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

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Abstract

The applicant BASF SE submitted a request to the competent national authority in the Netherlands to evaluate the confirmatory data that were identified for bentazone in the framework of the maximum residue level (MRL) review under Article 12 of Regulation (EC) No 396/2005 as not available. To address the data gaps, a new livestock feeding study and storage stability data for bentazone and 6-hydroxy bentazone in animal matrices were submitted. To address the data gap for potatoes, adjusted less critical good agricultural practices (GAPs) were reported and supporting residue data were provided. The data gap related to analytical methods in fat and herbal infusions were addressed in the framework of the peer review. The data gap for residue trials on leek has not been addressed. Further confirmation from the applicant/Member States are needed for the clarification of the GAP for herbal infusions. Based on the information submitted in support of the confirmatory data request, the existing EU MRLs for bentazone need to be modified for potato and leek, for swine fat and kidney and for bovine, equine, goat and sheep fat, liver and milk. The consumer risk assessment performed in the MRL review was updated, using new toxicological reference values derived by the peer review. No consumer intake concerns were identified.

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Keywords: bentazone, various crops, animal commodities, pesticide, MRL review, consumer risk assessment

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Summary

In 2012, when the European Food Safety Authority (EFSA) reviewed the maximum residue levels (MRLs) for bentazone according to Article 12 of Regulation (EC) No 396/2005, EFSA identified some information as unavailable (data gaps) and derived tentative MRLs for those uses which were not fully supported by data but for which no risk to consumers was identified. The following data gaps were noted:

1) Two additional residue trials supporting the northern outdoor good agricultural practice (GAP) and four additional residue trials supporting the southern outdoor GAP on potato;
2) Four residue trials supporting the northern outdoor GAP on spring onion;
3) Eight residue trials supporting the northern outdoor GAP on cucumber;
4) Four additional residue trials supporting the northern outdoor GAP on leek;
5) Four residue trials supporting the northern outdoor GAP on poppy seed;
6) Eight residue trials supporting the northern outdoor GAP and eight residue trials supporting the southern outdoor GAP on soya bean;
7) A confirmation on the validity of the existing Codex maximum residue limit (CXL) for rye;
8) Further clarification of the GAP of herbal infusion;
9) A validated analytical method (with confirmatory method and independent laboratory validation (ILV)) for enforcement of the proposed residue definition in herbal infusion;
10) An analytical method (with confirmatory method and ILV) for the enforcement of the residue in fat;
11) A livestock feeding study for meat ruminant;
12) Storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 1146/2014, including footnotes related to data gaps number 1, 4, 8, 9, 10, 11 and 12, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 29 October 2016.

Data gaps number 2, 3, 5, 6 and 7 related to the residue data in spring onion, cucumber, poppy seed, soybean and rye were not translated into footnote and were not implemented in the MRL regulation, because risk managers decided to set the MRL at the limit of quantification (LOQ) of 0.03* mg/kg or 0.1* mg/kg in the absence of any residue data supporting the authorised uses. Consequently, the existing uses on these crops had to be revoked.

Thus, in the framework of the current assessment, EFSA focused on the confirmatory data gaps number 1, 4, 8, 9, 10, 11 and 12.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016, the applicant BASF SE submitted an application to the competent national authority in the Netherlands (designated rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided residue trials supporting adjusted less critical northern Europe/southern Europe (NEU/SEU) GAPs on potatoes, a livestock feeding study and the storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk. The applicant referred to data submitted in the framework of the renewal of the approval to address the data gaps related to the clarification of the GAP for herbal infusions and analytical enforcement methods in fats and herbal infusions.

In the evaluation report prepared by the RMS, modified GAPs for pulses, legume vegetables and sorghum were reported for which the applicant requested the modification of the existing MRLs. However, since for these crops no data gaps were identified in the framework of the MRL review, it is not appropriate to derive MRL proposals for modified uses in the framework of the assessment of Article 12 confirmatory data. Thus, according to the working document of the European Commission SANTE/10235/2016, it is encouraged that the request is submitted in a separate MRL application (see also Section 1.2.1.2).

When assessing the evaluation report, EFSA identified points which needed further clarifications. On February 2019, the evaluating Member State (EMS) submitted a revised evaluation report which addressed the points for clarification.

The summary table below provides an overview of the assessment of confirmatory data and the recommended MRL modifications to Regulation (EU) No 396/2005.
**Evaluation of confirmatory data following the Article 12 MRL review for bentazone**

| Code(a) | Commodity                        | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|----------------------------------|-----------------|--------------|---------------------------|
| **Existing enforcement residue definition:** Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy- bentazone (free and conjugated), expressed as bentazone |
| **General considerations:** Following the renewal of the approval of bentazone, which was performed after the MRL review, the peer review proposed different residue definitions in plant commodities: ‘bentazone’ for enforcement and ‘the sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone’ for the risk assessment. The risk assessment residue definition was proposed on provisional basis, pending the clarification of the unidentified fraction in wheat metabolism studies. Moreover, the available toxicological information on metabolite 6-hydroxy-bentazone was found to be incomplete to conclude on the toxicological reference values. Once the relevant data gaps identified by the peer review are addressed, a review of the existing EU MRLs for bentazone would be required |

| 0211000 | Potato | 0.2 (ft 1) | 0.15 | The data gap identified by EFSA concerning residue trials has not been addressed. Adjusted, less critical SEU/NEU GAPs were proposed which were sufficiently supported by residue data. The previous consumer risk assessment was updated using revised toxicological reference values. No consumer intake concerns were identified |
| 0270060 | Leek   | 0.15 (ft 1) | 0.03* | The data gap identified by EFSA concerning residue trials has not been addressed. The lowering of the MRL to the LOQ is proposed. Member States should ensure that the existing uses on leeks are revoked |
| 0632000 | Leaves of herbal infusions | 0.1* (ft 2) | Risk management decision | The data gap related to the submission of validated enforcement method has been addressed. The requested clarification of the GAP has not been provided in a sufficiently clear way. If the applicant confirms the growth stage in the authorised GAP to be BBCH 10–18, a MRL proposal of 0.3* mg/kg is appropriate. If the applicant confirms that the minimum PHI is 35 days for the authorised GAP, the tentative MRL of 0.1* mg/kg can be maintained. Alternatively, the lowering of the existing MRL to the routinely achievable LOQ or the submission of a new MRL application according to Article 6 of Regulation (EC) No 396/2005 should be considered |

| **Existing enforcement residue definition:** Sum of bentazone, its salts and 6-hydroxy (free and conjugated), expressed as bentazone all animal commodities, except milk: 6-hydroxy-bentazone, expressed as bentazone(c) |
| **General considerations:** Following the renewal of the approval of bentazone, which was performed after the MRL review, the peer review proposed different enforcement residue definition as ‘6-hydroxy-bentazone, expressed as bentazone’ in all animal commodities, except in milk as ‘6-hydroxy-bentazone (sulfate) conjugates, expressed as bentazone’. The risk assessment residue definition was not modified. As soon as the required information regarding the toxicity of metabolite 6-hydroxy-bentazone is provided and the risk assessment residue definition for plant commodities is confirmed, the livestock dietary burden shall be recalculated, using the OECD methodology and the existing EU MRLs should be reviewed accordingly |

| 1011010 | Swine muscle | 0.02* (ft 3) | No new proposal | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate |
| 1011020 | Swine fat | 0.15 (ft 4) | 0.02* risk management decision | The data gaps have been sufficiently addressed. According to the new feeding study, a lower MRL of 0.02* mg/kg would be sufficient |
| 1011030 | Swine liver | 0.02* (ft 3) | No new proposal | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate |

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(a) Code: Unique identifier for the chemical substance.

(b) MRL: Maximum Residue Limit.

(c) The existing enforcement residue definition for animal commodities, except milk, is expected to be sufficient to cover the potential exposure from the metabolite 6-hydroxy-bentazone.
| Code  | Commodity            | Existing MRL (ft 3) | Proposed MRL | Conclusion/recommendation                                                                                                                                 |
|-------|----------------------|--------------------|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1011040 | Swine kidney         | 0.05               | 0.03         | The data gaps have been sufficiently addressed. According to the new feeding study, a lower MRL of 0.03 mg/kg would be sufficient.                   |
| 1011050 | Swine edible offal    | 0.15               | Risk         | To derive the MRL for edible offal, usually risk managers extrapolate the MRL from muscle, fat, liver or kidney, whatever is the highest value. Considering the modifications for the animal commodities, the existing MRL for edible offal should be revised accordingly. |
| 1012010 | Muscle: Bovine        | 0.02*              | No new proposal | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate.                                   |
| 1013010 | Sheep                |                    |              |                                                                                                                                                    |
| 1014010 | Goat                 |                    |              |                                                                                                                                                    |
| 1015000 | Equine               |                    |              |                                                                                                                                                    |
| 1012020 | Fat: Bovine          | 1.0                | Risk         | The data gaps have been sufficiently addressed. According to the new feeding study, a lower MRL of 0.03 mg/kg would be sufficient.                   |
| 1013020 | Sheep                |                    |              |                                                                                                                                                    |
| 1014020 | Goat                 |                    |              |                                                                                                                                                    |
| 1015020 | Equine               |                    |              |                                                                                                                                                    |
| 1012030 | Liver: Bovine        | 0.02*              | 0.05         | The data gaps have been sufficiently addressed. According to the new feeding study, a higher MRL would be required.                                 |
| 1013030 | Sheep                |                    |              |                                                                                                                                                    |
| 1014030 | Goat                 |                    |              |                                                                                                                                                    |
| 1015030 | Equine               |                    |              |                                                                                                                                                    |
| 1012040 | Kidney: Bovine       | 0.3                | No new proposal | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate.                                   |
| 1013040 | Sheep                |                    |              |                                                                                                                                                    |
| 1014040 | Goat                 |                    |              |                                                                                                                                                    |
| 1015040 | Equine               |                    |              |                                                                                                                                                    |
| 1012050 | Edible offal: Bovine | 1.0                | Risk         | To derive the MRL for edible offal, usually risk managers extrapolate the MRL from muscle, fat, liver or kidney, whatever is the highest value. Considering the modifications for the animal commodities, the existing MRL for edible offal should be revised accordingly. |
| 1013050 | Sheep                |                    |              |                                                                                                                                                    |
| 1014050 | Goat                 |                    |              |                                                                                                                                                    |
| 1015050 | Equine               |                    |              |                                                                                                                                                    |
| 1020000 | Milk                 | 0.02*              | 0.03         | The data gaps have been sufficiently addressed. According to the new feeding study, a higher MRL would be required.                                 |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: good agricultural practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval.

