REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for bentazone according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Bentazone was included in Annex I to Directive 91/414/EEC on 01 August 2001, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of afore mentioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Germany, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 20 October 2008 and, after having considered several comments made by EFSA, the RMS provided on 27 October 2009 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 23 January 2012 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 30 March 2012 were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of bentazone was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.1 mg/kg bw/d and an ARfD of 0.25 mg/kg bw.

Primary crop metabolism of bentazone was investigated following foliar application on root and tuber vegetables (potatoes), pulses and oilseeds (green beans, soya beans) and cereals (maize, rice). Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities could be defined as the sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone. Metabolism studies showed that 8-hydroxy bentazone is not found in most crops and might be disregarded from this residue definition, provided sufficiently detailed residue data were available to EFSA. A validated analytical method for enforcement of the residue definition is also available, with a combined LOQ of 0.03 mg/kg in high water content, high oil content, acidic and dry

[1] On request from EFSA, Question No EFSA-Q-2008-495, approved on 06 July 2012.

[2] Correspondence: pesticides.mrl@efsa.europa.eu

[3] Acknowledgement: EFSA wishes to thank the rapporteur Member State Germany for the preparatory work on this scientific output.

Suggested citation: European Food Safety Authority; Reasoned opinion on the review of the existing maximum residue levels (MRLs) for bentazone according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2012;10(7):2822. [65 pp.] doi:10.2903/j.efsa.2012.2822. Available online: www.efsa.europa.eu/efsajournal

commodities. A validated analytical method in herbal infusions is not available and is therefore required.

Regarding the magnitude of residues in all crops reported by the RMS, a sufficient number of supervised residue trials is available for some of the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs, except for potato, leeks, maize and herbal infusions where data were sufficient to derive a tentative MRL only. For spring onions, cucumber, poppy seed, soya bean, rice, alfalfa and clover, no residue trials were available. EFSA was therefore not able to derive MRL proposals for the above mentioned crops and further residue trials are required.

The effect of processing on the nature of bentazone was not investigated. Although quantifiable residues of bentazone are expected in several crops which can be processed, such studies are currently not necessary, as the chronic exposure is far below the ADI. Studies investigating the magnitude of residues in processed rice are available but they only allowed EFSA to derive indicative processing factors for rice. Further processing studies are not required because they are not expected to affect the outcome of the risk assessment. However, if there would be the intention from risk managers to derive more robust processing factors for enforcement purposes, additional processing studies might be required.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in Swiss chard, radish, turnip, sorghum and wheat. These studies showed a comparable metabolism to the primary crops and significant residues in rotational crops are not expected, provided that bentazone is applied according to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, significant exposures to bentazone and conjugates of 6-hydroxy bentazone are expected for dairy ruminants, meat ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in commodities of animal origin is proposed as the sum of bentazone and the metabolite 6-hydroxy bentazone (free and conjugated), expressed as bentazone. A validated analytical method for enforcement of the proposed residue definition is available with an LOQ of 0.02 mg/kg for meat, milk, liver and eggs, but a validated method is still required for fat. Based on the metabolism study on laying hens, it was concluded that residues of bentazone are not expected in poultry tissues nor in eggs, and that MRLs in these commodities can be set at the LOQ. A feeding study on lactating ruminants also demonstrated that residues of bentazone and its metabolite are not expected in significant amounts in milk and that the MRL in this commodity can be set at the LOQ, noting that storage stability data are in principle still required. Considering that this feeding study did not investigate residues in any other commodity than milk, tentative MRLs for ruminant and pig tissues were proposed based on an extrapolation from the metabolism study, but a feeding study is still required.

Chronic and acute consumer exposures resulting from the MRLs derived in the framework of this review were calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 1.6 % of the ADI (Dutch child) and the highest acute exposure amounted to 17.7 % of the ARfD (celery leaves).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for bentazone. Additional calculations of the consumer exposure, including these CXLs for products of plant origin, were therefore carried out. The highest chronic exposure represented also 1.6 % of the ADI (Dutch child) and the highest acute exposure amounted to 17.7 % of the ARfD (celery leaves).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see table below for a summary). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain tentative MRLs and existing EU MRLs still need to be confirmed by the following data:

- 2 additional residue trials supporting the northern outdoor GAP and 4 additional residue trials supporting the southern outdoor GAP on potatoes;
- 4 residue trials supporting the northern outdoor GAP on spring onions;
- 8 residue trials supporting the northern outdoor GAP on cucumbers;
- 4 additional residue trials supporting the northern outdoor GAP on leeks;
- 4 residue trials supporting the northern outdoor GAP on poppy seed;
- 8 residue trials supporting the northern outdoor GAP and 8 residue trials supporting the southern outdoor GAP on soya bean;
- a confirmation on the validity of the existing CXL for rye;
- further clarification of the GAP of herbal infusions;
- a validated analytical method (with confirmatory method and ILV) for enforcement of the proposed residue definition in herbal infusion;
- an analytical method (with confirmatory method and ILV) for the enforcement of the residue in fat;
- a livestock feeding study for meat ruminant;
- storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk.

It is highlighted that some of the 'Recommended' MRLs resulted from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the recommended MRLs but which might have an impact on national authorisations:

- 1 additional trial on beans with pods and 2 additional trials on peas without pods complying with the northern outdoor GAP;
- 8 residue trials supporting the northern outdoor GAP on barley and oats;
- 8 residue trials supporting the southern outdoor GAP on rice;
- 8 residue trials supporting the northern outdoor GAP on wheat and rye;
- 8 residue trials supporting the northern outdoor GAP and 8 residue trials supporting the southern outdoor GAP on maize;

- 4 additional residue trials supporting the northern outdoor GAP and 4 additional residue trials supporting the southern outdoor GAP on maize forage;
- 4 residue trials supporting the northern outdoor GAP and 4 residue trials supporting the southern outdoor GAP on alfalfa and clover.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

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

- elaboration of residue trials with an LOQ of 0.03 mg/kg;
- residue data in plants combining bentazone and 6-hydroxybentazone only;
- confirmation that all residues trials samples were stored in compliance with demonstrated storage stability;
- validation data on the hydrolysis step for enforcement of the proposed residue definition in food of animal origin.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone					
211000	Potatoes	0.1*	0.1	0.2	Further consideration needed [(a)]
220010	Garlic	0.1*	-	0.06	Recommended [(b)]
220020	Onions	0.1*	0.1	0.1	Recommended [(c)]
220030	Shallots	0.1*	-	0.06	Recommended [(b)]
220040	Spring onions	0.1*	-	0.1	Further consideration needed [(d)]
232010	Cucumbers	0.1*	-	0.1	Further consideration needed [(d)]
234000	Sweet corn	0.3	-	0.3	Recommended [(b)]
256000	Herbs	15	-	10	Recommended [(b)]
260010	Beans (fresh, with pods)	0.3	0.2	0.3	Recommended [(e)]
260020	Beans (fresh, without pods)	0.1*	-	0.05	Recommended [(b)]
260030	Peas (fresh, with pods)	0.5	0.2	0.3	Recommended [(e)]
260040	Peas (fresh, without pods)	0.2	-	0.05	Recommended [(b)]
260050	Lentils (fresh)	0.1*	-	0.05	Recommended [(b)]
270060	Leek	0.1*	-	0.15	Further consideration needed [(f)]
300010	Beans (dry)	0.1*	0.05*	0.1	Recommended [(e)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
300030	Peas (dry)	0.1*	1	1	Recommended [c]
401010	Linseed	0.1*	0.1	0.2	Recommended [e]
401020	Peanuts	0.1*	0.05	0.05	Recommended [g]
401030	Poppy seed	0.1*	-	0.1	Further consideration needed [d]
401070	Soya bean	0.1*	0.05	0.1	Further consideration needed [h]
500010	Barley grain	0.1*	0.1	0.1	Recommended [c]
500030	Maize grain	0.1*	0.2	0.2	Recommended [i]
500040	Millet	0.1*	-	0.08	Recommended [b]
500050	Oats grain	0.1*	0.1	0.1	Recommended [b]
500060	Rice grain	0.1*	0.1	0.1	Recommended [j]
500070	Rye grain	0.1*	0.1	0.1	Further consideration needed [k]
500080	Sorghum grain	0.1*	0.1	0.1	Recommended [c]
500090	Wheat grain	0.1*	0.1	0.1	Recommended [c]
632000	Herbal infusions (dried, leaves)	0.1*	-	0.1	Further consideration needed [f]
-	Other products of plant origin	See App C.1	-	-	Further consideration needed [l]
Enforcement residue definition: sum of bentazone, the metabolites 6-hydroxy bentazone and their conjugates, expressed as bentazone					
1011010	Swine meat	0.05*	0.05*	0.02*	Further consideration needed [m]
1011020	Swine fat (free of lean meat)	0.05*	-	0.15	Further consideration needed [f]
1011030	Swine liver	0.05*	-	0.02*	Further consideration needed [f]
1011040	Swine kidney	0.05*	-	0.05	Further consideration needed [f]
1012010	Bovine meat	0.05*	0.05*	0.02*	Further consideration needed [m]
1012020	Bovine fat	0.05*	-	1	Further consideration needed [f]
1012030	Bovine liver	0.05*	-	0.02*	Further consideration needed [f]
1012040	Bovine kidney	0.05*	-	0.3	Further consideration needed [f]
1013010	Sheep meat	0.05*	0.05*	0.02*	Further consideration needed [m]
1013020	Sheep fat	0.05*	-	1	Further consideration needed [f]
1013030	Sheep liver	0.05*	-	0.02*	Further consideration needed [f]
1013040	Sheep kidney	0.05*	-	0.3	Further consideration needed [f]
1014010	Goat meat	0.05*	0.05*	0.02*	Further consideration needed [m]
1014020	Goat fat	0.05*	-	1	Further consideration needed [f]
1014030	Goat liver	0.05*	-	0.02*	Further consideration needed [f]
1014040	Goat kidney	0.05*	-	0.3	Further consideration needed [f]
1016010	Poultry meat	0.05*	-	0.02*	Recommended [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
1016020	Poultry fat	0.05*	-	0.02*	Recommended [(b)]
1016030	Poultry liver	0.05*	-	0.02*	Recommended [(b)]
1020010	Cattle milk	0.02*	0.05*	0.02*	Further consideration needed [(m)]
1020020	Sheep milk	0.02*	0.05*	0.02*	Further consideration needed [(m)]
1020030	Goat milk	0.02*	0.05*	0.02*	Further consideration needed [(m)]
1030000	Birds' eggs	0.05*	0.05*	0.02*	Recommended [(n)]
-	Other products of animal origin	See App C.1	-	-	Further consideration needed [(l)]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(e): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).
(g): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(h): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; existing CXL is covered by the existing EU MRL (combination C-III in Appendix D).
(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(j): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the existing CXL (combination C-VII in Appendix D).
(k): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is fully supported by data, would lead to a lower MRL (combination G-V in Appendix D).
(l): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(m): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).
(n): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is not compatible with EU residue definitions (combination G-II in Appendix D).

KEY WORDS

Bentazone, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, benzothiadiazole, herbicide.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting as well as the review of pesticide MRLs at European level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As bentazone was included in Annex I to the above mentioned directive on 01 August 2001, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-495 was included in the EFSA Register of Questions.

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

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

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

Germany, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for bentazone and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 20 October 2008 and subsequently checked for completeness. On 27 October 2009, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 23 January 2012 and submitted to Member States (MS) for commenting. All MS comments received by 30 March 2012 were considered by EFSA for finalization of the reasoned opinion.

[4] Commission Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[5] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

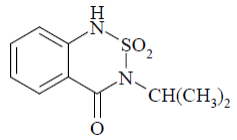
TERMS OF REFERENCE

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

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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Bentazone is the ISO common name for 3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide (IUPAC).



Bentazone belongs to the group of benzothiadiazole compounds which are used as herbicide. It is a non-systemic selective contact herbicide which is used to control broadleaf weeds. The active substance is mainly taken up by leaves but is slightly translocated via xylem. The herbicidal action is linked to the inhibition of the phytosynthetic electron transport in the chloroplasts (photosystem II) which ultimately causes growth inhibition.

Bentazone was evaluated in the framework of Directive 91/414/EEC with Germany being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were outdoor treatments on various crops as a foliar spray at application rates up to 1.60 kg a.s./ha in northern and southern Europe. The application is carried out at growth stage BBCH 13 to BBCH 67, depending on the crop. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2000/68/EC[6], entering into force on 01 August 2001. The expiry date for inclusion was subsequently extended to the 31 December 2015 by means of Commission Directive 2010/77/EU[7] and, according to Regulation (EU) No 540/2011[8], bentazone is deemed to have been approved under Regulation (EC) No 1107/2009[9] as well. This approval is restricted to use as herbicide only. As EFSA was not yet involved in the peer review of bentazone, a conclusion of EFSA on this active substance is not available.

The EU MRLs for bentazone are established in Annexes II and IIIB of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for sweet corn and for legume vegetables and fresh herbs (EFSA, 2010, 2011) which were legally implemented in Regulations (EU) No 893/2010[10] and No 270/2012[11]. All existing EU MRLs,

[6] Commission Directive 2000/68/EC of 23 October 2000, OJ L 276, 28.10.2000, p. 41-43.
[7] Commission Directive 2010/77/EU of 10 November 2010, OJ L 293, 11.11.2010, p. 48-57.
[8] Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.
[9] Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p. 1–50.
[10] Regulation (EU) No 2010/893 of 8 October 2010, OJ L 266, 9.10.2010, p. 10-38.
[11] Regulation (EU) No 2012/270 of 26 March 2012, OJ L 89, 27.3.2012, p. 5-63.

which are established for the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone, expressed as bentazone, in plant commodities and for bentazone only in animal commodities, are summarized in Appendix C.1 to this document. CXLs for bentazone were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to the same residue definition as the ones derived at EU level.

For the purpose of this MRL review, the critical uses of bentazone currently authorized within the EU have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the Member State's consultation were also considered (see Appendix A). According to the reported GAPs, bentazone is currently registered on a wide range of crops. The application rate varies from 0.36 to 1.60 kg a.s./ha and the PHI ranges between 7 and 60 days. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Germany, 1996), the Review Report on bentazone (EC, 2000b), the JMPR Evaluation reports (FAO, 1991, 1992, 1994, 1995, 1998, 1999, 2004), the previous reasoned opinions on bentazone (EFSA, 2010, 2011) as well as the evaluation reports submitted during the Member State's consultation (France, 2012; Germany, 2012a, 2012b; The Netherlands, 2012; United Kingdom, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[12] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000a, 2010a, 2010b, 2011).

