**Modification of the existing maximum residue levels for bentazone in soyabeans and poppy seeds**

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**Abstract**

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted an application to the competent national authority in the Netherlands to modify the existing maximum residue levels (MRLs) for bentazone in soyabeans and poppy seeds. The data submitted in support of the request were found to be sufficient to derive MRL proposals for both commodities. Adequate analytical methods for enforcement are available to control the residues of bentazone and its metabolites in plant matrices under consideration. The studies requested by EFSA in the framework of the peer review to address the toxicological properties of metabolite 6-hydroxy-bentazone were only partially provided. Instead of studies investigating the general toxicity of this metabolite, the applicant provided an argumentation to justify read-across from the available information on parent bentazone and 8-hydroxy-bentazone. EFSA did not agree with the provided reasoning for read-across. Therefore, the EMS asked EFSA to continue the assessment despite the data gap. EFSA performed an indicative short-term and long-term dietary risk assessment; the calculated dietary exposure was well below the toxicological reference values. The risk assessment however is affected by additional, non-standard uncertainties resulting from data gap related to the toxicological properties for 6-hydroxy-bentazone.

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the applicant BASF SE submitted an application to the competent national authority in the Netherlands (evaluating Member State, EMS) to set maximum residue levels (MRLs) for bentazone in poppy seeds and soyabean on the basis of intended European uses. 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 25 September 2018. The EMS proposed to set an MRL for bentazone in soyabean and poppy seeds at the level of 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps and points which needed further clarification, which were requested from the EMS. On 10 May 2019, the EMS submitted a revised evaluation report, which replaced the previously submitted evaluation report. According to EFSA, the data gap related to the toxicological profile of 6-hydroxy-bentazone was not fully addressed. The EMS, who did not agree with EFSA's views, asked EFSA to continue the assessment despite the data gap, and to outline the divergent views on 6-hydroxy-bentazone and the related impact on the risk assessment.

Based on the conclusions derived by EFSA in the framework of Regulation (EC) 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 treatment was investigated in the framework of the renewal of the approval of bentazone in crops belonging to the groups of root crops (potatoes), cereals/grass (rice, wheat, maize) and pulses and oilseeds (soyabean). The nature of bentazone in rotational crops (radish, lettuce and wheat) was investigated following soil treatment and indicated a similar metabolic pathway as in primary crops. In the framework of the peer review, an additional study with wheat treated as primary crop and grown in rotation with treated potatoes was assessed. The study represents a worst-case agriculture practice. For this study, the peer review set a data gap regarding an unidentified metabolite fraction M3 in wheat straw. New information on the identity of fraction M3 has not been provided to EFSA. The lack of this information is not expected to affect the current assessment as the forages of soyabeans and poppy seeds 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 proposed as ‘sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone’. This residue definition is provisional, pending the clarification of the identity of metabolite fraction M3 in the wheat metabolism study and lacking the full toxicological information on 6-hydroxy-bentazone to conclude whether separate toxicological reference values are necessary for this metabolite.

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) as well as for the proposed new, provisional residue definition. The risk assessment was performed for the current residue definition that comprises also 8-hydroxy-bentazone (free and conjugated), which is considered to give a more conservative result.

Studies investigating the effect of processing on the nature of bentazone (standard hydrolysis studies) are not available and are not currently required, considering the low consumer exposure to bentazone residues related to the crops under assessment.

Sufficiently validated analytical methods are available to quantify residues in the crops assessed in this application according to the enforcement residue definition.

The available residue trials are sufficient to derive an MRL proposal of 0.2 mg/kg for bentazone (sum of bentazone, its salts, 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone) in soyabean and poppy seeds in support of a more critical northern Europe (NEU) use. The same MRL proposal is appropriate for the proposed new residue definition that covers only parent bentazone.

Since by-products of soyabean can be fed to livestock, the potential carry-over of residues into food of animal origin was assessed. The livestock dietary burden was calculated according to the OECD methodology. Comparing the results with the results of the dietary burden calculated recently in the framework of the assessment of the Article 12 confirmatory data, where the calculations were performed using the EU methodology, a slightly lower exposure for cattle and sheep and a higher
exposure for swine and poultry was estimated. The difference was caused by the different calculation methodology. The contribution of bentazone residues in soyabean to the livestock exposure is insignificant. EFSA derived MRL proposals following the OECD methodology. While the MRL proposals derived in the assessment of Article 12 confirmatory data were confirmed for some animal products, such as meat and fat of swine, cattle, sheep, goat and equine, lower MRLs would be sufficient for liver and kidney of swine, cattle and sheep and for milk of cattle. In poultry commodities, no residues above the limit of quantification (LOQ) are expected to occur.

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 acceptable daily intake (ADI) of 0.09 mg/kg body weight (bw) per day and an acute reference dose (ARfD) of 1 mg/kg bw, which are applicable also to the metabolite 8-hydroxy-bentazone. Regarding the metabolite 6-hydroxy-bentazone, no conclusion could be reached. While in the present application, the genotoxicity potential of this metabolite has been clarified with a QSAR analysis and read across, EFSA is of the opinion that the general toxicity of the metabolite could not be concluded on the basis of the information provided.

EFSA performed an indicative consumer risk assessment with revision 3.1 of the EFSA Pesticide Residues Intake Model (PRIMo), considering the currently applicable risk assessment residue definitions for plant and animal commodities. The input values for the chronic exposure calculation for soyabean and poppy seeds were the STMR values as derived from the residue trials submitted for the current assessment. For the remaining plant and animal origin commodities, the input values were those considered in the recent EFSA opinion on the evaluation of confirmatory data following the Article 12 MRL review for bentazone. The acute exposure assessment was performed only for soyabean and poppy seeds, considering the STMR values as derived from the residue trials submitted for the current assessment. The risk assessment is indicative because of the data gap on the general toxicity for 6-hydroxy-bentazone.

No long-term consumer intake concerns were identified for the intended and the authorised uses of bentazone, as the estimated maximum long-term dietary intake accounted for 3% of the ADI (NL toddler diet). The maximum short-term exposure to oilseeds under consideration was insignificant (< 0.01% of the ARfD for soyabean and poppy seeds, respectively).

According to the exposure assessment, it is unlikely that the proposed use of bentazone on soyabean and poppy seeds will result in a consumer exposure exceeding the toxicological reference values. However, the risk assessment is affected by additional, non-standard uncertainties.

The assessment of the confirmatory data following the peer review of the active substance is not yet finalised and therefore the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of that assessment.

The conclusions of the assessment are summarised in the table below.