*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(b): Existing EU MRL and corresponding footnote on confirmatory data.
(c): According to feeding study results, the residue is not considered fat soluble.
ft 1: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 1 and 4).
ft 2: The European Food Safety Authority identified some information on analytical methods and GAP parameters as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 8 and 9).
ft 3: The European Food Safety Authority identified some information on storage stability and feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 11 and 12).
ft 4: The European Food Safety Authority identified some information on storage stability, feeding studies and analytical methods for fat as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 10).
The data gaps identified in the framework of the EFSA peer review, which are not subject of the current assessment (i.e. confirmatory information as regards Level 2/3 tests as currently indicated in the OECD Conceptual Framework investigating the potential for endocrine-mediated effects of bentazone), are not yet addressed. The deadline for submitting information to the rapporteur Member State is 1 February 2019. Once the missing information has been assessed, which may have an impact on the existing uses of bentazone, the existing bentazone MRLs may have to be reviewed again, taking into account modifications on the authorised uses and implementing the proposed new residue definitions. In this future, MRL review the information requested on the unidentified metabolite in wheat and the toxicological information requested on metabolite 6-hydroxy-bentazone should be taken into consideration.
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Assessment

The review of existing maximum residue levels (MRLs) for the active substance bentazone according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed in 2012, prior the renewal of the approval of bentazone under Regulation (EU) No 1107/2009 in 2015. In the MRL review, the European Food Safety Authority (EFSA) identified some information as unavailable (data gaps) and derived tentative MRLs for those uses not fully supported by data but for which no risk to consumers was identified. The following data gaps were identified by EFSA:

1) Two additional residue trials supporting the northern outdoor good agricultural practice (GAP) and four additional residue trials supporting the southern outdoor GAP on potato;
2) Four residue trials supporting the northern outdoor GAP on spring onion;
3) Eight residue trials supporting the northern outdoor GAP on cucumber;
4) Four additional residue trials supporting the northern outdoor GAP on leek;
5) Four residue trials supporting the northern outdoor GAP on poppy seed;
6) Eight residue trials supporting the northern outdoor GAP and eight residue trials supporting the southern outdoor GAP on soya bean;
7) A confirmation on the validity of the existing Codex maximum residue limit (CXL) for rye;
8) Further clarification of the GAP of herbal infusion;
9) A validated analytical method (with confirmatory method and independent laboratory validation (ILV)) for enforcement of the proposed residue definition in herbal infusion;
10) An analytical method (with confirmatory method and ILV) for the enforcement of the residue in fat;
11) A livestock feeding study for meat ruminant;
12) Storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk.

Tentative MRL proposals have been implemented in the MRL legislation by Commission Regulation (EU) No 1146/2014, including footnotes related to data gaps number 1, 4, 8, 9, 10, 11 and 12, indicating the type of confirmatory data that should be provided by a party having an interest in maintaining the proposed tentative MRL by 29 October 2016.

Data gaps number 2, 3, 5, 6 and 7, related to the residue data in spring onion, cucumber, poppy seed, soybean and rye, were not translated into footnote and were not implemented in the MRL regulation, because risk managers decided to set MRL at the limit of quantification (LOQ) of 0.03* mg/kg or 0.1* mg/kg in the absence of any residue data supporting the authorised uses. Consequently, the existing uses on these crops had to be revoked.

Thus, in the framework of the current assessment, EFSA focused on the confirmatory data gaps number 1, 4, 8, 9, 10, 11 and 12.

In accordance with the specific provisions set out in the working document of the European Commission SANTE/10235/2016 (European Commission, 2016), the applicant BASF SE submitted an application to the competent national authority in the Netherlands (designated rapporteur Member State (RMS)) to evaluate the confirmatory data identified during the MRL review. To address the data gaps identified by EFSA, the applicant provided residue trials supporting adjusted less critical northern Europe/southern Europe (NEU/SEU) GAPs on potatoes, a livestock feeding study and the storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk. The applicant referred to data submitted in the framework of the renewal of the approval to address the data gaps related to the clarification of the GAP for herbal infusions and analytical enforcement methods in fats and herbal infusions.

Although no data gaps were identified in the MRL review, the applicant submitted a wide range of residue trials in support of adjusted GAPs on beans and peas with and without pods, dry beans and peas and sorghum requesting to raise the existing MRLs. According to the procedural guidance document (SANTE/10235/2016), it is encouraged to submit a separate MRL application. However, acknowledging that the evaluating Member State (EMS) assessed the submitted residue data in its evaluation report, an indicative assessment of the submitted residue data was performed by EFSA. It

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1 Regulation (EC) No 396/2005 of the Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.03.2005, p. 1–16.
2 Commission Regulation (EU) No 1146/2014 of 23 October 2014 amending Annexes II, III, IV and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for antraquinone, benfluralin, bentazone, bromoxynil, chlorothalonil, famoxadone, imazamox, methyl bromide, propanil and sulphuric acid in or on certain products. OJ L 308, 29.10.2014, p. 3–60.
was concluded that the existing European Union (EU) MRLs are sufficient for the adjusted GAPs on beans (with/without pods), peas (with/without pods), dry beans, but lower MRLs would be sufficient for the adjusted GAPs on dry peas and sorghum.

The RMS assessed the new information in an evaluation report, which was submitted to the European Commission and forwarded to EFSA on 25 September (Netherlands, 2018). EFSA assessed the application as requested by the European Commission in accordance with Article 9 and Article 10 of Regulation (EC) No 396/2005.

Bentazone was first evaluated in the framework of Directive 91/414/EEC3 with Germany designated as RMS for the representative uses as outdoor foliar spraying against annual dicotyledonous weeds in various crops (Germany, 1996; European Commission, 2000b). The approval has been reviewed in 20184 following the peer review process with the Netherlands acting as the new RMS (Netherlands, 2013, 2015; EFSA, 2015).

EFSA based its assessment on the evaluation report submitted by the RMS (Netherlands, 2018), the conclusions from the review of the existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (EFSA, 2012), the Renewal Assessment Report (RAR) prepared under Regulation (EC) 1107/2009 (Netherlands, 2013), the conclusion on the peer review of the pesticide risk assessment of the active substance bentazone (EFSA, 2015) as well as the Commission review report on bentazone (European Commission, 2018).

For this application, the data requirements established in Regulation (EU) No 544/20115 and the relevant guidance documents at the date of implementation of the confirmatory data requirements by Regulation (EU) No 1146/2014 and at the date of submission of the application to the RMS are applicable (European Commission, 1997a–g, 2000a, 2010a,b, 2017; OECD, 2011, OECD, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/20116.

A detailed description of the GAPs assessed in the framework of the MRL review for which confirmatory data were requested as well as the corresponding adjusted GAPs that are currently supported by the applicant is reported in Appendix A.

An updated list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously are presented in Appendix B.

The evaluation report submitted by the RMS (Netherlands, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. **Residues in plants**

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

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

Not relevant for the current assessment.

1.1.2. **Nature of residues in rotational crops**

Not relevant for the current assessment.

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3 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.

4 Commission Implementing Regulation (EU) 2018/660 of 26 April 2018 renewing the approval of the active substance bentazone 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 110, 30.4.2018, p. 122–126.

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

6 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.
1.1.3. Nature of residues in processed commodities

Not relevant for the current assessment.

1.1.4. Methods of analysis in plants

In order to address the data gap number 9, new information was not submitted in the framework of the current assessment. The applicant referred to data assessed in the framework of the renewal of the approval of bentazone (Netherlands, 2013).

The EFSA peer review concluded that the analytical method using liquid chromatography with tandem mass spectrometry (LC–MS/MS) is sufficiently validated for the determination of bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone (free and conjugated) in plant matrices with high starch content (maize), high water content (onion), high acid content (orange), high oil content (soybean), and high protein content (dry peas) at the individual LOQs of 0.01 mg/kg (EFSA, 2015).

The above-mentioned analytical method has not been validated for the determination of bentazone and its metabolites in herbal infusions (matrix difficult to analyse). However, since the above-mentioned enforcement method was satisfactorily validated in onions, which from an analytical point of view is very similar to herbal infusion matrix given the high content of essential oils, it can reasonably be assumed that the method is also suitable for the determination of bentazone residues in herbal infusions at the combined validated LOQ of 0.03 mg/kg.

Thus, data gap number 9 is considered sufficiently addressed.

1.1.5. Stability of residues in plants

Not relevant for the current assessment.

1.1.6. Proposed residue definitions

The residue definitions proposed by the MRL review (EFSA, 2012) were:

- For enforcement and risk assessment: the sum of bentazone and the conjugates of 6-hydroxy bentazone and 8-hydroxy-bentazone, expressed as bentazone.

The same residue definition is enforced in Regulation (EC) No 396/2005.

In the framework of the renewal of the approval, the peer review concluded the following residue definitions for all plant commodities after foliar applications (EFSA, 2015):

- For enforcement: bentazone
- For risk assessment: the sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone\(^8\) (provisional).

The residue definitions were proposed for primary crops and rotational crops.

Since a formal decision on the revision of the enforcement residue definition has not been taken, the residue definitions in force at the time of the MRL review are considered relevant and MRL proposals are derived for the residue definition covering the sum of bentazone and the conjugates of 6-hydroxy bentazone and 8-hydroxy-bentazone. In addition, MRL proposals for the enforcement residue definition derived in the framework of the peer review (renewal process) were derived for the crops under assessment.

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\(^7\) Data gap number 9 refers to ‘a validated analytical method (with confirmatory method and ILV) for enforcement of the proposed residue definition in herbal infusion’.

\(^8\) The residue definition was considered provisional, due to an insufficient characterisation of the metabolite fraction (referred to as fraction M3) found in the primary crop metabolism study in wheat (wheat straw). Furthermore, the data to characterise the toxicological properties of 6-hydroxy-bentazone were not sufficient.

