Review of the existing maximum residue levels for 6-benzyladenine according to Article 12 of Regulation (EC) No 396/2005

European Food Safety Authority (EFSA), Maria Anastassiadou, Giovanni Bernasconi, Alba Brancato, Luis Carrasco Cabrera, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Jose Oriol Magrans, Ileana Miron, Stefanie Nave, Ragnor Pedersen, Hermine Reich, Alejandro Rojas, Angela Sacchi, Miguel Santos, Alois Stanek, Anne Theobald, Benedicte Vagenende and Alessia Verani

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 6-benzyladenine. To assess the occurrence of 6-benzyladenine residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Commission Regulation (EC) No 33/2008, 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. All information required by the regulatory framework was present and a risk to consumers was not identified.

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: 6-benzyladenine, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, plant growth regulator

Requestor: European Commission

Question number: EFSA-Q-2009-00083

Correspondence: pesticides.mrl@efs.europa.eu
Acknowledgement: EFSA wishes to thank the following EFSA staff members: Chris Anagnostopoulos, Laszlo Bura, Georgios Chatzisotiriou, Viktoria Krivova, Silvia Ruocco and Viktor Toth for the support provided and the rapporteur Member State, Sweden, for the preparatory work on this scientific output.

Suggested citation: EFSA (European Food Safety Authority), Anastassiadou M, Bernasconi G, Brancato A, Carrasco Cabrera L, Greco L, Jarrah S, Kazocina A, Leuschner R, Magrans JO, Miron I, Nave S, Pedersen R, Reich H, Rojas A, Sacchi A, Santos M, Stanek A, Theobald A, Vagenende B and Verani A, 2020. Reasoned Opinion on the review of the existing maximum residue levels for 6-benzyladenine according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(7):6220, 27 pp. https://doi.org/10.2903/j.efsa.2020.6220

ISSN: 1831-4732

© 2020 European Food Safety Authority. EFSA Journal published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the Creative Commons Attribution-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.

The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.
Summary

6-Benzyladenine was included in Annex I to Directive 91/414/EEC on 1 June 2011 by Commission Directive 2011/1/EU, and has been deemed to be approved under Regulation (EC) No 1107/2009, in accordance with Commission Implementing Regulation (EU) No 540/2011, as amended by Commission Implementing Regulation (EU) No 541/2011.

As the active substance 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 12 April 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 10 May 2019 their national Good Agricultural Practices (GAPs) in a standardised way, in the format of specific GAP forms, allowing the designated rapporteur Member State, Sweden, 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 21 October 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 and evaluation report, together with Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file were provided by the RMS to EFSA on 20 December 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 Commission Regulation (EC) No 33/2008, EFSA prepared in March 2020 a draft reasoned opinion, which was circulated to Member States and EURL for consultation via a written procedure. Comments received by 29 April 2020 were considered during the finalisation of this reasoned opinion. The following conclusions are derived.

The metabolism of 6-benzyladenine in plant 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 6-benzyladenine. No hydrolysis study is available and is not required as no residues are expected in the raw commodities.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high acid and dry matrices is available. Validation of the analytical method in high water matrices is desirable.

According to the EURL, 6-benzyladenine can be monitored in dry commodities with an LOQ of 0.01 mg/kg, and based on validation data, it can also be monitored in high water content and high acid content, as well as high oil content commodities with an LOQ of 0.01 mg/kg.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. A no residue situation is expected for all commodities.

6-Benzyladenine is authorised for use on crops that might be fed to livestock. 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 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 2% of the ADI (Dutch toddler). Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.
# Table of contents

Abstract........................................................................................................................................................... 1  
Summary.......................................................................................................................................................... 3  
Background ................................................................................................................................................... 5  
Terms of Reference ...................................................................................................................................... 6  
The active substance and its use pattern ........................................................................................................ 6  
Assessment.................................................................................................................................................... 6  
1. Residues in plants ........................................................................................................................................ 7  
   1.1. Nature of residues and methods of analysis in plants ............................................................................ 7  
      1.1.1. Nature of residues in primary crops .................................................................................................. 7  
      1.1.2. Nature of residues in rotational crops .............................................................................................. 7  
      1.1.3. Nature of residues in processed commodities ................................................................................... 7  
      1.1.4. Methods of analysis in plants ........................................................................................................... 7  
      1.1.5. Stability of residues in plants ............................................................................................................ 8  
      1.1.6. Proposed residue definitions ............................................................................................................ 8  
      1.2. Magnitude of residues in plants ........................................................................................................... 8  
      1.2.1. Magnitude of residues in primary crops ............................................................................................ 8  
      1.2.2. Magnitude of residues in rotational crops .......................................................................................... 9  
      1.2.3. Magnitude of residues in processed commodities .............................................................................. 9  
      1.2.4. Proposed MRLs .............................................................................................................................. 9  
2. Residues in livestock ..................................................................................................................................... 9  
3. Consumer risk assessment .......................................................................................................................... 9  
4. Conclusions.................................................................................................................................................. 9  
5. Recommendations .................................................................................................................................... 10  
References...................................................................................................................................................... 10  
Abbreviations ................................................................................................................................................ 11  
Appendix A – Summary of authorised uses considered for the review of MRLs .............................................. 14  
Appendix B – List of end points .................................................................................................................... 17  
Appendix C – Pesticide Residue Intake Model (PRIMo) .................................................................................... 22  
Appendix D – Input values for the exposure calculations ............................................................................ 24  
Appendix E – Decision tree for deriving MRL recommendations ..................................................................... 25  
Appendix F – Used compound codes ........................................................................................................ 27
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.

