Modification of the existing maximum residue levels for bentazone in beans and peas with and without pods

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted a request to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) for bentazone in beans and peas with and without pods. The data submitted in support of the request were found to be sufficient to derive MRL proposals for peas with pods. Results from the residue trials indicated that there is no need to modify the existing MRLs for beans with pods, beans without pods and peas without pods. Adequate analytical methods for enforcement are available to control the residues of bentazone and its metabolites in the commodity under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. EFSA concluded that the proposed use of bentazone on peas with pods will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health for parent bentazone. The risk assessment however is indicative and affected by additional, non-standard uncertainties resulting from the insufficient information related to the toxicological properties for 6-hydroxy-bentazone in the wheat metabolism study.

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Keywords: bentazone, 6-hydroxy-bentazone, beans and peas with and without pods, herbicide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing maximum residue levels (MRLs) for the active substance bentazone in beans and peas with and without pods. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 19 July 2020. To accommodate for the intended uses of bentazone, the EMS proposed to raise the existing MRLs from 0.3 to 0.4 mg/kg in beans and peas with pods and from 0.05 to 0.15 in beans and peas without pods, respectively.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS and the applicant. On 21 September 2020 the applicant submitted the requested clarification.

Based on the conclusions derived by EFSA in the framework of the renewal of approval under Regulation (EC) No 1107/2009, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of bentazone following foliar application was investigated in crops belonging to the groups of root crops, cereals and pulses/oilseeds. Metabolic patterns in the different studies were shown to be similar and the MRL review concluded on a residue for enforcement and risk assessment in all plant commodities as the sum of bentazone and the conjugates of metabolites 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone. The metabolism of bentazone in rotational crops (radish, lettuce and wheat) indicated that a specific residue definition is not necessary for rotational crops. In the framework of the European Union (EU) pesticides peer review, a significant unidentified fraction (M3) was found in an additional metabolism study with wheat and further attempts for identification of M3 were considered necessary. New information on the identity of fraction M3 has not been provided to EFSA. The lack of this information is not expected to affect specifically the current assessment as the forages of beans and peas with and without pods are not used as livestock feed in Europe.

Based on the metabolic pattern identified in metabolism studies and the toxicological significance of metabolites, the peer review on the renewal of the approval proposed ‘bentazone’ as the relevant residue for enforcement. For the risk assessment, a residue definition was provisionally proposed as ‘sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone’.

As the residue definitions derived by the peer review are not yet enforced, EFSA derived MRL proposals for the enforcement residue definition established in the Regulation (EC) No 396/2005 (sum of bentazone, its salts, 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone). Anticipating possible implementation of the residue definition for enforcement proposed in the framework of the EU pesticides peer review, EFSA derived also MRL proposals based on the residue definition restricted to parent bentazone. The risk assessment was performed for the residue definition proposed in the MRL review that comprises in addition to 6-hydroxy-bentazone (free and conjugated) also 8-hydroxy-bentazone (free and conjugated), which is considered to give a more conservative result.

Sufficiently validated analytical methods based on liquid chromatography with tandem mass spectrometry (LC–MS/MS) are available to quantify residues in the crops assessed in this application according to the enforcement residue definition. The methods enable quantification of each individual analyte at or above 0.01 mg/kg in the crops assessed (limit of quantification (LOQ)). The available residue trials are sufficient to derive an MRL proposal of 0.8 mg/kg for peas with pods based on the more critical southern Europe (SEU) use. Results from the residue trials submitted indicated that there is no need to modify the existing MRLs for beans with pods, beans without pods and peas without pods.

Specific studies investigating the nature (hydrolysis studies) and magnitude of bentazone and its relevant metabolites in processed commodities are currently not required, as the total theoretical maximum daily intake (TMDI) is below the trigger value of 10% of the acceptable daily intake (ADI).

The occurrence of bentazone residues in rotational crops was investigated in the framework of the EU pesticides peer review and the MRL review. Based on the available information, it was concluded that significant residue levels are unlikely to occur in rotational crops, provided that the active substance is used according to the proposed Good Agricultural Practice (GAP).

Residues of bentazone in commodities of animal origin were not assessed since the crops under consideration in this MRL application are normally not fed to livestock.
The toxicological profile of bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone was assessed during the renewal of the approval process of bentazone. New toxicological reference values were derived for bentazone as an ADI of 0.09 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 1 mg/kg bw. The peer review also concluded that the reference values of the parent can be applied to the metabolite 8-hydroxy-bentazone. Regarding the 6-hydroxy-bentazone metabolite, insufficient toxicological information on the general toxicity was available to draw a final conclusion whether the toxicological reference values of the parent bentazone are applicable also to the metabolite 6-hydroxy-bentazone. No new information has been submitted with the MRL application. Hence, EFSA performed an indicative dietary risk assessment assuming that the toxicity of the metabolite 6-hydroxy-bentazone is comparable to the parent compound.

The consumer risk assessment was performed with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo). The long-term exposure assessment was performed taking into account the STMR value derived from the residue trials on peas with pods leading to a new MRL proposal. The other input values selected were the risk assessment values derived by EFSA in previous opinions and corresponding to the MRLs as established in the MRL Regulation. 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. The acute exposure assessment was performed only for peas with pods leading to the new MRL proposal, considering the highest residue value derived from the residue trials submitted. An update of the consumer risk assessment for beans with and without pods and peas without pods was not necessary. The conclusion reached in the previously performed consumer risk assessments is still valid.

EFSA concluded that the proposed use of bentazone on peas with pods will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health for parent bentazone. The risk assessment however is indicative and affected by additional, non-standard uncertainties resulting from insufficient information related to the toxicological properties for 6-hydroxy-bentazone.

EFSA proposes to amend the existing MRLs as reported in the summary table below. Full details of all endpoints and the consumer risk assessment can be found in Appendices B-D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|-------------------------|-----------------------|
| 260010  | Beans with pods | 0.3 | No new proposal | The submitted data do not provide evidence that the existing MRL has to be modified |
| 260030  | Peas with pods | 0.3 | 0.8/0.01* | Further risk management considerations required |
|         |            | | | The MRL proposal reflects the more critical residue situation of the SEU use. According to the indicative dietary risk assessment, no consumer intake concerns were identified. Further risk management considerations required, considering that the toxicity of 6-hydroxy-bentazone is not fully characterised |
| 260020  | Beans without pods | 0.05 | No new proposal | The submitted data do not provide evidence that the existing MRL has to be modified |
| 260040  | Peas without pods | 0.05 | No new proposal | The submitted data do not provide evidence that the existing MRL has to be modified |

MRL: maximum residue level; SEU: southern Europe.
*: Indicates that the MRL is proposed at the limit of quantification.
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for bentazone in beans and peas with and without pods. The detailed description of the intended uses of bentazone, which are the basis for the current MRL application, is reported in Appendix A.

Bentazone is the ISO common name for 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide (IUPAC name). Bentazone is formulated and used as the sodium salt. The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Bentazone was evaluated for renewal of the approval in the framework of Regulation (EC) No 1107/2009 with the Netherlands designated as rapporteur Member State (RMS) for the representative uses as a foliar treatment on a variety of crops. The renewal assessment report (RAR) prepared by the RMS has been peer reviewed by EFSA (2015). The decision on the renewal of bentazone entered into force on 1 June 2018.