Once the missing studies are made available, the provisional residue definition should be reviewed and if relevant, the existing MRLs for bentazone need to be reconsidered.
1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

1.2.1.1. Data/information submitted to address requested confirmatory data

**Potatoes**

GAP assessed in MRL review: NEU/SEU $1 \times 1.5$ kg/ha, BBCH 12–50, preharvest interval (PHI) 42 days

Adjusted GAPs: NEU/SEU: $1 \times 0.96$ kg/ha, BBCH 12–19

In support of the data gap number 1, the applicant did not submit new residue trials for the authorised NEU and SEU uses.

Instead, adjusted NEU and SEU GAPs were reported for which the applicant submitted a wide range of residue trials. Among the submitted trials, 10 trials were considered compliant with the NEU adjusted GAP. Residue trials were performed in Germany, the Netherlands, Poland, Hungary, Sweden and Switzerland in the time period between 1978 and 2009. In support of the adjusted SEU GAP, the applicant submitted eight GAP-compliant residue trials, performed in Spain, Italy, Greece and France in 2009. In all residue trials, potato samples were analysed for bentazone and its metabolites 6-hydroxy- and 8-hydroxy-bentazone. According to the RMS, analytical methods used to analyse residue trial samples were sufficiently validated and fit for purpose (Netherlands, 2018). The residue trial samples prior to analysis were stored frozen for a time period not exceeding the demonstrated storage stability of bentazone and its metabolites of 2 years. Thus, residue trial data are considered valid regarding the storage stability of bentazone and its 6-hydroxy and 8-hydroxy metabolites.

Residue trials data indicate that for the existing enforcement residue definition an MRL of 0.15 mg/kg would be sufficient for both NEU and SEU GAPs. For the proposed revised enforcement residue definition covering only parent compound, an MRL proposal of 0.07 mg/kg is derived.

**Leek**

In support of the data gap number 4, new information was not provided. Thus, the use of bentazone on leeks is not sufficiently supported by data and therefore the lowering of the existing EU MRL to the LOQ of 0.03 mg/kg and the revocation of the authorised uses in leeks is proposed to be discussed within risk managers.

**Herbal infusions (leaves)**

GAP reported in the MRL review: NEU $1 \times 0.96$ kg/ha

For the GAP reported in the framework of the MRL review, information on the PHI and BBCH was not specified, and therefore, a data gap was set, requesting further clarification of the GAP. A tentative MRL for bentazone was established at $0.1^* \text{mg/kg}$ for dried leaves of herbal infusions on the basis of three NEU trials in peppermint and two NEU trials with St. John’s wort. In these trials, crops were treated according to the application rate defined in the GAP and crop samples were taken at the PHI intervals of 35–75 days.

In order to address the data gap number 8, the RMS referred to the NEU GAP ($1 \times 0.96$ kg/ha, BBCH 11–15) which was reported for the peer review on St. John’s wort and woolly foxglove, without clearly specifying the parameters of the GAP that were identified as missing in the MRL review.

If the applicant/Member States confirm that the authorised GAP for the leaves of herbal infusions is identical with the GAP assessed in the framework of the peer review where the growth stage of the last treatment was specified as BBCH 11–15, sufficient residue data are available for leaves of herbal infusions (Renewal Assessment Report, Netherlands, 2013 and the Evaluation report submitted for the MRL review, Germany, 2012) to derive a MRL proposal of $0.3^* \text{mg/kg}$.

However, if the applicant/Member States confirm a minimum PHI of 35 days, the existing tentative MRL of $0.1^* \text{mg/kg}$ can be converted to a definitive MRL.

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9 Data gap number 1 refers to ‘2 additional residue trials supporting the northern outdoor GAP and 4 additional residue trials supporting the southern outdoor GAP on potato’.

10 Data gap number 4 refers to ‘4 additional residue trials supporting the northern outdoor GAP on leek’.

11 Data gap number 8 refers to ‘further clarification of the GAP of herbal infusions’.
EFSA concludes that for herbal infusions the requested clarification of the GAP has not been provided in a sufficiently clear way. A risk management decision to be taken on the MRL proposal for the leaves of herbal infusions.

1.2.1.2. Data/information submitted for adjusted GAPs for legume vegetables and pulses

In the framework of the current assessment, the applicant submitted a wide range of modified, apparently less critical GAPs on fresh peas and beans, dried peas and beans and sorghum (Netherlands, 2018). According to the applicant, the existing EU MRLs in beans (with pods), peas (with pods), dry peas and dry beans should be raised to 0.40 mg/kg; for beans (without pods) and peas (without pods), MRLs of 0.15 mg/kg and for sorghum a MRL of 0.20 mg/kg would be required.

Since for these crops no data gaps were identified in the framework of the MRL review, it is not appropriate to derive MRL proposals in the framework of the assessment of Article 12 confirmatory data. Thus, according to the working document of the European Commission SANTE/10235/2016, the applicant is encouraged to submit a separate MRL application for the modification of the existing EU MRLs for bentazone.

Acknowledging that the EMS assessed the submitted residue data in its evaluation report, EFSA also performed an indicative assessment of the submitted residue data and concluded that the existing EU MRLs are sufficient to support the adjusted GAPs on beans (with/without pods), peas (with/without pods), dry beans, but lower MRLs would be necessary for the adjusted GAPs on dry peas and sorghum. Should the revised enforcement residue definition be implemented, sufficient residue data are available to derive MRLs of 0.03 mg/kg in beans (with pods) and peas (with pods), 0.01* mg/kg in beans (without pods), peas (without pods) and sorghum and of 0.04 mg/kg in dry peas and beans. Thus, based on the information provided by the applicant, the raising of the existing MRLs for the crops mentioned would not be justified.

1.2.2. Magnitude of residues in rotational crops

Not relevant for the current assessment.

1.2.3. Magnitude of residues in processed commodities

Not relevant for the current assessment.

1.2.4. Proposed MRLs

In the framework of the current assessment, MRL proposals were derived for the crops under consideration both for the existing and the proposed revised enforcement residue definitions:

- Potatoes: 0.15 mg/kg/0.07 mg/kg
- Leek: no MRL proposal
- Leaves (dried) of herbal infusions: 0.1* mg/kg or 0.3* mg/kg, pending the confirmation of the GAP from the applicant/Member States.

2. Residues in livestock

Bentazone is authorised on various crops that can be used as livestock feed items and therefore the livestock exposure to bentazone residues was assessed in the MRL review (EFSA, 2012). Under the current assessment, an adjusted GAP on potatoes was assessed, therefore the dietary burden calculated previously in the MRL review using PROFile rev. 2.3 was updated.

The input values were as reported in the MRL review, except those for potatoes, which were as derived from the residue trials submitted under the current assessment. The details of the input values are given in Appendix D.1.

The calculated livestock dietary burdens exceed the trigger value of 0.1 mg/kg dry matter (DM) for all livestock species (see Appendix B.2). Although the modified uses in potatoes leading to a lower MRL proposal had an insignificant impact on the dietary burden of livestock, EFSA recalculated the MRLs for animal commodities, taking into account the new feeding study submitted to address data gap number 11, and the proposed new residue definitions for animal products derived in the peer review.
2.1. Nature of residues and methods of analysis in livestock

The metabolism of bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone each labelled in the phenyl ring, was investigated in ruminants and poultry in the framework of the MRL review and in the renewal of the approval (EFSA, 2012, 2015).

The MRL review proposed to set the residue definitions for the risk assessment and enforcement in animal commodities as

- the sum of bentazone, the metabolite 6-hydroxy-bentazone and their conjugates, expressed as bentazone (EFSA, 2012).

This residue definition is also enforced in the Regulation (EU) No 396/2005.

In the renewal process, the experts proposed the following residue definitions (EFSA, 2015):

- For enforcement:
  - Milk: 6-hydroxy-bentazone (sulfate) conjugates, expressed as bentazone;
  - Other animal commodities (except milk): 6-hydroxy-bentazone, expressed as bentazone.

- For risk assessment (all matrices): sum of bentazone, 6-hydroxy-bentazone and their conjugates, expressed as bentazone

The residue definitions were proposed on provisional basis, pending the submission of the ruminant feeding study. In addition, further toxicological information on 6-hydroxy-bentazone was requested by the peer review.

The data gap number 10\textsuperscript{12} has been addressed in the framework of the renewal of the approval of bentazone (EFSA, 2015). A sufficiently validated enforcement method was provided that allows determination of bentazone, 6-hydroxy- and 8-hydroxy-bentazone and their conjugates in fat at the individual validated LOQ of 0.01 mg/kg.

2.2. Magnitude of residues in livestock

In order to address the data gap number 11,\textsuperscript{13} the applicant submitted a new ruminant feeding study, investigating the magnitude of bentazone and 6-hydroxy-bentazone in dairy cows (Netherlands, 2018).

Fifteen dairy cows were administered once a day the mixture of bentazone and 6-hydroxy-bentazone (1:5) (the sum expressed as bentazone) at the dose levels of 0.3 mg/kg, 1 mg/kg and 3 mg/kg body weight (bw) day. The duration of the study was 28 days. Milk samples were collected twice daily. Animals were sacrificed within 22–24 h after the final dosing. The samples of milk, cream, skimmed milk and tissues were analysed for residues of bentazone and 6-hydroxy-bentazone and its conjugates separately by high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) at an individually validated LOQs of 0.01 mg/kg. Control samples were free of residues.

The plateau levels in milk were reached 17–21 day after the dose administration. Bentazone residues in all milk samples were below the LOQ of 0.01 mg/kg, whereas 6-hydroxy bentazone ranged from < 0.01 to 0.015 mg/kg in the dose group of 1 mg/kg bw day and from 0.028 to 0.044 mg/kg in the highest dose group (3 mg/kg bw day). The samples of skimmed milk and milk fat were taken from 21 day milk sample and analysed for residues. The 6-hydroxy-bentazone accounted for a maximum of 0.02 mg/kg in skimmed milk and 0.013 mg/kg in fat in the samples from the highest dose group only. In muscle samples from all dose groups, no residues above the LOQ were observed.

In fat, parent bentazone was in all samples from all dose groups below the LOQ of 0.01 mg/kg. Metabolite 6-hydroxy-bentazone was present in samples from the highest dose group only and at levels ranging from < 0.01 to 0.048 mg/kg. The data did not provide evidence that the residues are mainly occurring in fat.