6-Benzyladenine was included in Annex I to Council Directive 91/414/EEC on 1 June 2011 by means of Commission Directive 2011/1/EU3 which has been deemed to be approved under Regulation (EC) No 1107/20094, in accordance with Commission Implementing Regulation (EU) No 540/20115, as amended by Commission Implementing Regulation (EU) No 541/20116. Therefore, EFSA initiated the review of all existing MRLs for that active substance.

By way of background information, in the framework of Commission Regulation (EC) No 33/2008, 6-benzyladenine 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, 2010). The approval of 6-benzyladenine is restricted to uses as plant growth regulator.

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 are 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 12 April 2019, EFSA initiated the collection of data for this active substance. In a first step, Member States were invited to submit by 10 May 2019 their Good Agricultural Practices (GAPs) that are authorised nationally, in a standardised way, in the format of specific GAP forms. In the framework of this consultation, 18 Member States provided feedback on their national authorisations of 6-benzyladenine. Based on the GAP data submitted, the designated RMS, Sweden, 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 21 October 2019.

On the basis of all the data submitted by Member States and the EU Reference Laboratories for Pesticides Residues (EURL), EFSA asked Sweden to complete the PROFile and to prepare a supporting

---

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 Directive 2011/1/EU of 3 January 2011 amending Council Directive 91/414/EEC to include 6-Benzyladenine as active substance and amending Decision 2008/941/EC. OJ L 1, 4.1.2011, p. 5–8.
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.
evaluation report. The PROFile and the supporting evaluation report, together with the Pesticide Residues Intake Model (PRIMo) calculations and an updated GAP overview file, were submitted to EFSA on 20 December 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, EFSA prepared in March 2020 a draft reasoned opinion, which was circulated to Member States and EURL for commenting via a written procedure. All comments received by 29 April 2020 were considered by EFSA during the finalisation of the reasoned opinion.

The evaluation report submitted by the RMS (Sweden, 2019), taking into account also the information provided by Member States during the collection of data (Germany, 2019), 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 PROFile 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

6-Benzyladenine is the ISO common name for \(N^6\)-benzyladenine (IUPAC).

The chemical structure of the active substance and its main metabolite are reported in Appendix F. For 6-benzyladenine default MRL of 0.01 mg/kg is established according to Art 18(1)(b) of Regulation (EC) No 396/2005. Codex maximum residue limits (CXLs) for 6-benzyladenine are not available. There are no MRL changes occurred since the entry into force of the Regulation mentioned above.

For the purpose of this MRL review, all the uses of 6-benzyladenine 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 GAPs for 6-benzyladenine 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.

In the framework of the peer review, 6-benzyladenine was initially assumed to be a naturally occurring plant hormone. As information was found only on similar compounds, but not on 6-benzyladenine itself, a data gap was set to provide quantitative evidence that 6-benzyladenine is naturally occurring in edible crops (EFSA, 2010). In the absence of this information, the toxicological reference values were reconsidered and an ADI was established (European Commission, 2011). No further information to support this assumption was received to date.

### Assessment

EFSA has based its assessment on the following documents:

- the PROFile submitted by the RMS;
- the evaluation report accompanying the PROFile (Sweden, 2019);
the draft assessment report (DAR) prepared under Council Directive 91/414/EEC (France, 2007);
the additional report (AR) and its addenda prepared under Commission Regulation (EC) No 33/2008
(United Kingdom, 2009);
final addendum to the additional report (AR) (United Kingdom, 2010);
the conclusion on the peer review of the pesticide risk assessment of the active substance 6-
benzyladenine (EFSA, 2010);
the review report on 6-benzyladenine (European Commission, 2011).

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
546/20117 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

In the framework of the peer review, the metabolism of 6-benzyladenine was investigated following
folliar treatment in fruits (apples) (United Kingdom, 2009; EFSA, 2010). The study was conducted at an
application rate of 0.7N covering the uses reported in this review. The metabolites identified in this
study were either conjugates of 6-benzyladenine or benzoic acid. In addition, scientific review reports
on root vegetables, cereals and pulses/oilseeds were also considered to establish the metabolic
pathway in crops (France, 2007; EFSA, 2010).

1.1.2. Nature of residues in rotational crops

6-Benzyladenine is authorised only on perennial and/or semi-permanent crops. In addition, the
field DT50 reported in the soil degradation studies evaluated in the framework of the peer review was 1–1.2
days (EFSA, 2010). Therefore, studies investigating the nature of 6-benzyladenine on rotational crops
were not reported and are not required.

1.1.3. Nature of residues in processed commodities

There were no studies investigating the nature of residues of 6-benzyladenine in processed
commodities available for this review. In all commodities, residues were below 0.01 mg/kg and the
total theoretical maximum daily intake is 2% of the ADI. Therefore, 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, a hyphenated analytical method based on HPLC detection coupled to MS/MS
was validated in dry commodities (maize) with an LOQ of 0.01 mg/kg (EFSA, 2010). An independent
laboratory validation (ILV) is not available, nor is it considered needed for this matrix as there are no
uses currently authorised on dry commodities.