1. Methods of analysis

1.1. Methods for enforcement of residues in food of plant origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-FPD was evaluated for determination of the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone. It was also mentioned in the PROFile as validated in plant matrices with an LOQ of 0.02 mg/kg in high water content (broad beans) commodities for the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone (Germany, 1996; EFSA, 2010). A confirmatory method and an ILV were not available. This method is therefore not considered satisfactory.

In addition, a HPLC-MS/MS method and its ILV for the determination of the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone were evaluated and validated in plant matrices with an LOQ of 0.01 mg/kg in high water content, high oil content, acidic and dry commodities for each individual compound (EFSA, 2010). Thus, a combined LOQ of 0.03 mg/kg applies to the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone.

The QuEChERS method in combination with HPLC-MS/MS is also available to dose the parent bentazone only with an LOQ of 0.01 mg/kg for acidic and dry commodities and 0.005 mg/kg for high water content (CEN, 2008).

According to the HPLC-MS/MS method evaluated by EFSA, the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone can be enforced in food of plant origin with a

[12] Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

combined LOQ of 0.03 mg/kg in high water content, high oil content, acidic and dry commodities. However, an analytical method (including confirmatory method and ILV) in herbal infusions is still required.

1.2. Methods for enforcement of residues in food of animal origin

During the peer review under Directive 91/414/EEC, an analytical method using GC-FPD was evaluated for the determination of the sum of bentazone and the metabolite 6-hydroxybentazone (free and conjugated) in foods of animal origin. It was also mentioned as validated in food of animal origin with an LOQ of 0.05 mg/kg in meat and 0.02 mg/kg in eggs for the sum of bentazone and the conjugates of 6-hydroxybentazone and 8-hydroxybentazone (Germany, 1996). A confirmatory method and an ILV were not available. This method is therefore not considered satisfactory.

In addition, after Annex I inclusion, an HPLC-MS/MS method and its ILV for the determination of the sum of bentazone and its metabolites 6-hydroxybentazone (free and conjugated) and 8-hydroxybentazone (free and conjugated) were evaluated and validated in food of animal origin with an LOQ of 0.01 mg/kg in meat, milk, liver and eggs for each individual compound (Germany, 2012b). Thus, a combined LOQ of 0.02 mg/kg applies to the residue definition. Nevertheless, as the analytical method contains a hydrolysis step to convert the conjugates of 6-hydroxybentazone and 8-hydroxybentazone to 6-hydroxybentazone and 8-hydroxybentazone respectively, validation data on the hydrolysis step are desirable.

Hence it is concluded that the sum of bentazone and the metabolite 6-hydroxybentazone (free and conjugated) can be enforced in food of animal origin with a combined LOQ of 0.02 mg/kg in meat, milk, liver and eggs. However, an analytical method including a confirmatory method and an ILV are still required for fat. Furthermore, validation data on the hydrolysis step are still desirable.

2. Mammalian toxicology

The toxicological assessment of bentazone was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2000b). These toxicological reference values are summarized in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Bentazone					
ADI	EC	2000	0.1 mg/kg bw/d	24 months rat feeding study	100
ARfD	EC	2000	0.25 mg/kg bw	90 days rat feeding study	100

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

During the peer review under Directive 91/414/EEC, metabolism of bentazone was investigated for foliar application on potatoes, green beans, soya beans, maize and rice using [^{14}C–phenyl] labeled bentazone (Germany, 1996). The basic characteristics of the metabolism studies are summarised in Table 3-1.

In seeds of soya bean and green bean, TRR was low and amounted to 0.4-1.1 and 0.6-1.3 mg eq/kg respectively, while in hay harvested at the same PHI, TRR amounted to 21.2-79.5 and 20.4-115 mg eq/kg respectively. This observed difference of TRR concentrations in hay and in seeds indicates low translocation of residues to seeds. The radioactive residues found in the seed were natural products with incorporation of radioactivity rather than the bentazone transformed metabolites. Yet, bentazone and the conjugated 6- and 8-hydroxy bentazone were identified in beans (proportions not known).

In potato tubers and rice grain, TRR was essentially incorporated into starch (58 and 69.7 % respectively). Parent bentazone and the conjugate of 6-hydroxy bentazone were the major identified components. Bentazone was accounting for a maximum of 4 % TRR (0.005 mg eq/kg) in potato tubers and was found to be below the LOQ of 0.02 mg/kg in rice grain; 6-hydroxy bentazone was accounting for a maximum of 15 % TRR (0.034 mg eq/kg) in potato tubers and was found to be below the LOQ of 0.02 mg/kg in rice grain.

In maize, TRR decreased significantly with time. In forage (63 DAT) and grain (126 DAT), TRR accounted for 0.21 and 0.04 mg eq/kg respectively. Bentazone and the conjugate of 6-hydroxy bentazone were found to be below the LOQ (0.05 mg/kg) in grain. In forage, residue level of 6-hydroxy bentazone glycoside amounted to 0.09 mg/kg while residue level of parent bentazone was under the LOQ.

A metabolism study was also conducted on cell culture suspensions, confirming the results found in crops after foliar application. According to the available plant metabolism studies, the relevant residue in plants was bentazone and the conjugate of 6-hydroxy bentazone. 8-hydroxy bentazone was only found in pulses and oilseeds, at low levels (2% TRR in soya bean forage). 6-hydroxy bentazone was also identified in the rat metabolism (Germany, 1996).

Based on the above findings, the RMS proposes to set the residue for both enforcement and risk assessment in all plant commodities as the sum of bentazone and the conjugates of 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone. As the conjugate of 8-hydroxy bentazone is not relevant, this residue definition appears to be very protective for the consumer. According to EFSA, the residue defined as the sum of bentazone and the conjugates of 6-hydroxy bentazone, expressed as bentazone, would be sufficient for both enforcement and risk assessment. Nevertheless, as the residue data (see section 3.1.1.2) are combining residue levels of the three compounds, EFSA proceeded with the residue definition as proposed by the RMS but a review of the proposed residue definition would be desirable. The definition proposed by the RMS is also in line with the residue definition set by the JMPR (FAO, 1998). Validated analytical methods for enforcement of the proposed residue definition are available, except for herbal infusions (see also section 1.1).

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Root and tuber vegetables	Potatoes	[^{14}C–phenyl] bentazone	Foliar, n.r.	1.12 + 1.12	2	Tubers: 41	First application: 23 days after planting; Interval between applications: 21 days.
Pulses and oilseeds	Green beans	[^{14}C–phenyl] bentazone	Foliar, n.r.	2.24	1	Foliage (forage): 9, 36 Succulent beans: 36 Seeds: 79 Hull and hay: 79	
				1.68 + 1.12	2	Foliage (forage): 8 Succulent beans: 8 Seeds: 51 Hull and hay: 51	Interval between applications: 28 days
	Soya beans	[^{14}C–phenyl] bentazone	Foliar, n.r.	2.24	1	Foliage (forage): 9, 36 Hay: 93 Seeds: 93	
				1.68 + 1.12	2	Foliage (forage): 11 Hay: 48 Seeds: 48	Interval between applications: 45 days
Cereals	Maize	[^{14}C–phenyl] bentazone	Foliar, F	1.68	1	Forage: 0, 7, 14, 21, 42, 63 Grain: 126 Cob: 126 Husk: 126 Stover: 126	Application at 6 leaves stage (BBCH 16).
	Rice	[^{14}C–phenyl] bentazone	Foliar, n.r.	1.00	1	Plant: 26 Grain: 63 Straw: 63	

n.r.: F or G not reported
(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

3.1.1.2. Magnitude of residues

According to the RMS, the active substance bentazone is authorised for outdoor foliar treatments on a wide range of crops in northern and southern Europe (see Appendix A). To assess the magnitude of bentazone residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (Germany, 1996) or in the framework of an MRL application (EFSA, 2010, 2011) and additional data submitted during the

Member State's consultation (France, 2012; Germany, 2012a, 2012b; The Netherlands, 2012; United Kingdom, 2012). All available residue trials that comply with the authorised GAPs are summarized in Table 3-2.

The number of residues trials and extrapolations were evaluated in view of the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- Potatoes: the number of residue trials supporting the northern and southern uses of bentazone is not compliant with the data requirements for this crop. Tentative MRL and risk assessment values can be derived from the northern data but 2 additional trials on potatoes complying with the northern GAP and 4 additional trials on potatoes complying with the southern GAP are still required;

- Onions, garlic, shallots: the number of residue trials supporting the northern use of bentazone is not compliant with the data requirements for this crop. The reduced number was considered sufficient because all available residue levels were below the LOQ, indicating that no residues are expected. Further residue trials are therefore not required;

- Leek: the number of residue trials supporting the northern uses of bentazone is not compliant with the data requirements for this crop (4 trials instead of 8). Tentative MRL and risk assessment values can be derived from the available data but 4 additional trials on leek complying with the northern GAP are still required;

- Beans with pods and peas without pods: the number of residue trials supporting the northern uses of bentazone is not compliant with the data requirements for these crops. Although appropriate MRL and risk assessment values can be derived from the southern data, 1 additional trial on beans with pods and 2 additional trials on peas without pods complying with the northern GAPs are in principle still required;

- Barley, oats, wheat and rye: no residue trials are available to support the northern use of bentazone and the number of residue trials reported for the southern use is not compliant with the data requirements. However, the reduced number of residue trials supporting the southern use of bentazone was considered sufficient because all available residue levels were below the LOQ, indicating that no residues are expected. Therefore, although appropriate MRL and risk assessment values can be derived from the southern Europe data, 8 trials on, barley and wheat complying with the northern GAPs are still required.

- Herbal infusions: the GAP was not fully reported (PHI and BBCH stage not specified). Further clarification of the GAP is required;

- Maize grain: trials submitted by The Netherland (2012) during the Member State's consultation were not considered adequate by EFSA. However, northern trials on maize submitted by France and conducted at a more critical growth stage (BBCH 55 instead of BBCH 15) and a less critical dose rate (1.2 kg/ha instead of 1.5 kg/ha) can be used on a tentative basis to support the northern GAP on maize grain (France, 2012). Southern trials submitted by France can also tentatively support the less critical GAP in southern Europe (PHI of 28 days instead of 60 days). Consequently, tentative MRL and risk assessment values can be derived from the available data but 8 residue trials complying with the northern outdoor GAP and 8 residue trials complying with the southern GAP are still required.

- Maize forage: residue levels in several trials (4 in each area) are overestimated. Tentative MRL and risk assessment values can be derived from the southern and northern data but 4

additional trials complying with the northern GAP and 4 additional trials complying with the southern GAP are still required.

For some of the reported crops, no residue trials are available for any GAP. Consequently neither MRLs nor risk assessment values can be derived for the crops listed below and the following data gaps were identified:

- Spring onions: considering that it is a minor crop in northern Europe, 4 residue trials complying with the northern outdoor GAP are required;
- Cucumbers: considering that it is a major crop in northern Europe, 8 residue trials complying with the northern outdoor GAP are required;
- Poppy seed: considering that it is a minor crop in northern Europe, 4 residue trials complying with the northern outdoor GAP are required;
- Soya beans: considering that it is a major crop in northern and southern Europe, 8 residue trials complying with the northern outdoor GAP and 8 residue trials complying with the southern GAP are required;
- Rice: considering that it is a major crop in southern Europe, 8 residue trials complying with the southern outdoor GAP are required;
- Alfalfa and clover forage: considering that they are minor crops in northern and southern Europe, 4 residue trials complying with the northern outdoor GAP and 4 residue trials complying with the southern GAP are required.

The potential degradation of residues during storage of the residue trials samples was not assessed in the framework of the peer review nor by the JMPR. However, the RMS reported a storage stability study demonstrating stability of bentazone and the glycoside derivates of 6-hydroxy and 8-hydroxy bentazone for a period of 1 month at -20 °C in commodities with high water and high oil content, as well as in dry commodities (Germany, 2000). In the framework of MRL applications, France also indicated that a storage stability study was demonstrating the stability of bentazone and its metabolites for 2 years in high water content, high oil content and dry commodities (EFSA, 2010, 2011; France, 2012). However, in order to ensure that no decline of residues occurred during storage of the residues trials samples, a confirmation that all samples were stored for not more than 2 years is desirable.

The available residue data are considered acceptable to derive adequate MRL proposals as well as risk assessment values for all commodities under evaluation, except for potatoes, leeks, maize and herbal infusions, where the MRLs are tentative only (see also Table 3-2). For spring onions, cucumbers, poppy seed, soya beans, rice, alfalfa forage and clover forage, available datasets were insufficient to derive tentative MRLs. Tentative MRLs were also derived for cereals straw, maize forage and grass in view of the future need to set MRLs in feed items. In case where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in the table.

It is also highlighted that an MRL of 0.06 mg/kg is proposed for onions, garlic, shallots, barley, oats, wheat and rye grains because all residue levels were found to be below the LOQ values. Considering however that a LOQ of 0.03 mg/kg can be achieved for enforcement purposes (see also section 1.1), the elaboration of residue trials with a LOQ of 0.03 mg/kg is desirable.