The EU MRLs for bentazone are established in Annex II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2012) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued one reasoned opinion on the evaluation of confirmatory data following the Article 12 MRL review for bentazone (EFSA, 2019b) and one reasoned opinion on the modification of MRLs for bentazone (EFSA, 2019c). The proposals from these reasoned opinions have been considered in recent MRL regulations.4

In accordance with Article 6 of Regulation (EC) No 396/2005, BASF SE submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to modify the existing MRLs for the active substance bentazone in beans and peas with and without pods. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 19 July 2020. To accommodate for the intended uses of bentazone, the EMS proposed to raise the existing MRLs from 0.3 to 0.4 mg/kg in beans and peas with pods and from 0.05 to 0.15 mg/kg in beans and peas without pods.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified points which needed further clarification, which were requested from the EMS and the applicant. On 21 September 2020 the applicant submitted the requested clarification.

EFSA based its assessment on the evaluation report submitted by the EMS (Netherlands, 2020), the renewal assessment report (RAR) and its addenda (Netherlands, 2013, 2015) prepared under Regulation (EC) 1107/2009, the conclusion on the peer review of the pesticide risk assessment of the active substance bentazone (EFSA, 2015), the Commission review report on bentazone (European Commission, 2018), the reasoned opinion on MRL review according to Article 12 of Regulation (EC) No 396/2005 and of its confirmatory data (EFSA, 2012, 2019b), as well as the conclusions from a previous EFSA opinion on bentazone (EFSA, 2019c).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2011). 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 546/2011.

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1 Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
2 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.
3 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, 16.3.2005, p. 1–16.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=pesticide.residue.selection&language=EN
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.
A selected 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, is presented in Appendix B.

The evaluation report submitted by the EMS (Netherlands, 2020) 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

The metabolism of bentazone in primary crops belonging to the groups of root and tuber crops (potatoes), cereals/grass (rice, maize, wheat) and pulses/oilseeds (soya beans, green beans) following foliar application has been investigated in the framework of the MRL review (EFSA, 2012) and the EU pesticides peer review (EFSA, 2015).

Parent bentazone was extensively metabolised in plants. It was rarely detected in any crop part (maximum 8% of the total radioactive residues (TRR)), except in wheat forage and straw (up to 56% TRR). The metabolite 6-hydroxy-bentazone in its conjugated form was identified in significant proportions, mainly in the feed commodities (24% TRR in maize forage and up to 41% TRR in wheat hay), whilst the glucoside conjugate of the 8-hydroxy-bentazone metabolite was detected in soya bean forage and in wheat straw, but at lower levels (28% TRR and 3% TRR, respectively). A major part of the radioactivity in the soya bean seeds, potato tuber and cereal grain was found to be incorporated into natural plant constituents (up to 70% TRR).

The results of new metabolism studies on foliar treated potato and wheat assessed in the EU pesticides peer review provided additional information on the metabolic pathway of bentazone (EFSA, 2015). In potato tubers, numerous fractions above the 10% TRR were recovered, which were not further identified as their actual levels were mostly below 0.01 mg eq/kg and because consisted mainly of a mixture of polar compounds. In wheat straw, a significant unidentified fraction M3 was found (57% TRR; 1.1 mg eq/kg) and further attempts for identification were considered necessary in the EU pesticides peer review.

The metabolic pathway of bentazone in plants consisted mainly of hydroxylation of the parent molecule to form the metabolites 6-hydroxy-bentazone and 8-hydroxy-bentazone, followed by an O-glycosylation conjugation step (EFSA, 2015).

For the intended uses, the metabolic behaviour in primary crops is sufficiently addressed.

1.1.2. Nature of residues in rotational crops

Beans and peas can be grown in rotation with other crops. During the renewal of the approval of bentazone (EFSA, 2015), the studies investigating the rate of degradation of bentazone in soil were assessed, indicating faster degradation of bentazone under field conditions (DT90 of 87 days) than under laboratory conditions (DT90 of 163 days). In soil a minor metabolite (N-methyl-bentazone, 2.4-5.7% of applied radioactivity (AR)) was identified, which exhibits higher persistence in soil than the parent bentazone (DT90 up to 508 days). A detailed assessment of the nature of bentazone residues in rotational crops is therefore considered relevant.

The metabolism of bentazone in rotational crops was investigated in the framework of the MRL review (EFSA, 2012) and the EU pesticides peer review for the renewal of the approval of bentazone (EFSA, 2015). In the confined rotational crop metabolism studies on leafy crops, root crops and cereals after a bare soil application of 14C-phenyl-labelled bentazone, the radioactive residues were characterised as polar fractions which were further incorporated into the natural compounds of the plant tissues (30% of TRR in wheat straw, up to 75% of TRR in wheat grain).

An additional metabolism study with foliar-treated wheat, grown as a rotational crop following the harvest of potatoes as primary crop previously treated with bentazone, was submitted in the framework of the renewal of the approval (EFSA, 2015). Wheat was either treated by foliar spraying with bentazone (1.5 kg/ha) or left untreated to assess the uptake from the soil as rotational crop. In wheat straw, a significant fraction (M3) (57% TRR, 1.1 mg eq/kg) was not identified. The EU pesticides peer review requested to characterise and identify this fraction (data gap). New information
related to the identity of the fraction M3 has not been provided in the framework of the current MRL application. The lack of this information is not expected to specifically affect the current assessment as forages of beans and peas are not used as livestock feed in Europe. However, EFSA reiterates that the data gap on the identity of the metabolite fraction M3 flagged in the renewal of approval is still open. Pending the clarification of this open issue, it cannot be excluded that in crops unidentified residues resulting from the uptake form the soil might occur.

The peer review concluded that a specific residue definition for rotational crops was not deemed necessary. However, the residue definition for risk assessment was provisionally proposed, pending on the clarification with regard to the identity of fraction M3 in wheat straw (EFSA, 2015).

1.1.3. Nature of residues in processed commodities

Standard hydrolysis studies with bentazone and its relevant metabolites representative for pasteurisation, boiling/cooking and sterilisation are not available. Such studies are not required, considering the low consumer exposure to bentazone residues resulting from the crops under assessment.

1.1.4. Methods of analysis in plants

Analytical methods for the determination of bentazone residues were assessed in the framework of the MRL review and the EU pesticides peer review for renewal of the approval of bentazone (EFSA, 2012, 2015). The methods are sufficiently validated for residues of bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone (free and conjugated) in plant matrices with high water content (onions, peas), high acid content (orange), high oil content (soya beans), dry/high protein content (dry peas) and dry/high starch content (maize grains) at the individual limits of quantification (LOQs) of 0.01 mg/kg (EFSA, 2015). The combined LOQ is 0.03 mg/kg.

The QuEChERS method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) is also available to dose the parent bentazone only with an LOQ of 0.005 mg/kg in high water content matrices (EFSA, 2012).

Thus, a sufficiently validated enforcement method is available for the determination of bentazone residues according to the current enforcement residue definition in beans and peas with and without pods (high water content matrices). The method includes a hydrolysis step to cover compounds included in the residue definition currently established in Regulation (EC) No 396/2005.

1.1.5. Storage stability of residues in plants

The storage stability of bentazone and 6-hydroxy-bentazone and 8-hydroxy-bentazone metabolites in plant matrices stored under frozen conditions was investigated in the framework of the EU pesticides peer review (EFSA, 2015). These studies demonstrated that bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone are stable for 2 years in high water content matrices (maize green plants), dry/high starch matrices (maize grain), dry/high protein matrices (pea seed) and high oil content matrices (linseed seed).