Full details of all end points and the consumer risk assessment can be found in Appendices B–D.

| Code (a) | Commodity | Existing MRL | Proposed MRL | Conclusion/recommendation |
|----------|------------|--------------|--------------|---------------------------|
| **Existing enforcement residue definition:** Bentazone (sum of bentazone, its salts, 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone) |
| **Proposed new residue definition** (not yet implemented): Bentazone |
| 0401030  | Poppy seeds | 0.03*        | 0.2/0.2      | The submitted residue data are sufficient to derive an MRL proposal for the intended NEU use. According to the indicative dietary risk assessment, no consumer intake concerns were identified. Further risk management considerations required, considering that the general toxicity of 6-hydroxy-bentazone is not fully characterised |
| 0401070  | Soyabean   | 0.03*        | 0.2/0.2      | The submitted residue data are sufficient to derive an MRL proposal for the new intended NEU/SEU uses. The MRL reflects the more critical NEU use. According to the indicative dietary risk assessment, no consumer intake concerns were identified. Further risk management considerations required, considering that the general toxicity of 6-hydroxy-bentazone is not fully characterised |
### Modification of MRLs for bentazone in soyabean and poppy seeds

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

| Code<sup>(a)</sup> | Commodity | Existing MRL | Proposed MRL | Conclusion/recommendation |
|-------------------|-----------|--------------|--------------|---------------------------|
| 1011040           | Swine kidney | 0.05/0.03<sup>(b)</sup> | 0.02          | Further risk management considerations required |
| 1012030 1013030 1014030 1015030 | Liver: Bovine Sheep Goat Equine | 0.02*/0.05<sup>(b)</sup> | 0.03 (cattle) 0.04 (sheep) | Further risk management considerations required |
| 1012040 1013040 1014040 1015040 | Kidney: Bovine Sheep Goat Equine | 0.3/0.3<sup>(b)</sup> | 0.15          | Further risk management considerations required |
| 1020000           | Milk       | 0.02*/0.03<sup>(b)</sup> | 0.02* (cattle) 0.03 (sheep) | Further risk management considerations required |

The MRL proposals were derived based on the revised dietary burden calculation according to the OECD methodology including the new use on soyabean. The MRLs for other animal products derived in the recently published EFSA reasoned opinion on the evaluation of the Article 12 confirmatory data for bentazone were confirmed.

According to the indicative dietary risk assessment, no consumer intake concerns identified.

Further risk management considerations required, considering that the general toxicity of 6-hydroxy-bentazone is not fully characterised.

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**MRL:** maximum residue level; **NEU:** northern Europe; **SEU:** southern Europe; **OECD:** Organisation for Economic Co-operation and Development.

*: 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): The MRL proposals derived in the EFSA reasoned opinion on the evaluation of the Article 12 confirmatory data for bentazone (EFSA, 2019b).

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Assessment

The detailed description of the intended Good Agricultural Practices (GAPs) of bentazone on poppy seeds and soyabeans, which are the basis for the current maximum residue level (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). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Bentazone was first evaluated in the framework of Directive 91/414/EEC1 with Germany designated as rapporteur Member State (RMS) for the representative uses as outdoor foliar spraying against annual dicotyledonous weeds in various crops. In 2018, the approval for bentazone has been renewed,2 following the peer review process in the framework Reg. (EC) No 1107/20093 with the Netherlands as the new RMS (Netherlands, 2013; EFSA, 2015).

The review of existing MRLs for the active substance bentazone according to Article 12 of Regulation (EC) No 396/20054 (MRL review) has been performed in 2012 prior the renewal of the approval of bentazone (EFSA, 2012). The MRL proposals of the MRL review were implemented in the Commission Regulation (EU) No 1146/20145 along with confirmatory data to be addressed by the applicants. Recently an EFSA reasoned opinion was issued on the evaluation of Article 12 confirmatory data of bentazone (EFSA, 2019b).

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 European Union (EU) MRLs for bentazone in poppy seeds and soyabeans in support of the new intended EU uses. 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 25 September 2018. The EMS proposed to set an MRL for bentazone in soyabeans and poppy seeds at 0.2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation. EFSA identified data gaps or points which needed further clarifications, which were requested from the EMS. The EMS did not agree with certain points for which further information was requested, and asked EFSA to resume the assessment based on the information provided in the revised evaluation report submitted on 10 May 2019 (Netherlands, 2018). EFSA considered that the data gap related to the toxicological profile of 6-hydroxy-bentazone was not fully addressed and finalised the reasoned opinion considering the different view expressed by the EMS on 6-hydroxy-bentazone and the related impact on the risk assessment.

EFSA based its assessment on the evaluation report submitted by the EMS (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 544/20116 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000a,b, 2010a,b, 2017; OECD, 2011, 2013). The assessment is

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1 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.
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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1–50.
4 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.
5 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 anthraquinone, 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.
6 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
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 546/2011.7

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, submitted in support of the current MRL application, are presented in Appendix B.

The evaluation report submitted by the EMS (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. Mammalian toxicology

The toxicological reference values of bentazone were reviewed under the renewal of the approval of the active substance bentazone in 2015. The acceptable daily intake (ADI) of bentazone was established at 0.09 mg/kg body weight (bw) per day, based on the no observed adverse effect level (NOAEL) of 9 mg/kg bw per day for blood, liver and kidney toxicity observed in the 2-year study in rats and applying the standard uncertainty factor (UF) of 100. The acute reference dose (ARfD) was established at 1 mg/kg bw, based on the NOAEL of 100 mg/kg bw per day for increased post-implantation loss, reduced number of live fetuses and retarded fetal development observed in a developmental toxicity study in rats, 100 UF applied (EFSA, 2015).

The toxicological properties of metabolites included in the risk assessment residue definition were also assessed during the procedure of renewal of the approval. The peer review concluded that 8-hydroxy-bentazone is relatively less toxic than the parent bentazone from the acute, short-term and developmental toxicity point of view and is unlikely to be genotoxic. The toxicological reference values of the parent apply to this metabolite (EFSA, 2015).

Regarding 6-hydroxy-bentazone, insufficient toxicological information (acute toxicity studies in rat and mouse, as well as an Ames test) was available during the renewal of approval of bentazone and a data gap was identified by the peer review for further data to derive toxicological reference values (EFSA, 2015). This means that the clastogenic/aneugenic potential, and repeated-dose toxicity of 6-hydroxy-bentazone have to be addressed by appropriate toxicological data.

For this metabolite, in support of the current MRL application, the applicant provided a QSAR analysis using combination of a statistical model (Case Ultra ver. 1.7.0.5) and expert knowledge system (DEREK Nexus ver. 2.2). The end points predicted were in vivo micronucleus (Case Ultra model) and in vitro and in vivo chromosomal damage (Derek Nexus model). Negative predictions were obtained from both models. It should be mentioned that in order to straighten the reliability of the predictions the applicant has expanded the applicability domain of the statistical model to pesticides chemistry by including in the training set substances from EFSA Genotoxicity database as well as from their own proprietary plant protection database. Although the full details of the model are not reported in the evaluation report, e.g. whether only validated in vivo experimental data were used for which the bioavailability of the test substance to the bone marrow was demonstrated and of the statistical performance of the model, EFSA agrees with the EMS that based on the QSAR analysis it can be concluded that 6-hydroxy-bentazone is unlikely to be genotoxic with regards to chromosome aberration and aneugenicity in vivo. In addition, read across with bentazone and 8-hydroxy-bentazone is acceptable regarding genotoxicity considering that no alerts were found in any of these compounds, which did not exhibit genotoxic concerns based on experimental data and the different position of the hydroxy group in the aromatic ring is not expected to lead to positive chromosomal damage potential. Taking the QSAR predictions supported by read across and the negative Ames test into account, 6-hydroxy-bentazone is unlikely to be genotoxic.