In liver, no residues above the LOQ were observed in samples taken from the low dose group animals. In higher dose groups of 1 and 3 mg/kg bw day, residues of bentazone were present at < 0.01–0.011 mg/kg and 0.022–0.049 mg/kg, respectively, and of metabolite 6-hydroxy-bentazone at 0.012–0.018 mg/kg and 0.026–0.042 mg/kg, respectively.

\textsuperscript{12} Data gap number 10 refers to ‘an analytical method (with confirmatory method and ILV) for the enforcement of the residue in fat’.

\textsuperscript{13} Data gap number 11 refers to ‘a livestock feeding study for meat ruminant’.
In kidney, residues were observed in samples from all dose groups. In kidney from animals dosed at a rate of 0.3 mg/kg bw day, bentazone accounted for < 0.01–0.01 mg/kg and 6-hydroxy-bentazone for 0.014–0.023 mg/kg. In the samples from the highest dose group, residues of bentazone were present at 0.067–0.144 mg/kg and its 6-hydroxy metabolite at 0.09–0.32 mg/kg. Residues in fat and liver declined below the LOQ 2 days after the withdrawal, and in kidney 2–5 days after the withdrawal.

In order to address the data gap number 12, the applicant submitted a new study investigating the freezer storage stability of bentazone and its 6-hydroxy metabolite in animal tissues and milk (Netherlands, 2018). The samples were separately spiked with bentazone and 6-hydroxy-bentazone at 0.1 mg/kg and stored frozen at −20°C for a time period of 120–125 days. The results of the study indicate that bentazone is stable in all animal matrices for the investigated period of time. The metabolite 6-hydroxy-bentazone is stable for 120 days in liver and 125 days in kidney but it could not be recovered from milk, muscle and fat samples after 120–125 days of frozen storage.

The samples from the feeding study prior to analysis were stored 63 days for milk, 119 days for fat, 98 days for liver, 115 days for kidney and 47 days for muscle. Thus, the feeding study results are considered valid for bentazone residues in all matrices and for 6-hydroxy-bentazone residues in kidney and liver.

The storage stability of 6-hydroxy-bentazone in muscle, milk and fat could not be demonstrated for the relevant storage intervals. The applicant re-analysed the incurred samples that were stored frozen at −20°C for the validation of the analytical method. The re-analysis indicated that 6-hydroxy-bentazone had not degraded in milk and fat samples following the storage for 372 and 249 days, respectively. In muscle, the storage stability of 6-hydroxy-bentazone is not confirmed, but since the muscle samples were stored only slightly longer than 30 days (47 days), it can be concluded that 6-hydroxy-bentazone is not accumulating in the muscle. This is confirmed by the data from metabolism studies, where at the dose level of 2 mg/kg bw day, the total radioactive residue (TRR) in muscle was low, accounting for 0.011 mg eq/kg. Thus, EFSA concludes that the feeding study results are valid with regard to the storage stability of bentazone and its 6-hydroxy metabolite.

The newly submitted feeding study was used to estimate the MRLs and risk assessment values in the commodities of animal origin at the dietary burdens calculated in the framework of the current assessment. Results indicate that higher MRLs would be required for bovine, equine, sheep and goat liver (0.05 mg/kg) and milk (0.03 mg/kg), but lower MRLs would be sufficient for swine fat and kidney and for bovine, equine, sheep and goat fat.

For poultry commodities, the same conclusion as derived in the MRL review are applicable that no residues above the LOQ are expected in any poultry tissues or eggs, on the basis of the metabolism study. EFSA notes that although the dietary burdens calculated in the MRL review and under the current assessment are the same, different MRL proposals were derived in the MRL review on a basis of a feeding study with goats. The EMS also derived slightly different MRL proposals using the OECD methodology.

It is concluded that the existing bentazone MRLs for animal commodities shall be reviewed using the OECD methodology as soon as the uncertainties identified by the peer review are addressed and the new residue definitions for plant and animal commodities are implemented.

3. Consumer risk assessment

EFSA updated the dietary risk assessment performed under the MRL review, using revision 2 of the EFSA PRIMo (EFSA, 2007). This exposure assessment model contains food consumption data for different sub-groups of the EU population and allows the acute and chronic exposure assessment to be performed in accordance with the internationally agreed methodology for pesticide residues (EFSA, 2007).

The toxicological reference values for bentazone used in the risk assessment (i.e. acceptable daily intake (ADI) and the acute reference dose (ARfD) value) were as amended in the framework of the EU pesticides peer review (EFSA, 2015; European Commission, 2018). The toxicological properties of metabolites included in the risk assessment residue definition were re-assessed during the renewal of the approval process of bentazone. The peer review concluded that 8-hydroxy-bentazone is less toxic than the parent bentazone from the acute, short-term and developmental toxicity point of view. For risk assessment, the reference values of the parent would apply to this metabolite. Regarding

14 Data gap number 12 refers to ‘storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk’.
6-hydroxy-bentazone, insufficient toxicological information was available and a data gap has been identified by the peer review for further data to derive toxicological reference values (EFSA, 2015).

Since the toxicological reference values for bentazone differ from those applied in the framework of the MRL review, EFSA recalculated the consumer exposure, using new ADI of 0.09 mg/kg bw day and the ARfD of 1 mg/kg bw. According to the MRL review, the toxicological profile of metabolite 6-hydroxy-bentazone was assumed to be of the same or of a comparable toxicity as a parent compound and the same consideration will be taken in the assessment of confirmatory data.

The input values for the exposure calculation were those considered in the MRL review, except for those commodities for which the existing EU MRL is not confirmed or a proposal for modification is derived under the current assessment. Those commodities for which no uses were reported in the MRL review and for which the MRL was implemented at the LOQ following the MRL review due to lack of residue data, were excluded from the exposure calculation. For the leaves of herbal infusions, the risk assessment values as derived in support of a higher MRL proposal of 0.3* mg/kg (option 1) were considered in the consumer exposure calculation. For animal commodities, the risk assessment values were as derived in the framework of the current assessment.

The input values are summarised in Appendix D.2.

No long-term consumer intake concerns were identified for the authorised uses of bentazone, as the estimated maximum long-term dietary intake accounted for 1.6% of the ADI (NL child diet). The maximum short-term exposure was calculated for celery leaves (4.4% of the ARfD).

The results of the consumer risk assessment calculation are summarised in Appendix B.3.

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. Conclusion and Recommendations

To address the data gaps identified by EFSA, the applicant provided new residue trials supporting the adjusted less critical GAPs on potatoes, submitted cow feeding study and the study on the storage stability of bentazone and 6-hydroxy bentazone in livestock tissues and milk. The applicant referred to data submitted in the framework of the renewal of the approval to address the data gaps related to the clarification of the GAP for herbal infusions and analytical enforcement methods in fats and herbal infusions.

EFSA concludes that data gaps related to analytical methods in fat and herbal infusions are sufficiently addressed. The data gap for residue trials on leek is not addressed. The requested clarification of the GAP for herbal infusions has not been provided in a sufficiently clear way and a further confirmation of the authorised GAP is required from the applicant/Member States.

Based on the information submitted in support of the confirmatory data request, the existing EU MRLs for bentazone would need to be modified for potato and leek, for swine fat and kidney and for bovine, equine, goat and sheep fat, liver and milk. For the herbal infusions, no conclusion can be derived, pending the clarification of the authorised GAP by the applicant.

Although no data gaps were identified by the MRL review, the applicant also reported adjusted GAPs on beans (with/without pods), peas (with/without pods), dry beans, dry peas and sorghum. An indicative assessment of submitted residue trials indicates no need to modify existing EU MRLs for bentazone in these crops.

The peer review on the renewal of the approval, which was performed after the MRL review, derived different (provisional) enforcement and risk assessment residue definitions for plant and animal commodities. It also concluded that the available toxicological information was insufficient to assess the toxicological importance of 6-hydroxy bentazone. Since a formal decision on the revision of the enforcement residue definition has not been taken yet, the residue definitions in force at the time of the MRL review are considered for the current assessment.

The consumer risk assessment performed by the MRL review was updated, using new toxicological reference values derived by the peer review. The 6-hydroxy bentazone was considered of the same toxicity as the parent bentazone, according to the conclusions of the MRL review. No consumer intake concerns were identified.

EFSA is of the opinion that bentazone MRLs shall be reviewed and the consumer risk assessment updated once the data gaps identified by the EFSA peer review are addressed.

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

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers’ health arising from proposed temporary EU MRLs. EFSA Journal 2007;5(3):32r, 1141 pp. https://doi.org/10.2903/j.efsa.2007.32r

EFSA (European Food Safety Authority), 2012. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for bentazone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10 (7):2822, 65 pp. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2015. Conclusion on the peer review of the pesticide risk assessment of the active substance bentazone. EFSA Journal 2015;13(4):4077, 153 pp. https://doi.org/10.2903/j.efsa.2015.4077

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/V/95-rev. 6, 22 July 1997.

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

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

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

European Commission, 2000a. 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. SANCO/3029/99-rev. 4.

European Commission, 2000b. Review report for the active substance bentazone. Finalised in the Standing Committee on Plants Health at its meeting on 13 July 2000 in view of the inclusion of bentazone in Annex I of Directive 91/414/EEC. 7585/V/97-final, 30 November 2000.

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, 2016. Commission staff working document on the evaluation of data submitted to confirm MRLs following the review of existing MRLs Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 17 June 2016. SANTE/E4/VW 10235/2016 - Rev. 2, 3 pp. Brussels, 17 June 2016.

European Commission, 2017. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/V/95-rev. 10.3, 13 June 2017.

European Commission, 2018. Review report for the active substance bentazone. Finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 23 March 2018 in view of the renewal of the approval of the active substance bentazone in accordance with Regulation (EC) No 1107/2009. SANTE/12012/2015 Rev 8, 23 March 2018.

Germany, 1996. Draft assessment report on the active substance bentazone prepared by the rapporteur Member State Germany in the framework of Council Directive 91/414/EC, February 1996.

Germany, 2012. Additional Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Authorised uses to be considered for the review of the existing MRLs for bentazone, March 2012.

Netherlands, 2013. Renewal Assessment Report (RAR) on the active substance bentazone prepared by the rapporteur Member State Netherlands in the framework of Commission Regulation (EU) No 1141/2010, December 2013. Available online: www.efsa.europa.eu

Netherlands, 2015. Final Addendum to the Renewal Assessment Report on bentazone, compiled by EFSA, January 2015. Available online: http://www.efsa.europa.eu

Netherlands, 2018 (year of first submission). Evaluation report on the evaluation of confirmatory data following the review according to Article 12 of Regulation (EC) No 396/2005 and on the setting of MRLs for bentazone in various crops and products of animal origin. July 2018, revised in February, 2019, 278 pp.