1.1.6. Proposed residue definitions

Based on the metabolic pattern identified in metabolism studies, the toxicological significance of metabolites and the capabilities of enforcement analytical methods, the following residue definitions were initially proposed by the MRL review for plant products (EFSA, 2012):

- Residue definition for both risk assessment and enforcement: Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone.

In Regulation (EC) No 396/2005, a slightly modified enforcement residue definition was established: Bentazone (Sum of bentazone, its salts, 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone).

However, in the framework of the renewal of the approval, the peer review concluded on the following residue definitions for all plant commodities after foliar applications (EFSA, 2015):
residue definition for enforcement: Bentazone
residue definition for risk assessment: Sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone⁷ (provisional).

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

Considering the new information provided, the EU pesticides peer review agreed on parent alone for enforcing bentazone residues, even though in pulses/oilseeds and in cereal grains the parent compound was hardly ever detected. The 8-hydroxy-bentazone metabolite generally occurred at low levels in crops (around the LOQ) and was excluded from the residue definition for risk assessment. The enforcement residue definition for plant commodities as proposed by the EU pesticides peer review is equivalent with the residue definition derived by the JMPR (EFSA, 2015).

Since a formal decision on the revision of the enforcement residue definition has not been taken, the residue definition implemented in Regulation (EC) No 396/2005 is relevant for the current application and MRL proposals are derived for the residue definition covering the sum of bentazone and 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone. Anticipating possible implementation of the residue definition for enforcement proposed in the framework of the EU pesticides peer review, EFSA derived also MRL proposals based on the residue definition restricted to parent bentazone.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of this MRL application, the applicant submitted several residue trials performed in beans and peas with and without pods. A number of trials were conducted in the same location as side-by-side trials with and without the use of an adjuvant as foreseen in the GAP. In some cases, the residue values were higher with the presence of this adjuvant but in other cases residue values were higher for the treatment without adjuvant. The results of the trials compliant with the intended GAPs are reported in Appendix B (Table B.1.2.1). Results from trials with or without adjuvant were reported separately and combined. When combined, the highest residue value from the side-by-side trials was selected.

The samples were analysed for the parent compound and the metabolites included in the residue definitions for enforcement and risk assessment. Residues of metabolite 8-hydroxy-bentazone were always below or at the LOQ, except in one sample (0.012 mg/kg); residues of 6-hydroxy-bentazone ranged from < LOQ of 0.01 to 0.11 mg/kg with a sample at 0.34 mg/kg. According to the assessment of the EMS, the analytical methods used were sufficiently validated and fit for purpose (Netherlands, 2020). The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated.

Beans and peas with pods

For beans with pods (major crop), the applicant provided eight residue trials from the northern Europe (NEU) and eight residue trials from the southern Europe (SEU). EFSA noted that all residue trials performed in NEU are independent and compliant with the intended GAP, while in two out of eight residue trials performed in the SEU (Trial L110251-05/06) the product was applied at a later growth stage than in the intended GAP (application at BBCH 25-60 vs the intended BBCH 12-25). EFSA disregarded these two trials as incompliant with the intended GAP, also noting that, the residues in beans from these trials were higher than in the remaining trials, indicating that later application affects the residue levels in the crop. Therefore, EFSA considers that for the SEU use the minimum number of trials required is not met. At least two additional independent and GAP-compliant residue trials should be submitted since beans with pods is a major crop for which at least eight residue trials are required according to the EU extrapolation guidance (European Commission, 2017).

EFSA concludes that only the NEU use is sufficiently supported by residue trials to derive an MRL proposal of 0.06 mg/kg, which is however lower than the existing EU MRL (0.3 mg/kg) and therefore no MRL modification would be required. Individual results from the four NEU trials conducted with an

⁷ 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.
adjvant in the formulation showed to be on the same order of magnitude of the trials conducted without adjuvant. The intended SEU use was not supported by a sufficient number of residue trials in beans with pods. Beans with pods is a major crop and a minimum of eight trials are required to derive an MRL proposal. Although extrapolation from residue data in peas with pods to beans with pods is possible and the GAPs are comparable (European Commission, 2017), the number of trials on peas with pods available is not sufficient to support the extrapolation.

For **peas with pods** (minor crop), the applicant provided eight independent residue trials from the NEU and four independent residue trials from the SEU. EFSA noted that for two out of eight residue trials performed in the NEU the product was applied at a growth stage which is not in line with the intended GAP (application at BBCH 51 vs the intended BBCH 12-25). However, despite the deviation from the intended GAP, these trials were performed at a growth stage where the edible part was not formed yet (BBCH 51: first flower buds visible) and resulted in residue levels below the LOQ. Therefore, EFSA considered the deviation from the BBCH stage at application acceptable in this case and agreed with the EMS to include them in the MRL calculation.

Regarding the trials conducted in the SEU, EFSA further noted that one trial (Trial A/SF/H/07/163 with adjuvant and trial A/SF/H/07/140 without adjuvant) resulted in significant higher level of residues. The applicant investigated possible deviations with this trial but concluded that all parameters were appropriate, there was no evidence of misapplication, improper sampling or contamination and product was applied and sample collected at appropriate growth stage (BBCH 14 and 79, respectively). However, in this trial, peas with pods were collected 31 days after the application. The applicant indicated that this is a relatively short interval to transition from BBCH 14 to 79 and this was the shortest PHI in the study despite the fact that the weather condition was not unusual and the peas variety was not fast-growing. The applicant concluded that, since no other discrepancy than short PHI was noted, the high value should not be disregarded as the trial is compliant with the intended GAP. EFSA agrees with this conclusion for such a minor crop and also considering that peas with pods could be consumed even at an immature growth stage.

EFSA derived an MRL of 0.8 mg/kg based on SEU use. Sufficient evidence that the use in NEU is less critical for residues is provided.

EFSA noted that the EMS proposed to pool together the NEU residue trials on beans and peas with pods to derive an MRL proposal of 0.08 mg/kg and the SEU residue trials on beans and peas with pods to derive an MRL proposal of 0.5 mg/kg (the proposal includes the two SEU residue trials on beans which shall be disregarded because not-compliant). Finally, the EMS combined all the residue trials on beans and peas with pods from each zone together proposing an MRL of 0.4 mg/kg (Netherlands, 2020). EFSA acknowledge that according to the extrapolation guidance residues from beans can be extrapolated to peas (and vice versa) and may be extrapolated to the whole group of legume vegetables if the application is made before the forming of the edible part of the plant. However, the extrapolation is acceptable only if the minimum number of trials required per each individual crop and per zone is available.

**Beans and peas without pods**

For **beans without pods** (minor crop), the applicant provided seven residue trials in NEU and six residue trials in SEU. EFSA noted that all residue trials performed in NEU and SEU are independent and compliant with the intended GAP and all result in residue levels below the LOQ.

For **peas without pods** (major crop), the applicant provided eight independent residue trials in NEU and only four residue trials in SEU. EFSA noted that for two out of eight residue trials performed in the NEU the product was applied at a growth stage which is not in line with the intended GAP (application at BBCH 51 vs the intended BBCH 12-25). However, despite the deviation from the intended GAP, these trials were performed at a growth stage where the edible part was not formed yet (even before the flowering stage) and resulted in residue levels below the LOQ. Therefore, EFSA considered the deviation from the application rate acceptable in this case and agreed with the EMS to include them in the MRL calculation.