Regarding general toxicity, EFSA does not agree with the EMS conclusion that based on read-across with bentazone and 8-hydroxy-bentazone, 6-hydroxy-bentazone is considered to be not more toxic than the parent (Netherlands, 2018). On one hand, the QSAR analysis does not inform on the relative toxicity of the test compound and on the other hand, the configuration of 6-hydroxy-bentazone (hydroxy group in the para-position) could potentially lead to a different reactivity and to different steric interactions of the molecule compared to the ortho-position of 8-hydroxy-bentazone and accordingly a higher toxicity of the metabolite compared with 8-hydroxy-bentazone and the parent

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7 Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.
bentazone could not be excluded. The External Scientific Report on the impact of metabolic and degradation processes on the toxicological properties of residues of pesticides in food commodities (Bergmann et al., 2010), reports similar toxicity for hydroxylation on another ring position based on acute toxicity studies, these studies are of low relevance to consumer exposure unlike repeated-dose toxicity studies; the report also notes that ‘one and the same metabolic step can cause detoxification of one substance and toxification of another’.

According to EFSA, on the basis of the available information, no conclusion can be drawn whether the toxicological reference values of the parent bentazone are applicable to the metabolite 6-hydroxy-bentazone.

It is noted that the toxicity of this metabolite was discussed by risk managers in the framework of the renewal of the approval of bentazone, taking into account the conclusions of JMPR (FAO, 2012). According to JMPR, 8-hydroxy-bentazone and 6-hydroxy-bentazone are of comparable toxicity by oral route of administration and both metabolites are less toxic than the parent compound (European Commission, 2018). For the reasons outlined above, EFSA does not share the view of JMPR.

2. Residues in plants

2.1. Nature of residues and methods of analysis in plants

2.1.1. Nature of residues in primary crops

The metabolism of bentazone following foliar application was investigated in the framework of the renewal of the approval according to Regulation (EC) 1107/2009 in pulses/oilseed (soyabeans), root and tuber crops (potatoes) and cereals/grass (rice, maize, wheat), using 14C-phenyl labelled bentazone (EFSA, 2015).

Parent bentazone was hardly ever 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 also identified in significant proportions, mainly in the feed commodities (24% TRR in maize forage up to 41% TRR in wheat hay), while the glucoside conjugate of 8-hydroxy-bentazone was detected in soyabean forage and in wheat straw, but at lower levels (28% TRR and 3% TRR, respectively). The major part of the radioactivity in the soyabean seeds, potato tuber and cereal grain was found to be incorporated into natural plant constituents (up to 70% TRR).

An additional metabolism study with foliar treated wheat, grown as a rotational crop following the harvest of potatoes which were also treated with bentazone, was submitted in the framework of the renewal of the approval. In potato tubers (primary crop), numerous fractions were recovered at a level > 10% of TRR, which were not further identified as their actual levels were mostly below 0.01 mg/kg and consisted mainly of a mixture of polar compounds. In wheat straw, a significant unidentified fraction M3 (57% TRR – 1.1 mg eq./kg) was found; the peer review identified a data gap requesting further attempts to characterise and identify this fraction based on all analytical evidence available from the wheat metabolism study and considering also the potential uptake by the plants of soil metabolites (EFSA, 2015).

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 affect the current assessment as the forages of soyabeans and poppy seeds are not used as livestock feed in Europe.

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

2.1.2. Nature of residues in rotational crops

Soyabeans and poppy seeds can be grown in a crop rotation. During the renewal of the approval of bentazone, 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 the soil, a minor metabolite (N-methyl-bentazone, 2.4 – 5.7% of applied radioactivity (AR)) was identified, which exhibits higher persistence in the soil than parent bentazone, with maximum DT90 accounting for up to 508 days, being above the threshold limit of 100 days (EFSA, 2015).
The metabolism of bentazone in rotational crops was investigated in the framework of the renewal of the approval of bentazone according to Regulation (EC) 1107/2009 (EFSA, 2015). In the confined rotational crop metabolism studies on leafy crops, root crops and cereals after a bare soil application of \(^{14}\)C-phenyl labelled bentazone at 1 kg/ha 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). The peer review concluded that the metabolism of bentazone in rotational crops proceeds according to the same pathway as in primary crops (EFSA, 2015).

An additional metabolism study is available where wheat was grown as rotational crop following the harvest of potatoes\(^8\) (see further details in Appendix B.1.1.1).

EFSA reiterates that the data gap on the identity of the metabolite fraction M3 is still open. Pending the clarification of this open issue, it cannot be excluded that in crops, treated annually at the maximum authorised application rates, unidentified residues resulting from the use of bentazone might occur. However, for the uses assessed in this application, the data gap is of minor relevance.

2.1.3. 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 related to the crops under assessment.

2.1.4. Methods of analysis in plants

The availability of analytical methods for the determination of bentazone residues in plant matrices was investigated in the framework of the renewal of the approval of bentazone according to Regulation (EC) 1107/2009 (EFSA, 2015).

The 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 (onions, peas), high acid content (orange), high oil content (soyabeans), and high protein content (dry peas) at the individual limit of quantifications (LOQs) of 0.01 mg/kg (EFSA, 2015).

Thus, a sufficiently validated enforcement method is available for the determination of bentazone residues according to the enforcement residue definition in oilseeds. The method covers the parent compound and the metabolites included in the residue definition currently established in Regulation (EC) No 396/2005.

2.1.5. Stability of residues in plants

The freezer storage stability of bentazone residues was investigated in the framework of the renewal of the approval of bentazone according to Regulation (EC) 1107/2009 and studies demonstrated that residues of bentazone and conjugates of 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), high oil content matrices (flax seed) (EFSA, 2015).

2.1.6. Proposed residue definitions

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

- For enforcement and risk assessment: 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).

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):

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\(^8\) Potatoes were treated with \(^{14}\)C-phenyl-labelled bentazone at 1.5 kg/ha 30 days after planting; 90 days later potatoes were harvested. Wheat was sown (160 days after treatment (DAT)) and treated again with \(^{14}\)C-phenyl-labelled bentazone at 1.5 kg/ha 160 days after sowing. The study was assessed as primary crop metabolism study (EFSA, 2015).
For enforcement: Bentazone
For risk assessment: Sum of bentazone, 6-hydroxy-bentazone and its conjugates, expressed as bentazone⁹ (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 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 the conjugates of 6-hydroxy bentazone and 8-hydroxy-bentazone.