Table 3-2: Overview of the available residues trials data

Commodity	Region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Potatoes	NEU	Outdoor	3 x <0.06; 0.07; 0.08; 0.10	3 x <0.06; 0.07; 0.08; 0.10	**0.07**	**0.10**	**0.2 (tentative)**	1	Trials compliant with GAP. Rber = 0.17 Rmax = 0.13
	SEU	Outdoor	<0.06; 0.07; 0.07; 0.10	<0.06; 0.07; 0.07; 0.10	0.07	0.10	0.2	1	Trials compliant with GAP. Rber = 0.19 Rmax = 0.16
Onions, garlic, shallots	NEU	Outdoor	4 x <0.06	4 x <0.06	0.06	0.06	0.06	1	Trials on onions compliant with GAP on onions. Extrapolation to the less critical GAP on garlic and shallots is acceptable considering the no residues situation observed in onions (United Kingdom, 2012).
Spring onions	NEU	Outdoor	-	-	-	-	-	1	Trials submitted by UK (2012) were not considered adequate by EFSA.
Cucumbers	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Sweet corn	NEU	Outdoor	3 x <0.03; 0.03; 0.1; 0.21	3 x <0.03; 0.03; 0.1; 0.21	0.03	**0.21**	**0.3**	1	Trials compliant with GAP (EFSA, 2010). Rber = 0.26 Rmax = 0.34
	SEU	Outdoor	2 x <0.03; 0.04; 0.05; 0.06; 0.10	2 x <0.03; 0.04; 0.05; 0.06; 0.10	**0.05**	0.10	0.15	1	Trials compliant with GAP (EFSA, 2010). Rber = 0.14 Rmax = 0.15
Fresh herbs	NEU	Outdoor	0.12; 0.21; 0.97; 1.50; 1.92; 7.72	0.12; 0.21; 0.97; 1.50; 1.92; 7.72	1.24	7.72	10	1	Trials on basil compliant with GAP; extrapolation to the whole group of herbs is possible (EFSA, 2011). Rber = 6.74 Rmax = 12.67
Beans (fresh, with pods) Peas (fresh, with pods)	NEU	Outdoor	Beans: 0.03; 0.04; 0.05; 0.06; 0.07; 0.09; 0.10	Beans: 0.03; 0.04; 0.05; 0.06; 0.07; 0.09; 0.10	**0.06**	0.1	0.2	1	Trials on beans with pods compliant with GAP (EFSA, 2011). Rber = 0.18 Rmax = 0.15
	SEU	Outdoor	3 x <0.03; 0.03; 0.04; 0.06; 0.08; 0.11; 0.21	3 x <0.03; 0.03; 0.04; 0.06; 0.08; 0.11; 0.21	0.04	**0.21**	**0.3**	1	Trials on beans with pods compliant with GAP (EFSA, 2011). Rber = 0.19 Rmax = 0.25

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Beans (fresh, without pods) Peas (fresh, without pods) Lentils (fresh)	NEU	Outdoor	Beans: 5 x <0.03; 0.03	Beans: 5 x <0.03; 0.03	0.03	0.03	0.03	1	Trials on beans (without pods) compliant with GAP (EFSA, 2011); extrapolation to lentils possible. Rber = 0.06 Rmax = 0.03
	SEU	Outdoor	8 x <0.03; 0.04	8 x <0.03; 0.04	**0.03**	**0.04**	**0.05**	1	Trials on beans compliant with GAP; extrapolation to lentils possible (EFSA, 2011). Rber = 0.06 Rmax = 0.04
Leek	NEU	Outdoor	3x <0.06; 0.081	3x <0.06; 0.081	0.06	0.081	0.15 (tentative)	1	Trials on leek compliant with GAP (United Kingdom, 2012). Rber = 0.15 Rmax = 0.12
Beans (dry) Peas (dry)	NEU	Outdoor	8x <0.06; 0.06	8x <0.06; 0.06	**0.06**	**0.06**	**0.1**	**1**	Trials on dry beans compliant with GAP, extrapolation to dry peas possible (Germany, 2012b). Rber = 0.12 Rmax = 0.06
	SEU	Outdoor	4 x <0.06	4 x <0.06	0.06	0.06	0.06	1	Trials on dry beans compliant with GAP.

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Linseed	NEU	Outdoor	8x <0.06; 0.12; 0.14	8x <0.06; 0.12; 0.14	**0.06**	**0.14**	**0.2**	**1**	Trials compliant with GAP. Rber = 0.15 Rmax = 0.16
	SEU	Outdoor	4 x <0.06	4 x <0.06	0.06	0.06	0.06	1	Trials compliant with GAP.
Poppy seed	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
Soya bean	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
	SEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
Barley grain Oats grain	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
	SEU	Outdoor	5 x <0.06	5 x <0.06	0.06	0.06	0.06	1	Trials on barley grain compliant with GAP.
Barley straw Oats straw	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
	SEU	Outdoor	0.10; 0.14; 0.16; 0.38; 0.65	0.10; 0.14; 0.16; 0.38; 0.65	0.16	0.65	1.5	1	Trials on barley straw compliant with GAP. Rber = 1.03 Rmax = 1.26

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Maize grain	NEU	Outdoor	3x <0.03; 2x 0.04	3x <0.03; 2x 0.04	**0.03**	**0.04**	**0.08 (tentative)**	1	Trials submitted by NL (2012) were not considered adequate by EFSA but French trials on maize conducted at a more critical growth stage (BBCH 55) and a less critical dose rate (1.2 kg a.s./ha) can be used to tentatively support the NL GAP (France, 2012). Rber = 0.08 Rmax = 0.06
	SEU	Outdoor	5x <0.03	5x <0.03	0.03	0.03	0.03* (tentative)	1	Trials on maize conducted at a more critical GAP (PHI 28d) but less critical dose rate (1.2 kg a.s./ha) can be used to support the southern GAP on a tentative basis (France, 2012).
Millet	NEU	Outdoor	3x <0.03; 2x 0.04	3x <0.03; 2x 0.04	0.03	0.04	0.08	1	Trials on maize compliant with GAP (considering a 25 % deviation on the application rate: 1.2 kg/ha, instead of 1.4 kg/ha) (France, 2012). Rber = 0.08 Rmax = 0.06

Commodity	Region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Sorghum	SEU	Outdoor	5x <0.03	5x <0.03	0.03	0.03	0.03*	1	Trials on maize compliant with GAP (considering a 25 % deviation on the application rate: 1.2 kg/ha, instead of 1.4 kg/ha) (France, 2012).
Rice grain	SEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
Wheat grain Rye grain	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
	SEU	Outdoor	3 x <0.06	3 x <0.06	0.06	0.06	0.06	1	Trials on wheat grain compliant with GAP.
Wheat straw Rye straw	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP
	SEU	Outdoor	0.09; 0.09; 0.10	0.09; 0.09; 0.10	0.09	0.10	0.15	1	Trials on wheat straw compliant with GAP. Rber = - Rmax = 0.14
Herbal infusions (dried leaves)	NEU	Outdoor	3 x <0.05; 0.06; 0.07	3 x <0.05; 0.06; 0.07	0.05	0.07	0.1 (tentative)	1	Trials on peppermint and on St Johnswort but accurate comparison with GAP is not possible since PHI and BBCH were not reported. Rber = 0.13 Rmax = 0.09
Alfalfa forage	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
	SEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) (b)	Highest residue (mg/kg) (c)	MRL proposal (mg/kg)	Median CF (d)	Comments
			Enforcement (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)	Risk assessment (sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone expressed as bentazone)					
Clover forage	NEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
	SEU	Outdoor	-	-	-	-	-	1	No trials compliant with GAP.
Grass	NEU	Outdoor	2.2; 2.6; 4.3; 5.1; 5.8; 6.4; 6.8; 7.2	2.2; 2.6; 4.3; 5.1; 5.8; 6.4; 6.8; 7.2	5.45	7.20	15	1	Trials compliant with GAP. Rber = 13.40 Rmax = 11.05
Maize forage	NEU	Outdoor	0.49; 0.57(e); 0.68; 0.84; 0.90; 1.11(e); 1.17; 2x1.78(e)	0.49; 0.57(e); 0.68; 0.84; 0.90; 1.11(e); 1.17; 2x1.78(e)	0.9	1.78	3 (tentative)	1	Trials on maize and sweet corn compliant with GAP but residue levels are overestimated in 4 trials (see footnote (e)) (France, 2012). Rber = 2.95 Rmax = 2.49
	SEU	Outdoor	0.57(e); 0.60(e); 0.80; 1.0(e); 1.56(e); 1.80	0.57(e); 0.60(e); 0.80; 1.0(e); 1.56(e); 1.80	**0.92**	**1.8**	**4 (tentative)**	**1**	Trials on maize and sweet corn compliant with GAP but residue levels are overestimated in 4 trials (see footnote (e)) (France, 2012). Rber = 3.24 Rmax = 2.97

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Residue levels in whole plant without cob and root.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of bentazone was neither investigated in the framework of the peer review nor by the JMPR. Although quantifiable residues of bentazone are expected in several crops which can be processed, such studies are currently not necessary, as the chronic exposure is far below the ADI (see also section 4).

Although not required, studies investigating the magnitude of residues in processed rice were reported in the framework of the peer review (Germany, 1996). An overview of all available processing studies is available in Table 3-3. Rice polishing is not expected to impact on the nature of residues. Nevertheless, the processing factors reported for rice should be considered indicative as they are not sufficiently supported by studies; a minimum of 3 processing studies is normally required for deriving robust processing factors.

Further processing studies are anyhow not required in this case as they are not expected to affect the outcome of the risk assessment. If there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Enforcement residue definition: sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone				
Indicative processing factors (limited dataset)				
Rice, polished	2	0.13	1	Exaggerated application rate of 2.3 kg a.s./ha, US trial (Germany, 1996).
Rice, bran	2	1.30	1	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.
(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Most crops evaluated in the framework of this MRL review might be grown in rotation with other crops. During the peer review under Directive 91/414/EEC, it was demonstrated in several degradation studies that bentazone is persistent in soil and that DT_{90} exceeds the trigger value of 100 days (DT_{90lab} = 198 days) (Germany, 1996). A detailed assessment of the nature and magnitude of bentazone residues is therefore considered relevant.

3.1.2.2. Nature of residues

In the peer-review the nature of bentazone residues in rotational crops was studied in chard, radish, turnip, sorghum and wheat with [^{14}C]-bentazone (Germany, 1996). The soil was treated at an application rate of 2.24 kg a.s./ha and crops were sown or planted at 39, 102-145 and 316-369 DAT. Data are summarized in Table 3-4.

The highest TRR levels for bentazone and/or related hydroxyl metabolites were identified in Swiss chard (0.044 mg/kg), turnip top (0.024 mg/kg) and sorghum fodder (0.013 mg/kg) planted 39 DAT and in Swiss chard (0.023 mg/kg) planted 102-145 DAT.

Polar compounds represented the majority of the TRR. The study also shows that bentazone, 6-hydroxy-, 8-hydroxy bentazone and their conjugates are low in crops planted 39 DAT (0.9-2.8 % TRR; 0.004-0.044 mg/kg) and of minor importance in crops planted 102-145 DAT (0.003-0.006 mg/kg in cereals, 0.005-0.006 mg/kg in root crops, 0.023 mg/kg in leafy vegetables) and 316-369 DAT (<0.001 – 0.003 mg/kg).

It was concluded that the metabolism of bentazone residues in succeeding/rotational crops proceeds in a similar pathway as in primary crops and the same residue definition applies.

Table 3-4: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Swiss chard	[^{14}C]-bentazone	Soil application, G	2.24	39, 102-145, 316-369	n.r.	-
Root and tuber vegetables	radish, turnip	[^{14}C]-bentazone	Soil application, G	2.24	39 (turnip), 102-145 (radish), 316-369 (radish)	n.r.	-
Cereals	sorghum, wheat	[^{14}C]-bentazone	Soil application, G	2.24	39 (sorghum), 102-145 (wheat), 316-369 (sorghum)	n.r.	-

n.r.: not reported
(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

3.1.2.3. Magnitude of residues

In the framework of the peer review, the magnitude of bentazone residues was investigated on several succeeding and rotational crops: alfalfa, corn, lettuce, mustard, radishes, snap beans, sugar beets, spinach, etc. (Germany, 1996). Bentazone was applied on soya bean at 2 x 1.12 kg a.s./ha and different plant-back intervals were considered, corresponding to crop failure cases (16 to 35 DAT), autumn and annual rotational crops. At harvest, the highest residues in succeeding crops were 0.019 mg/kg in radishes (planting interval: 16 DAT) and 0.017 mg/kg in mustard, spinach and turnips (plant back interval: 29 DAT).

Thus, the peer review concluded that there was no need to propose risk mitigating measures, considering the overall low residue situation in succeeding and rotational crops (Germany, 1996). These conclusions also apply to the GAPs reported in the framework of this revies (see Appendix A).

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Bentazone is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for the different types of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Tables 3-5. For grass hay, wheat bran, rye bran, linseed meal and soya bean meal, default processing factors have been included in the calculation in order to consider potential concentration of residues in these commodities.

The lack of residues trials for soya bean, alfalfa and clover is not expected to significantly underestimate the livestock dietary burden considering that sufficient data are available for grass which is one of the main contributors.

Table 3-5: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of bentazone and the metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone				
Grass (fresh and silage)	5.45	Median residue	7.20	Highest residue
Maize (forage)	0.92	Median residue	1.80	Highest residue
Grass hay	21.80	Median residue x 4	28.80	Highest residue x 4
Wheat & rye grain	0.06	Median residue	0.06	Median residue
Barley & oat grain	0.06	Median residue	0.06	Median residue
Wheat & rye bran	0.48	Median residue x 8	0.48	Median residue x 8
Wheat & rye straw	0.09	Median residue	0.10	Highest residue
Barley & oat straw	0.16	Median residue	0.65	Highest residue
Beans & peas (dry)	0.06	Median residue	0.06	Median residue
Potatoes	0.07	Median residue	0.10	Highest residue
Linseed	0.06	Median residue	0.06	Median residue
Linseed meal	0.12	Median residue x 2	0.12	Median residue x 2

The results of the calculations are reported in Table 3-6. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-6: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy ruminants	1.309	0.991	Grass (fresh)	36.364	Yes
Meat ruminants	1.543	1.168	Grass (fresh)	35.880	Yes
Poultry	0.016	0.013	Potatoes	0.250	Yes
Pigs	0.237	0.179	Grass silage	5.915	Yes

3.2.2. Nature of residues

The nature of bentazone residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Germany, 1996). Animal metabolism was investigated in three lactating goats studies and three laying hens studies with ^{14}C-phenyl labeled bentazone, ^{14}C-phenyl labeled 6-hydroxy bentazone and ^{14}C-phenyl labeled 8-hydroxy bentazone (each separately). The basic characteristics of the metabolism studies are summarised in Table 3-7.

In a first study, lactating goats were administered ^{14}C-bentazone for 5-8 days. The majority of the administered dose was eliminated in urine (91.41 and 80.59 % of the AR for the low and high doses respectively, corresponding to 163 and 634.5 mg eq/kg). All milk and tissue extracts contained predominantly unchanged bentazone, ranging between 70.8 % and 97.9 % TRR. For each dose respectively, bentazone was identified in the extracts of milk (0.03-0.04 and 0.15-0.39 mg/kg), fat (1.58 and 2.80 mg/kg), kidney (0.55 and 48.90 mg/kg), muscle (0.01 and 1.24 mg/kg) and liver (0.03 and 3.06 mg/kg). In liver extract from the high dosed goat, 11 % of the TRR (0.40 mg/kg) was identified as bentazone-N-glucuronide[13]. Other metabolites were minor and unknown. 6-hydroxy bentazone and 8-hydroxy bentazone could only be found in urine at low levels (0.2 % TRR each) (Germany, 1996).

