appendix F – Used compound codes

| Code/trivial name<sup>a</sup> | IUPAC name/SMILES notation/InChiKey<sup>b</sup> | Structural formula<sup>c</sup> |
|-----------------------------|-----------------------------------------------|--------------------------------|
| **Meptyldinocap**<br>DE-126<br>2,4-DNMHP<br>2,4-DNOPC | (RS)-2,4-dinitro-6-(octan-2-yl)phenyl (2 E/Z)-but-2-enoate<br>CCCCCCCC(C)C1=C(CC(C=C1)(N+)(-O=)[O-][N+](=O)OC(-O)/C=C/C | ![Structural formula](image1) |
|                            | CCCCCCC(C)C1=C(CC(C=C1)(N+)(-O=)[O-][N+](=O)OC(-O)/C=C/C | ![Structural formula](image2) |
|                            | NIO2P2CMRQGZCE-WEVXXLNSA-N | ![Structural formula](image3) |
|                            | *Note: Isomer ratio: trans:cis (25:1-20:1), R : S (50:50 racemic mixture)* | |
| **2,4-DNMHP**<br>2,4-DNOP<br>2,4-dinitro-6-(meptylheptyl) phenol | 2,4-dinitro-6-[(2RS)-octan-2-yl]phenol<br>CCCCCCCC(C)C1=C(CC(C=C1)(N+)(-O=)[O-][N+](=O)OC(-O)/C=C/C | ![Structural formula](image4) |
|                            | DVOCCVCLRHDYOB-UHFFFAOYSA-N | ![Structural formula](image5) |
| **X103317** | (3RS)-3-(2-hydroxy-3,5-dinitro-phenyl)-butanoic acid<br>O-[N-][(O-)]c1cc(cc(C)(C)CC(-O)O)c1O[N-][(O-)]-O<br>UCQKHTBVAKRGBR-UHFFFAOYSA-N | ![Structural formula](image6) |
| **X12335709** | (2RS)-2-(2-hydroxy-3,5-dinitro-phenyl)-propionic acid<br>CC(C1)=C(CC(C=C1)(N+)(-O=)[O-][N+](=O)OC(-O)O<br>PJNALGEFYTZH-UHFFFAOYSA-N | ![Structural formula](image7) |

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

<sup>a</sup> The metabolite name in bold is the name used in the conclusion.

<sup>b</sup> ACD/Name 2019.1.1 ACD/Labs 2019 Release (File version N05E41, Build 110555, 18 July 2019).

<sup>c</sup> ACD/ChemSketch 2019.1.1 ACD/Labs 2019 Release (File version C05H41, Build 110712, 24 July 2019).