While regarding the residue trials in the SEU, the applicant has provided only four residue trials, whereas, according to the EU extrapolation guidance, peas without pods is a major crop for which at least eight GAP-compliant residue trials should be submitted (European Commission, 2017). The number of trials conducted on beans without pods in the SEU (total of six) is not sufficient to derive an MRL proposal for the intended use on peas without pods by extrapolation (European Commission, 2017).
Therefore, considering the insufficient number of trials provided, EFSA considers residues data in SEU not sufficient for a major crop like peas without pods and derived MRL only based on residue levels of NEU trials, resulting in levels below the LOQ.

EMS proposed to pool together the NEU residue trials on beans and peas without pods to derive an MRL proposal of < 0.03 mg/kg and the SEU residue trials on beans and peas without pods to derive an MRL proposal of 0.15 mg/kg (including the four SEU residue trials on peas which are not sufficient for such a major crop). Finally, the EMS combined all the residue trials on beans and peas without pods from each zone together proposing an MRL of 0.15 mg/kg (Netherlands, 2020). EFSA acknowledge that according to the extrapolation guidance residues from beans can be extrapolated to peas (and vice-versa) and may be extrapolated to the whole group of legume vegetables if the application is made before the forming of the edible part of the plant. However, the extrapolation is acceptable only if the minimum number of trials required per each individual crop and per zone is available, which is not the case here.

1.2.2. Magnitude of residues in rotational crops

The studies on the magnitude of bentazone residues in rotational crops were investigated in the framework of the peer review (EFSA, 2015). Bentazone was applied on soya beans twice at 1.12 kg/ha and various rotational crops (alfalfa, corn, lettuce, mustard, radishes, snap beans, sugar beets, spinach, etc.) were planted at different plant-back intervals (PBI), corresponding to crop failure, autumn and annual rotation. The highest residues in succeeding crops ranged from 0.01 to 0.019 mg/kg in radishes, mustard, turnip and spinach planted 16-30 DAT. In the remaining rotational crops at the longer PBI, residues of bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone were below the individual LOQs of 0.01 mg/kg.

The EU pesticides peer review concluded that residues above 0.01 mg/kg are not expected to occur in rotational crops, provided that bentazone is applied in compliance with representative uses (EFSA, 2015). Since the intended use on beans and peas with and without pods is less critical compared to the representative uses, the same conclusion is valid for the current assessment.

1.2.3. Magnitude of residues in processed commodities

Specific processing studies investigating residues in cooked and canned legumes were not submitted with this application and are not required as the total TMDI is below the trigger value of 10% of the acceptable daily intake (ADI).

1.2.4. Proposed MRLs

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

For beans with pods, only the NEU use is sufficiently supported by residue trials to derive an MRL of 0.06 mg/kg, which is, however, lower than the existing EU MRL (0.3 mg/kg) and therefore no MRL modification would be required. While for peas with pods both NEU and SEU are sufficiently supported by residue trials to derive an MRL of 0.09 mg/kg based on NEU trials and an MRL of 0.8 mg/kg based on SEU trials.

For beans without pods, both NEU and SEU are sufficiently supported by residue trials to derive an MRL proposal at the LOQ of 0.03 mg/kg, which is however lower than the existing EU MRL (0.05 mg/kg) and therefore no MRL modification would be required. While for peas without pods only the NEU use is sufficiently supported by residue trials to derive an MRL proposal at the LOQ of 0.03 mg/kg, which is also lower than the existing EU MRL (0.05 mg/kg) and therefore no MRL modification would be required as well.

Anticipating possible implementation of the residue definition for enforcement proposed in the framework of the EU pesticides peer review, EFSA derived also MRL proposals based on the residue definition limited to bentazone (see Table B.1.2.1).

In Section 3 EFSA assessed whether residues on these crops resulting from the intended uses are likely to pose a consumer health risk.

2. Residues in livestock

Not relevant as beans and peas with and without pods are not used for feed purposes.
3. **Consumer risk assessment**

EFSA performed the dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2018, 2019a). 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.

The toxicological reference values for bentazone used in the risk assessment (i.e. ADI of 0.09 mg/kg body weight (bw) per day and the acute reference dose (ARfD) value of 1 mg/kg bw) were derived in the framework of the EU pesticides peer review (European Commission 2018). The EU pesticides peer review concluded that 8-hydroxy-bentazone is less toxic than the parent bentazone and the reference values of the parent can be applied for this metabolite.

Regarding the 6-hydroxy-bentazone metabolite, 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). In a previous MRL application, the genotoxicity potential of this metabolite has been clarified with a QSAR analysis and read across. However, EFSA was of the opinion that the general toxicity of the metabolite could not be concluded on the basis of the information provided (EFSA, 2019b). No new information has been submitted with this MRL application. Lacking a final conclusion on the toxicological profile for the metabolite 6-hydroxy-bentazone, the risk assessment is indicative, as it was performed under the assumption that the toxicity of the metabolite 6-hydroxy-bentazone is comparable to the parent compound.

Finally, as the residue definition derived by the peer review is not yet enforced, the risk assessment was performed with the residue definition proposed during the MRL review which comprises also 8-hydroxy-bentazone (free and conjugated). The assessment is considered to give a more conservative result.

**Short-term (acute) dietary risk assessment**

The short-term exposure assessment was performed only for peas with pods in accordance with the internationally agreed methodology (FAO, 2016). The calculations were based on the HR derived from supervised field trials and the complete list of input values can be found in Appendix D.1. The short-term exposure was low as well (maximum 0.3% of the ARfD).

**Long-term (chronic) dietary risk assessment**

In the framework of the MRL review a comprehensive long-term consumer exposure to residues arising in food from the existing EU uses of bentazone was performed (EFSA, 2012) and revised twice (EFSA, 2019b,c). The calculation was updated with the median residue value (STMR) derived for peas with pods from the residue trials assessed in this application. The input values for the exposure assessment were the risk assessment values derived by the EFSA and corresponding to the MRLs as established in the MRL Regulation (EU) No 2020/1633. The complete list of input values is presented in Appendix D.1.

Under this assumption that the toxicity of metabolite 6-hydroxy-bentazone is covered by the reference values of the parent compound, the estimated maximum long-term dietary intake accounted for maximum 3% of the ADI (NL toddler). The contribution of residues in peas with pods to the overall long-term exposure was very low (maximum 0.01% of the ADI).

An update of the acute and chronic consumer risk assessment for the intended uses on beans with and without pods and peas without pods was deemed not necessary. The conclusion reached in the previously performed consumer risk assessments is still valid (EFSA, 2012, 2019b,c).

The risk assessment is affected by additional, non-standard uncertainties resulting from the lack of toxicological data related to the metabolite 6-hydroxy-bentazone and the unidentified metabolite fraction M3 in the wheat metabolism study. When taking a decision on the acceptability of the MRL proposal derived for peas with pods from these residue trials, risk managers should take into account the additional non-standard uncertainties.

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

The data submitted in support of the request were found to be sufficient to derive MRL proposals for peas with pods. Results from the residue trials indicated that there is no need to modify the existing MRLs for beans with pods, beans without pods and peas without pods.