For high water content commodities, the peer review identified a data gap considering the
submitted method of analysis not acceptable due to unexplained low recoveries and communications
between the primary and ILV laboratories (EFSA, 2010). During the data collection phase of the
current review, a fully validated method, including ILV for high acid content commodities was
submitted (Sweden, 2019). This method, validated in strawberries, is the same analytical method
assessed in the peer review for apples. In addition, an analytical method used in residue trials to
determine 6-benzyladenine residues in apples has been validated and found capable of determining 6-
benzyladenine residues at an LOQ of 0.01 mg/kg using HPLC detection coupled to UV (Germany,
2019). Therefore, the submission of a fully validated analytical method according to SANCO/825/00 rev. 8.1 guidance in high water content commodities is only desirable.

According to the EURL, 6-benzyladenine can be monitored in dry commodities with an LOQ of 0.01 mg/kg. The EURL reported that validation data show 6-benzyladenine can also be monitored in high water content and high acid content, as well as high oil content commodities with an LOQ of 0.01 mg/kg (EURL, 2019).

1.1.5. Stability of residues in plants

The storage stability of 6-benzyladenine was investigated in the framework of the peer review (France, 2007; EFSA, 2010). Accordingly, in high water content matrices, the storage stability for 6-benzyladenine was demonstrated for a period of 18 months when stored at \(-18^\circ C\). A storage stability study in acidic commodities is not available. Nevertheless, this study is not required in the framework of this review, as samples from trials on strawberries were analysed within one month.

1.1.6. Proposed residue definitions

During the peer review, based on the metabolism study and other supporting information, and that at harvest no significant residues were present, it was concluded that the residue definition for risk assessment and monitoring is 6-benzyladenine (EFSA, 2010). This conclusion is considered still applicable for the present review.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high acid (Sweden, 2019) and dry matrices is available (EFSA, 2010); no further analytical method for the enforcement in other matrices was provided. Validation of the analytical method in high water matrices is desirable.

According to the EURL, 6-benzyladenine can be monitored in all major matrices with an LOQ of 0.01 mg/kg (EURL, 2019). The analytical standard for 6-benzyladenine is commercially available (EURL, 2019).

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

To assess the magnitude of 6-benzyladenine residues resulting from the reported GAPs, EFSA considered all residue trials reported by the RMS in its evaluation report (Sweden, 2019), additional residue trials submitted during data collection (Germany, 2019), as well as the residue trials evaluated in the framework of the peer review (EFSA, 2010). All residue trial samples considered in this framework were either stored in compliance with the conditions for which storage stability of residues was demonstrated or was analysed within 30 days. Decline of residues during storage of the trial samples is therefore not expected.

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

Available residue trials are sufficient to derive MRL and risk assessment values for all crops under assessment, taking note of the following considerations:

Pome fruits: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. However, the reduced number of overdosed residue trials is considered acceptable in this case because all results were below the LOQ of 0.01 mg/kg and a no residues situation is expected. This is also supported by the eight residue trials supporting the northern outdoor GAP. Further residue trials are therefore not required.

Stone fruits (apricots, cherries, peach): Although no residue trials are available, as for these crops, 6-benzyladenine is authorised for the use in nurseries, and considering the results of the metabolism studies and the properties of the active substance, a no residue situation is expected. Therefore, the MRLs can be set at the LOQ and no further residue trials are required.

Strawberries: The number of residue trials supporting the indoor GAP is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ of 0.01 mg/kg even on the day of application. Further residue trials are therefore not required.
1.2.2. **Magnitude of residues in rotational crops**

There are no studies investigating the magnitude of residues in rotational crops available. Based on the uses and the persistence of 6-benzyladenine no further studies are required (see also Section 1.1.2).

1.2.3. **Magnitude of residues in processed commodities**

The effect of industrial processing and/or household preparation was assessed in studies conducted on apples (France, 2007, EFSA, 2010). An overview of all available processing studies is available in Appendix B.1.2.3. Concentration of 6-benzyladenine was not observed, in processed commodities, residues were below the LOQ of 0.005 mg/kg. Tentative processing factors based on one study were derived for apple juice and apple wet pomace. Further processing studies are not required as residues in the raw commodities under assessment are below the LOQ of 0.01 mg/kg.

1.2.4. **Proposed MRLs**

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation.

2. **Residues in livestock**

6-Benzyladenine is authorised for use on pome fruits that might be fed to livestock. However, the dietary burdens of livestock are not expected to be significant, as residues in the raw commodities are below the LOQ and the processing studies show that only further reduction of residues is expected in processed commodities. Therefore, further investigation of the occurrence of residues in commodities of animal origin is not required and the setting of MRLs in these commodities is not considered necessary.

3. **Consumer risk assessment**

Chronic exposure calculations for all crops reported in the framework of this review were performed using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019). Input values for the exposure calculations were derived in compliance with the decision tree reported in Appendix E. Hence, for those commodities where an 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. Acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for this active substance.

The exposure values calculated were compared with the toxicological reference value for 6-benzyladenine, included in the Review Report (European Commission, 2011). The highest chronic exposure was calculated for the Dutch toddler, representing 2% of the acceptable daily intake (ADI).

These calculations indicate that the uses assessed under this review result in a consumer exposure lower than the toxicological reference value. Therefore, these uses are unlikely to pose a risk to consumer’s health.

4. **Conclusions**

The metabolism of 6-benzyladenine in plant 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 6-benzyladenine. No hydrolysis study is available and is not required as no residues are expected in the raw commodities.

An analytical method for the enforcement of the proposed residue definition at the LOQ of 0.01 mg/kg in high acid and dry matrices is available. Validation of the analytical method in high water matrices is desirable.