In a second study, lactating goats were administered ^{14}C-6-OH-bentazone for 5-6 days. The proportions of the total administered dose excreted in urine and faeces were 70 % and 86 % of the AR, containing mainly 6-hydroxy bentazone and conjugates of 6-hydroxy bentazone (10 % TRR). For each dose respectively, TRR levels represented 0.02 and 0.53 mg/kg in milk, 0.03 and 0.95 mg/kg in fat, 0.14 and 22.46 mg/kg in kidney, 0.01 and 0.24 mg/kg in muscle, and 0.02 and 0.92 mg/kg in liver. Sample extracts contained predominantly unchanged 6-hydroxy bentazone, ranging between 44 % TRR in muscles and liver, and 94 % in fat. In milk, the main metabolite identified was the sulfate of 6-hydroxy bentazone (43 % TRR), while 6-hydroxybentazone itself accounted for only 1 %. In addition, three minor metabolites were detected, each at about 5-6 % TRR (0.026-0.033 mg eq/kg). The proportion of conjugates amounted to 5 % TRR in kidney, 7 % in muscle, and 35 % in liver. The liver conjugate was identified as the sulfate of 6-hydroxybentazone (FAO, 1995).

A similar experiment was carried out with the administration of ^{14}C-8-OH-bentazone for 5-6 days. Results were similar to those found in the 6-hydroxy bentazone goat metabolism study. The majority of the administered dose was eliminated in urine (83.3 % and 91.4 % of the AR for the low and high doses respectively) and similar ranges of TRR values in milk and tissues were found. Residues in milk, muscle, fat, liver and kidneys were identified as unchanged 8-hydroxybentazone (29 %, 61 %,

[13] 2-[2,2-dioxido-4-oxo-3-(propan-2-yl)-3,4-dihydro-1*H*-2,1,3-benzothiadiazin-1-yl]-4,5,6-trihydroxytetrahydro-2*H*-pyran-3-carboxylic acid. See appendix E.

82 %, 75 % and 95 % of the TRR respectively) and conjugates thereof (41 %, 21 %, 5 %, 11 % and 3 %) (FAO, 1995).

Table 3-7: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate	Duration (days)	Commodity	Time
Lactating ruminants	Goat	[phenyl-^{14}C] bentazone	1	3 mg/kg bw/d	5	Milk	n.r.
			1	50 mg/kg bw/d	8	Urine and faeces	n.r.
						Tissues	After sacrifice
		[phenyl-^{14}C] 8-OH-bentazone	1	2 mg/kg bw/d	5	Milk	n.r.
			1	40 mg/kg bw/d	6	Urine and faeces	n.r.
						Tissues	After sacrifice
		[phenyl-^{14}C] 6-OH-bentazone	1	2 mg/kg bw/d	5	Milk	n.r.
			1	40 mg/kg bw/d	6	Urine and faeces	n.r.
						Tissues	After sacrifice
Laying poultry	Hen	[phenyl-^{14}C] bentazone	10	10 mg/animal/d (100 mg/kg diet)	5	Eggs	n.r.
						Excreta	n.r.
						Tissues	After sacrifice
		[phenyl-^{14}C] 8-OH-bentazone	10	10 mg/animal/d (100 mg/kg diet)	5	Eggs	n.r.
						Excreta	n.r.
						Tissues	After sacrifice
		[phenyl-^{14}C] 6-OH-bentazone	10	10 mg/animal/d (100 mg/kg diet)	5	Eggs	n.r.
						Excreta	n.r.
						Tissues	After sacrifice

n.r.: Not reported

In a first study, laying hens were administered ^{14}C-bentazone for 5 days. Like the bentazone goat metabolism study, results showed that parent was the major residue component in all tissues and eggs. Bentazone residues accounted for 100 % TRR in muscle (0.29 mg/kg), fat (0.06 mg/kg) and eggs (0.13 mg/kg) and for 84 % TRR in liver (0.91 mg/kg). Glucuronide of bentazone was only detected in liver (0.17 mg/kg, 16 % TRR). In excreta, bentazone (45 % TRR), its glucuronide (12 % TRR) and 6-hydroxy bentazone (15 % TRR) were the major residue components.

In the second and third studies, laying hens were administered ^{14}C-6-OH-bentazone or ^{14}C-8-OH-bentazone for 5 days. It seems that 6- hydroxy bentazone and 8- hydroxy bentazone, respectively, were the major components in excreta. Yet no conclusion could be derived for tissues and eggs as TRR levels were too low for further analysis.

Metabolic patterns identified in goats and hens are similar. Parent bentazone is transferred to a small extent to tissues, milk and eggs and only a limited metabolism was observed. Only its glucuronide conjugate is identified in goat and hen livers as a major metabolite. As bentazone-N-glucuronide is not expected to exhibit a higher toxicity than bentazone, it is not considered as a residue of particular concern. 6-hydroxy bentazone and 8-hydroxy bentazone are also transferred to a small extent to tissues, milk and eggs, due to their polar nature. Apart from the formation of conjugates, only a limited metabolism of these compounds was observed. Since metabolism in rats and ruminants was also demonstrated to be similar, the findings in ruminants can also be extrapolated to pigs.

Consequently, EFSA proposes to set the residue definition in animals for both enforcement and risk assessment as the sum of bentazone, the metabolite 6-hydroxy bentazone and their conjugates, expressed as bentazone. This definition is not in line with the residue definition set by the RMS or by JMPR (FAO, 1995), which consider parent bentazone only. However, 6-hydroxy bentazone is a major metabolite in feedstuffs and significant residues could be transferred to some tissues. The metabolism study clearly demonstrates that residue may be expected and this should be confirmed by a livestock feeding study reflecting the combined exposure to both compounds and where both compounds (including conjugates) are dosed in the animal tissues at slaughter. Therefore the inclusion of this metabolite in the residue definition is more consistent with the requirement to further investigate both compounds. 8-hydroxy bentazone is found in very minor amounts in feedstuffs, thus no residue of this metabolite is expected in products of animal origin.

A validated analytical method for enforcement of the proposed residue definition is available for all commodities of animal origin, except fat (see section 1.2). Furthermore, the residue is not considered fat soluble as its log $P_{o/w}$ is lower than 3 (Germany, 1996).

3.2.3. Magnitude of residues

For poultry, the metabolism study in laying hens was performed at a dose level of approximately 100 mg/kg feed. This represents 400 fold the calculated dietary intake. When extrapolating residue levels obtained in the metabolism study to the calculated intake, no residues exceeding the LOQ are expected in any poultry tissues or eggs. Hence, MRLs are proposed at the LOQ for all poultry products.

For dairy ruminants, the magnitude of bentazone and its 6-hydroxy metabolite residues in milk was investigated during the peer review under Directive 91/414/EEC by means of a feeding study with lactating goats (Germany, 1996). Two groups of lactating goats, each consisting of three animals, were dosed for 21 days at two different levels: one with bentazone (15 mg/kg DM/day) and 6-hydroxy bentazone (75 mg/kg DM/day), and the second group with bentazone (75 mg/kg DM/day) and 6-hydroxy bentazone (150 mg/kg DM/day). Results of the livestock feeding study are summarized in Table 3-8. Plateau levels in milk were reached rapidly, i.e. during the two first weeks of dosing. The mean concentrations observed in milk at plateau level amounted to 0.04 and 0.05 mg/kg in the low and the high dose groups, respectively.

Although the RMS considered this feeding study as adequate, no information on the storage stability of bentazone and its hydroxy metabolites was reported. A storage stability study in products of animal origin is therefore required. The storage conditions of samples of the livestock feeding study were also not reported and should be provided.

Consequently, based on the above feeding study, it can be concluded that no residues are expected in milk and a tentative MRL at the LOQ is proposed in the absence of the storage stability data.

Concerning meat ruminants and pigs, the magnitude of bentazone residues in those commodities was not investigated and a representative feeding study for ruminants is therefore still required (the above

reported feeding study only investigated residues in milk). In order to allow for an indicative risk assessment in these commodities of animal origin, EFSA decided to derive tentative MRLs and risk assessment values from the available metabolism studies on lactating goats; the metabolism study with bentazone was considered to be the most appropriate, as this study showed the highest concentration of residues compared to the exposure rates and is expected to be a worst case situation. Results of the study are summarized in Table 3-8 and MRL and risk assessment values were calculated in compliance with the latest international recommendations on this matter (FAO, 2009). These values should be considered on a tentative basis only because they are based on one test animal only while they should normally also take into account the intraspecies variability.

Table 3-8: Overview of the values derived from the livestock metabolism study with bentazone in lactating goats

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[a]	Highest residue (mg/kg)[b]	MRL proposal (mg/kg)[c]	CF for RA
	Med. (mg/kg bw/d)	Max. (mg/kg bw/d)	Dose Level (mg/kg bw/d)	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement residue definition: sum of bentazone, metabolite 6-hydroxy bentazone and their conjugates, expressed as bentazone.												
Pig meat	0.179	0.237	3	1	0.010	n.a.	See results for enforcement		0.02	0.02	0.02* (tentative)	1
			50	1	1.244	n.a.						
Pig fat			3	1	1.579	n.a.			0.09	0.13	0.15 (tentative)	1
			50	1	2.792	n.a.						
Pig liver			3	1	0.033	n.a.			0.02	0.02	0.02* (tentative)	1
			50	1	3.058	n.a.						
Pig kidney			3	1	0.553	n.a.			0.03	0.04	0.05 (tentative)	1
			50	1	48.901	n.a.						
Ruminant meat	1.168	1.543	3	1	0.010	n.a.			0.02	0.02	0.02* (tentative)	1
			50	1	1.244	n.a.						
Ruminant fat			3	1	1.579	n.a.			0.62	0.81	1 (tentative)	1
			50	1	2.792	n.a.						
Ruminant liver			3	1	0.033	n.a.			0.02	0.02	0.02* (tentative)	1
			50	1	3.058	n.a.						
Ruminant kidney			3	1	0.553	n.a.			0.22	0.28	0.3 (tentative)	1
			50	1	48.901	n.a.						

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk
(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).

(b): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(c): The median conversion factor for enforcement to risk assessment.

4. Consumer risk assessment

In the framework of this review, only the uses of bentazone reported by the RMS in Appendix A were considered but the use of bentazone was previously also assessed by the JMPR (FAO, 1991, 1992, 1994, 1995, 1998, 1999, 2004). The CXLs, resulting from these assessments by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

Chronic and acute exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the intake calculations were derived in compliance with Appendix D and are summarized in Table 4-1. The (tentative) median residue and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities. For those commodities where data were insufficient to derive an MRL in section 3, EFSA considered the existing EU MRL for an indicative calculation. The contributions of other commodities, for which no authorised use was reported in the framework of this review, were not included in the calculation.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone				
Potatoes	0.07	Median residue (tentative) [b]	0.10	Highest residue (tentative) [b]
Garlic	0.06	Median residue [a]	0.06	Highest residue [a]
Onions	0.06	Median residue [a]	0.06	Highest residue [a]
Shallots	0.06	Median residue [a]	0.06	Highest residue [a]
Spring onions	0.10	EU MRL [c]	0.10	EU MRL [c]
Cucumbers	0.10	EU MRL [c]	0.10	EU MRL [c]
Sweet corn	0.05	Median residue [a]	0.21	Highest residue [a]
Fresh herbs	1.24	Median residue [a]	7.72	Highest residue [a]
Beans (fresh, with pods)	0.06	Median residue [a]	0.21	Highest residue [a]
Beans (fresh, w/o pods)	0.03	Median residue [a]	0.04	Highest residue [a]
Peas (fresh, with pods)	0.06	Median residue [a]	0.21	Highest residue [a]
Peas (fresh, w/o pods)	0.03	Median residue [a]	0.04	Highest residue [a]
Lentils (fresh)	0.03	Median residue [a]	0.04	Highest residue [a]
Leek	0.06	Median residue (tentative) [b]	0.081	Highest residue (tentative) [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Beans (dry)	0.06	Median residue [a]	0.06	Highest residue [a]
Peas (dry)	0.06	Median residue [a]	0.06	Median residue [a]
Linseed	0.06	Median residue [a]	0.14	Highest residue [a]
Poppy seed	0.10	EU MRL [c]	0.10	EU MRL [c]
Soya bean	0.10	EU MRL [c]	0.10	EU MRL [c]
Barley grain	0.06	Median residue [a]	0.06	Highest residue [a]
Maize grain	0.03	Median residue (tentative) [b]	0.04	Highest residue (tentative) [b]
Millet	0.03	Median residue [a]	0.04	Highest residue [a]
Oats grain	0.06	Median residue [a]	0.06	Highest residue [a]
Rice grain	0.10	EU MRL [c]	0.10	EU MRL [c]
Rye grain	0.06	Median residue [a]	0.06	Highest residue [a]
Sorghum	0.03	Median residue (= LOQ) [a]	0.03	Highest residue (= LOQ) [a]
Wheat grain	0.06	Median residue [a]	0.06	Highest residue [a]
Herbal infusions (dried, leaves)	0.05	Median residue (tentative) [b]	0.07	Highest residue (tentative) [b]
Risk assessment residue definition: sum of bentazone, metabolite 6-hydroxy bentazone and their conjugates, expressed as bentazone				
Swine meat	0.02	Median residue (= LOQ) (tentative) [d]	0.02	Highest residue (= LOQ) (tentative) [d]
Swine fat (free of lean meat)	0.09	Median residue (tentative) [d]	0.13	Highest residue (tentative) [d]
Swine liver	0.02	Median residue (= LOQ) (tentative) [d]	0.02	Highest residue (= LOQ) (tentative) [d]
Swine kidney	0.03	Median residue (tentative) [d]	0.04	Highest residue (tentative) [d]
Ruminant meat	0.02	Median residue (= LOQ) (tentative) [d]	0.02	Highest residue (= LOQ) (tentative) [d]
Ruminant fat	0.62	Median residue (tentative) [d]	0.81	Highest residue (tentative) [d]
Ruminant liver	0.02	Median residue (= LOQ) (tentative) [d]	0.02	Highest residue (= LOQ) (tentative) [d]
Ruminant kidney	0.22	Median residue (tentative) [d]	0.28	Highest residue (tentative) [d]
Poultry meat	0.02	Median residue (= LOQ) [e]	0.02	Highest residue (= LOQ) [e]
Poultry fat	0.02	Median residue (= LOQ) [e]	0.02	Highest residue (= LOQ) [e]
Poultry liver	0.02	Median residue (= LOQ) [e]	0.02	Highest residue (= LOQ) [e]
Ruminant milk	0.02	Median residue (= LOQ) (tentative) [d]	0.02	Highest residue (= LOQ) (tentative) [d]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Birds' eggs	0.02	Median residue (= LOQ) (e)	0.02	Highest residue (= LOQ) (e)

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Use reported by the RMS is not fully supported by data; the existing EU MRL is used for indicative exposure calculations.
(d): Livestock dietary burden resulting from the GAPs reported by the RMS is not fully supported by data for this commodity but the risk assessment values derived in section 3 are used for the exposure calculations.
(e): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is fully supported by data; the risk assessment values derived in section 3 are used for the exposure calculations.