EFSA concluded that the proposed use of bentazone on peas with pods will not result in a consumer exposure exceeding the toxicological reference values and therefore is unlikely to pose a risk to consumers’ health for parent bentazone. The risk assessment however is indicative and affected by additional, non-standard uncertainties resulting from the insufficient information related to the toxicological properties for 6-hydroxy-bentazone.

In Appendix B.4, the overall EFSA recommendations are reported.

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

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AR applied radioactivity
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
DAR draft assessment report
DAT days after treatment
DT90 period required for 90% dissipation (define method of estimation)
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
IEIDI international estimated daily intake
IESTI international estimated short-term intake
InChiKey International Chemical Identifier Key.
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC liquid chromatography
LOQ limit of quantification
MRL maximum residue level
MS Member States
MS/MS tandem mass spectrometry detector
MW molecular weight
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAC raw agricultural commodity
RD residue definition
| Acronym | Definition |
|--------|------------|
| RMS    | rapporteur Member State |
| SANCO  | Directorate-General for Health and Consumers |
| SEU    | southern Europe |
| SL     | soluble concentrate |
| STMR   | supervised trials median residue |
| TMDI   | theoretical maximum daily intake |
| TRR    | total radioactive residue |
| WHO    | World Health Organization |
## Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | Pests or group of pests controlled | Preparation | Application | Application rate per treatment | PHI (days) | Remarks |
|-----------------------|-------------------------|-----------------------------------|-------------|-------------|--------------------------------|------------|---------|
|                       |                         |                                   | Type (b)    | Conc. a.s.  | Method kind                     |            |         |
|                       |                         |                                   |             |             | Range of growth stages & season (c) |            |         |
|                       |                         |                                   |             |             | Number min.–max                 |            |         |
|                       |                         |                                   |             |             | Interval between application (min) |            |         |
|                       |                         |                                   |             |             | g a.s./hl min.–max               |            |         |
|                       |                         |                                   |             |             | Water L/ha min.–max              |            |         |
|                       |                         |                                   |             |             | Rate                            |            |         |
|                       |                         |                                   |             |             | Unit                            |            |         |
|                       |                         |                                   |             |             | Remarks                          |            |         |
|                       |                         |                                   |             |             |                                 |            |         |
| Beans (with pods/without pods) | NEU/SEU | F | Weeds general | SL | 480 g/L | Foliar treatment – broadcast spraying | BBCH 12-25 | 1 | 100–400 | 0.60 kg a.s./ha | n.a. | Or split application 2 × 0.30 kg a.s./ha with/without adjuvant (max 1 L/ha) |
| Peas (with pods/without pods) | NEU/SEU | F | Weeds general | SL | 480 g/L | Foliar treatment – broadcast spraying | BBCH 12-25 | 1 | 100–400 | 0.60 kg a.s./ha | n.a. | Or split application 2 × 0.30 kg/ha with/without adjuvant (max 1 L/ha) |

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.

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

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

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

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

### B.1. Residues in plants

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

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

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/Source |
|----------------------------------|-------------|---------|----------------|----------------|----------------|
| **Root crops**                   |             |         |                |                |                |
|                                  | Potatoes    | Foliar  | 2 × 1.12 kg/ha, 21 days interval | 41 | Radiolabelled active substance: 14C-phenyl bentazone (Netherlands, 2013; EFSA, 2015) |
|                                  |             | Foliar  | 1 × 1.5 kg/ha | 60 (immature), 90 (mature) | Radiolabelled active substance: 14C-phenyl bentazone (Netherlands, 2013; EFSA, 2015) |
| **Cereals/ grass**              | Rice        | Foliar  | 1 × 1.00 kg/ha | 26, 63 | Radiolabelled active substance: 14C-phenyl bentazone (Netherlands, 2013; EFSA, 2015) |
|                                  | Maize       | Foliar  | 1 × 1.68 kg/ha | 0, 7, 14, 21, 42, 63, 126 | Radiolabelled active substance: 14C-phenyl bentazone (Netherlands, 2013; EFSA, 2015) |
|                                  | Wheat       | Foliar  | 1 × 1.00 kg/ha, BBCH 31-32 | 20, 83 | Radiolabelled active substance: phenyl-14C-bentazone (Netherlands, 2013; EFSA, 2015) |
| **Pulses/ oilseeds**            | Soya beans  | Foliar  | 1 × 2.24 kg/ha | 9, 36, 93 | Radiolabelled active substance: 14C-phenyl bentazone (Netherlands, 2013; EFSA, 2015) |
|                                  |             | Foliar  | 1.68 + 1.12 kg/ha, 45 days interval | 11, 48 |                |
|                                  | Green beans | Foliar  | 1 × 2.24 kg/ha | 9, 36, 79 | Radiolabelled active substance: 14C-phenyl bentazone (EFSA, 2012) Supplementary information only |
|                                  |             | Foliar  | 1.68 + 1.12 kg/ha, 28 days interval | 8, 51 |                |
| **Rotational crops**            |             |         |                |                |                |
| (available studies)             |             |         |                |                |                |
| **Root/tuber crops**            | Radish      | Soil    | 1 kg/ha | 30, 120, 365 | Radiolabelled active substance: 14C-phenyl bentazone (EFSA, 2015) |
| **Leafy crops**                 | Lettuce     | Soil    | 1 kg/ha | 30, 120, 365 | Radiolabelled active substance: 14C-phenyl bentazone (EFSA, 2015) |
| **Cereals (small grain)**       | Spring wheat| Soil    | 1 kg/ha | 30, 120, 365 | Radiolabelled active substance: 14C-phenyl bentazone (EFSA, 2015) |
|                                  | Wheat       | Potato  | 1 × 1.5 kg/ha | 160 | Radiolabelled active substance: 14C-phenyl bentazone. Wheat grown in rotation of potatoes was either left untreated or treated with 1 foliar application of 1.5 kg/ha (EFSA, 2015) |
| Processed commodities (hydrolysis study) | Conditions                                      | Stable?          | Comment/Source                          |
|-----------------------------------------|------------------------------------------------|------------------|----------------------------------------|
|                                        | Pasteurisation (20 min, 90°C, pH 4)            | Not investigated | Not triggered                           |
|                                        | Baking, brewing and boiling (60 min, 100°C, pH 5) |                  |                                        |
|                                        | Sterilisation (20 min, 120°C, pH 6)            |                  |                                        |
|                                        | Other processing conditions                    |                  |                                        |

Can a general residue definition be proposed for primary crops?

Rotational crop and primary crop metabolism similar?