According to the EURL, 6-benzyladenine can be monitored in dry commodities with an LOQ of 0.01 mg/kg, and based on validation data, it can also be monitored in high water content and high acid content, as well as high oil content commodities with an LOQ of 0.01 mg/kg.

Available residue trials data were considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation. A no residue situation is expected for all commodities.
6-Benzyladenine is authorised for use on crops that might be fed to livestock. 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 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 2% of the ADI (Dutch toddler). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

5. Recommendations

MRL recommendations were derived in compliance with the decision tree reported in Appendix E of the reasoned opinion (see Table 1). All MRL values listed as ‘Recommended’ in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

Minor deficiencies were identified in the assessment, but these deficiencies are not expected to impact either the validity of the MRLs derived or the national authorisations. The following data are therefore considered desirable but not essential:

- Full validation of the analytical method for high water commodities according to European Commission Guidance (European Commission, 2010b).

Table 1: Summary table

| Code number | Commodity       | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment |
|-------------|-----------------|-------------------------|----------------------|-----------------------|---------|
|             |                 |                         |                      | MRL (mg/kg) |                  |
| Enforcement residue definition: 6-benzyladenine | | | | |
| 130010      | Apples          | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 130020      | Pears           | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 130030      | Quinces         | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 130040      | Medlar          | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 130050      | Loquat          | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 140010      | Apricots        | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 140020      | Cherries (sweet)| 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 140030      | Peaches         | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 140040      | Plums           | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| 152000      | Strawberries    | 0.01*                   | –                    | 0.01*      | Recommended(a)   |
| –           | Other commodities of plant and/or animal origin | Art. 18(1)(b) Reg 396/2005 | – | Further consideration needed(b) |

MRL: maximum residue level; CXL: codex maximum residue limit.
*: Indicates that the MRL is set at the limit of quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).
(b): 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).

References

EFSA (European Food Safety Authority), 2010. Conclusion on the peer review of the pesticide risk assessment of the active substance 6-benzyladenine. EFSA Journal 2010;8(10):1716, 49 pp. https://doi.org/10.2903/j.efsa.2010.1716

EFSA (European Food Safety Authority), 2019. Pesticide Residue Intake Model- EFSA PRIMo revision 3.1. EFSA supporting publication 2019;16(3):EN-1605, 15 pp. https://doi.org/10.2903/sp.efsa.2019.EN-1605

EFSA (European Food Safety Authority), 2020a. Completeness check report on the review of the existing MRLs of 6-benzyladenine prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 27 March 2020. Available online: www.efsa.europa.eu
EFSA (European Food Safety Authority), 2020b. Member States consultation report on the review of the existing MRLs of 6-benzyladenine prepared by EFSA in the framework of Article 12 of Regulation (EC) No 396/2005, 19 May 2020. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), Brancato A, Brocca D, Ferreira L, Greco L, Jarrah S, Leuschner R, Medina P, Miron I, Nougadere A, Pedersen R, Reich H, Santos M, Stanek A, Tarazona J, Theobald A and Villamar-Bouza L, 2018. Guidance on use of EFSA Pesticide Residue Intake Model (EFSA PRIMo revision 3). EFSA Journal 2018;16(1):5147, 43 pp. https://doi.org/10.2903/j.efsa.2018.5147

EURL (European Union Reference Laboratories for Pesticide Residues), 2019. Evaluation report prepared under Article 12 of Regulation (EC) No 396/2005. Analytical methods validated by the EURL and overall capability of official laboratories to be considered for the review of the existing MRLs for 6-benzyladenine. October 2019. Available online: www.efsa.europa.eu

European Commission, 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev., 22 July 1996.

European Commission, 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev. 6, 22 July 1997.

European Commission, 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev. 2, 22 July 1997.

European Commission, 1997d. Appendix E. Processing studies. 7035/VI/95-rev. 5, 22 July 1997.

European Commission, 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev. 3, 22 July 1997.

European Commission, 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev. 5, 22 July 1997.

European Commission, 1997g. Appendix I. Calculation of maximum residue level and safety intervals.7039/VI/95 22 July 1997. As amended by the document: classes to be used for the setting of EU pesticide maximum residue levels (MRLs). SANCO 10634/2010, finalised in the Standing Committee on the Food Chain and Animal Health on its meeting at 23–24 March 2010.

European Commission, 2000. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414/EEC. SANCO/3029/99-rev. 4.

European Commission, 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010-rev. 0, Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting of 23–24 March 2010.

European Commission, 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev. 8.1, 16 November 2010.

European Commission, 2011. Review report for the active substance 6-benzyladenine. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 23 November 2010 in view of the inclusion of 6-benzyladenine in Annex I of Council Directive 91/414/EEC. SANCO/12667/2010-Final, 4 January 2011.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.10.3, June 2017.

FAO (Food and Agriculture Organization of the United Nations), 2009. Submission and evaluation of pesticide residues data for the estimation of Maximum Residue Levels in food and feed. Pesticide Residues. 2nd Edition. FAO Plant Production and Protection Paper 197, 264 pp.

France, 2007. Draft Assessment Report (DAR) on the active substance 6-benzyladenine. prepared by the rapporteur Member State France in the framework of Directive 91/414/EEC, October 2007.