2.2. Magnitude of residues in plants

2.2.1. Magnitude of residues in primary crops

In support of the intended uses in soyabean and poppy seeds, the applicant submitted in total 10 northern Europe (NEU) and 12 southern Europe (SEU) residue trials on soyabean, which were performed in various European countries over growing seasons of 2007, 2009, 2011 and 2014. Two trials from NEU and one trial from SEU were disregarded as they were not fully GAP compliant since the application was made at a significantly later growth stage (BBCH 69–70) compared to the GAP. In seven other trials, the growth stage of the application was not complying with the GAP, but this deviation was considered acceptable, as the treatment was still before flowering. In these trial samples, residues were within the same range as in trials treated at a growth stage of BBCH 25.

The samples were analysed for the parent compound and the metabolites included in the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. The samples of these residue trials were stored under conditions for which integrity of the samples has been demonstrated (Netherlands, 2018).

In none of the soyabean samples from SEU trials, the residues of bentazone and its metabolites were above the LOQ. In the selected NEU trials that were found to be representative for the intended GAP, parent bentazone was found in concentrations greater than the LOQ in three trials; 6-hydroxy bentazone and 8-hydroxy-bentazone was quantified in one trial (0.018 mg/kg and 0.016 mg/kg, respectively). Based on the NEU residue trials, an MRL of 0.2 mg/kg was calculated.

The applicant proposed to extrapolate residue data from soyabeans to poppy seeds in support of the NEU use of bentazone on poppy. According to EU guidance document, such an extrapolation is acceptable as the treatment is performed before the flowering (European Commission, 2017).

The available residue data allow to derive also MRL proposals for the proposed new residue definition derived in the framework of the peer review which covers only parent bentazone (see Appendix B.1.2.1).

2.2.2. 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 in three studies where soyabees were treated twice at 1.12 kg/ha and various rotational crops were planted reflecting crop failure, autumn and annual rotation (Netherlands, 2013). The highest residues 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 plant-back intervals (PBI), residues of bentazone, 8-hydroxy-bentazone and 6-hydroxy-bentazone were below the individual LOQs of 0.05 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 soyabeans and poppy seeds is less critical compared to the representative uses, the same conclusion is valid for the current assessment.

⁹ 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.
2.2.3. Magnitude of residues in processed commodities

Specific processing studies with soyabeans were submitted for the renewal of the approval of bentazone (EFSA, 2015). Two studies were available with soyabeans treated at an exaggerated application rate of 2.24 kg/ha; harvested seeds were processed into oil; crude oil, refined oil, hulls, meal and soapstock were analysed for bentazone, 6-hydroxy-bentazone and 8-hydroxy-bentazone residues (Netherlands, 2013). In seeds, no residues above the LOQ of 0.05 mg/kg were identified; similarly, in hulls, refined oil and soapstock no residues above the LOQ were found. An increased residue concentration of bentazone and 8-hydroxy-bentazone was observed in meal (0.055 mg/kg and 0.07 mg/kg) and crude oil (0.095 mg/kg and 0.054 mg/kg) and of 6-hydroxy-bentazone in meal fraction only (0.07 mg/kg). However, since residues in unprocessed seeds were below the LOQ, reliable processing factors could not be derived.

2.2.4. Proposed MRLs

The available data are considered sufficient to derive MRL proposals as well as risk assessment values for soyabeans and poppy seeds in support of the intended uses, according to the existing and proposed enforcement and risk assessment residue definitions (see Appendix B.1.2.1).

3. Residues in livestock

Soyabeans and soyabean by-products may be used for feed purposes. Hence, it was necessary to perform a dietary burden calculation for livestock to estimate whether the intended use of bentazone on soyabeans would have an impact on the current livestock exposure, triggering a revision of the existing MRLs for animal products.

The livestock dietary burden was recently calculated in the framework of the assessment of Article 12 confirmatory data for bentazone using the EU methodology used in the MRL review (PROFile) (EFSA, 2019b). The dietary burden was now recalculated according to the OECD methodology (OECD, 2013).

Since the new residue definition for plant commodities derived in the framework of the renewal of the approval (EFSA, 2015) is not yet implemented in the MRL legislation and since residue data are not available for all feed crops for the new residue definition, the livestock dietary burden was calculated for the current plant residue definition (the sum of bentazone and the conjugates of 6-hydroxy bentazone and 8-hydroxy-bentazone, expressed as bentazone) which covers additional metabolites and therefore is considered to lead to a slightly higher result.

The input values for the exposure calculations for livestock are presented in Appendix D. The results of the dietary burden calculation are presented in Appendix B.2; the calculated exposure exceeds the trigger value of 0.1 mg/kg DM for all livestock species. However, the contribution of residues in soyabeans to the calculated exposure is insignificant.

The use of the OECD methodology results in a lower dietary burden for cattle and a slightly higher one for poultry and swine compared with the EU methodology used previously (EFSA, 2019b). These results have an impact on the MRLs for animal products, resulting in slightly different MRL proposals for swine and ruminants compared to the MRLs derived in the assessment of Article 12 confirmatory data (EFSA, 2019b). For poultry, the previously derived MRLs are still valid; the calculations confirm that residues above the LOQ are not expected in poultry matrices. The summary of livestock feeding studies and the estimated MRL proposals are presented in Appendix B.2.2.1.

As regards the new residue definitions for plant and animal commodities proposed in the framework of the renewal of the approval (see Appendix B), EFSA is of the opinion that once the relevant data gaps are addressed and the residue data are available for all crops on which the use of bentazone is authorised, the magnitude of bentazone residues in livestock should be reassessed.

4. Consumer risk assessment

EFSA performed the dietary risk assessment using revision 3.1 of the EFSA PRIMo (EFSA, 2017, 2019a).

The toxicological reference values for bentazone used in the risk assessment (i.e. ADI of 0.09 mg/kg bw per day and the ARfD value of 1 mg/kg bw) were set 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 can be applied for this metabolite. Regarding 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). Although in the current application, some new toxicological data and argumentation were provided, EFSA is of the opinion that a final conclusion cannot be drawn whether the toxicological reference values of the parent bentazone are applicable to the metabolite 6-hydroxy-bentazone.

The chronic exposure assessment was performed using the STMR values as derived for soyabeans and poppy seeds from the residue trials submitted under the current assessment. For the remaining commodities of plant and animal origin, the input values were those considered in the recent EFSA opinion on the evaluation of confirmatory data following the Article 12 MRL review for bentazone (EFSA, 2019b). It is noted that 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.

The acute exposure assessment was performed only for soyabeans and poppy seeds, considering the STMR values as derived from the residue trials submitted for the current assessment.

The input values are summarized in Appendix D.2.

Lacking a final conclusion on the toxicological profile for metabolite 6-hydroxy-bentazone, the risk assessment is indicative, and was performed under the assumption that the toxicity of metabolite 6-hydroxy-bentazone is comparable to parent compound. Under this assumption, the estimated maximum long-term dietary intake accounted for maximum 3% of the ADI (NL toddler). The contribution of residues in soyabeans and poppy seeds to the overall long-term exposure was low (maximum 0.16% of the ADI for soyabeans and less than 0.001% of the ADI for poppy seeds). The maximum short-term exposure for oilseeds under consideration was low as well (< 0.01% of the ARfD for soyabeans and poppy seeds, respectively).