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

Plant residue definition for monitoring (RD-Mo)

```
| Plant residue definition for monitoring (RD-Mo) |
|------------------------------------------------|
| EFSA MRL review (EFSA, 2012):                  |
| Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone |
| Regulation (EC) No 396/2005:                    |
| Bentazone (sum of bentazone, its salts, 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone) |
| EFSA peer review (EFSA, 2015):                 |
| Bentazone (all crop categories for foliar treatment) |
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Plant residue definition for risk assessment (RD-RA)

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| Plant residue definition for risk assessment (RD-RA) |
|-----------------------------------------------------|
| EFSA 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 (EFSA, 2015):

- 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)

```
| Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs) |
|------------------------------------------------------------------------------------------|
| Existing RD-Mo (Regulation (EC) No 396/2005).                                             |
| Matrices with high water content (onions, peas whole plant), high oil content (soybeans), high acid content (oranges), dry/high protein content (dry peas) and dry/high starch content (maize grains): |
| LC–MS/MS, individual LOQ 0.01 mg/kg for bentazone, 6-hydroxy and 8-hydroxy-bentazone (free and conjugated) (EFSA, 2015). |
| QuEChERS method (HPLC–MS/MS): LOQ of 0.005 mg/kg for bentazone only in high water content matrices (EFSA, 2012). |
```

DAT: days after treatment; PBI: plant-back interval; BBCH: growth stages of mono- and dicotyledonous plants; MRL: maximum residue level; LOQ: limit of quantification; LC–MS/MS: liquid chromatography with tandem mass spectrometry; HPLC–MS/MS: high performance liquid chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe.
### B.1.1.2. Stability of residues in plants

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

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

| Commodity | Region/Indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL (mg/kg) | \(HR^{(b)}\) (mg/kg) | \(STMR^{(c)}\) (mg/kg) | CF\(^{(d)}\) |
|-----------|--------------------------|-----------------------------------------------------------------|-----------------|------------------------|------------------|-------------------|------|
| **Beans with pods (major crop)** | NEU | Without adjuvant: \(6 \times < 0.03; 2 \times 0.04\) | Residue trials compliant with GAP; 4 trials without adjuvant and 4 side-by-side trials without and with adjuvant | 0.06 | 0.04 | 0.03 | 1 |
| | | With adjuvant: \(3 \times 0.03; 0.032\) | 0.06 | 0.04 | 0.03 | 1 |
| | | \(5 \times < 0.03; 0.032; 2 \times 0.04\) | Combined dataset of residue trials compliant with the GAP; 4 trials without adjuvant and the highest residue value of 4 side-by-side trials without and with adjuvant | 0.06 | 0.04 | 0.03 | 1 |
| | SEU | Without adjuvant: \(6 \times < 0.03\) | Insufficient number of residue trials compliant with GAP; 2 trials without adjuvant and 4 side-by-side trials without and with adjuvant | – | – | – | – |
| | | With adjuvant: \(3 \times < 0.03; 0.042\) | – | – | – | – |
| | | \(5 \times < 0.03; 0.042\) | Insufficient number of residue trials compliant with GAP; combined dataset of 2 trials without adjuvant and the highest residue value from 4 side-by-side trials without and with adjuvant | – | – | – | – |
| **Peas with pods (minor crop)** | NEU | Without adjuvant: \(7 \times < 0.03; 0.033\) | Residue trials compliant with GAP; 2 trials without adjuvant and 6 side-by-side trials without and with adjuvant | 0.04 | 0.03 | 0.03 | 1 |
| | | With adjuvant: \(3 \times < 0.03; 0.032; 0.045; 0.067\) | 0.1 | 0.07 | 0.03 | – |
| | | \(4 \times < 0.03; 0.032; 0.033; 0.045; 0.067\) | Combined dataset of residue trials compliant with the GAP; 2 trials without adjuvant and the highest residue value from 6 side-by-side trials without and with adjuvant | 0.09 | 0.07 | 0.03 | 1 |
| | SEU | Without adjuvant: \(2 \times < 0.03, 0.073, 0.342\) | Residue trials compliant with GAP; 4 side-by-side trials without and with adjuvant | 0.8 | 0.34 | 0.05 | 1 |
| | | With adjuvant: \(2 \times < 0.03; 0.048; 0.323\) | 0.7 | 0.32 | 0.04 | – |
| | | \(2 \times < 0.03; 0.073; 0.342\) | Combined dataset of residue trials compliant with the GAP; highest residue value from 4 side-by-side trials without and with adjuvant | 0.8 | 0.34 | 0.05 | 1 |

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

\(^{(a)}\) Indoor: trials conducted in greenhouses.

\(^{(b)}\) HR: Highest residue.

\(^{(c)}\) STMR: Sum of the Maximum Residue Levels.

\(^{(d)}\) CF: Conversion factor.
| Commodity                      | Region/Indoor | 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) |
|-------------------------------|---------------|-----------------------------------------------------------------|---------------------------------------------------------------------------------|------------------------|----------------|-----------------|-------|
| Beans without pods (minor crop) | NEU           | Without adjuvant: 7 × < 0.03 Without adjuvant: 4 × < 0.03       | Residue trials compliant with GAP; 4 side-by-side trials without and with adjuvant | 0.03*                  | 0.03           | 0.03            | 1     |
|                               | SEU           | Without adjuvant: 6 × < 0.03 Without adjuvant: 4 × < 0.03       | Residue trials compliant with GAP; 4 side-by-side trials without and with adjuvant | 0.03*                  | 0.03           | 0.03            | 1     |
| Peas without pods (major crop) | NEU           | Without adjuvant: 8 × < 0.03 Without adjuvant: 6 × < 0.03       | Residue trials compliant with GAP; 6 side-by-side trials without and with adjuvant | 0.03*                  | 0.03           | 0.03            | 1     |
|                               | SEU           | Without adjuvant: < 0.03; 0.043; 0.044; 0.12 With adjuvant: 2 × < 0.03; 0.03; 0.105 | Insufficient number of residue trials compliant with GAP; 4 side-by-side trials without and with adjuvant | –                     | –              | –               | –     |
| Proposed enforcement residue definition (EFSA, 2015): Bentazone(e) | | | | | | | |
| Beans with pods (major crop)   | NEU           | Mo: 8 × < 0.01 RA: n.c. With adjuvant: Mo: 4 × < 0.01 RA: n.c. | Residue trials compliant with GAP; 4 trials without adjuvant and 4 side-by-side trials without and with adjuvant | 0.01*                  | Mo: 0.01 RA: n.c | Mo: 0.01 RA: n.c | n.c.  |
|                               | SEU           | Mo: 6 × < 0.01 RA: n.c. With adjuvant: Mo: 4 × < 0.01 RA: n.c. | Insufficient number of residue trials compliant with GAP                          | –                     | –              | –               | –     |
| Peas with pods (minor crop)    | NEU           | Mo: 8 × < 0.01 RA: n.c. With adjuvant: Mo: 6 × < 0.01 RA: n.c. | Residue trials compliant with GAP; 2 trials without adjuvant and 6 side-by-side trials without and with adjuvant | 0.01*                  | Mo: 0.01 RA: n.c | Mo: 0.01 RA: n.c | n.c.  |
|                               | SEU           | Mo: 4 × < 0.01 RA: n.c. With adjuvant: Mo: 4 × < 0.01 RA: n.c. | Residue trials compliant with GAP; 4 side-by-side trials without and with adjuvant | 0.01*                  | Mo: 0.01 RA: n.c | Mo: 0.01 RA: n.c | n.c.  |
| Commodity                          | Region/Indoor(a) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source                                                                 | Calculated MRL (mg/kg) | HR(b) (mg/kg) | STMR(c) (mg/kg) | CF(d) |
|-----------------------------------|------------------|-----------------------------------------------------------------|--------------------------------------------------------------------------------|------------------------|--------------|----------------|-------|
| Beans without pods (minor crop)   | NEU              | Mo: 7 × < 0.01; RA: n.c.                                       | Residue trials compliant with GAP; 3 trials without adjuvant and 4 side-by-side trials without and with adjuvant | 0.01* Mo: 0.01 RA: n.c | Mo: 0.01 RA: n.c | n.c.           |       |
|                                   | SEU              | Mo: 6 × < 0.01; RA: n.c.                                       | Residue trials compliant with GAP; 2 trials without adjuvant and 4 side-by-side trials without and with adjuvant | 0.01* Mo: 0.01 RA: n.c | Mo: 0.01 RA: n.c | n.c.           |       |
| Peas without pods (major crop)    | NEU              | Mo: 8 × < 0.01; RA: n.c.                                       | Residue trials compliant with GAP; 2 trials without adjuvant and 6 side-by-side trials without and with adjuvant | 0.01* Mo: 0.01 RA: n.c | Mo: 0.01 RA: n.c | n.c.           |       |
|                                   | SEU              | Mo: 4 × < 0.01; RA: n.c.                                       | Insufficient number of residue trials compliant with GAP                         | – – – –               |              |               |       |

**MRL**: maximum residue level; **GAP**: Good Agricultural Practice; **Mo**: monitoring; **RA**: risk assessment; **n.c.**: not calculated.

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

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

(e): STMR/HR according to the residue definition for risk assessment (sum of bentazone, 6-hydroxy-and its conjugates, expressed as bentazone) provisionally proposed in the framework of the EU pesticides peer review (EFSA, 2015) were not calculated (n.c.).
B.1.2.2. Residues in rotational crops

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

No

The radioactivity was mainly characterised as polar fractions with incorporation into the natural plant constituents. A significant unidentified fraction M3 (57% TRR; 1.1 mg/kg) was found in the metabolism study on wheat grown after primary use of bentazone on potato (EFSA, 2015).