Germany, 2019. Additional data to be considered for the review of the existing MRLs for 6-benzyladenine report prepared under Article 12.1 of Regulation (EC) No 396/2005. 9 October 2019. Available online: www.efsa.europa.eu

OECD (Organisation for Economic Co-operation and Development), 2011. OECD MRL calculator: spreadsheet for single data set and spreadsheet for multiple data set, 2 March 2011. In: Pesticide Publications/Publications on Pesticide Residues. Available online: http://www.oecd.org

OECD (Organisation for Economic Co-operation and Development), 2013. Guidance document on residues in livestock. In: Series on Pesticides No 73, ENV/JM/MONO(2013)8, 04 September 2013.

Sweden, 2019. Evaluation report prepared under Article 12.1 of Regulation (EC) No 396/2005. Review of the existing MRLs for 6-benzyladenine, 20 December 2019. Available online: www.efsa.europa.eu

United Kingdom, 2009. Additional Report to the Draft Assessment Report on the active substance 6-benzyladenine prepared by the rapporteur Member State the United Kingdom in the framework of Commission Regulation (EC) No 33/2008, November 2009.

United Kingdom, 2010. Final Addendum to the Additional Report on 6-benzyladenine, compiled by EFSA, July 2010.

**Abbreviations**

- a.i. active ingredient
- a.s. active substance
- ADI acceptable daily intake
AL any other liquid
AR applied radioactivity
ARFD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Germany
bw body weight
CAC Codex Alimentarius Commission
CAS Chemical Abstract Service
CCPR Codex Committee on Pesticide Residues
CEN European Committee for Standardization (Comité Européen de Normalisation)
CF conversion factor for enforcement residue definition to risk assessment residue definition
CIRCA (EU) Communication & Information Resource Centre Administrator
CS capsule suspension
CV coefficient of variation (relative standard deviation)
CXL codex maximum residue limit
DALA days after last application
DAR draft assessment report
DAT days after treatment
DB dietary burden
DM dry matter
DS powder for dry seed treatment
DT$_{90}$ period required for 90% dissipation (define method of estimation)
DTU Danish Technical University
EC emulsifiable concentrate
EMS evaluating Member State
EURL European Union Reference Laboratories for Pesticide Residues (former CRLs)
FAO Food and Agriculture Organization of the United Nations
FID flame ionisation detector
FLD fluorescence detector
FPD flame photometric detector
GAP Good Agricultural Practice
GC gas chromatography
GC-ECD gas chromatography with electron capture detector
GC-FID gas chromatography with flame ionisation detector
GC-FPD gas chromatography with flame photometric detector
GC-MS gas chromatography with mass spectrometry
GC-MS/MS gas chromatography with tandem mass spectrometry
GC-NPD gas chromatography with nitrogen/phosphorous detector
GCPF Global Crop Protection Federation (formerly International Group of National Associations of Manufacturers of Agrochemical Products; GIFAP)
GLP Good Laboratory Practice
GR Granule
GS growth stage
HPLC high-performance liquid chromatography
HPLC-MS high-performance liquid chromatography with mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HPLC-UVD high-performance liquid chromatography with ultra-violet detector
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
IPCS International Programme of Chemical Science
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)
| Abbreviation | Definition |
|--------------|------------|
| LC           | liquid chromatography |
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOAEL        | lowest observed adverse effect level |
| LOD          | limit of detection |
| LOQ          | limit of quantification |
| Mo           | Monitoring |
| MRL          | maximum residue level |
| MS           | Member States |
| MS           | mass spectrometry detector |
| MS/MS        | tandem mass spectrometry detector |
| MW           | molecular weight |
| NEU          | northern European Union |
| NOAEL        | no observed adverse effect level |
| NPD          | nitrogen/phosphorous detector |
| OECD         | Organisation for Economic Co-operation and Development |
| PAFF         | Standing Committee on Plants, Animals, Food and Feed |
| PBI          | plant back interval |
| PF           | processing factor |
| PHI          | pre-harvest interval |
| P<sub>ow</sub> | partition coefficient between n-octanol and water |
| Ppm          | parts per million (10<sup>-6</sup>) |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| RA           | risk assessment |
| RAC          | raw agricultural commodity |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| RPF          | relative potency factor |
| RSD          | relative standard deviation |
| SANCO        | Directorate-General for Health and Consumers |
| SBI          | sterol biosynthesis inhibitors |
| SC           | suspension concentrate |
| SCPAFF       | Standing Committee on Plants, Animals, Food and Feed (formerly: Standing Committee on the Food Chain and Animal Health; SCFCAH) |
| SEU          | southern European Union |
| SMILES       | simplified molecular-input line-entry system |
| SG           | water soluble granule |
| SL           | soluble concentrate |
| SP           | water soluble powder |
| STMR         | supervised trials median residue |
| TAR          | total applied radioactivity |
| TMDI         | theoretical maximum daily intake |
| UV           | ultraviolet (detector) |
| WG           | water dispersible granule |
| 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<sup>(a)</sup> | Pests or group of pests controlled | Preparation | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Application | Application rate per treatment | PHI (days)<sup>(d)</sup> | Remarks |
|-----------------------|---------------|-------------------------|-----------------------------------|-------------|-----------------|-----------|-------------|----------------|-----------------------------|----------------|---------|
| Apples                | NL            | F                       | Fruit thinning                    | SL          | 20 g/L          | Foliar treatment – general (see also comment field) | 71–74        | 1            | 225 g a.i./ha | 90             | –       |
| Pears                 | BE            | F                       | Excessiv fruit production         | SL          | 20 g/L          | Foliar treatment – general (see also comment field) | 71–71        | 1            | 227.8 g a.i./ha | 90             | –       |
| Quinces               | FR            | F                       | Fruit thinning                    | SL          | 20 g/L          | Foliar treatment – general (see also comment field) | 71–74        | 1            | 150 g a.i./ha | 90             | –       |
| Medlars               | FR            | F                       | Fruit thinning                    | SL          | 20 g/L          | Foliar treatment – general (see also comment field) | 71–74        | 1            | 150 g a.i./ha | 90             | –       |
| Loquats               | FR            | F                       | Fruit thinning                    | SL          | 20 g/L          | Foliar treatment – general (see also comment field) | 71–74        | 1            | 150 g a.i./ha | 90             | –       |

MS: Member State; SL: soluble concentrate.