The risk assessment is affected by additional, non-standard uncertainties resulting from the lack of toxicological data related to metabolite 6-hydroxy-bentazone. The exposure related to 6-hydroxy-bentazone which was found in one of the 19 valid residue trials representative for the assessed use (0.018 mg/kg), was low (maximum chronic exposure 0.15 µg/kg bw per day, maximum acute exposure 0.09 µg/kg bw).

When taking a decision on the acceptability of the MRL proposals derived for soyabeans and poppy seeds from the residue trials, risk managers should take into account the additional non-standard uncertainties.

The results of the consumer risk assessment calculation are summarized 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.

5. Conclusion and recommendations

The residue data submitted in support of the intended NEU use on poppy seeds and NEU/SEU uses on soyabeans were found to be sufficient to derive an MRL proposal of 0.2 mg/kg for the current enforcement residue definition. The same MRL proposal is appropriate if the enforcement residue definition is modified as proposed in the framework of the renewal of the approval (EFSA, 2015).

Adequate analytical methods for enforcement are available to control the residues of bentazone in the oilseeds under consideration.

An indicative short-term and long-term dietary risk assessment was performed, taking into account residues resulting from the existing authorised uses and the intended use of bentazone on soyabeans and poppy seeds. The calculated dietary exposure did not exceed the toxicological reference values. However, since according to EFSA, the data provided by the applicant are not sufficient to conclude that the metabolite 6-hydroxy-bentazone is not more toxic than the parent compound, the risk assessment is considered indicative.

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

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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
DM dry matter
DT$_{90}$ period required for 90% dissipation (define method of estimation)
EMS evaluating Member State
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
ILV independent laboratory validation
InChIKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LC-MS/MS liquid chromatography with tandem mass spectrometry
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
NOAEL no observed adverse effect level
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PF processing factor
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
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
TRR total radioactive residue
WHO World Health Organization
## Appendix A – Summary of authorised GAP in exporting country triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | FG or I<sup>(a)</sup> | 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> | |
| Soyabeans             | NEU/SEU                | F                 | Annual dicotyledonous weeds       | SL          | 480 g/L     | Spraying   | 12–19                  | 1 (or 2 split applications) | –         | –          | 100–400 | kg/ha | –          | |
|                       | NEU/SEU                | F                 | Annual dicotyledonous weeds       | SG          | 87%         | Spraying   | 12–19                  | 1 (or 2 split applications) | –         | –          | 100–400 | kg/ha | –          | |
|                       | NEU/SEU                | F                 | Weeds general                     | SL          | 480         | Spraying   | 12–25                  | 1 (or 2 split applications) | –         | –          | 100–400 | kg/ha | –          | With/without DASH (max 1 l/ha) |
| Poppy seeds           | NEU                    | F                 | Annual dicotyledonous weeds       | SL          | 480 g/L     | Spraying   | 13–39                  | 2                      | 7–14       | 200–400  | 0.360   | kg/ha | –          | |
|                       | F                      |                   | Annual dicotyledonous weeds       | SG          | 87%         | Spraying   | 13–39                  | 1 (or 2 split applications) | –         | –          | 200–400 | kg/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; SG: water-soluble granule.

<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 (Netherlands, 2013; EFSA, 2015) |
| Cereals/ grass                   | Rice        | Foliar, 1 × 1 kg/ha | 26, 63 | Radiolabelled active substance: phenyl-14C-bentazone (Netherlands, 2013; EFSA, 2015) |
|                                  | Maize       | Foliar, 1.68 kg/ha | 0, 7, 14, 21, 42, 63, 126 | Radiolabelled active substance: phenyl-14C-bentazone (Netherlands, 2013; EFSA, 2015) |
|                                  | Wheat       | Foliar, 1 kg/ha, BBCH 31–32 | 20, 83 | Radiolabelled active substance: phenyl-14C-bentazone (Netherlands, 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) |

| 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     |          |             |           |                |
| Cereals (small grain)                | Spring wheat|          |             |           |                |
### 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)             |              |                                                          |

### 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 characterised 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):**
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)

### 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)

DAT: days after treatment; PBI: plant-back interval; LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification.
## B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category            | Commodity           | T (°C) | Stability period | Compounds covered                                      | Comment/ Source                       |
|------------------------------------|---------------------|---------------------|--------|------------------|--------------------------------------------------------|---------------------------------------|
|                                    | High water content  | 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     | 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, its salts, 6-hydroxy-bentazone (free and conjugated) and 8-hydroxy-bentazone (free and conjugated), expressed as bentazone | Soyabeans, Poppy seeds | NEU Soyabeans: 4 × < 0.03; 0.04; 2 × 0.1; 0.044 | Residue trials on soyabean compliant with the GAP. Extrapolation to poppy seeds possible | 0.20 | 0.10 | 0.04 | n/a |
| | | SEU Soyabeans: 11 × < 0.03 | Residue trials on soyabean compliant with the GAP. Extrapolation to poppy seeds possible | 0.03* | 0.03 | 0.03 | n/a |
| **Risk assessment residue definition** (EFSA, 2012): Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone | Soyabeans, Poppy seeds | NEU Soyabeans: Mo: 5 × < 0.01; 0.02; 2 × 0.08 RA: 4 × < 0.02; 0.03; 0.028; 2 × 0.09 | Residue trials on soyabean compliant with the GAP. Extrapolation to poppy seeds possible | 0.20 | RD enf: 0.08 | RD RA: 0.09 | RD RA: 0.02 |
| | | SEU Soyabeans: Mo: 11 × < 0.01 RA: 11 × < 0.01 | Residue trials on soyabean compliant with the GAP. Extrapolation to poppy seeds possible | 0.01* | RD enf: 0.01 | RD RA: 0.02 | RD RA: 0.02 |

MRL: maximum residue level; GAP: Good Agricultural Practice; RD: residue definition; RA: risk assessment.

*: 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 according to the residue definition for monitoring.

(c): Supervised trials median residue according to the residue definition for monitoring.

(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

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | No |

Following the treatment of soybeans at 2 x 1.12 kg/ha, 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) (Netherlands, 2013).