The calculated exposures were compared with the toxicological reference values derived for bentazone (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for Dutch children, representing 1.6 % of the ADI and the highest acute exposure was calculated for celery leaves, representing 17.7 % of the ARfD.

Based on the above calculations, EFSA concludes that the use of bentazone on crops fully supported by data (footnotes a and e in Table 4-1) is acceptable with regard to consumer exposure. For all remaining crops, major uncertainties remain due to the data gaps identified in section 3 but considering tentative MRLs or the existing EU MRLs in the exposure calculation did not indicate a risk to consumers.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. The CXLs in products of plant origin were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarized in Table 4-2.The MRLs proposed in the framework of this review and for which no consumer intake concerns were identified (see section 4.1), were then compared with the existing CXLs for bentazone. For each commodity, the highest value was selected and corresponding input values for risk assessment are summarized in Table 4-2.

However, all CXLs in products of animal origin for bentazone have been established for parent compound only. Considering that the residue definition derived at EU level also includes metabolite 6-hydroxybentazone (free and conjugated), CXLs for commodities of animal origin were not further considered.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone				
Potatoes	0.07	Median residue (tentative) [b]	0.10	Highest residue (tentative) [b]
Garlic	0.06	Median residue [a]	0.06	Highest residue [a]
Onions	0.10	Median residue (CXL) [e]	0.10	Highest residue (CXL) [e]
Shallots	0.06	Median residue [a]	0.06	Highest residue [a]
Spring onions	0.10	EU MRL [c]	0.10	EU MRL [c]
Cucumbers	0.10	EU MRL [c]	0.10	EU MRL [c]
Sweet corn	0.05	Median residue [a]	0.21	Highest residue [a]
Fresh herbs	1.24	Median residue [a]	7.72	Highest residue [a]
Beans (fresh, with pods)	0.06	Median residue [a]	0.21	Highest residue [a]
Beans (fresh, w/o pods)	0.03	Median residue [a]	0.04	Highest residue [a]
Peas (fresh, with pods)	0.06	Median residue [a]	0.21	Highest residue [a]
Peas (fresh, w/o pods)	0.03	Median residue [a]	0.04	Highest residue [a]
Lentils (fresh)	0.07	Median residue [a]	0.14	Highest residue [a]
Leek	0.06	Median residue (tentative) [b]	0.081	Highest residue (tentative) [b]
Beans (dry)	0.06	Median residue [a]	0.06	Highest residue [a]
Peas (dry)	0.16	Median residue (CXL) [e]	0.79	Highest residue (CXL) [e]
Linseed	0.06	Median residue [a]	0.14	Highest residue [a]
Peanuts	0.02	Median residue (CXL) [e]	0.05	Highest residue (CXL) [e]
Poppy seed	0.10	EU MRL [c]	0.10	EU MRL [c]
Soya bean	0.10	EU MRL [c]	0.10	EU MRL [c]
Barley grain	0.06	Median residue (CXL) [e]	0.06	Highest residue (CXL) [e]
Maize grain	0.05	Median residue (CXL) [e]	0.15	Highest residue (CXL) [e]
Millet	0.03	Median residue [a]	0.04	Highest residue [a]
Oats grain	0.06	Median residue (CXL) [e]	0.06	Highest residue (CXL) [e]
Rice grain	0.02	Median residue (CXL) [e]	0.11	Highest residue (CXL) [e]
Rye grain	0.10	CXL [f]	0.10	CXL [f]
Sorghum grain	0.15	Median residue (CXL) [e]	0.15	Highest residue (CXL) [e]
Wheat grain	0.06	Median residue (CXL) [e]	0.10	Highest residue (CXL) [e]
Herbal infusions (dried, leaves)	0.05	Median residue (tentative) [b]	0.07	Highest residue (tentative) [b]

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: sum of bentazone, 6-hydroxy-bentazone and their conjugates, expressed as bentazone				
Swine meat	0.02	Median residue (= LOQ) (tentative) (d)	0.02	Highest residue (= LOQ) (tentative) (d)
Swine fat (free of lean meat)	0.09	Median residue (tentative) (d)	0.13	Highest residue (tentative) (d)
Swine liver	0.02	Median residue (= LOQ) (tentative) (d)	0.02	Highest residue (= LOQ) (tentative) (d)
Swine kidney	0.03	Median residue (tentative) (d)	0.04	Highest residue (tentative) (d)
Ruminant meat	0.02	Median residue (= LOQ) (tentative) (d)	0.02	Highest residue (= LOQ) (tentative) (d)
Ruminant fat	0.62	Median residue (tentative) (d)	0.81	Highest residue (tentative) (d)
Ruminant liver	0.02	Median residue (= LOQ) (tentative) (d)	0.02	Highest residue (= LOQ) (tentative) (d)
Ruminant kidney	0.22	Median residue (tentative) (d)	0.28	Highest residue (tentative) (d)
Poultry meat	0.02	Median residue (= LOQ) (g)	0.02	Highest residue (= LOQ) (g)
Poultry fat	0.02	Median residue (= LOQ) (g)	0.02	Highest residue (= LOQ) (g)
Poultry liver	0.02	Median residue (= LOQ) (g)	0.02	Highest residue (= LOQ) (g)
Ruminant milk	0.02	Median residue (= LOQ) (tentative) (d)	0.02	Highest residue (= LOQ) (tentative) (d)
Birds' eggs	0.02	Median residue (= LOQ) (g)	0.02	Highest residue (= LOQ) (g)

(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Use reported by the RMS is not fully supported by data; the existing EU MRL is used for indicative exposure calculations.
(d): Livestock dietary burden resulting from the GAPs reported by the RMS is not fully supported by data for this commodity but the risk assessment values derived in section 3 are used for the exposure calculations.
(e): CXL is supported by data; the corresponding risk assessment values are used for the exposure calculations.
(f): CXL is not sufficiently supported by data; the existing CXL is used for indicative exposure calculations.
(g): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is fully supported by data; the risk assessment values derived in section 3 are used for the exposure calculations.

Chronic and acute exposure calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference values derived for bentazone (see Table 2-1); detailed results of the calculations are presented as the EU/Codex scenario in Appendix B.2. The highest chronic exposure was calculated for Dutch children, representing 1.6 % of the ADI, and the highest acute exposure was calculated for celery leaves, representing 17.7 % of the ARfD.

Based on the above calculations, EFSA concludes that the CXLs supported by data (footnote f in Table 4-2) are not expected to be of concern for European consumers. For the remaining CXL on rye, uncertainties remain as it is not well supported by data. Nevertheless, inclusion of this CXL in the exposure calculation did not indicate any risk to European consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of bentazone was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.1 mg/kg bw/d and an ARfD of 0.25 mg/kg bw.

Primary crop metabolism of bentazone was investigated following foliar application on root and tuber vegetables (potatoes), pulses and oilseeds (green beans, soya beans) and cereals (maize, rice). Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities could be defined as the sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone. Metabolism studies showed that 8-hydroxy bentazone is not found in most crops and might be disregarded from this residue definition, provided sufficiently detailed residue data were available to EFSA. A validated analytical method for enforcement of the residue definition is also available, with a combined LOQ of 0.03 mg/kg in high water content, high oil content, acidic and dry commodities. A validated analytical method in herbal infusions is not available and is therefore required.

Regarding the magnitude of residues in all crops reported by the RMS, a sufficient number of supervised residue trials is available for some of the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs, except for potato, leeks, maize and herbal infusions where data were sufficient to derive a tentative MRL only. For spring onions, cucumber, poppy seed, soya bean, rice, alfalfa and clover, no residue trials were available. EFSA was therefore not able to derive MRL proposals for the above mentioned crops and further residue trials are required.

The effect of processing on the nature of bentazone was not investigated. Although quantifiable residues of bentazone are expected in several crops which can be processed, such studies are currently not necessary, as the chronic exposure is far below the ADI. Studies investigating the magnitude of residues in processed rice are available but they only allowed EFSA to derive indicative processing factors for rice. Further processing studies are not required because they are not expected to affect the outcome of the risk assessment. However, if there would be the intention from risk managers to derive more robust processing factors for enforcement purposes, additional processing studies might be required.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in Swiss chard, radish, turnip, sorghum and wheat. These studies showed a comparable metabolism to the primary crops and significant residues in rotational crops are not expected, provided that bentazone is applied according to the GAPs supported in the framework of this review.

Based on the uses reported by the RMS, significant exposures to bentazone and conjugates of 6-hydroxy bentazone are expected for dairy ruminants, meat ruminants, poultry and pigs. Metabolism in lactating ruminants and poultry was sufficiently investigated and findings can be extrapolated to pigs as well. The relevant residue definition for both enforcement and risk assessment in commodities of animal origin is proposed as the sum of bentazone and the metabolite 6-hydroxy bentazone (free and conjugated), expressed as bentazone. A validated analytical method for enforcement of the proposed residue definition is available with an LOQ of 0.02 mg/kg for meat, milk, liver and eggs, but a

validated method is still required for fat. Based on the metabolism study on laying hens, it was concluded that residues of bentazone are not expected in poultry tissues nor in eggs, and that MRLs in these commodities can be set at the LOQ. A feeding study on lactating ruminants also demonstrated that residues of bentazone and its metabolite are not expected in significant amounts in milk and that the MRL in this commodity can be set at the LOQ, noting that storage stability data are in principle still required. Considering that this feeding study did not investigate residues in any other commodity than milk, tentative MRLs for ruminant and pig tissues were proposed based on an extrapolation from the metabolism study, but a feeding study is still required.

Chronic and acute consumer exposures resulting from the MRLs derived in the framework of this review were calculated using revision 2 of the EFSA PRIMo. For those commodities where data were insufficient to derive an MRL, EFSA considered the existing EU MRL for an indicative calculation. The highest chronic exposure represented 1.6 % of the ADI (Dutch child) and the highest acute exposure amounted to 17.7 % of the ARfD (celery leaves).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for bentazone. Additional calculations of the consumer exposure, including these CXLs for products of plant origin, were therefore carried out. The highest chronic exposure represented also 1.6 % of the ADI (Dutch child) and the highest acute exposure amounted to 17.7 % of the ARfD (celery leaves).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D (see table below for a summary). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain tentative MRLs and existing EU MRLs still need to be confirmed by the following data:

- 2 additional residue trials supporting the northern outdoor GAP and 4 additional residue trials supporting the southern outdoor GAP on potatoes;
- 4 residue trials supporting the northern outdoor GAP on spring onions;
- 8 residue trials supporting the northern outdoor GAP on cucumbers;
- 4 additional residue trials supporting the northern outdoor GAP on leeks;
- 4 residue trials supporting the northern outdoor GAP on poppy seed;
- 8 residue trials supporting the northern outdoor GAP and 8 residue trials supporting the southern outdoor GAP on soya bean;
- a confirmation on the validity of the existing CXL for rye;
- further clarification of the GAP of herbal infusions;
- a validated analytical method (with confirmatory method and ILV) for enforcement of the proposed residue definition in herbal infusion;

- an analytical method (with confirmatory method and ILV) for the enforcement of the residue in fat;
- a livestock feeding study for meat ruminant;
- storage stability data for bentazone and 6-hydroxy bentazone in livestock tissues and milk.

It is highlighted that some of the 'Recommended' MRLs resulted from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gaps which are not expected to impact on the validity of the recommended MRLs but which might have an impact on national authorisations:

- 1 additional trial on beans with pods and 2 additional trials on peas without pods complying with the northern outdoor GAP;
- 8 residue trials supporting the northern outdoor GAP on barley and oats;
- 8 residue trials supporting the southern outdoor GAP on rice;
- 8 residue trials supporting the northern outdoor GAP on wheat and rye;
- 8 residue trials supporting the northern outdoor GAP and 8 residue trials supporting the southern outdoor GAP on maize;
- 4 additional residue trials supporting the northern outdoor GAP and 4 additional residue trials supporting the southern outdoor GAP on maize forage;
- 4 residue trials supporting the northern outdoor GAP and 4 residue trials supporting the southern outdoor GAP on alfalfa and clover.