<sup>(a)</sup> Outdoor or field use (F), greenhouse application (G) or indoor application (I).

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

<sup>(c)</sup> 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.

<sup>(d)</sup> PHI – minimum preharvest interval.
### A.2. Authorised outdoor uses in southern EU

| MS or country | Preparation | Range of growth stages & season[3](c) | Application rate per treatment | PHI (days)[4](d) | Remarks |
|---------------|-------------|--------------------------------------|--------------------------------|------------------|---------|
| Preparatory   | Method kind | Number of treatments | Concentration per application | Rate and unit | |
|               | Type(b) Conc. a.s. | | | |
| Apples IT F | PGR; Fruit thinning and fruit size improvement | 71–74 | 1 | 210 g a.i./ha | 90 | Applications occurs when fruit is between 12 and 14 mm on old woods (2 years and more) |
| Pears EL F | Fruit thinning | 71–74 | 1 | 200 g a.i./ha | n.a. | 'When the fruits have a diameter 10–13 mm' |
| Quinces FR F | Fruit thinning | 71–74 | 1 | 150 g a.i./ha | 90 | – |
| Medlars FR F | Fruit thinning | 71–74 | 1 | 150 g a.i./ha | 90 | – |
| Loquats FR F | Fruit thinning | 71–74 | 1 | 150 g a.i./ha | 90 | – |
| Apricots PT F | Stimulation of lateral branching | 55 | 1 | 570 g a.i./ha | n.a. | Stone fruit nurseries |
| Cherries PT F | Stimulation of lateral branching | 55 | 1 | 570 g a.i./ha | n.a. | Stone fruit nurseries |
| Peaches PT F | Stimulation of lateral branching | 55 | 1 | 570 g a.i./ha | n.a. | Stone fruit nurseries |
| Plums PT F | Stimulation of lateral branching | 55 | 1 | 570 g a.i./ha | n.a. | Stone fruit nurseries |

**Notes:**
- **MS:** Member State; **AL:** any other liquid; **SL:** soluble concentrate.
- **PHI:** Preharvest interval.
- **Remarks:** See table for specific remarks.
(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 I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days)(d) | Remarks |
|-----------------------|---------------|-------------|------------------------------------|-------------|-------------|-------------------------------|----------------|---------|
| Strawberries          | ES            | I           | Increased flowering and peduncle enlargement | SL          | Foliar treatment – spraying | 19 g/L | 60–87 4 14 | 1.9 g a.i./ha | 600–1000 L/ha of water |

MS: Member State; SL: soluble concentrate.
(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.
### 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       | Foliar  | ~ 15 g as/hl   | 0, 7, 50, 90   | United Kingdom (2009), EFSA (2010) |
| Root crops                        | Radish      | Seedings|                |                | Supporting publications were considered to establish the metabolic pathway (France, 2007; EFSA, 2010) |
| Leafy crops                       | Celery      | Cell culture|          |                | |
| Cereals/grass                     | Wheat       | Shoots  |                |                | |
| Pulses/oilseeds                   | Soybean     | Tissue  |                |                | |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|----------------|-----------|----------------|
| Root/tuber crops                     | --          |         |                |           | Not triggered, rapid degradation DT<sub>50</sub> between 1 day to 1.2 days (EFSA, 2010) and uses only on (semi) permanent crops |
| Leafy crops                          | --          |         |                |           | |
| Cereal (small grain)                 | --          |         |                |           | |

| Processed commodities (hydrolysis study) | Conditions | Stable? | Comment/Source |
|------------------------------------------|------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)      | Not triggered |       | Studies on the nature and levels of residues following processing are not required as there are no residues in the raw commodities |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Not triggered |       | |
| Sterilisation (20 min, 120°C, pH 6)      | Not triggered |       | |
Can a general residue definition be proposed for primary crops?

Yes

Metabolism study only available for fruits. However, considering the available supporting studies and given the nature of the active substance, significant residues are not expected, and the default residue definition of parent only is applicable.

Rotational crop and primary crop metabolism similar?

Not applicable

Degrades rapidly in soil

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

Not applicable

Residues are below the LOQ in the raw commodities

Plant residue definition for monitoring (RD-Mo)

6-Benzyladenine

Plant residue definition for risk assessment (RD-RA)

6-Benzyladenine

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

Matrices with high acid content and dry matrices: LC–MS/MS, LOQ 0.01 mg/kg
ILV available for strawberries, ILV for dry matrices not required as no uses for dry commodities authorised (EFSA, 2010; Sweden, 2019)
High water content matrices: Validated for residue trials, LC-UV, LOQ 0.01 mg/kg (Germany, 2019)
Full validation according to SANCO/825/00 rev. 8.1 is desirable

According to, the EURL, 6-benzyladenine can be monitored in dry commodities with an LOQ of 0.01 mg/kg. Validation data show 6-benzyladenine can also be monitored in high water content and high acid content, as well as high oil content commodities with an LOQ of 0.01 mg/kg (EURL, 2019).

a.s.: active substance; DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LC-UV: liquid chromatography with ultra-violet detection; LOQ: limit of quantification; ILV: independent laboratory validation.