DAT: days after treatment; PBI: plant-back interval; 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

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

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

| Relevant groups (subgroups) | Dietary burden expressed in mg/kg bw per day | Dietary burden expressed in mg/kg DM | Previously calculated maximum dietary burden (mg/kg DM) | Most critical subgroup(a) | Most critical commodity(b) | Trigger exceeded (Y/N) |
|----------------------------|---------------------------------------------|-------------------------------------|--------------------------------------------------------|---------------------------|--------------------------|------------------------|
| Cattle (all)               | 0.688                                       | 0.872                               | 17.89(c)                                               | Dairy cattle              | Grass hay                | Y                      |
| Cattle (dairy only)        | 0.688                                       | 0.872                               | 17.89                                                 | Dairy cattle              | Grass hay                | Y                      |
| Sheep (all)                | 0.777                                       | 1.015                               | 23.30(d)                                               | n.c.                      | Ram/Ewe                  | Y                      |
| Sheep (ewe only)           | 0.777                                       | 1.015                               | 30.45(d)                                               | n.c.                      | Ram/Ewe                  | Y                      |
| Swine (all)                | 0.164                                       | 0.202                               | 7.11                                                   | Swine (breeding)          | Grass hay                | Y                      |
| Poultry (all)              | 0.047                                       | 0.063                               | 0.69(e)                                                | Poultry layer             | Corn forage/silage       | Y                      |
| Poultry (layer only)       | 0.047                                       | 0.063                               | 0.69                                                   | Poultry layer             | Corn forage/silage       | Y                      |

bw: body weight; DM: dry matter.
(a): When one group of livestock includes several subgroups (e.g. poultry ‘all’ including broiler, layer and turkey), the result of the most critical subgroup is identified from the maximum dietary burdens expressed as ‘mg/kg bw per day’.
(b): The most critical commodity is the major contributor identified from the maximum dietary burden expressed as ‘mg/kg bw per day’.
(c): The highest dietary burden expressed in mg/kg DM result from dairy cattle.
(d): The highest dietary burden expressed in mg/kg DM result from ram/ewe.
(e): The highest dietary burden expressed in mg/kg DM result from layer poultry.
(f): Calculated in the framework of the evaluation of the Article 12 confirmatory data, using PROFile rev.2.3 (EFSA, 2019b)
### 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; EFSA, 2019b) |
|-----------------------|-----------------|---------------------------------------------------|
| Eggs                  | Not investigated |                                                   |
| Metabolism in rat and ruminant similar | Yes | EFSA (2015) |
| Can a general residue definition be proposed for animals? | No | Residue definition differs for milk (EFSA, 2015) |

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

- MRL review (EFSA, 2012): Sum of bentazone and the metabolite 6-hydroxy bentazone (free and conjugated), expressed as bentazone
- Regulation (EC) No 396/2005: Sum of bentazone, its salts and 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 (provisional)

**Fat soluble residues**

- No

**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)

LC–MS/MS: liquid chromatography with tandem mass spectrometry; LOQ: limit of quantification; ILV: independent laboratory validation.
### B.2.1.2. Stability of residues in livestock

| Animal | Commodity | T (°C) | Stability period Value | 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) |
|        | Kidney    | –20    | 305* Days              | Bentazone         |
|        |           | –20    | 125 Days               | 6-Hydroxy-bentazone |
|        | Milk      | –20    | 121 Days               | Bentazone         | Netherlands (2018) |
|        | Fat       | –20    | 124 Days               | Bentazone         | Netherlands (2018) |
|        |           | –20    | 249* Days              | 6-Hydroxy-bentazone |

*: 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.2.2. Magnitude of residues in livestock

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

| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | Mean | Highest | STMR(a),(g) (mg/kg) | HR(b),(g) (mg/kg) | MRL proposal(g) (EFSA, 2019b) | MRL proposal(g) (EFSA, 2019b) | Existing EU MRL(g) in Regulation (EU) No 1146/2014 | Mean Highest STMR(a),(g) | HR(b),(g) (mg/kg) | MRL proposal(g) (EFSA, 2019b) | MRL proposal(g) (EFSA, 2019b) | Existing EU MRL(g) in Regulation (EU) No 1146/2014 |
|------------------|-----------------------------------------------|---------------------------------------------|------|---------|---------------------|-----------------|---------------------------|-----------------------------|-----------------------------------------------|----------------------|----------------------|-----------------------------|-----------------------------|-----------------------------------------------|
| Cattle (all)     |                                              |                                             |      |         |                     |                 |                           |                             |                                 |                        |                      |                             |                             |                                 |
| Closest feeding level (1 mg/kg bw; 1.1 N rate dairy cattle (highest diet))<sup>(c)</sup> | Muscle | 0.02 | 0.02 | 0.02 | 0.02 | 0.02* | 0.02* | 0.02* | 0.02* | 0.02* | 0.02* |
|                   | Fat | 0.02 | 0.02 | 0.02 | 0.02 | 0.02 | 0.03 | 0.03 | 0.03 |
|                   | Liver | 0.02 | 0.03 | 0.02 | 0.03 | 0.03 |
|                   | Kidney | 0.08 | 0.13 | 0.06 | 0.11 | 0.15 | 0.3 |
| Cattle (dairy only) |                                              |                                             |      |         |                     |                 |                           |                             |                                 |                        |                      |                             |                             |                                 |
| Closest feeding level (1 mg/kg bw; 1.1 N rate)<sup>(c)</sup> | Milk<sup>(g)</sup> | 0.02 | 0.02 | 0.02 | 0.02 | 0.02* | 0.03 |
| Sheep (all)<sup>(e)</sup> |                                              |                                             |      |         |                     |                 |                           |                             |                                 |                        |                      |                             |                             |                                 |
| Closest feeding level (1 mg/kg bw; 1.0 N ram/ewe (highest diet))<sup>(c)</sup> | Muscle | 0.02 | 0.02 | 0.02 | 0.02 | 0.02* | 0.02* |
|                   | Fat | 0.02 | 0.02 | 0.02 | 0.02 | 0.03 |
|                   | Liver | 0.02 | 0.03 | 0.02 | 0.03 | 0.04 |
|                   | Kidney | 0.08 | 0.13 | 0.07 | 0.14 | 0.15 |
| Sheep (ewe only)<sup>(e)</sup> |                                              |                                             |      |         |                     |                 |                           |                             |                                 |                        |                      |                             |                             |                                 |
| Closest feeding level (1 mg/kg bw; 1.0 N rate)<sup>(c)</sup> | Milk<sup>(g)</sup> | 0.02 | 0.02 | 0.02 | 0.02 | 0.03 |

<sup>(a)</sup>: Mean Highest STMR: Standardized Total Maximum Residue.  
<sup>(b)</sup>: Estimated Maximum Residue of the substance in the specific food or feedstuffs.  
<sup>(c)</sup>: Mean Highest STMR and HR: Standardized Total Maximum Residue and Highest Residue.  
<sup>(d)</sup>: Mean Highest STMR: Standardized Total Maximum Residue.  
<sup>(e)</sup>: Mean Highest STMR and HR: Standardized Total Maximum Residue and Highest Residue.  
<sup>(f)</sup>: Mean Highest STMR and HR: Standardized Total Maximum Residue and Highest Residue.
| Animal commodity | Residues at the closest feeding level (mg/kg) | Estimated value at 1N MRL proposal (mg/kg) | MRL proposal (mg/kg) | Existing EU MRL in Regulation (EU) No 1146/2014 |
|------------------|---------------------------------------------|------------------------------------------|----------------------|-----------------------------------------------|
|                  | Mean | Highest | STMR<sup>a</sup>,<sup>d</sup> [mg/kg] | HR<sup>b</sup>,<sup>c</sup> [mg/kg] |                                |
| Swine (all)<sup>e</sup> |      |         |                                |                            |                            |
| Muscle           | 0.02 | 0.02    | 0.02                           | 0.02                      | 0.02* 0.02* 0.02*          |
| Fat              | 0.02 | 0.02    | 0.02                           | 0.02                      | 0.02* 0.02* 0.15           |
| Liver            | 0.02 | 0.02    | 0.02                           | 0.02                      | 0.02* 0.02* 0.02*          |
| Kidney           | 0.03 | 0.03    | 0.01                           | 0.02                      | 0.02 0.03 0.05             |

bw: body weight; MRL: maximum residue level; STMR: supervised trials median residue; HR: highest residue; n.a.: not applicable; n.r.: not reported.