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

No

Following the treatment of soya beans at 2 × 1.12 kg/ha and the planting of various rotational crops (alfalfa, corn, lettuce, mustard, radishes, snap beans, sugar beets, spinach, etc.) at different plant-back intervals (PBI), the highest residues in rotational crops were observed at 0.01–0.019 mg/kg in radishes, mustard, spinach, turnips, planted at 16–30 DAT. In the remaining rotational crops at longer PBIs, residues were below the LOQ of 0.05 mg/kg for each analyte (bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone) (EFSA, 2012).

TRR: total radioactive residue; PBI: plant-back interval; DAT: days after treatment; LOQ: limit of quantification.

B.1.2.3. Processing factors

New processing studies were not submitted in the framework of the present MRL application and are not required.

B.2. Residues in livestock

Not relevant.
B.3. Consumer risk assessment

**ARfD**

- Highest IESTI, according to EFSA PRIMo: Peas with pods: 0.3% of the ARfD (NL child)
- Assumptions made for the calculations: PRIMo rev. 3.1. With the assumption that the toxicity of metabolite 6-hydroxy-bentazone is comparable to parent compound.

The calculation is based on the highest residue level expected in peas with pods according to residue trials supporting the more critical residue situation of the SEU use.

For the other commodities assessed in this application, the previous consumer risk assessments do not need to be updated and the results are still valid (EFSA, 2019b,c).

**ADI**

- Highest IEDI, according to EFSA PRIMo: 3% of the ADI (NL toddler diet)
- Assumptions made for the calculations: PRIMo rev. 3.1. With the assumption that the toxicity of metabolite 6-hydroxy-bentazone is comparable to parent compound.

The calculation was performed taking into account the STMR value derived for peas with pods according to residue trials supporting the more critical residue situation of the SEU use.

For the remaining commodities, including the other crops under assessment in this opinion, the input values were the risk assessment values derived by the EFSA in previous opinions (EFSA, 2012, 2019b,c) and corresponding to the MRLs as established in the MRL Regulation (EU No. 2020/1633).

For the other commodities assessed in this application, the previous consumer risk assessments do not need to be updated and the results are still valid (EFSA, 2019b,c).

B.4. Recommended MRLs

| Code | Commodity                | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                 |
|------|--------------------------|-------------------------|-------------------------|---------------------------------------------------------------------------------------|
| 260010 | Beans with pods          | 0.3                     | No new proposal         | The submitted data do not provide evidence that the existing MRL has to be modified   |

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; ADI: acceptable daily intake; IEDI: international estimated daily intake; GEMS: Global Environment Monitoring System; STMR: supervised trials median residue; MRL: maximum residue level; SEU: southern Europe.
| Code\(^{(a)}\) | Commodity               | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                                                                                                                 |
|---------------|-------------------------|-------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 260030        | Peas with pods          | 0.3                     | 0.8/0.01*               | The MRL proposal reflects the more critical residue situation of the SEU use. According to the indicative dietary risk assessment, no consumer intake concerns were identified. Further risk management considerations required, considering that the toxicity of 6-hydroxy-bentazone is not fully characterised |
| 260020        | Beans without pods      | 0.05                    | No new proposal         | The submitted data do not provide evidence that the existing MRL has to be modified                                                                              |
| 260040        | Peas without pods       | 0.05                    | No new proposal         | The submitted data do not provide evidence that the existing MRL has to be modified                                                                              |

MRL: maximum residue level; SEU: southern Europe.

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

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
Appendix C – Pesticide Residue Intake Model (PRiMo)

Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone)

| Commodity | ADI (mg/kg bw/day) | ARfD (mg/kg bw) | Total contribution to ADI | Total contribution to ARfD | Input values |
|-----------|--------------------|----------------|---------------------------|---------------------------|--------------|
| Milk: Cattle | 0.25 | 0.2 | 0.31 | 0.22 | 0.12 |
| Wheat | 0.25 | 0.2 | 0.29 | 0.16 | 0.13 |

### Input values

- ADI (mg/kg bw/day): 1
- ARfD (mg/kg bw): 0.3

### Supplementary results – chronic risk assessment/children

- Year of evaluation: 2018
- Comments: Refined calculation mode

### Details – chronic risk assessment

- JMPR methodology (IEDI/TMDI)
- No of diets exceeding the ADI: ---
- Exposure resulting from commodities not under assessment

| Commodity group of commodities | MS Diet | No of diets exceeding ADI | % of ADI | Expsoure (µg/kg bw per MS diet) | % of ADI |
|--------------------------------|---------|--------------------------|----------|--------------------------------|----------|
| Milk: Cattle | 0.25 | 0.31 | 0.31 | 0.31 | 0.31 |
| Wheat | 0.25 | 0.29 | 0.29 | 0.29 | 0.29 |

### Details – acute risk assessment/children

- Year of evaluation: 2018
- Comments: Refined calculation mode

### Details – acute risk assessment/adults

- Year of evaluation: 2018
- Comments: Refined calculation mode

### Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The long term intake of residues of Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), expressed as bentazone), is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD.

The calculation is based on the large portion of the most critical consumer group.

### Results for all crops

| Commodity                        | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) | Commodity                        | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|----------------------------------|---------------------------|---------------------|----------------------------------|---------------------------|---------------------|
| Potatoes                         | 0.15/0.08                 | 12                  | Parsley                          | 0.9%                      | 10/7.2             |
| Chervil                          | 10/7.2                    | 10.0                | Sweet corn                       | 0.3%                      | 0.3/3.21           |
| Parsley                          | 10/7.2                    | 8.4                 | Potatoes                         | 0.2%                      | 0.15/0.08          |
| Chives                           | 10/7.2                    | 6.3                 | Beans (with pods)                | 0.2%                      | 0.3/0.21           |
| Sage                             | 10/7.2                    | 5.8                 | Sage                             | 0.2%                      | 10/7.2             |
| Basil and edible flowers         | 10/7.2                    | 5.6                 | Onions                           | 0.1%                      | 10/1.1             |
| Celery leaves                    | 10/7.2                    | 3.7                 | Chives                           | 0.1%                      | 10/7.2             |
| Peas (with pods)                 | 0.8/0.34                  | 2.8                 | Peas (with pods)                 | 0.1%                      | 0.8/0.34           |
| Milk: Cattle                     | 0.02/0.02                 | 2.5                 | Basil and edible flowers         | 0.09%                     | 10/7.2             |
| Beans (with pods)                | 0.3/0.21                  | 2.4                 | Rosemary                         | 0.08%                     | 10/7.2             |
| Onions                           | 0.1/1.1                   | 2.3                 | Rosemary                         | 0.08%                     | 10/7.2             |
| Beans                            | 0.1/0.06                  | 1.1                 | Rosemary                         | 0.08%                     | 10/7.2             |
| Peas                             | 1/0.16                    | 1.1                 | Rosemary                         | 0.08%                     | 10/7.2             |
| Wheat                            | 0.1/0.06                  | 0.87                | Milk: Cattle                     | 0.08%                     | 0.2/0.02           |

### Unprocessed commodities

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

### Processed commodities

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

### Conclusion

A short term intake of residues of Bentazone (Sum of bentazone, its salts and 6-hydroxy (free and conjugated) and 8-hydroxy bentazone (free and conjugated), For processed commodities, no exceedance of the ARfD/ADI was identified.
### Appendix D – Input values for the exposure calculations

#### D.1. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|-----------------------|
|                            | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment<sup>(a)</sup> |
| Beans (with pods)          | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Beans (without pods)       | 0.03                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Peas (with pods)           | 0.05                    | STMR-RAC (proposed)   |                      |                         |