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

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

- elaboration of residue trials with an LOQ of 0.03 mg/kg;
- residue data in plants combining bentazone and 6-hydroxybentazone only;
- confirmation that all residues trials samples were stored in compliance with demonstrated storage stability;
- validation data on the hydrolysis step for enforcement of the proposed residue definition in food of animal origin.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: sum of bentazone and the conjugates of metabolites 6-hydroxy bentazone and 8-hydroxy bentazone, expressed as bentazone					
211000	Potatoes	0.1*	0.1	0.2	Further consideration needed [a]
220010	Garlic	0.1*	-	0.06	Recommended [b]
220020	Onions	0.1*	0.1	0.1	Recommended [c]
220030	Shallots	0.1*	-	0.06	Recommended [b]
220040	Spring onions	0.1*	-	0.1	Further consideration needed [d]
232010	Cucumbers	0.1*	-	0.1	Further consideration needed [d]
234000	Sweet corn	0.3	-	0.3	Recommended [b]
256000	Herbs	15	-	10	Recommended [b]
260010	Beans (fresh, with pods)	0.3	0.2	0.3	Recommended [e]
260020	Beans (fresh, without pods)	0.1*	-	0.05	Recommended [b]
260030	Peas (fresh, with pods)	0.5	0.2	0.3	Recommended [e]
260040	Peas (fresh, without pods)	0.2	-	0.05	Recommended [b]
260050	Lentils (fresh)	0.1*	-	0.05	Recommended [b]
270060	Leek	0.1*	-	0.15	Further consideration needed [f]
300010	Beans (dry)	0.1*	0.05*	0.1	Recommended [e]
300030	Peas (dry)	0.1*	1	1	Recommended [c]
401010	Linseed	0.1*	0.1	0.2	Recommended [e]
401020	Peanuts	0.1*	0.05	0.05	Recommended [g]
401030	Poppy seed	0.1*	-	0.1	Further consideration needed [d]
401070	Soya bean	0.1*	0.05	0.1	Further consideration needed [h]
500010	Barley grain	0.1*	0.1	0.1	Recommended [c]
500030	Maize grain	0.1*	0.2	0.2	Recommended [i]
500040	Millet	0.1*	-	0.08	Recommended [b]
500050	Oats grain	0.1*	0.1	0.1	Recommended [b]
500060	Rice grain	0.1*	0.1	0.1	Recommended [j]
500070	Rye grain	0.1*	0.1	0.1	Further consideration needed [k]
500080	Sorghum grain	0.1*	0.1	0.1	Recommended [c]
500090	Wheat grain	0.1*	0.1	0.1	Recommended [c]
632000	Herbal infusions (dried, leaves)	0.1*	-	0.1	Further consideration needed [f]
-	Other products of plant origin	See App C.1	-	-	Further consideration needed [l]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: sum of bentazone, the metabolites 6-hydroxy bentazone and their conjugates, expressed as bentazone					
1011010	Swine meat	0.05*	0.05*	0.02*	Further consideration needed (m)
1011020	Swine fat (free of lean meat)	0.05*	-	0.15	Further consideration needed (f)
1011030	Swine liver	0.05*	-	0.02*	Further consideration needed (f)
1011040	Swine kidney	0.05*	-	0.05	Further consideration needed (f)
1012010	Bovine meat	0.05*	0.05*	0.02*	Further consideration needed (m)
1012020	Bovine fat	0.05*	-	1	Further consideration needed (f)
1012030	Bovine liver	0.05*	-	0.02*	Further consideration needed (f)
1012040	Bovine kidney	0.05*	-	0.3	Further consideration needed (f)
1013010	Sheep meat	0.05*	0.05*	0.02*	Further consideration needed (m)
1013020	Sheep fat	0.05*	-	1	Further consideration needed (f)
1013030	Sheep liver	0.05*	-	0.02*	Further consideration needed (f)
1013040	Sheep kidney	0.05*	-	0.3	Further consideration needed (f)
1014010	Goat meat	0.05*	0.05*	0.02*	Further consideration needed (m)
1014020	Goat fat	0.05*	-	1	Further consideration needed (f)
1014030	Goat liver	0.05*	-	0.02*	Further consideration needed (f)
1014040	Goat kidney	0.05*	-	0.3	Further consideration needed (f)
1016010	Poultry meat	0.05*	-	0.02*	Recommended (b)
1016020	Poultry fat	0.05*	-	0.02*	Recommended (b)
1016030	Poultry liver	0.05*	-	0.02*	Recommended (b)
1020010	Cattle milk	0.02*	0.05*	0.02*	Further consideration needed (m)
1020020	Sheep milk	0.02*	0.05*	0.02*	Further consideration needed (m)
1020030	Goat milk	0.02*	0.05*	0.02*	Further consideration needed (m)
1030000	Birds' eggs	0.05*	0.05*	0.02*	Recommended (n)
-	Other products of animal origin	See App C.1	-	-	Further consideration needed (l)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).
(b): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(c): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(d): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; no CXL is available (combination C-I in Appendix D).
(e): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).

(g): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-VII in Appendix D).
(h): GAP evaluated at EU level is not supported by data but no risk to consumers could be identified for the existing EU MRL; existing CXL is covered by the existing EU MRL (combination C-III in Appendix D).
(i): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(j): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level is not supported by data but the existing EU MRL is lower than the existing CXL (combination C-VII in Appendix D).
(k): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; GAP evaluated at EU level, which is fully supported by data, would lead to a lower MRL (combination G-V in Appendix D).
(l): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(m): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).
(n): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; CXL is not compatible with EU residue definitions (combination G-II in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on bentazone prepared by the rapporteur Member State Germany in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 20 October 2008. Last updated on 27 October 2009.

REFERENCES

CEN (European Committee for Standardization), 2008. Foods of plant origin - Determination of pesticide residues using GC-MS and/or LC-MS/MS following acetonitrile extraction/partitioning and clean-up by dispersive SPE. QuEChERS-method. EN 15662, November 2008.

EC (European Commission), 1996. Appendix G. Livestock Feeding Studies. 7031/VI/95 rev.4. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 1997g. Appendix I. Calculation of maximum residue level and safety intervals. 7039/VI/95. As amended by the document: classes to be used for the setting of EU

pesticide maximum residue levels (MRLs). SANCO 10634/2010. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2000a. Residue analytical methods. For pre-registration data requirement for Annex II (part A, section 4) and Annex III (part A, section 5 of Directive 91/414. SANCO/3029/99-rev.4. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2000b. Review report for the active substance bentazone. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 13 July 2000 in view of the inclusion of bentazone in Annex I of Council Directive 91/414/EEC. SANCO 7585/VI/97-Final, 30 November 2000. Available online: http://ec.europa.eu/sanco_pesticides/public/index.cfm?event=activesubstance.selection

EC (European Commission), 2010a. Classes to be used for the setting of EU pesticide Maximum Residue Levels (MRLs). SANCO 10634/2010 Rev. 0, finalized in the Standing Committee on the Food Chain and Animal Health at its meeting of 23-24 March 2010. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2010b. Residue analytical methods. For post-registration control. SANCO/825/00-rev.7. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EC (European Commission), 2011. Appendix D. Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs. 7525/VI/95-rev.9. Available online: http://ec.europa.eu/food/plant/protection/resources/publications_en.htm

EFSA (European Food Safety Authority), 2007. Reasoned opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to Regulation (EC) No 396/2005 on Maximum Residue Levels of Pesticides in Food and Feed of Plant and Animal Origin. 15 March 2007.

EFSA (European Food Safety Authority), 2010. Reasoned opinion on the modification of the existing MRL for bentazone in sweet corn. EFSA Journal 2010;8(5):1617,21pp. doi:10.2903/j.efsa.2010.1617. Available online: www.efsa.europa.eu/efsajournal.htm

EFSA (European Food Safety Authority), 2011. Reasoned opinion on the modification of the existing MRLs for bentazone in legume vegetables and fresh herbs. EFSA Journal 2011;9(5):2188,29pp. doi:10.2903/j.efsa.2011.2188. Available online: www.efsa.europa.eu/efsajournal.htm

EURL (European Union Reference Laboratories for Pesticide Residues), 2010. Data pool on method validation for pesticide residues. Status on 25 February 2011. Available online: www.crl-pesticides-datapool.eu

FAO (Food and Agriculture Organization of the United Nations), 1991. bentazone. In: Pesticide residues in food – 1991. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 111. Available online: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

FAO (Food and Agriculture Organization of the United Nations), 1994. bentazone. In: Pesticide residues in food – 1994. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 127. Available online: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

FAO (Food and Agriculture Organization of the United Nations), 1995. bentazone. In: Pesticide residues in food – 1995. Evaluations. Part I. Residues. FAO Plant Production and Protection Paper 137. Available online: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

FAO (Food and Agriculture Organization of the United Nations), 1998. bentazone. In: Pesticide residues in food – 1998. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 148. Available online: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

FAO (Food and Agriculture Organization of the United Nations), 1999. bentazone. In: Pesticide residues in food – 1999. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 153. Available online: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

FAO (Food and Agriculture Organization of the United Nations), 2004. bentazone. In: Pesticide residues in food – 2004. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 178. Available online: http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

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

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

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

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

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

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

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

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Potatoes	*Tuber form Solanum Spp*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	50		1				1500,00	g a.i./ha	42	application: spraying
Garlic	*Allium sativum*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying				1				1444,00	g a.i./ha	21	United Kingdom (2012)
Onions	*Allium cepa*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying				1				1500,00	g a.i./ha	21	
Shallots	*Allium ascalonicum (Allium cepa var. aggregatum)*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying				1				1444,00	g a.i./ha	21	United Kingdom (2012)
Spring onions	*Allium cepa*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying				2				480,00	g a.i./ha	21	United Kingdom (2012)
Cucumbers	*Cucumis sativus*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			2	14	14		1000,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Sweet corn	*Zea mays var. sacharata*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	35		1				1200,00	g a.i./ha	28	EFSA Journal 2010; 8(5):1617
Chervil	*Anthriscus cerefolium*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Chives	*Allium schoenoprasum*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Celery leaves	*Apium graveolens var. seccalinum*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Parsley	*Petroselinum crispum*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Sage	*Salvia officinalis*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Rosemary	*Rosmarinus officinalis*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Thyme	*Thymus spp.*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Basil	*Ocimum basilicum*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Bay leaves (laurel)	*Laurus nobilis*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Tarragon	*Artemisia dracunculus*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying	12			1				1435,00	g a.i./ha	21	EFSA Journal 2011; 9(5):2188
Beans (with pods)	*Phaseolus vulgaris,*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Beans (without pods)	*Phaseolus vulgaris*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Peas (with pods)	*Pisum sativum*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Peas (without pods)	*Pisum sativum*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Lentils (fresh)	*Lens culinaris syn. L. esculenta*	NEU	Outdoor	FR	Dicotyledonous weeds	SG	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Leek	*Allium porrum*	NEU	Outdoor	UK	weeds	SG	870,0	g/kg	Foliar treatment - spraying		13		2				370,00	g a.i./ha	n.a.	United Kingdom (2012)
Beans (dry)	*Phaseolus vulgaris*	NEU	Outdoor	DE	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying		29		2				480,00	g a.i./ha	n.a.	Germany (2012)
Peas (dry)	*Pisum sativum*	NEU	Outdoor	DE	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying		29		2				480,00	g a.i./ha	n.a.	Germany (2012)
Linseed	*Linum usitatissimum*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	11	13		1				1500,00	g a.i./ha	n.a.	Similar to 1x1200 g/ha, BBCH 14-35 (supported by residue trials reported in the monograph)
Poppy seed	*Papaver somniferum*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	11	13		2	7	7		360,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Soya bean	*Glycine max*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	11	51		1				1500,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Barley	*Hordeum spp.*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	21		1				1500,00	g a.i./ha	42	or cGAP: 2 x 1 kg a.i./ha, PHI 42 d, application: spraying
Maize	*Zea mays*	NEU	Outdoor	NL	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	11	15		1				1500,00	g a.i./ha	n.a.	or cGAP: 2 x 1 kg a.i./ha, PHI 60 d, application: spraying
Millet	*Panicum spp.*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying				1				1392,00	g a.i./ha	90	France (2012)
Oats	*Avena fatua*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	21		1				1500,00	g a.i./ha	42	or cGAP: 2 x 1 kg a.i./ha, PHI 42 d, application: spraying
Rye	*Secale cereale*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	21		1				1500,00	g a.i./ha	42	or cGAP: 2 x 1 kg a.i./ha, PHI 42 d, application: spraying
Wheat	*Triticum aestivum*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	21		1				1500,00	g a.i./ha	42	or cGAP: 2 x 1 kg a.i./ha, PHI 42 d, application: spraying

Herbal infusions (leaves)	*Not specified*	NEU	Outdoor		Dicotyledonous weeds	EC	480,0	g/L	Foliar treatment - spraying				1				960,00	g a.i./ha	n.a.	mint/ balm leaves: application: spraying; PHI not necessary
Alfalfa	*Medicago Sativa*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	11	13		2	14	14		1000,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Clover	*Trifolium spp.*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	11	13		2	14	14		1000,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Grass	*not specified*	NEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	13	15		1				1500,00	g a.i./ha	7	or cGAP: 2 x 1 kg a.i./ha, PHI 42 d, application: spraying
Maize (for forage)	*Zea mays*	NEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying				1				1200,00	g a.i./ha	28	

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		**Region**	**Outdoor/ Indoor**	**Member state or Country**	**Pests controlled**	**Formulation**			**Application**							**Application rate**			**PHI or wiaiting period (days)**	**Comments (max. 250 charachters)**
Common name	**Scientific name**					**Type**	**Content**		**Method**	**Growth stage**		**Number**		**Interval (days)**		**Min. rate**	**Max. rate**	**Rate Unit**		
							Conc.	**Unit**		**From BBCH**	**Until BBCH**	**Min.**	**Max.**	**Min.**	**Max.**					
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	42	application: spraying
Sweet corn	*Zea mays var. sacharata*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	35		1				1200,00	g a.i./ha	28	EFSA Journal 2010; 8(5):1617
Beans (with pods)	*Phaseolus vulgaris,*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Beans (without pods)	*Phaseolus vulgaris*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Peas (with pods)	*Pisum sativum*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Peas (without pods)	*Pisum sativum*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Lentils (fresh)	*Lens culinaris syn. L. esculenta*	SEU	Outdoor	FR	Dicotyledonous weeds	SG	480,0	g/L	Foliar treatment - spraying	12	55		1				1218,00	g a.i./ha	n.a.	EFSA Journal 2011; 9(5):2188
Beans (dry)	*Phaseolus vulgaris*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9	14		1				1500,00	g a.i./ha	n.a.	PHI not necessary, application: spraying
Peas (dry)	*Pisum sativum*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9	14		1				1500,00	g a.i./ha	n.a.	application: spraying
Linseed	*Linum usitatissimum*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9	15		1				1500,00	g a.i./ha	n.a.	PHI not necessary, application: spraying
Soya bean	*Glycine max*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	60	application: spraying
Barley	*Hordeum spp.*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	60	PHI not necessary, application: spraying
Maize	*Zea mays*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	60	or cGAP: 2 x 1 kg a.i./ha, PHI 60 d, application: spraying
Oats	*Avena fatua*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	60	PHI not necessary, application: spraying
Rice	*Oryza sativa*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1600,00	g a.i./ha	60	application: spraying
Rye	*Secale cereale*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	60	PHI not necessary, application: spraying
Sorghum	*Sorghum bicolor*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying				1				1392,00	g a.i./ha	90	France (2012)
Wheat	*Triticum aestivum*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	60	PHI not necessary, application: spraying
Alfalfa	*Medicago Sativa*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Clover	*Trifolium spp.*	SEU	Outdoor		Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying	9			1				1500,00	g a.i./ha	n.a.	application: spraying; PHI not necessary
Maize (for forage)	*Zea mays*	SEU	Outdoor	FR	Dicotyledonous weeds	SL	480,0	g/L	Foliar treatment - spraying				1				1200,00	g a.i./ha	28	

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario including demonstrated safe EU MRL proposals and all CXLs

APPENDIX B.1 – EU SCENARIO INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