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

(a): The mean residue level for milk and the mean residue levels for eggs and tissues were recalculated at the 1N rate for the median dietary burden.

(b): The mean residue level in milk and the highest residue levels in eggs and tissues, were recalculated at the 1N rate for the maximum dietary burden.

(c): Closest feeding level and N dose rate related to the maximum dietary burden.

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

(e): 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.

(f): MRL proposals extrapolated from cattle.

(g): MRL proposals, HR and STMR values refer to the current enforcement/risk assessment residue definitions (i.e. Sum of bentazone, its salts and 6-hydroxy (free and conjugated), expressed as bentazone/ Sum of bentazone and the metabolite 6-hydroxy bentazone (free and conjugated), expressed as bentazone).

### B.3. Consumer risk assessment

| ARfD | 1 mg/kg bw (EFSA, 2015, European Commission, 2018) |
|------|------------------------------------------------------|
| Highest IESTI, according to EFSA PRIMo | Soyabean: < 0.01% of the ARfD (DE child)  
Poppy seeds: < 0.01% of the ARfD (DE women 14-50 years) |
| Assumptions made for the calculations | PRIMo rev. 3.1  
Residue definition: Sum of bentazone and the conjugates of 6-hydroxy-bentazone and 8-hydroxy-bentazone, expressed as bentazone  
The calculation is based on the median residue levels expected in soyabean and poppy seed according to residue trials supporting the intended NEU use |
Highest IEDI, according to EFSA PRIMo

| Commodity | Existing MRL | Proposed MRL | Conclusion/recommendation |
|-----------|--------------|--------------|---------------------------|
| Poppy seeds | 0.03* | 0.2/0.2 | The submitted residue data are sufficient to derive an MRL proposal for the intended NEU use. According to the indicative dietary risk assessment, no consumer intake concerns were identified. Further risk management considerations required, considering that the general toxicity of 6-hydroxy-bentazone is not fully characterised |
| Soybeans | 0.03* | 0.2/0.2 | The submitted residue data are sufficient to derive an MRL proposal for the new intended NEU/SEU uses. The MRL reflects the more critical NEU use. According to the indicative dietary risk assessment, no consumer intake concerns were identified. Further risk management considerations required, considering that the general toxicity of 6-hydroxy-bentazone is not fully characterised |

B.4. Recommended MRLs

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; STMR: supervised trials median residue; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level; NEU: northern Europe; LOQ: limit of quantification.
**Existing enforcement residue definition:** Sum of bentazone, its salts and 6-hydroxy-bentazone (free and conjugated), expressed as bentazone

| Code\(^{(a)}\) | Commodity | Existing MRL | Proposed MRL | Conclusion/recommendation |
|----------------|-----------|--------------|--------------|----------------------------|
| 1011040        | Swine kidney | 0.05/0.03\(^{(b)}\) | 0.02 | Further risk management considerations required |
| 1012030        | Liver: Bovine | 0.02*/0.05\(^{(c)}\) | 0.03 (cattle) 0.04 (sheep) | Further risk management considerations required |
| 1013030        | Sheep | | | |
| 1014030        | Goat | | | |
| 1015030        | Equine | | | |
| 1012040        | Kidney: Bovine | 0.3/0.3\(^{(b)}\) | 0.15 | Further risk management considerations required |
| 1013040        | Sheep | | | |
| 1014040        | Goat | | | |
| 1015040        | Equine | | | |
| 1020000        | Milk | 0.02*/0.03\(^{(b)}\) | 0.02* (cattle) 0.03 (sheep) | Further risk management considerations required |

**MRL:** maximum residue level; **NEU:** northern Europe; **SEU:** southern Europe; **OECD:** Organisation for Economic Co-operation and Development.

\(^{(a)}\): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

\(^{(b)}\): The MRL proposals derived in the EFSA reasoned opinion on the evaluation of the Article 12 confirmatory data for bentazone (EFSA, 2019b).

\(^{(c)}\): Indicates that the MRL is set at the limit of analytical quantification (LOQ).
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Bentazone

| Commodity/group of commodities | Calculated exposure (% of ADI) | Exposure resulting from (µg/kg bw per day) | 2nd contributor to MS diet (% of ADI) | 3rd contributor to MS diet (% of ADI) |
|-------------------------------|-------------------------------|------------------------------------------|-------------------------------------|-------------------------------------|
| Potatoes                      | 0.6%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Wheat                         | 0.9%                          | 0.3%                                     | 0.3%                                 | 0.2%                                 |
| Milk:  Cattle                 | 1.2%                          | 0.2%                                     | 0.2%                                 | 0.2%                                 |
| Wheat                         | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Milk:  Cattle                 | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Milk:  Cattle                 | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Milk:  Cattle                 | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Milk:  Cattle                 | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |
| Potatoes                      | 1.2%                          | 0.3%                                     | 0.3%                                 | 0.1%                                 |

The estimated long-term dietary intake (THEDI/NDEDI) was below the ADI. The long-term intake of residues of 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 children

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|--------------------------|---------------------|
| 1%                    | Potatoes    | 0.20/0.08                | 12                  |
| 0.9%                  | Sweet corn  | 0.30/0.21                | 9.1                 |
| 0.8%                  | Leeks       | 0.15/0.15                | 8.8                 |
| 0.7%                  | Cucumbers   | 0.10/0.1                 | 6.6                 |
| 0.6%                  | Sage        | 0.10/0.1                 | 5.8                 |
| 0.6%                  | Basil and edible flowers | 0.10/0.72 | 5.6 |
| 0.3%                  | Cucumbers   | 0.10/0.1                 | 2.6                 |
| 0.2%                  | Leeks       | 0.10/0.1                 | 2.6                 |
| 0.2%                  | Spring onions/green onions | 0.10/0.72 | 2.6 |
| 0.1%                  | Maize/Boiled| 0.10/0.1                 | 1.1                 |
| 0.1%                  | Beans (without pods)/boiled | 0.10/0.06 | 0.73 |
| 0.0%                  | Rice/milling (polishing) | 0.10/0.01 | 0.12 |

### Results for adults

| Highest % of ARfD/ADI | Commodities | MRL/input for RA (mg/kg) | Exposure (µg/kg bw) |
|-----------------------|-------------|--------------------------|---------------------|
| 0.9%                  | Parsley     | 0.10/0.1                 | 9.2                 |
| 0.3%                  | Sweet corn  | 0.30/0.21                | 3.3                 |
| 0.3%                  | Cucumbers   | 0.10/0.1                 | 2.8                 |
| 0.2%                  | Leeks       | 0.15/0.15                | 2.0                 |
| 0.2%                  | Sage        | 0.10/0.1                 | 1.5                 |
| 0.1%                  | Cucumbers   | 0.10/0.1                 | 1.3                 |
| 0.1%                  | Maize/Boiled| 0.10/0.1                 | 1.0                 |
| 0.1%                  | Beans (without pods)/boiled | 0.10/0.06 | 0.77 |
| 0.0%                  | Rice/milling (polishing) | 0.10/0.01 | 0.00 |

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Bentazone is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI was identified.