| Peas (without pods)        | 0.03                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Potatoes                   | 0.06                    | STMR-RAC (EFSA, 2019b)| 0.34                 | HR-RAC (proposed)       |
| Garlic                     | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Onions                     | 0.1                     | STMR-RAC (EFSA, 2012) |                      |                         |
| Shallots                   | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Sweet corn                 | 0.05                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Chervil                    | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Chives                     | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Celery leaves              | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Parsley                    | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Sage                       | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Rosemary                   | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Thyme                      | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Basil and edible flowers   | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Laurel/bay leaves          | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Tarragon                   | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Other herbs                | 1.24                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Lentils (fresh)            | 0.03                    | STMR-RAC (EFSA, 2019b)|                      |                         |
| Beans                      | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Peas                       | 0.16                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Linseeds                   | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Peanuts/groundnuts         | 0.02                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Poppy seeds                | 0.04                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Sunflower seeds            | 0.04                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Barley                     | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Maize/corn                 | 0.05                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Common millet/proso millet | 0.03                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Oat                        | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Rice                       | 0.02                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Rye                        | 0.1                     | STMR-RAC (EFSA, 2012) |                      |                         |
| Sorghum                    | 0.15                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Wheat                      | 0.06                    | STMR-RAC (EFSA, 2012) |                      |                         |
| Swine: Muscle/meat         | 0.02                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Swine: Fat tissue          | 0.02                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Swine: Liver               | 0.02                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Swine: Kidney              | 0.01                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Swine: Edible offals (other than liver and kidney) | 0.01 | STMR-RAC (EFSA, 2019c) |                      |                         |
| Swine: Other products      | 0.01                    | STMR-RAC (EFSA, 2019c)|                      |                         |
| Bovine: Muscle/meat        | 0.02                    | STMR-RAC (EFSA, 2019c)|                      |                         |

<sup>(a)</sup> The acute exposure assessment was performed only for the commodities for which a new MRL is proposed.
| Commodity                                      | Input value (mg/kg) | Comment                      | Input value (mg/kg) | Comment<sup>(a)</sup> |
|------------------------------------------------|---------------------|------------------------------|---------------------|------------------------|
| Bovine: Fat tissue                             | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Bovine: Liver                                  | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Bovine: Kidney                                 | 0.06                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Bovine: Edible offals (other than liver and kidney) | 0.06                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Bovine: Other products                         | 0.06                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Sheep: Muscle/meat                             | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Sheep: Fat tissue                              | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Sheep: Liver                                   | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Sheep: Kidney                                  | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Sheep: Edible offals (other than liver and kidney) | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Sheep: Other products                          | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Goat: Muscle/meat                              | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Goat: Fat tissue                               | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Goat: Liver                                    | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Goat: Kidney                                   | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Goat: Edible offals (other than liver and kidney) | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Goat: Other products                           | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Equine: Muscle/meat                            | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Equine: Fat tissue                             | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Equine: Liver                                  | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Equine: Kidney                                 | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Equine: Edible offals (other than liver and kidney) | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Equine: Other products                         | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Other farmed animals: Muscle/meat              | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Other farmed animals: Fat tissue               | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Other farmed animals: Liver                    | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Other farmed animals: Kidney                   | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Other farmed animals: Edible offals (other than liver and kidney) | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Other farmed animals: Other products           | 0.07                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Milk: Cattle                                   | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Milk: Sheep                                    | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Milk: Goat                                     | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Milk: Horse                                    | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |
| Milk: Others                                   | 0.02                | STMR-RAC (EFSA, 2019c)       |                     |                        |

STMR-RAC: supervised trials median residue in raw agricultural commodity; HR-RAC: highest residue in raw agricultural commodity.
## Appendix E – Used compound codes

| Code/trivial name | IUPAC name/SMILES notation/InChiKey<sup>(a)</sup> | Structural formula<sup>(b)</sup> |
|------------------|-----------------------------------------------|---------------------------------|
| Bentazone        | 3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide | ![Structural formula for Bentazone](image) |
|                  | CC(N1=C(=O)c2ccccc2NS1(=O)=O)                    |                                 |
|                  | ZOMSMJLGFBRBS-UHFFFAOYSA-N                      |                                 |
| 8-hydroxy-bentazone | 8-hydroxy-3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide | ![Structural formula for 8-hydroxy-bentazone](image) |
|                  | CC(N1=C(=O)c2cccc(O)c2NS1(=O)=O)                |                                 |
|                  | WJILUCOKVGHGK-UHFFFAOYSA-N                      |                                 |
| 6-hydroxy-       | 6-hydroxy-3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide | ![Structural formula for 6-hydroxy-bentazone](image) |
| bentazone        | CC(N1=C(=O)c2cc(O)c2ccccNS1(=O)=O)              |                                 |
|                  | PVKWI0BXPFFARA-UHFFFAOYSA-N                     |                                 |
| N-methyl-bentazone | 3-isopropyl-1-methyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide | ![Structural formula for N-methyl-bentazone](image) |
|                  | CC(N1=C(=O)c2ccccc2N(C)=O)                      |                                 |
|                  | XFTQFXBQDVOCY-UHFFFAOYSA-N                     |                                 |

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

<sup>(a)</sup>: ACD/Name 2019.1.3 ACD/Labs 2019 Release (File version N05E41, Build 111418, 3 September 2019).

<sup>(b)</sup>: ACD/ChemSketch 2019.1.3 ACD/Labs 2019 Release (File version C05H41, Build 111302, 27 August 2019).