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category          | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source                              |
|-----------------------------------|-------------------|-----------|--------|------------------|-------------------|---------------------------------------------|
|                                   | High water content| Apple     | –18    | 18 Months        | 6-Benzyladenine   | France (2007), EFSA (2010)                  |
|                                   | High acid content | –         | –      | –                | –                 | Not available and not required in this review as samples were analysed within 1 month. (Sweden, 2019) |
## 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<sup>(a)</sup> | 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) |
|----------------------------------|-----------------------------|----------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|------------------------|--------------------------|---------------------------|
| Apples                           | NEU                         | 6 × < 0.005<br>2 × < 0.01                                         | Overdosed and GAP compliant trials on apples (France, 2007; Germany, 2019)                                                                | 0.01*                  | 0.01                     | 0.01                      |
| Pears                            | SEU                         | 4 × < 0.005                                                                 | Overdosed trials on apples (France, 2007)                                                                                               | 0.01*                  | 0.01                     | 0.01                      |
| Quinces                          |                             |                                                                |                                                                                                                                             |                        |                          |                           |
| Medlars                          |                             |                                                                |                                                                                                                                             |                        |                          |                           |
| Loquats/Japanese medlars          |                             |                                                                |                                                                                                                                             |                        |                          |                           |
| Strawberries                     | EU                          | 4 × < 0.01                                                                 | Trials on strawberries compliant with the GAP (Sweden, 2019)                                                                                     | 0.01*                  | 0.01                     | 0.01                      |
| Apricots                         | SEU                         | –                                                              | As authorised uses are for nurseries and based on the metabolism study, no residues are expected                                             | 0.01*                  | 0.01                     | 0.01                      |
| Cherries (sweet)                 |                             |                                                                |                                                                                                                                             |                        |                          |                           |
| Peaches                          |                             |                                                                |                                                                                                                                             |                        |                          |                           |
| Plums                            |                             |                                                                |                                                                                                                                             |                        |                          |                           |

GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; MRL: maximum residue level; Mo: residue levels expressed according to the monitoring residue definition; RA: residue levels expressed according to risk assessment residue definition.

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

(a): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, EU: indoor 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.

### B.1.2.2. Residues in rotational crops

#### Residues in rotational and succeeding crops expected based on confined rotational crop study?
Not triggered

No study available, and not required since 6-benzyladenine degrades rapidly in soil

#### Residues in rotational and succeeding crops expected based on field rotational crop study?
Not triggered

No study available, and not required since 6-benzyladenine degrades rapidly in soil

### B.1.2.3. Processing factors

| Processed commodity     | Number of valid studies<sup>(a)</sup> | Processing Factor (PF) | Comment/Source |
|-------------------------|---------------------------------------|------------------------|----------------|
|                         |                                       | Individual values | Median PF   |               |
| Apples, juice           | 1                                     | 0.04                  | 0.04         | Tentative<sup>(b)</sup> |
| Apples, wet pomace      | 1                                     | 0.04                  | 0.04         | Tentative<sup>(b)</sup> |

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): A tentative PF is derived based on a limited data set.
**B.2. Residues in livestock**

Following normal practice of the authorised uses, significant residues are not expected to occur in livestock feed.

**B.3. Consumer risk assessment**

**B.3.1. Consumer risk assessment**

Acute exposure calculations were not carried out since no ARfD has been considered necessary.

| Table: Consumer risk assessment |
|--------------------------------|
| **ADI** | 0.01 mg/kg bw per day (European Commission, 2011) |
| **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)** | 2% ADI (NL toddler) |
| **NEDI (% ADI)** | Not assessed in this review |
| **Assumptions made for the calculations** | The calculation is based on the LOQ as no residues are expected, following the authorised uses. 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)

| Table: Consumer exposure assessment through drinking water |
|------------------------------------------------------------|
| **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.4. Proposed MRLs**

| Code number | Commodity | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review |
|-------------|-----------|-------------------------|----------------------|-----------------------|
| 130010      | Apples    | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 130020      | Pears     | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 130030      | Quinces   | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 130040      | Medlar    | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 130050      | Loquat    | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 140010      | Apricots  | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 140020      | Cherries (sweet) | 0.01*       | –                    | 0.01* Recommended(6)  |
| 140030      | Peaches   | 0.01*                   | –                    | 0.01* Recommended(6)  |
| 140040      | Plums     | 0.01*                   | –                    | 0.01* Recommended(6)  |
| Code number | Commodity                                      | Existing EU MRL (mg/kg) | Existing CXL (mg/kg) | Outcome of the review | Comment                      |
|-------------|-----------------------------------------------|-------------------------|----------------------|------------------------|-------------------------------|
| 152000      | Strawberries                                  | 0.01*                   | –                    | 0.01*                  | Recommended\(^{(a)}\)         |
| –           | Other commodities of plant and/or animal origin| Art. 18(1)\(^{(b)}\) Reg 396/2005 | –                    | –                      | Further consideration needed \(^{(b)}\) |

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

\(^{(a)}\): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination H-I in Appendix E).