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.
**Abbreviations**

| Abbreviation | Description |
|--------------|-------------|
| a.s.         | active substance |
| ADI          | acceptable daily intake |
| ARfD         | acute reference dose |
| BBCH         | growth stages of mono- and dicotyledonous plants |
| bw           | body weight |
| CF           | conversion factor for enforcement to risk assessment residue definition |
| CXL          | Codex maximum residue limit |
| DAR          | draft assessment report |
| DAT          | days after treatment |
| DM           | dry matter |
| EC           | emulsifiable concentrate |
| EMS          | evaluating Member State |
| eq           | residue expressed as a.s. equivalent |
| FAO          | Food and Agriculture Organization of the United Nations |
| GAP          | Good Agricultural Practice |
| HPLC–MS/MS   | high-performance liquid chromatography with tandem mass spectrometry |
| HR           | highest residue |
| IEDI         | international estimated daily intake |
| IESTI        | international estimated short-term intake |
| ILV          | independent laboratory validation |
| InChiKey     | International Chemical Identifier Key |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC–MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOQ          | limit of quantification |
| MRL          | maximum residue level |
| MS           | Member States |
| NEU          | northern Europe |
| OECD         | Organisation for Economic Co-operation and Development |
| PBI          | plant-back interval |
| PHI          | preharvest interval |
| PRIMo        | (EFSA) Pesticide Residues Intake Model |
| PROFile      | (EFSA) Pesticide Residues Overview File |
| RA           | risk assessment |
| RAR          | Renewal Assessment Report |
| RD           | residue definition |
| RMS          | rapporteur Member State |
| SANCO        | Directorate-General for Health and Consumers |
| SC           | suspension concentrate |
| SEU          | southern Europe |
| SG           | water-soluble granule |
| SL           | soluble concentrate |
| STMR         | supervised trials median residue |
| TRR          | total radioactive residue |
| WHO          | World Health Organization |
## Appendix A – Summary of the authorised/adjusted GAPs relevant for the assessment of confirmatory data

| Crop and/or situation | NEU/SEU, MS or country | F or T(a) | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|------------------------|----------|-----------------------------------|-------------|-------------|------------------------------|------------|---------|
| **Potato**            |                        |          |                                   |             |             |                              |            |         |
|                       | NEU/SEU                | F        | Dicotyledonous weeds               | SL 480      | Spray 12–50 | 1.5 kg/ha                    | 42         | Authorised GAP assessed in MRL review (EFSA, 2012) |
|                       |                        |          |                                   | SL 280      | Spray 12–19 | 1 (or 2 split) 7–14 100–400 kg/ha | 0.960 kg/ha | Adjusted GAP |
|                       | NEU/SEU                | F        | Annual dicotyledonous weeds        | SL 280      | Spray 12–19 | 1 (or 4 split) 7–14 100–400 kg/ha | 0.960 kg/ha | Adjusted GAP |
|                       | NL (NEU)               | F        | Annual dicotyledonous weeds        | SL 280      | Spray 12–19 | 1 (or 4 split) 7–14 100–400 kg/ha | 0.957 kg/ha | Adjusted GAP |
|                       | NEU/SEU                | F        | Annual dicotyledonous weeds        | SG 87%      | Spray 12–19 | 1 (or 2 split) 100–400 kg/ha | 0.957 kg/ha | Adjusted GAP |
|                       | NL (NEU)               | F        | Annual dicotyledonous weeds        | SG 87%      | Spray 12–19 | 1 (or 4 split) 100–400 kg/ha | 0.957 kg/ha | Adjusted GAP |
| **Beans**             |                        |          |                                   | SL 480 g/L  | Spray 12–55 | 1.218 kg/ha                   |            |         |
| (with pods/without pods) | NEU/SEU              | F        | Annual dicotyledonous weeds        | SL 480 g/L  | Spray 12–39 | 1 (or 2 split) 100–400 kg/ha | 0.960 kg/ha | Adjusted GAP |
|                       |                       |          |                                   | SL 480 g/L  | Spray 12–39 | 1 (or 2 split) 100–400 kg/ha | 0.957 kg/ha | Adjusted GAP |
|                       |                       |          |                                   | SL 480 g/L  | Spray 12–29 | 1 (or 2 split) 100–400 kg/ha | 0.957 kg/ha | Adjusted GAP |

(a) F: Full; T: Temporary; (b) Type: g/L, g/L; Conc. a.s.: %, %; Method: SL 480 g/L; (c) Range of growth stages & season: 12–19; (d) PHI: PHI (days)
### Table: Evaluation of confirmatory data following the Article 12 MRL review for bentazone

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment |
|-----------------------|-------------------------|------------------------------------|-------------|-------------|-------------------------------|
|                       | F                       | Weeds general                      | SL          | Spray       | g a.s./ha                      |
|                       |                         |                                    | 480 g/L     | 12–25       | 1 (or 2 split)                |
|                       |                         |                                    | NEU/SEU     |             | 100–400                       |
|                       |                         |                                    | 0.600 kg/ha | 35          |                               |
| Peas (with pods/without pods) | NEU/SEU | Annual dicotyledonous weeds | SL          | Spray       | g a.s./L                      |
|                       |                         |                                    | 480 g/L     | 12–55       | 1                             |
|                       |                         |                                    | NEU/SEU     |             | 1.218 kg/ha                   |
|                       |                         |                                    | Authorised GAP assessed in MRL review (EFSA, 2012) | | |
| Beans (dry)          | NEU                     | Annual dicotyledonous weeds       | SL          | Spray       | kg/ha                         |
|                       |                         |                                    | 480 g/L     | 29          | 0.480                         |
|                       |                         |                                    | NEU/SEU     |             | Authorised GAP assessed in MRL review (EFSA, 2012) |
## Evaluation of confirmatory data following the Article 12 MRL review for bentazone

| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|--------------------------|-----------------------------------|-------------|-------------|-------------------------------|---------|
|                       |                          |                                   | Type(b) Conc. a.s. Method kind Range of growth stages & season(c) Number min–max Interval between application (min) g a.s./hL min–max Water L/ha min–max Rate Unit PHI (days) (d) | | |
| SEU                   | F                        | Annual dicotyledonous weeds       | SL 480 g/L Spray 9–14 1 | 1.5 kg/ha | | Authorised GAP assessed in MRL review (EFSA, 2012) |
| NEU/SEU               | F                        | Annual dicotyledonous weeds       | SL 480 g/L Spray 12–29 1 (or 2 split) | 100–400 0.960 kg/ha | | Adjusted GAP |
| NEU/SEU               | F                        | Annual dicotyledonous weeds       | SG 87% Spray 12–29 1 (or 2 split) | 100–400 0.957 kg/ha | | Adjusted GAP Mechanical harvesting |
| NEU/SEU               | F                        | Weeds general                     | SL 480 g/L Spray 12–25 1 (or 2 split) | 100–400 0.600 kg/ha | 35 | Adjusted GAP Mechanical harvesting. With/without adjuvant DASH (max 1 L product/ha) |
| Peas (dry)            | NEU                      | Annual dicotyledonous weeds       | SL 480 g/L Spray 29 2 | 0.480 kg/ha | | Authorised GAP assessed in MRL review (EFSA, 2012) |
| SEU                   | F                        | Annual dicotyledonous weeds       | SL 480 g/L Spray 9–14 1 | 1.5 kg/ha | | Authorised GAP assessed in MRL review (EFSA, 2012) |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|------------|-----------------------------|---------|
|                       |                        |                                   | Type \(b\) | Conc. a.s.  | Method kind | Range of growth stages & season \(c\) | Number min–max | Interval between application (min) | g a.s./hL min–max | Water L/ha min–max | Rate | Unit | PHI (days) \(d\) | Remarks |
| NEU/SEU F             | Annual dicotyledonous weeds | SL 480 g/L | Spray | 12–39 | 1 (or 2 split) | | | | 100–400 | 0.960 | kg/ha | Adjusted GAP |
| NEU/SEU F             | Annual dicotyledonous weeds | SG 87% | Spray | 12–39 | 1 (or 2 split) | | | | – | 100–400 | 0.957 | kg/ha | Adjusted GAP Mechanical harvesting |
| NEU/SEU F             | Weeds general | SL 480 g/L | Spray | 12–39 | 1 (or 2 split) | | | | – | 100–400 | 0.600 | kg/ha | 35 |
| Leeks NEU F           | weeds | SG 870 g/kg | Spray | 13 | 2 | | | | 0.37 | kg/ha | Authorised GAP assessed in MRL review (EFSA, 2012) |
| Sorghum SEU F         | Annual dicotyledonous weeds | SL 480 g/L | Spray | 1 | | | | | 1.392 | kg/ha | Authorised GAP assessed in MRL review (EFSA, 2012) |
| SEU F                 | Annual dicotyledonous weeds | SG 87% | Spray | 12–19 | 1 (or 2 split) | | | | – | 100–400 | 0.957 | kg/ha | Adjusted GAP max 1.1 kg/ha |
| Crop and/or situation | NEU, SEU, MS or country | Pests or Group of pests controlled | Preparation | Application | Application rate per treatment | Remarks |
|-----------------------|-------------------------|-----------------------------------|------------|------------|------------------------------|---------|
|                       |                         |                                   | Type<sup>(b)</sup> | Conc. a.s. | Method kind | Range of growth stages & season<sup>(c)</sup> | Number min–max | Interval between application (min) | g a.s./hL min–max | Water L/ha min–max | Rate | Unit | PHI (days)<sup>(d)</sup> | |
| SEU F                  | Weeds general           | SL                                | 320 g/L     | Spray      | 13–16          | 1                           | –              | –                        | 200–300         | 0.960 kg/ha       | Adjusted GAP With adjuvant DASH (max 1 L product/ha) |
| Herbal infusions (leaves) | NEU F                  | Annual dicotyledonous weeds       | EC          | 480 g/L    | Spray         | 1                           |                | 0.960 kg/ha               | n.a.            | Authorised GAP assessed in MRL review (EFSA, 2012) |
| NEU (DE) F             | St. John's wort; woolly foxglove | Annual dicotyledonous weeds       | EC          | 480 g/L    | Spray         | 11–15                      | 1              | 240–480                  | 200–400         | 0.96 kg/ha        | GAP assessed in the EFSA peer review (EFSA, 2015) |