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### 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 × PF (4) (EFSA, 2012) | 28.80 HR × PF (4) (EFSA, 2012) |                        |                        |
| Maize (corn) forage             | 0.92 STMR (EFSA, 2012) | 1.80 HR (EFSA, 2012)   |                        |                        |
| barley, oat straw               | 0.16 STMR (EFSA, 2012) | 0.65 HR (EFSA, 2012)   |                        |                        |
| Wheat, rye straw                | 0.09 STMR (EFSA, 2012) | 0.10 HR (EFSA, 2012)   |                        |                        |
| barley, oat grain               | 0.06 STMR (EFSA, 2012) | 0.06 STMR (EFSA, 2012) |                        |                        |
| Wheat, rye grain                | 0.06 STMR (EFSA, 2012) | 0.06 STMR (EFSA, 2012) |                        |                        |
| potato culls                    | 0.06 STMR (EFSA, 2019b) | 0.08 HR (EFSA, 2019b)  |                        |                        |
| beans, peas, dry                | 0.06 STMR              |                        | 0.06 STMR              |                        |
| linseed meal                    | 0.12 STMR (linseed) × PF (2) (EFSA, 2012) | 0.06 STMR (linseed) × PF (2) (EFSA, 2012) |                        |                        |
| dried brewer's grain            | 0.20 STMR (grain) × PF (3.3) (EFSA, 2012) | 0.20 STMR (grain) × PF (3.3) (EFSA, 2012) |                        |                        |
| dried distiller's grain         | 0.20 STMR (grain) × PF (3.3) (EFSA, 2012) | 0.20 STMR (grain) × PF (3.3) (EFSA, 2012) |                        |                        |
| potato process waste            | 1.20 STMR (potatoes) × PF (20) (a) | 1.20 STMR (potatoes) × PF (20) (a) |                        |                        |
| potato, dried pulp              | 2.28 STMR (potatoes) × PF (38) (a) | 2.28 STMR (potatoes) × PF (38) (a) |                        |                        |
| soyabean (seed)                 | 0.04 STMR              | 0.04 STMR              |                        |                        |
| soyabean meal                   | 0.05 STMR (soybean) × PF (1.3) (a) | 0.05 STMR (soybean) × PF (1.3) (a) |                        |                        |
| soyabean hulls                  | 0.52 STMR (soybean) × PF (13) (a) | 0.52 STMR (soybean) × PF (13) (a) |                        |                        |
| wheat gluten meal               | 0.11 STMR (grain) × PF (1.8) (a) | 0.11 STMR (grain) × PF (1.8) (a) |                        |                        |
| wheat, milled by products       | 0.42 STMR (grain) × PF (7) (a) | 0.42 STMR (grain) × PF (7) (a) |                        |                        |

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

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|----------------------|
|                            | Input value (mg/kg)     | Comment              | Input value (mg/kg) | Comment              |
|                            |                        |                      |                     |                      |
| Soyabean, poppy seeds      | 0.04 STMR (NEU use)     | 0.04 STMR (NEU use)  |                      |                      |

STMR: supervised trials median residue; HR: highest residue; PF: processing factor.
(a): For linseed meal, dried brewer's grain, dried distiller's grain, potato process waste, potato dried pulp, soybean meal, soybean hulls, wheat gluten meal, wheat milled by-products, alfalfa fodder and meal, alfalfa silage and clover hay default processing factors of 2, 3.3, 3.3, 20, 38, 1.3, 13, 1.8, 7, 2.5, 1.1 and 3 were, respectively, included in the calculation to consider the potential concentration of residues in these commodities.

#### D.2. Consumer risk assessment

| Commodity                  | Chronic risk assessment | Acute risk assessment |
|----------------------------|-------------------------|----------------------|
|                            | Input value (mg/kg)     | Comment              | Input value (mg/kg) | Comment              |
|                            |                        |                      |                     |                      |
| Soyabean, poppy seeds      | 0.04 STMR (NEU use)     | 0.04 STMR (NEU use)  |                      |                      |
| Commodity                                      | Chronic risk assessment                                      | Acute risk assessment                                      |
|-----------------------------------------------|--------------------------------------------------------------|------------------------------------------------------------|
|                                               | **Input value (mg/kg)** | **Comment**                                               | **Input value (mg/kg)** | **Comment**                                               |
| Other commodities of plant origin STMR       | Reasoned opinion on the evaluation of confirmatory data      | The acute exposure assessment was performed only for the   |
|                                               | following the Article 12 MRL review for bentazone (EFSA, 2019b) | commodities under consideration                             |
| Residue definition for risk assessment for    | Bentazone and the metabolite 6-hydroxy bentazone (free and   |                                                            |
| animal products: Sum of bentazone (free and   | conjugated), expressed as bentazone                           |                                                            |
| conjugated)                                   |                                                              |                                                            |
| Other commodities of animal origin STMR       | Reasoned opinion on the evaluation of confirmatory data      | The acute exposure assessment was performed only for the   |
|                                               | following the Article 12 MRL review for bentazone (EFSA, 2019b) | commodities under consideration                             |

STMR: supervised trials median residue; MRL: maximum residue level; NEU: northern Europe.
### 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)c2 ccccc2NS1(=O) = O  
ZOMSMJKLGFRB8S-UHFFFAOYSA-N | ![Bentazone Structural Formula](image1) |
| 8-hydroxy-bentazone            | 8-hydroxy-3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide  
CC(C)N1C(=O)c2cc(O)c2NS1(=O) = O  
WJJLUCLOKVGHGK-UHFFFAOYSA-N | ![8-hydroxy-bentazone Structural Formula](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)c2NS1(=O) = O  
PVKWIOBXPPFARA-UHFFFAOYSA-N | ![6-hydroxy-bentazone Structural Formula](image3) |
| N-methyl-bentazone             | 3-isopropyl-1-methyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide  
CC(C)N1C(=O)c2cccc2N(C)S1(=O) = O | ![N-methyl-bentazone Structural Formula](image4) |

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

(a): The metabolite name in bold is the name used in the conclusion.

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

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