\(^{(b)}\): 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).
### Appendix C – Pesticide Residue Intake Model (PRIMo)

#### PRIMo(EU)

| LOQs (mg/kg) | Range | ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI | Source of ARfD | Year of evaluation | No of diets exceeding the ADI: --- |
|--------------|-------|------------------------|----------------|--------------|----------------|-------------------|--------------------------------|
|              | 0.01  | 0.01                   |                | EC           | EFSA PRIMo revision 3.1; 2019/03/19 | 2010              |                                 |

| Calculated exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | Commodities not under assessment (in % of ADI) |
|---------------------------------------|------------------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| 0.0% 6-benzyladenine                  | 1% DE child                              | 0.15                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% NL child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI child                            | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult                            | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% DE general                          | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% PL general                          | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% FI child 15 yr                      | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% UK child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% UK toddler                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% NL child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% NL adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI child                            | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult                            | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI general                          | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult 15 yr                      | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% DE general                          | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% FI child 15 yr                      | 0.03                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% GI adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT child                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT general                          | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult                            | 0.06                            | 0.0%                            | Pears                           | 0.0%                            | 0.0%                            |
|                                       | 0.0% IT adult 15 yr                      | 0.06                            | 0.0%                            | Pears                           | 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 6-benzyladenine is unlikely to present a public health concern.
As an ARfD is not necessary/not applicable, no acute risk assessment is performed.

### Results for children

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

### Results for processed commodities

| IESTI | Highest % of ARfD/ADI | Commodity | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|-----------------------|-----------|---------------------------|---------------------|
|       |                       |           |                           |                     |

### Results for unprocessed commodities

| IESTI | Highest % of ARfD/ADI | Commodity | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|-----------------------|-----------|---------------------------|---------------------|
|       |                       |           |                           |                     |

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

### Results for adults

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

### Results for processed commodities

| IESTI | Highest % of ARfD/ADI | Processed commodities | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|-----------------------|-----------------------|---------------------------|---------------------|
|       |                       |                       |                           |                     |

### Results for unprocessed commodities

| IESTI | Highest % of ARfD/ADI | Commodity | MRL / input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------|-----------------------|-----------|---------------------------|---------------------|
|       |                       |           |                           |                     |

Conclusion:

Total number of commodities exceeding the ARfD/ADI in children and adult diets (IESTI calculation)
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity               | Chronic risk assessment | Acute risk assessment |
|-------------------------|-------------------------|-----------------------|
|                         | Input value (mg/kg)     | Comment               | Input value (mg/kg)     | Comment               |
| **Risk assessment residue definition: 6-benzyladenine** |
| Pome fruits             | 0.01*                   | STMR                  | 0.01*                   | HR                    |
| Stone fruits            | 0.01*                   | STMR                  | 0.01*                   | HR                    |
| Strawberry              | 0.01*                   | STMR                  | 0.01*                   | HR                    |

*: Indicates that the input value is proposed at the limit of quantification.
Appendix E – Decision tree for deriving MRL recommendations
Comparison of the EU recommendation with the existing CXL

- CXL available?
  - Yes
    - RD comparable?
      - Yes
        - CXL higher?
          - Yes
          - Maintain EU recommendation indicating that no CXL is available.
          - Maintain EU recommendation indicating CXL is not compatible.
          - Maintain EU recommendation indicating that CXL is covered.
          - Maintain EU recommendation; higher CXL is not safe for consumer.
          - Maintain current CXL or EU recommendation?
        - No
          - Maintain EU recommendation; higher CXL is not safe for consumer.
      - No
        - CXL supported by data?
          - Yes
            - Maintain EU recommendation indicating CXL is covered.
          - No
            - CXL is included in the RA.
              - Risk identified?
                - Yes
                  - Result EU assessment
                - No
                  - Input values for the RA remain unchanged.
        - No
          - CXL is supported by data?
            - Yes
              - Maintain EU recommendation indicating CXL is covered.
            - No
              - Input values for the RA remain unchanged.

Consumer risk assessment with consideration of the existing CXL

- Input values for the RA remain unchanged.
  - CXL supported by data?
    - Yes
      - CXL is included in the RA.
        - Risk identified?
          - Yes
            - Result EU assessment
          - No
            - Input values for the RA remain unchanged.
    - No
      - CXL is included in the RA.
        - Risk identified?
          - Yes
            - Result EU assessment
          - No
            - Input values for the RA remain unchanged.

Recommendations with consideration of the existing CXL

- Maintain EU recommendation indicating that no CXL is available.
- Maintain EU recommendation indicating CXL is not compatible.
- Maintain EU recommendation indicating that CXL is covered.
- Maintain EU recommendation; higher CXL is not safe for consumer.
- Maintain current CXL or EU recommendation?
- Maintain EU recommendation; higher CXL is not safe for consumer.
- CXL is recommended; EU recommendation is covered as well.
## Appendix F – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|----------------------------------|
| **6-Benzyladenine**           | $N^6$-benzyladenine or $N$-benzyl-9H-purin-6-amine  
n1cnc(NCc2cccccc2)c2nc[NH]c12  
NWBJYWHLCVSVIJ-UHFFFAOYSA-N | ![6-Benzyladenine](image) |
| **Benzoic acid**              | benzoic acid  
O=C(O)c1ccccc1  
WPYMKLBDIGXBTP-UHFFFAOYSA-N | ![Benzoic acid](image) |

<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).