Bold: GAPs assessed in the framework of the MRL review (EFSA, 2012).
GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; a.s.: active substance; SL: soluble concentrate; SG: water-soluble granule; EC: emulsifiable 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 formulation types and international coding system.
<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.
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 |
|-----------------------------------|-------------|---------|----------------|----------------|----------------|
| Root crops                        | Potatoes    | Foliar 1.12 + 1.12 kg/ha, 21-day interval | 41             | Radiolabelled active substance: phenyl-¹⁴C-bentazone (EFSA, 2012; Netherlands, 2013) |
| Cereals/ grass                    | Rice        | Foliar, 1 × 1 kg/ha | 26, 63         | Radiolabelled active substance: phenyl-¹⁴C-bentazone (EFSA, 2012; Netherlands, 2013) |
|                                   | Maize       | Foliar, 1 × 1.68 kg/ha | 0, 7, 14, 21, 42, 63, 126 | Radiolabelled active substance: phenyl-¹⁴C-bentazone (EFSA, 2012; Netherlands, 2013) |
|                                   | Wheat       | Foliar, 1 kg/ha, BBCH 31-32 | 20, 83         | Radiolabelled active substance: phenyl-¹⁴C-bentazone (EFSA, 2013; EFSA, 2015) |
|                                   |             | Treatment regime: see comments | 4 months       | Wheat planted after the harvest of potatoes, which were treated at 1.5 kg/ha 30 days post planting. Wheat was sown 2 months after the harvest of potatoes (160 DAT of potatoes) and treated with 1.5 kg/ha Radiolabelled active substance: phenyl-¹⁴C-bentazone (Netherlands, 2013) |
| Pulses/oilseeds                  | Soybean     | Foliar, 1 × 2.24 kg/ha | 9, 36, 93 DAT | Radiolabelled active substance: phenyl-¹⁴C-bentazone (Netherlands, 2013) |
|                                   |             | Foliar, 1.68 + 1.12 kg/ha, 45 day interval | 11, 48         | Radiolabelled active substance: phenyl-¹⁴C-bentazone (EFSA, 2012; Netherlands, 2013) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application | PBI (DAT) | Comment/Source |
|--------------------------------------|-------------|---------|-------------|-----------|----------------|
| Root/tuber crops                     | Radish      | Soil, 1 kg/ha | 30, 120, 365 | Radiolabelled active substance: ¹⁴C-phenyl bentazone (EFSA, 2015) |
| Leafy crops                         | Lettuce     |         |             |           |                 |
| Cereal (small grain)                 | Spring wheat|         |             |           |                 |
## Processed Commodities (Hydrolysis Study)

| Conditions | Stable? | Comment/Source |
|------------|--------|----------------|
| Pasteurisation (20 min, 90°C, pH 4) | Not investigated | Not triggered (EFSA, 2015) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | | |
| Sterilisation (20 min, 120°C, pH 6) | | |

### Can a General Residue Definition Be Proposed for Primary Crops?
- **Yes**
  - All crop categories for foliar application (EFSA, 2015)

### Rotational Crop and Primary Crop Metabolism Similar?
- **Yes**
  - The radioactivity is mainly characterized as polar fractions with incorporation into the natural plant constituents. A specific residue definition is not deemed necessary (EFSA, 2015)

### Residue Pattern in Processed Commodities Similar to Residue Pattern in Raw Commodities?
- **Not investigated**

### Plant Residue Definition for Monitoring (RD-Mo)
- MRL review (EFSA, 2012), Regulation (EC) No 396/2005: Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone
- EFSA peer review (EFSA, 2015): Bentazone (all crop categories for foliar treatment)

### Plant Residue Definition for Risk Assessment (RD-RA)
- MRL review (EFSA, 2012): Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone
- EFSA peer review (EFSA, 2015): Sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone (provisional, pending clarification on the identity of fraction M3 in wheat straw from the wheat metabolism study)

### Conversion Factors for Enforcement and Risk Assessment Residue Definition Derived by the Peer Review from Residue Trials:
- Potatoes: 2
- Sweet corn: 9
- Pulses, dry: 2
- Maize, sorghum: 2.8
- Herbal infusions: 1.9

### Methods of Analysis for Monitoring of Residues (Analytical Technique, Crop Groups, LOQs)
- Matrices with high water content (onions, peas whole plant), high oil content (soybean), high acid content (oranges), high protein content (peas), dry matrices (maize grain): LC–MS/MS, individual LOQ 0.01 mg/kg for bentazone, 6-hydroxy- and 8-hydroxy bentazone (free and conjugated) (EFSA, 2015)

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DAT: days after treatment; BBCH: growth stages of mono- and dicotyledonous plants; PBI: plant-back interval; MRL: maximum residue level; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
### Stability of residues in plants

| Plant products (available studies) | Category          | Commodity       | T (°C) | Stability period | Compounds covered | Comment/Source                  |
|-----------------------------------|-------------------|-----------------|--------|------------------|-------------------|---------------------------------|
|                                   | High water content| Maize green plant| –20    | 2 Years          | Bentazone, 6-hydroxy-bentazone, 8-hydroxy-bentazone | Netherlands (2013); EFSA (2015) |
|                                   | High oil content  | Flax seed       | –20    | 2 Years          | Bentazone, 6-hydroxy-bentazone, 8-hydroxy-bentazone | Netherlands (2013); EFSA (2015) |
|                                   | High protein content| Peas          | –20    | 2 Years          | Bentazone, 6-hydroxy-bentazone, 8-hydroxy-bentazone | Netherlands (2013); EFSA (2015) |
|                                   | Dry/High starch   | Maize grain     | –20    | 2 Years          | Bentazone, 6-hydroxy-bentazone, 8-hydroxy-bentazone | Netherlands (2013); EFSA (2015) |
### B.1.2. Magnitude of residues in plants

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

| Commodity (to which GAP refers) | 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) | CF(d) |
|---------------------------------|------------------|---------------------------------------------------------------|----------------|------------------------|---------------|-----------------|-------|
| **Enforcement residue definition** (EFSA, 2012): Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone | | | | | | | |
| **Risk assessment residue definition** (EFSA, 2012): Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone | | | | | | | |
| **Potatoes** | NEU | 2 × < 0.03; 0.043; 5 × < 0.06; 0.06; 0.077 | Residue trials on potatoes compliant with the GAP | 0.15 | 0.08 | 0.06 | n/a |
| | NEU | 5 × < 0.03; 2 × 0.04; 0.08 | | | | | |
| | SEU | | | | | | |
| **Herbal infusions (leaves)** | NEU | Option 1) Use pattern in trials from the Renewal Assessment Report (Netherlands, 2013) and the Evaluation Report submitted for the MRL review (Germany, 2012): 1 × 0.96 kg/ha, BBCH 10–18, PHI 111–145 days Woolly foxglove (dry leaves): 2 × < 0.066; < 0.155 Peppermint (dry leaves): 2 × < 0.05 | If the applicant confirms the BBCH of ca. 10–18 for the authorised GAP, a MRL proposal of 0.3* mg/kg is derived | 0.3* | 0.16 | 0.07 | n/a |
| | NEU | Option 2) Use pattern in trials submitted for the MRL review (EFSA, 2012): 1 × 0.96 kg/ha, PHI 35–75 days Peppermint: < 0.05; 0.06; 0.07 St. John's wort: 2 × < 0.05 | If the applicant confirms the minimum PHI interval of 35 days, the MRL proposal of 0.1* mg/kg is appropriate Extrapolation to the whole group of dried leaves of herbal infusions would be possible | 0.1* | 0.07 | 0.05 | n/a |
| **Enforcement residue definition** (EFSA, 2015): Bentazone | | | | | | | |
| **Risk assessment residue definition** (EFSA, 2015): Sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone | | | | | | | |
| **Potatoes** | NEU | Mo: 3 × < 0.01; 0.011; 5 × < 0.02; 0.02 RA: 2 × < 0.02 (0.019); 0.034; 5 × < 0.04; 0.04; 0.068 | Residue trials on potatoes compliant with the GAP | 0.07 | 0.02 | 0.02 | 2 |
| | SEU | Mo: 5 × < 0.01; 2 × 0.02; 0.06 RA: 5 × < 0.02; 2 × 0.03; 0.07 | | | | | |
| Commodity (to which GAP refers) | 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) | CF(d) |
|--------------------------------|------------------|---------------------------------------------------------------|----------------|------------------------|--------------|---------------|-------|
| Herbal infusions (leaves)      | NEU              | Option 1) Use pattern in trials from the Renewal Assessment Report (Netherlands, 2013) and the Evaluation Report submitted for the MRL review (Germany, 2012): 1 × 0.96 kg/ha, BBCH 10–18, PHI 111–145 days Woolly foxglove (dry leaves): Mo: 2 × < 0.019; < 0.062 RA: 2 × < 0.04; < 0.101 Peppermint: residue concentration for individual components of the residue definition are not available. Option 2) Use pattern in trials submitted for the MRL review (EFSA, 2012): 1 × 0.96 kg/ha, PHI 35–75 days Peppermint, St. John’s wort: residue concentrations for the individual components of the residue definition are not available | Insufficient number of residue trials available | – | – | – |

MRL: maximum residue level; GAP: Good Agricultural Practice; OECD: Organisation for Economic Co-operation and Development; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval; Mo: monitoring; RA: risk assessment.

* Refers to the value at the LOQ.

(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 refers to the whole commodity and not to the edible portion.

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

(d): Conversion factor to recalculate residues according to the residue definition for monitoring to the residue definition for risk assessment.
B.1.2.2. Residues in rotational crops
Not relevant for the current assessment.

B.1.2.3. Processing factors
Not relevant for the current assessment.

B.2. Residues in livestock

### Risk assessment residue definition (plant commodities):

1. Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone

| Livestock group | Dietary burden expressed in | Maximum dietary burden (mg/kg bw d) MRL review (EFSA, 2012) | Most critical commodity(a) | Trigger exceeded (Y/N) |
|-----------------|-----------------------------|-------------------------------------------------------------|-----------------------------|------------------------|
|                 | mg/kg bw per day | mg/kg DM | Median | Maximum | Median | Maximum |
| Dairy ruminant  | 0.99 | 1.31 | 27.53 | 36.36 | 1.31 | Grass (fresh) | Y |
| Meat ruminant   | 1.17 | 1.54 | 27.16 | 35.88 | 1.54 | Grass (fresh) | Y |
| Poultry         | 0.014 | 0.012 | 0.196 | 0.22 | 0.016 | Wheat bran | Y |
| Pig             | 0.178 | 0.23 | 4.44 | 5.83 | 0.237 | Grass silage | Y |

bw: body weight; DM: dry matter; MRL: maximum residue level.
(a): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.

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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

#### Time needed to reach a plateau concentration in milk and eggs (days)

- Milk: 17–21 days
- New feeding study (Netherlands, 2018)
- Eggs: Not investigated

#### Metabolism in rat and ruminant similar

- Yes
- EFSA (2015)

#### Can a general residue definition be proposed for animals?

- Yes
- Residue definition differs for milk (EFSA, 2015)

#### Animal residue definition for monitoring (RD-Mo)

- MRL review (EFSA, 2012), Regulation (EC) No 396/2005:
  - Sum of bentazone and the metabolite 6-hydroxy bentazone (free and conjugated), expressed as bentazone
- **EFSA peer review (EFSA, 2015):**
  - Milk: 6-hydroxy-bentazone (sulphate) conjugates, expressed as bentazone
  - Other animal commodities, except milk: 6-hydroxy-bentazone alone, expressed as bentazone
  - (provisional, pending the outcome of the requested ruminants feeding study with bentazone and 6-hydroxy-bentazone mixture)

#### Animal residue definition for risk assessment (RD-RA)

- MRL review (EFSA, 2012):
  - Sum of bentazone and the metabolite 6-hydroxy bentazone (free and conjugated), expressed as bentazone
EFSA peer review (EFSA, 2015): Sum of bentazone, 6-hydroxy-bentazone and their conjugates, expressed as bentazone

| Fat soluble residues | No | According to the feeding studies submitted under the current assessment |

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

- LC–MS/MS; individual LOQ 0.01 mg/kg for bentazone, 6-hydroxy- and 8-hydroxy-bentazone in eggs, meat, liver, fat, milk. ILV available
- LC–MS/MS; LOQ 0.02 mg/kg for bentazone, 6-hydroxy- and 8-hydroxy-bentazone in eggs, muscle, liver, fat/skin, milk. No ILV available (EFSA, 2015)

MRL: maximum residue level; LC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation

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

| Animal products (available studies) | Animal | Commodity | T (°C) | Stability period | Compounds covered | Comment/Source |
|---|---|---|---|---|---|---|
| | Bovine | Muscle | –20 | 120 Days | Bentazone | Netherlands (2018) |
| | | | –20 | – | 6-Hydroxy-bentazone | The stability could not be demonstrated (Netherlands, 2018) |
| | Liver | | –20 | 316* Days | Bentazone | Netherlands (2018) |
| | | | | 120 Days | 6-Hydroxy-bentazone | |
| | Kidney | | –20 | 305* Days | Bentazone | |
| | | | | 125 Days | 6-Hydroxy-bentazone | |
| | Milk | | –20 | 121 Days | Bentazone | Netherlands (2018) |
| | | | | 372* Days | 6-Hydroxy-bentazone | Netherlands (2018) |
| | Fat | | –20 | 124 Days | Bentazone | Netherlands (2018) |
| | | | | 249* Days | 6-Hydroxy-bentazone | Netherlands (2018) |

*: Demonstrated in re-analysing incurred samples (high-dose animals), stored frozen at –20°C as part of the validation of analytical method (Netherlands, 2018).
### B.2.3. Magnitude of residues in livestock

#### B.2.3.1. Summary of the residue data from livestock feeding studies

| Animal commodity | Dietary burden (mg/kg) | Estimated value at 1N | MRL proposal (mg/kg) | CF<sub>c</sub> |
|------------------|------------------------|-----------------------|----------------------|--------------|
|                  | Mean                   | Highest               | STMR (mg/kg)         |              |
|                  |                        |                       | HR (mg/kg)           |              |
| **Cattle (meat)**|                        |                       |                      |              |
| Muscle           | 1.167                  | 1.543                 | 0.02                 | 0.02*        |
| Fat              |                        |                       | 0.02                 | 0.02         |
| Liver            |                        |                       | 0.027                | 0.05         |
| Kidney           |                        |                       | 0.098                | 0.3          |
| **Cattle (dairy only)**|                 |                       |                      |              |
| Milk<sup>a</sup> | 0.99                   | 1.309                 | 0.02                 | 0.03         |
| **Swine<sup>b</sup>**|                |                       |                      |              |
| Muscle           | 0.177                  | 0.233                 | 0.02                 | 0.02*        |
| Fat              |                        |                       | 0.02                 | 0.02         |
| Liver            |                        |                       | 0.02                 | 0.02         |
| Kidney           |                        |                       | 0.02                 | 0.03         |

STMR: supervised trials median residue; HR: highest residue; MRL: maximum residue level; CF: conversion factor for enforcement to risk assessment residue definition; n/a: not applicable.

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

(a): Highest residue level from day 1 to day 28 (daily mean of 3 cows).

(b): Since extrapolation from cattle to other ruminants and swine is acceptable, results of the livestock feeding study on ruminants were relied upon to derive the MRL and risk assessment values in sheep and swine.
**B.3. Consumer risk assessment**

| ARfD | 1 mg/kg bw (EFSA, 2015, European Commission, 2018) |
|------|--------------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Potatoes: 1.2% of ARfD  
Milk (cattle): 0.2% of ARfD  
Edible offal (bovine): 0.2% of ARfD  
Other commodities under assessment: ≤ 0.1% of the ARfD |

**Assumptions made for the calculations**

- The calculation is based on the highest residue levels expected in raw agricultural commodities, for which the authorised uses were reported in the MRL review and which are supported by residue data. For livestock commodities, the highest residues according to the feeding study reflecting the calculated dietary burden were used as input values.
- The calculations were performed for the residue definitions derived in the framework of the MRL review.

| ADI | 0.09 mg/kg bw per day (EFSA, 2015; European Commission, 2018) |
|-----|---------------------------------------------------------------|
| Highest IEDI, according to EFSA PRIMo | 1.6% ADI (NL child diet)  
Contribution of commodities assessed: Potatoes: 0.4% of ADI (NL child diet)  
Milk (cattle): 0.9% of ADI (FR toddler) |

**Assumptions made for the calculations**

- The calculation is based on the median residue levels expected in raw agricultural commodities, for which the authorised uses were reported in the MRL review and which are supported by residue data. For livestock commodities, the median residues according to the feeding study reflecting the calculated dietary burden were used as input values.
- The calculations were performed for the residue definitions derived in the framework of the MRL review.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; MRL: maximum residue level; ADI: acceptable daily intake; IEDI: international estimated daily intake.

**B.4. Recommended MRLs**

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|--------|-----------|----------------|--------------|---------------------------|
| 0211000 | Potato | 0.2 (ft 1) | 0.15 | The data gap identified by EFSA concerning residue trials has not been addressed |

*Existing enforcement residue definition:* Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy- bentazone (free and conjugated), expressed as bentazone.

*General considerations:*

Following the renewal of the approval of bentazone, which was performed after the MRL review, the peer review proposed different residue definitions in plant commodities: ‘bentazone’ for enforcement and ‘the sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone’ for the risk assessment.

The risk assessment residue definition was proposed on provisional basis, pending the clarification of the unidentified fraction in wheat metabolism studies. Moreover, the available toxicological information on metabolite 6-hydroxy-bentazone was found to be incomplete to conclude on the toxicological reference values. Once the relevant data gaps identified by the peer review are addressed, a review of the existing EU MRLs for bentazone would be required.
### Evaluation of confirmatory data following the Article 12 MRL review for bentazone

| Code(a) | Commodity | Existing MRL(b) | Proposed MRL | Conclusion/recommendation |
|---------|-----------|----------------|--------------|----------------------------|
| 0270060 | Leek      | 0.15 (ft 1)    | 0.03*        | Adjusted, less critical SEU/NEU GAPs were proposed which were sufficiently supported by residue data. The previous consumer risk assessment was updated using revised toxicological reference values. No consumer intake concerns were identified. |
| 0632000 | Leaves of herbal infusions | 0.1* (ft 2) | Risk management decision | The data gap identified by EFSA concerning residue trials has not been addressed. The lowering of the MRL to the LOQ is proposed. Member States should ensure that the existing uses on leeks are revoked. |
| 1011010 | Swine muscle | 0.02* (ft 3) | No new proposal | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate. |
| 1011020 | Swine fat | 0.15 (ft 4) | 0.02* risk management decision | The data gaps have been sufficiently addressed. According to the new feeding study, a lower MRL of 0.02* mg/kg would be sufficient. |
| 1011030 | Swine liver | 0.02* (ft 3) | No new proposal | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate. |
| 1011040 | Swine kidney | 0.05 (ft 3) | 0.03 risk management decision | The data gaps have been sufficiently addressed. According to the new feeding study, a lower MRL of 0.03 mg/kg would be sufficient. |

**Existing enforcement residue definition:** Sum of bentazone, its salts and 6-hydroxy (free and conjugated), expressed as bentazone. Except for all animal commodities, except milk: 6-hydroxy-bentazone, expressed as bentazone. (c)

**General considerations:** Following the renewal of the approval of bentazone, which was performed after the MRL review, the peer review proposed different enforcement residue definition as '6-hydroxy-bentazone, expressed as bentazone' in all animal commodities, except in milk as '6-hydroxy-bentazone (sulfate) conjugates, expressed as bentazone'. The risk assessment residue definition was not modified. As soon as the required information regarding the toxicity of metabolite 6-hydroxy-bentazone is provided and the risk assessment residue definition for plant commodities is confirmed, the livestock dietary burden shall be recalculated, using the OECD methodology and the existing EU MRLs should be reviewed accordingly.
| Code<sup>(a)</sup> | Commodity        | Existing MRL<sup>(b)</sup> | Proposed MRL            | Conclusion/recommendation                                                                                                                                                                                                 |
|------------------|------------------|----------------------------|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1011050          | Swine edible offal | 0.15 ft<sup>3</sup>       | Risk management decision | To derive the MRL for edible offal, usually risk managers extrapolate the MRL from muscle, fat, liver or kidney, whatever is the highest value. Considering the modifications for the animal commodities, the existing MRL for edible offal should be revised accordingly |
| 1012010          | Muscle:          | 0.02* ft<sup>3</sup>      | No new proposal         | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate                                                                                                       |
| 1013010          | Bovine          |                            |                         |                                                                                                                                                                                                                        |
| 1014010          | Sheep           |                            |                         |                                                                                                                                                                                                                        |
| 1015000          | Goat            |                            |                         |                                                                                                                                                                                                                        |
| 1012020          | Fat:            | 1.0 ft<sup>4</sup>        | 0.03                    | The data gaps have been sufficiently addressed. According to the new feeding study, a lower MRL of 0.03 mg/kg would be sufficient                                                                                       |
| 1013020          | Bovine          |                            |                         |                                                                                                                                                                                                                        |
| 1014020          | Sheep           |                            |                         |                                                                                                                                                                                                                        |
| 1015020          | Goat            |                            |                         |                                                                                                                                                                                                                        |
| 1012030          | Liver:           | 0.02* ft<sup>3</sup>      | 0.05                    | The data gaps have been sufficiently addressed. According to the new feeding study, a higher MRL would be required                                                                                                    |
| 1013030          | Bovine          |                            |                         |                                                                                                                                                                                                                        |
| 1014030          | Sheep           |                            |                         |                                                                                                                                                                                                                        |
| 1015030          | Goat            |                            |                         |                                                                                                                                                                                                                        |
| 1012040          | Kidney:         | 0.3 ft<sup>3</sup>        | No new proposal         | The data gaps have been sufficiently addressed. According to the new feeding study, the existing MRL is appropriate                                                                                                       |
| 1013040          | Bovine          |                            |                         |                                                                                                                                                                                                                        |
| 1014040          | Sheep           |                            |                         |                                                                                                                                                                                                                        |
| 1015040          | Goat            |                            |                         |                                                                                                                                                                                                                        |
| 1012050          | Edible offal:    | 1.0 ft<sup>3</sup>        | Risk management decision | To derive the MRL for edible offal, usually risk managers extrapolate the MRL from muscle, fat, liver or kidney, whatever is the highest value. Considering the modifications for the animal commodities, the existing MRL for edible offal should be revised accordingly |
| 1013050          | Bovine          |                            |                         |                                                                                                                                                                                                                        |
| 1014050          | Sheep           |                            |                         |                                                                                                                                                                                                                        |
| 1015050          | Goat            |                            |                         |                                                                                                                                                                                                                        |
| 1020000          | Milk            | 0.02* ft<sup>3</sup>      | 0.03                    | The data gaps have been sufficiently addressed. According to the new feeding study, a higher MRL would be required                                                                                                    |

MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; GAP: good agricultural practice; BBCH: growth stages of mono- and dicotyledonous plants; PHI: preharvest interval.  
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).  
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.  
(b): Existing EU MRL and corresponding footnote on confirmatory data.  
(c): According to feeding study results, the residue is not considered fat soluble.  
ft 5: The European Food Safety Authority identified some information on residue trials as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps No 1 and 4).  
ft 6: The European Food Safety Authority identified some information on analytical methods and GAP parameters as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps Nos 8 and 9).  
ft 7: The European Food Safety Authority identified some information on storage stability and feeding studies as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gaps Nos 11 and 12).  
ft 8: The European Food Safety Authority identified some information on storage stability, feeding studies and analytical methods for fat as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 29 October 2016, or, if that information is not submitted by that date, the lack of it (Footnote related to data gap No 10).
Appendix C – Pesticide Residue Intake Model (PRIMo)

### Bentazone

| Toxicological endpoints | Status of the active substance: | Code no. |
|-------------------------|--------------------------------|----------|
|                         | Included                       |          |
| LOQ (mg/kg bw)          | Proposed LOQ                   | 8.63     |

| ADI (mg/kg bw per day) | ARfD (mg/kg bw) | Source of ADI: | Source of ARfD: | Year of evaluation: |
|------------------------|-----------------|----------------|-----------------|---------------------|
| 0.09                   | 1               | EC             | EC              | 2018                |

| Year of evaluation: | 02 |

| No of diets exceeding ADI: | 0 --- 2 |

#### Chronic risk assessment–refined calculations

| Commodity/group of commodities | TMDI (range) in % of ADI | minimum–maximum |
|-------------------------------|--------------------------|-----------------|
| Milk and cream                | 0.2                      | 0.3             |
| Wheat                         | 0.1                      | 0.2             |
| 0.4 Potatoes                  | 0.2                      | 0.3             |
| 0.3 Milk and cream            | 0.2                      | 0.3             |
| 0.3 Milk and cream            | 0.2                      | 0.3             |
| 0.2 Potatoes                  | 0.2                      | 0.3             |
| 0.2 Wheat                     | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |
| 0.1 Milk and cream            | 0.1                      | 0.2             |
| 0.1 Potatoes                  | 0.1                      | 0.2             |

### Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Bentazone is unlikely to present a public health concern.
### Acute risk assessment/children–refined calculations

The acute risk assessment is based on the ARfD.

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

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

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

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

**No of commodities for which ARfD/ADI is exceeded:**

For each commodity, the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS, an average European unit weight was used for the IESTI calculation.

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

#### No of critical MRLs (IESTI 1)

| IESTI 1 | **l** | **l** |
|---------|-------|-------|
| **No of critical MRLs (IESTI 1)** | --- | --- |

#### No of critical MRLs (IESTI 2)

| IESTI 2 | **l** | **l** |
|---------|-------|-------|
| **No of critical MRLs (IESTI 2)** | --- | --- |

### Conclusion

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

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

For processed commodities, no exceedance of the ARfD/ADI was identified.
# 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                | Input value (mg/kg) | Comment                |
| Grass (fresh and silage)   | 5.45                  | STMR (EFSA, 2012)      | 7.20                | HR (EFSA, 2012)        |
| Grass hay                  | 21.80                 | STMR (EFSA, 2012)      | 28.80               | HR (EFSA, 2012)        |
| Maize (corn) forage        | 0.92                  | STMR (EFSA, 2012)      | 1.80                | HR (EFSA, 2012)        |
| Wheat, rye grain           | 0.06                  | STMR (EFSA, 2012)      | 0.06                | STMR (EFSA, 2012)      |
| Barley, oat grain          | 0.06                  | STMR (EFSA, 2012)      | 0.06                | STMR (EFSA, 2012)      |
| Wheat and rye bran         | 0.48                  | STMR (EFSA, 2012)      | 0.48                | STMR (EFSA, 2012)      |
| Wheat, rye straw           | 0.09                  | STMR (EFSA, 2012)      | 0.10                | HR (EFSA, 2012)        |
| Barley, oat straw          | 0.16                  | STMR (EFSA, 2012)      | 0.65                | HR (EFSA, 2012)        |
| Beans, peas, dry           | 0.06                  | STMR (EFSA, 2012)      | 0.06                | STMR (EFSA, 2012)      |
| Potato                     | 0.06                  | STMR                   | 0.08                | HR                     |
| Linseed                    | 0.06                  | STMR (EFSA, 2012)      | 0.06                | STMR (EFSA, 2012)      |
| Linseed meal               | 0.12                  | STMR (EFSA, 2012)      | 0.12                | STMR (EFSA, 2012)      |

Risk assessment residue definition (plants): Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone.

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

## D.2. Consumer risk assessment

| Commodity                | Chronic risk assessment | Acute risk assessment |
|--------------------------|-------------------------|-----------------------|
|                          | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Residue definition for risk assessment: Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone |
| Potatoes                 | 0.06                    | STMR                  | 0.08                | HR                    |
| Lentils (fresh)          | 0.03                    | Median residue ((peas/beans (without pods)) (EFSA, 2012) | 0.04                | Highest residue ((peas/beans (without pods)) (EFSA, 2012) |
| Leaves of herbal infusions | 0.07                  | STMR (option 1)       | 0.16                | HR (option 1)         |
| Other plant products     | STMR                    | EFSA (2012)           | Not under assessment in this reasoned opinion |

Residue definition for risk assessment: Sum of bentazone and the conjugates of 6-hydroxy-bentazone, expressed as bentazone.

| Swine, bovine, sheep, goat, equine, other farm animal meat | 0.02 | STMR | 0.02 | HR |
| Swine fat, Swine liver                                     | 0.02 | STMR | 0.02 | HR |
| Swine kidney, Swine edible offal                           | 0.02 | STMR | 0.024| HR |
| Bovine, sheep, goat, equine, other farm animal meat       | 0.02 | STMR | 0.02 | HR |
### Commodity

| Commodity                                                                 | Chronic risk assessment | Acute risk assessment |
|---------------------------------------------------------------------------|-------------------------|-----------------------|
|                                                                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment |
| Bovine, sheep, goat, equine, other farm animal fat                        | 0.02                    | STMR                  | 0.029               | HR      |
| Bovine, sheep, goat, equine, other farm animal liver                      | 0.027                   | STMR                  | 0.043               | HR      |
| Bovine, sheep, goat, equine, other farm animal kidney and Bovine, sheep, goat, equine, other farm animal edible offal | 0.098                   | STMR                  | 0.21                | HR      |
| Milk                                                                      | 0.02                    | STMR                  | 0.02                | STMR    |

STMR: supervised trials median residue; HR: highest residue.
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|-----------------------------------------------|----------------------------------|
| Bentazone                     | 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide  
CC (C)N1C(=O)c2cccccc2NS1(=O)=O  
ZOMSMJKLGFBRBS-UHFFFAOYSA-N | ![Structural formula of Bentazone](image1) |
| 8-hydroxy-bentazone           | 8-hydroxy-3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide  
CC(C)N1C(=O)c2ccccc(O)c2NS1(=O)=O  
WJJLUCLOKVGHGK-UHFFFAOYSA-N | ![Structural formula of 8-hydroxy-bentazone](image2) |
| 6-hydroxy-bentazone           | 6-hydroxy-3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide  
CC(C)N1C(=O)c2cc(O)ccc2NS1(=O)=O  
PVKWIOBXPPFARA-UHFFFAOYSA-N | ![Structural formula of 6-hydroxy-bentazone](image3) |

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 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).