BENTAZONE			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.1**	ARfD (mg/kg bw):	**0.25**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2000**	Year of evaluation:	**2000**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 2
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
1.6	NL child	0.6	Milk and milk products: Cattle	0.4	Potatoes	0.3	Wheat	
1.5	WHO Cluster diet B	0.5	Wheat	0.2	Maize	0.2	Potatoes	
1.2	WHO cluster diet D	0.4	Wheat	0.3	Potatoes	0.1	Milk and milk products: Cattle	
1.0	WHO cluster diet E	0.3	Potatoes	0.2	Wheat	0.1	Parsley	
1.0	DE child	0.3	Milk and milk products: Cattle	0.2	Wheat	0.2	Potatoes	
1.0	DK child	0.3	Wheat	0.3	Rye	0.2	Potatoes	
1.0	FR infant	0.5	Milk and milk products: Cattle	0.3	Potatoes	0.1	Beans (with pods)	
0.9	SE general population 90th percentile	0.3	Potatoes	0.2	Milk and milk products: Cattle	0.2	Wheat	
0.9	IE adult	0.2	Maize	0.2	Potatoes	0.1	Wheat	
0.9	ES child	0.3	Wheat	0.2	Milk and milk products: Cattle	0.1	Potatoes	
0.9	WHO regional European diet	0.3	Potatoes	0.2	Wheat	0.1	Milk and milk products: Cattle	
0.8	WHO Cluster diet F	0.2	Potatoes	0.2	Wheat	0.1	Milk and milk products: Cattle	
0.8	PT General population	0.4	Potatoes	0.2	Wheat	0.1	Rice	
0.7	FR toddler	0.4	Potatoes	0.2	Wheat	0.1	Beans (with pods)	
0.7	UK Infant	0.2	Potatoes	0.2	Wheat	0.1	Maize	
0.7	UK Toddler	0.2	Potatoes	0.2	Wheat	0.1	Rice	
0.6	NL general	0.2	Potatoes	0.1	Milk and milk products: Cattle	0.1	Wheat	
0.6	LT adult	0.2	Potatoes	0.1	Milk and milk products: Cattle	0.1	Rye	
0.5	IT kids/toddler	0.4	Wheat	0.1	Potatoes	0.0	Rice	
0.5	ES adult	0.1	Wheat	0.1	Milk and milk products: Cattle	0.1	Potatoes	
0.4	FR all population	0.2	Wheat	0.1	Potatoes	0.1	Milk and milk products: Cattle	
0.4	IT adult	0.2	Wheat	0.0	Potatoes	0.0	Rice	
0.3	DK adult	0.1	Wheat	0.1	Potatoes	0.0	Rye	
0.3	UK vegetarian	0.1	Wheat	0.1	Potatoes	0.0	Rice	
0.3	UK Adult	0.1	Wheat	0.1	Potatoes	0.0	Rice	
0.3	PL general population	0.2	Potatoes	0.0	Onions	0.0	Celery leaves	
0.3	FI adult	0.1	Potatoes	0.1	Wheat	0.0	Rye	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of BENTAZONE is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
17.7	Celery leaves	7.72 / -	17.7	Celery leaves	7.72 / -	3.7	Parsley	7.72 / -	3.7	Parsley	7.72 / -
6.2	Sweet corn	0.21 / -	4.4	Sweet corn	0.21 / -	1.8	Sweet corn	0.21 / -	1.3	Sweet corn	0.21 / -
6.2	Potatoes	0.1 / -	4.4	Potatoes	0.1 / -	1.2	Potatoes	0.1 / -	0.9	Potatoes	0.1 / -
4.0	Chervil	7.72 / -	4.0	Chervil	7.72 / -	0.8	Cucumbers	0.1 / -	0.8	Cucumbers	0.1 / -
2.3	Parsley	7.72 / -	2.3	Parsley	7.72 / -	0.4	Beans (with pods)	0.21 / -	0.4	Beans (with pods)	0.21 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
0.5	Potato puree (flakes)	0.1 / -		0.1	Bread/pizza	0.06 / -	
0.3	Wheat flour	0.06 / -		0.0	Potato uree (flakes)	0.1 / -	
0.2	Maize flour	0.1 / -		0.0	Fried potatoes	0.1 / -	
0.1	Fried potatoes	0.1 / -		0.0	Maize flour	0.1 / -	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For BENTAZONE IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX B.2 – EU/CODEX SCENARIO INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

BENTAZONE			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0.1**	ARfD (mg/kg bw):	**0.25**
Source of ADI:	**EC**	Source of ARfD:	**EC**
Year of evaluation:	**2000**	Year of evaluation:	**2000**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	0 2
No of diets exceeding ADI:	---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
1.6	NL child	0.6	Milk and milk products: Cattle	0.4	Potatoes	0.3	Wheat	
1.4	WHO Cluster diet B	0.5	Wheat	0.2	Potatoes	0.1	Maize	
1.2	DK child	0.4	Rye	0.3	Wheat	0.2	Potatoes	
1.2	WHO cluster diet D	0.4	Wheat	0.3	Potatoes	0.1	Milk and milk products: Cattle	
1.1	WHO cluster diet E	0.3	Potatoes	0.2	Wheat	0.1	Soya bean	
1.0	DE child	0.3	Milk and milk products: Cattle	0.2	Wheat	0.2	Potatoes	
1.0	FR infant	0.5	Milk and milk products: Cattle	0.3	Potatoes	0.1	Beans (with pods)	
0.9	WHO Cluster diet F	0.2	Potatoes	0.2	Wheat	0.1	Soya bean	
0.9	SE general population 90th percentile	0.3	Potatoes	0.2	Milk and milk products: Cattle	0.2	Wheat	
0.9	WHO regional European diet	0.3	Potatoes	0.2	Wheat	0.1	Milk and milk products: Cattle	
0.8	ES child	0.3	Wheat	0.2	Milk and milk products: Cattle	0.1	Potatoes	
0.8	IE adult	0.2	Potatoes	0.1	Wheat	0.1	Maize	
0.8	PT General population	0.4	Potatoes	0.2	Wheat	0.0	Soya bean	
0.7	FR toddler	0.4	Potatoes	0.2	Wheat	0.1	Beans (with pods)	
0.6	UK Toddler	0.2	Potatoes	0.2	Wheat	0.0	Beans	
0.6	NL general	0.2	Potatoes	0.1	Milk and milk products: Cattle	0.1	Wheat	
0.6	UK Infant	0.2	Potatoes	0.2	Wheat	0.1	Maize	
0.6	LT adult	0.2	Potatoes	0.1	Rye	0.1	Milk and milk products: Cattle	
0.5	IT kids/toddler	0.4	Wheat	0.1	Potatoes	0.0	Onions	
0.5	ES adult	0.1	Wheat	0.1	Milk and milk products: Cattle	0.1	Potatoes	
0.4	FR all population	0.2	Wheat	0.1	Potatoes	0.1	Milk and milk products: Cattle	
0.4	DK adult	0.1	Wheat	0.1	Potatoes	0.1	Rye	
0.3	IT adult	0.2	Wheat	0.0	Potatoes	0.0	Parsley	
0.3	UK vegetarian	0.1	Wheat	0.1	Potatoes	0.0	Onions	
0.3	PL general population	0.2	Potatoes	0.0	Onions	0.0	Celery leaves	
0.3	FI adult	0.1	Potatoes	0.1	Rye	0.1	Wheat	
0.3	UK Adult	0.1	Wheat	0.1	Potatoes	0.0	Onions	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of BENTAZONE is unlikely to present a public health concern.

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
17.7	Celery leaves	7.72 / -	17.7	Celery leaves	7.72 / -	3.7	Parsley	7.72 / -	3.7	Parsley	7.72 / -
6.2	Sweet corn	0.21 / -	4.4	Sweet corn	0.21 / -	1.8	Sweet corn	0.21 / -	1.3	Sweet corn	0.21 / -
6.2	Potatoes	0.1 / -	4.4	Potatoes	0.1 / -	1.2	Potatoes	0.1 / -	1.0	Peas	0.79 / -
4.0	Chervil	7.72 / -	4.0	Chervil	7.72 / -	1.0	Peas	0.79 / -	0.9	Potatoes	0.1 / -
2.3	Parsley	7.72 / -	2.3	Parsley	7.72 / -	0.8	Cucumbers	0.1 / -	0.8	Cucumbers	0.1 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---				**No of commodities for which ARfD/ADI is exceeded:** ---			
		***)				***)	
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)		Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	
0.5	Potato puree (flakes)	0.1 / -		0.2	Bread/pizza	0.1 / -	
0.5	Wheat flour	0.1 / -		0.0	Potato uree (flakes)	0.1 / -	
0.3	Maize flour	0.15 / -		0.0	Fried potatoes	0.1 / -	
0.1	Fried potatoes	0.1 / -		0.0	Maize flour	0.15 / -	

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.
**) pTMRL: provisional temporary MRL
***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For BENTAZONE IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

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

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs (File created on 06/01/2012 12:01))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Bentazone (sum of bentazone and the conjugates of 6-OH and 8-OH bentazone expressed as bentazone) (R)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,1*
110000	(i) Citrus fruit	0,1*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,1*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,1*
110030	Lemons (Citron, lemon)	0,1*
110040	Limes	0,1*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,1*
110990	Others	0,1*
120000	(ii) Tree nuts (shelled or unshelled)	0,1*
120010	Almonds	0,1*
120020	Brazil nuts	0,1*
120030	Cashew nuts	0,1*
120040	Chestnuts	0,1*
120050	Coconuts	0,1*
120060	Hazelnuts (Filbert)	0,1*
120070	Macadamia	0,1*
120080	Pecans	0,1*
120090	Pine nuts	0,1*
120100	Pistachios	0,1*
120110	Walnuts	0,1*
120990	Others	0,1*
130000	(iii) Pome fruit	0,1*
130010	Apples (Crab apple)	0,1*
130020	Pears (Oriental pear)	0,1*
130030	Quinces	0,1*
130040	Medlar	0,1*
130050	Loquat	0,1*
130990	Others	0,1*
140000	(iv) Stone fruit	0,1*
140010	Apricots	0,1*
140020	Cherries (sweet cherries, sour cherries)	0,1*
140030	Peaches (Nectarines and similar hybrids)	0,1*
140040	Plums (Damson, greengage, mirabelle)	0,1*
140990	Others	0,1*
150000	(v) Berries & small fruit	0,1*
151000	(a) Table and wine grapes	0,1*
151010	Table grapes	0,1*
151020	Wine grapes	0,1*
152000	(b) Strawberries	0,1*
153000	(c) Cane fruit	0,1*
153010	Blackberries	0,1*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0,1*
153030	Raspberries (Wineberries)	0,1*
153990	Others	0,1*
154000	(d) Other small fruit & berries	0,1*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,1*
154020	Cranberries	0,1*
154030	Currants (red, black and white)	0,1*
154040	Gooseberries (Including hybrids with other ribes species)	0,1*
154050	Rose hips	0,1*
154060	Mulberries (arbutus berry)	0,1*
154070	Azarole (mediteranean medlar)	0,1*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0,1*
154990	Others	0,1*
160000	(vi) Miscellaneous fruit	0,1*
161000	(a) Edible peel	0,1*
161010	Dates	0,1*
161020	Figs	0,1*
161030	Table olives	0,1*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,1*
161050	Carambola (Bilimbi)	0,1*
161060	Persimmon	0,1*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0,1*
161990	Others	0,1*
162000	(b) Inedible peel, small	0,1*
162010	Kiwi	0,1*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,1*
162030	Passion fruit	0,1*
162040	Prickly pear (cactus fruit)	0,1*
162050	Star apple	0,1*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,1*
162990	Others	0,1*
163000	(c) Inedible peel, large	0,1*
163010	Avocados	0,1*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,1*
163030	Mangoes	0,1*
163040	Papaya	0,1*
163050	Pomegranate	0,1*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0,1*
163070	Guava	0,1*
163080	Pineapples	0,1*
163090	Bread fruit (Jackfruit)	0,1*
163100	Durian	0,1*
163110	Soursop (guanabana)	0,1*
163990	Others	0,1*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,1*
211000	(a) Potatoes	0,1*
212000	(b) Tropical root and tuber vegetables	0,1*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,1*
212020	Sweet potatoes	0,1*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,1*
212040	Arrowroot	0,1*
212990	Others	0,1*
213000	(c) Other root and tuber vegetables except sugar beet	0,1*
213010	Beetroot	0,1*
213020	Carrots	0,1*
213030	Celeriac	0,1*
213040	Horseradish	0,1*
213050	Jerusalem artichokes	0,1*
213060	Parsnips	0,1*
213070	Parsley root	0,1*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,1*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,1*
213100	Swedes	0,1*
213110	Turnips	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Bentazone (sum of bentazone and the conjugates of 6-OH and 8-OH bentazone expressed as bentazone) (R)
213990	Others	0,1*
220000	(ii) Bulb vegetables	0,1*
220010	Garlic	0,1*
220020	Onions (Silverskin onions)	0,1*
220030	Shallots	0,1*
220040	Spring onions (Welsh onion and similar varieties)	0,1*
220990	Others	0,1*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	0,1*
231010	Tomatoes (Cherry tomatoes,)	0,1*
231020	Peppers (Chilli peppers)	0,1*
231030	Aubergines (egg plants) (Pepino)	0,1*
231040	Okra, lady's fingers	0,1*
231990	Others	0,1*
232000	(b) Cucurbits - edible peel	0,1*
232010	Cucumbers	0,1*
232020	Gherkins	0,1*
232030	Courgettes (Summer squash, marrow (patisson))	0,1*
232990	Others	0,1*
233000	(c) Cucurbits-inedible peel	0,1*
233010	Melons (Kiwano)	0,1*
233020	Pumpkins (Winter squash)	0,1*
233030	Watermelons	0,1*
233990	Others	0,1*
234000	(d) Sweet corn	0.3
239000	(e) Other fruiting vegetables	0,1*
240000	(iv) Brassica vegetables	0,1*
241000	(a) Flowering brassica	0,1*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,1*
241020	Cauliflower	0,1*
241990	Others	0,1*
242000	(b) Head brassica	0,1*
242010	Brussels sprouts	0,1*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,1*
242990	Others	0,1*
243000	(c) Leafy brassica	0,1*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,1*
243020	Kale (Borecole (curly kale), collards)	0,1*
243990	Others	0,1*
244000	(d) Kohlrabi	0,1*
250000	(v) Leaf vegetables & fresh herbs	0,1*
251000	(a) Lettuce and other salad plants including Brassicacea	0,1*
251010	Lamb´s lettuce (Italian cornsalad)	0,1*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,1*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,1*
251040	Cress	0,1*
251050	Land cress	0,1*
251060	Rocket, Rucola (Wild rocket)	0,1*
251070	Red mustard	0,1*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,1*
251990	Others	0,1*
252000	(b) Spinach & similar (leaves)	0,1*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,1*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0,1*
252030	Beet leaves (chard) (Leaves of beetroot)	0,1*
252990	Others	0,1*
253000	(c) Vine leaves (grape leaves)	0,1*
254000	(d) Water cress	0,1*
255000	(e) Witloof	0,1*
256000	(f) Herbs	15
256010	Chervil	15
256020	Chives	15
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	15
256040	Parsley	15
256050	Sage (Winter savory, summer savory,)	15
256060	Rosemary	15
256070	Thyme (marjoram, oregano)	15
256080	Basil (Balm leaves, mint, peppermint)	15
256090	Bay leaves (laurel)	15
256100	Tarragon (Hyssop)	15
256990	Others	15
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,3
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,1*
260030	Peas (with pods) (Mangetout (sugar peas))	0.5
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.2
260050	Lentils	0,1*
260990	Others	0,1*
270000	(vii) Stem vegetables (fresh)	0,1*
270010	Asparagus	0,1*
270020	Cardoons	0,1*
270030	Celery	0,1*
270040	Fennel	0,1*
270050	Globe artichokes	0,1*
270060	Leek	0,1*
270070	Rhubarb	0,1*
270080	Bamboo shoots	0,1*
270090	Palm hearts	0,1*
270990	Others	0,1*
280000	(viii) Fungi	0,1*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,1*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,1*
280990	Others	0,1*
290000	(ix) Sea weeds	0,1*
300000	3. PULSES, DRY	0,1*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,1*
300020	Lentils	0,1*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,1*
300040	Lupins	0,1*
300990	Others	0,1*
400000	4. OILSEEDS AND OILFRUITS	0,1*
401000	(i) Oilseeds	0,1*
401010	Linseed	0,1*
401020	Peanuts	0,1*
401030	Poppy seed	0,1*
401040	Sesame seed	0,1*
401050	Sunflower seed	0,1*
401060	Rape seed (Bird rapeseed, turnip rape)	0,1*
401070	Soya bean	0,1*
401080	Mustard seed	0,1*
401090	Cotton seed	0,1*
401100	Pumpkin seeds	0,1*
401110	Safflower	0,1*
401120	Borage	0,1*
401130	Gold of pleasure	0,1*
401140	Hempseed	0,1*
401150	Castor bean	0,1*
401990	Others	0,1*
402000	(ii) Oilfruits	0,1*
402010	Olives for oil production	0,1*
402020	Palm nuts (palmoil kernels)	0,1*
402030	Palmfruit	0,1*
402040	Kapok	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Bentazone (sum of bentazone and the conjugates of 6-OH and 8-OH bentazone expressed as bentazone) (R)
402990	Others	0,1*
500000	5. CEREALS	0,1*
500010	Barley	0,1*
500020	Buckwheat	0,1*
500030	Maize	0,1*
500040	Millet (Foxtail millet, teff)	0,1*
500050	Oats	0,1*
500060	Rice	0,1*
500070	Rye	0,1*
500080	Sorghum	0,1*
500090	Wheat (Spelt Triticale)	0,1*
500990	Others	0,1*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,1*
900010	Sugar beet (root)	0,1*
900020	Sugar cane	0,1*
900030	Chicory roots	0,1*
900990	Others	0,1*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,02*
1020010	Cattle	0,02*
1020020	Sheep	0,02*
1020030	Goat	0,02*
1020040	Horse	0,02*
1020990	Others	0,02*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by	0,05*

	steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(R) The residue definition differs for the following combinations pesticide-code number 1000000: bentazone

(*) Indicates lower limit of analytical determination

APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for bentazone in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
211000	Potatoes	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.04	0.1	n.a.	1	1991	No	The residue definition is to be reviewed. All residues were <LOQ which ranged from 0.02 to 0.1 depending on whether the methods of analyses were for the total definition or for the individual metabolites. Trials generated in Germany and Brazil to support many GAPs including some non-
220020	Onions	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	n.k.	0.08	n.a.	1	1991	No	The residue definition is to be reviewed. 3 of 4 residues were <LOQ which ranged from 0.02 to 0.08 depending on whether the methods of analyses were for the total definition or for the individual metabolites. A single residue was found at 0.05. Not appropriate to calculate an STMR as two of the LOQ residues could be higher than the quantifiable residue. Trials generated in Brazil, UK and NL to support many GAPs including some non-EU.
260010	Beans (fresh, with pods)	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.2	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	n.k.	0.18	n.a.	1	1991	No	The residue definition is to be reviewed. Residues ranged from n.d. to <0.18 (including a parent residue of 0.14) depending on whether the methods of analyses were for the total definition or for the individual metabolites. It was not appropriate to calculate an STMR as it was unclear which trials supported the MRL. Trials generated in many countries including some non-EU. NB Also there is an immature Lima bean CXL of 0.05 based on US trials.
260030	Peas (fresh, with pods)	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.2	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	n.k.	0.11	n.a.	1	1991	No	The residue definition is to be reviewed. Residues ranged from n.d. to <0.11 (including a 6-OH residue of 0.07) depending on whether the methods of analyses were for the total definition or for the individual metabolites. It was not appropriate to calculate an STMR as it was unclear which trials were relevant to the MRL. Trials generated in many countries including some non-EU.
300010	Beans (dry)	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.05 *	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.02	0.06	n.a.	1	1991	No	The residue definition is to be reviewed. All residues were <LOQ which ranged from 0.02 to 0.06 depending on whether the methods of analyses were for the total definition or for the individual metabolites. It is not clear how many trials were used to set the CXL but the majority had residues of <0.02 which is therefore the STMR. Trials generated in many countries to support many GAPs including some non-EU.

Summary of CXLs for bentazone in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
300030	Peas (dry)	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.16	0.79	n.a.	1	1994	No	The residue definition is to be reviewed. Data were available from 6 USA trials. Residues in 3 were <0.05 for each component of the residue individually. 1 sample had a 6-OH residue of 0.06 and 2 had total residues of 0.28 and 0.79.
401010	Linseed	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.05	0.06	n.a.	1	1991	No	The residue definition is to be reviewed. 3 of 4 residues were <LOQ which ranged from 0.02 to 0.06 depending on whether the methods of analyses were for the total definition or for the individual metabolites. In one GB trial the total residue was 0.28 however the reasons for not using this value to propose the CXL are unclear. The highest residue may therefore be considered as <0.06. Trials were carried out in the UK and Canada.
401020	Peanuts	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.05	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.02	0.05	n.a.	1	1991	No	The residue definition is to be reviewed. Trials and GAP all non-EU. All residues were <LOQ with total residues ranging from n.d. to <0.05.
401070	Soya bean	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.05	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.15	0.15	n.a.	1	1995	no	6 USA trials were evaluated in 1995. Residues for all 3 components of the residue definition were individually <0.05, however the total residue was also stated as <0.05.
500010	Barley grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.06	0.06	n.a.	1	1991 &1994	No	The residue definition is to be reviewed. GAP and trials include Canada data. Residues were all <LOQ and range from <0.02-<0.06 depending on method of analysis.
500030	Maize grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.2	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.05	0.15	n.a.	1	1991 & 1994	No	The residue definition is to be reviewed. Residues ranged from <0.02 to <0.15 (including a 6-OH residue of 0.11) depending on the method of analysis. The trials were generated in a number countries including some non-EU.
500050	Oats grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.06	0.06	n.a.	1	1991 &1994	Yes	The residue definition is to be reviewed. Trials and GAP from DE and NL only. All residue were <LOQ with the majority being <0.06.
500060	Rice grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.02	0.11	n.a.	1	1991 & 1994	No	The residue definition is to be reviewed. Residues ranged from <0.02 to <0.11 (including a parent residue of 0.07) depending on the method of analysis. The trials were generated in a number countries including some non-EU.
500070	Rye grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	n.k.	n.k.	n.a.	1	1991 &1994	Yes	It is unclear which data were considered in support of the CXL. 2 trials had data <0.06 which would seem appropriate. However additional trials had residues in the region of 2 mg/kg (short PHIs), therefore the relevant values cannot be concluded.
500080	Sorghum grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.15	0.15	n.a.	1	1991 &1994	No	1 USA trial on sorghum with residues for each analyte being <LOQ of 0.05 individually. Therefore <0.15 is not a true STMR and is likely to be an overestimate of the HR. May have been combined with the data for maize.

Summary of CXLs for bentazone in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
500090	Wheat grain	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	0.1	sum of bentazone, 6-hydroxybentazone and 8-hydroxybentazone expressed as bentazone	n.c.	n.c.	1	n.c.	0.06	0.10	n.a.	1	1991 &1994	No	The residue definition is to be reviewed. Trials and GAP were from various countries including Brazil. Nearly all residues were <LOQ with total residues ranging from <0.02 to <0.06 depending on the method of analysis. Only 1 trial had a quantifiable residue of <0.10 (based on 2 individual residues of <0.02 for parent and 8-OH and a residue of 0.06 6-OH). One trial had a total residue of <0.3 based on 3xLOQ of <0.1, this result has been discounted based on the low analytical capability.

(*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

n.k.: not known

Summary of CXLs for bentazone in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in livestock tissues on the basis of a goat feeding study(STMR = 0.005, HR = 0.008). CXL therefore set at the analytical LOQ.
1012010	Bovine meat	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in livestock tissues on the basis of a goat feeding study(STMR = 0.005, HR = 0.008). CXL therefore set at the analytical LOQ.
1013010	Sheep meat	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in livestock tissues on the basis of a goat feeding study(STMR = 0.005, HR = 0.008). CXL therefore set at the analytical LOQ.
1014010	Goat meat	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in livestock tissues on the basis of a goat feeding study(STMR = 0.005, HR = 0.008). CXL therefore set at the analytical LOQ.
1015010	Horses, asses, mules or hinnies meat	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in livestock tissues on the basis of a goat feeding study(STMR = 0.005, HR = 0.008). CXL therefore set at the analytical LOQ.
1017010	Other farm animals meat	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in livestock tissues on the basis of a goat feeding study(STMR = 0.005, HR = 0.008). CXL therefore set at the analytical LOQ.
1020010	Cattle milk	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in milk on the basis of a goat feeding study (<0.003 mg/kg). CXL therefore set at the analytical LOQ.
1020020	Sheep milk	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in milk on the basis of a goat feeding study (<0.003 mg/kg). CXL therefore set at the analytical LOQ.
1020030	Goat milk	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in milk on the basis of a goat feeding study (<0.003 mg/kg). CXL therefore set at the analytical LOQ.
1020040	Horse milk	Bentazone	no	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in milk on the basis of a goat feeding study (<0.003 mg/kg). CXL therefore set at the analytical LOQ.
1030000	Birds' eggs	Bentazone	n.a.	0.05 *	Bentazone	n.c.	n.c.	1995	no	Low residues expected in eggs on the basis of a hen feeding study (<0.001 mg/kg). CXL therefore set at the analytical LOQ.

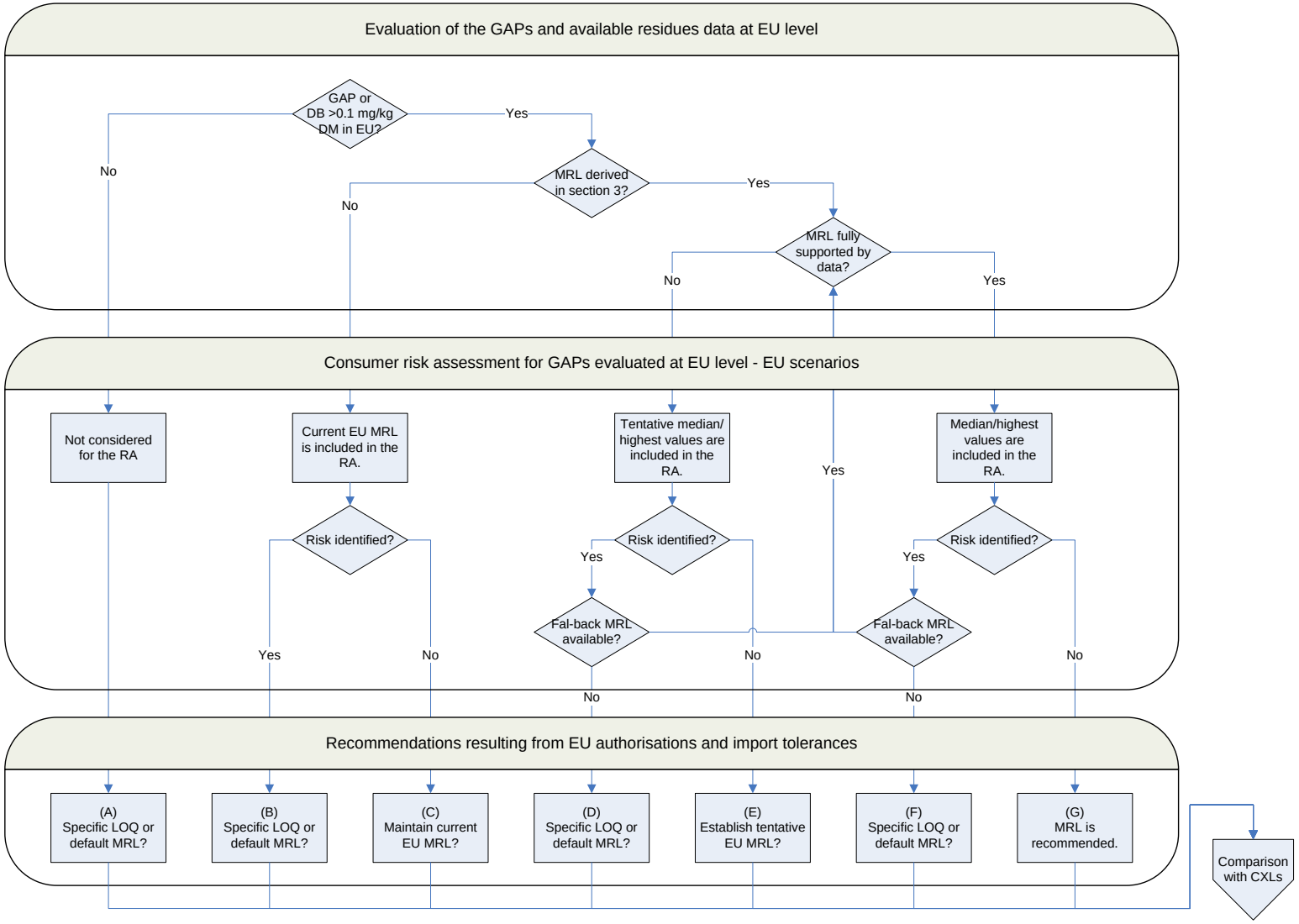
(*) Indicates the lower limit of analytical quantification.

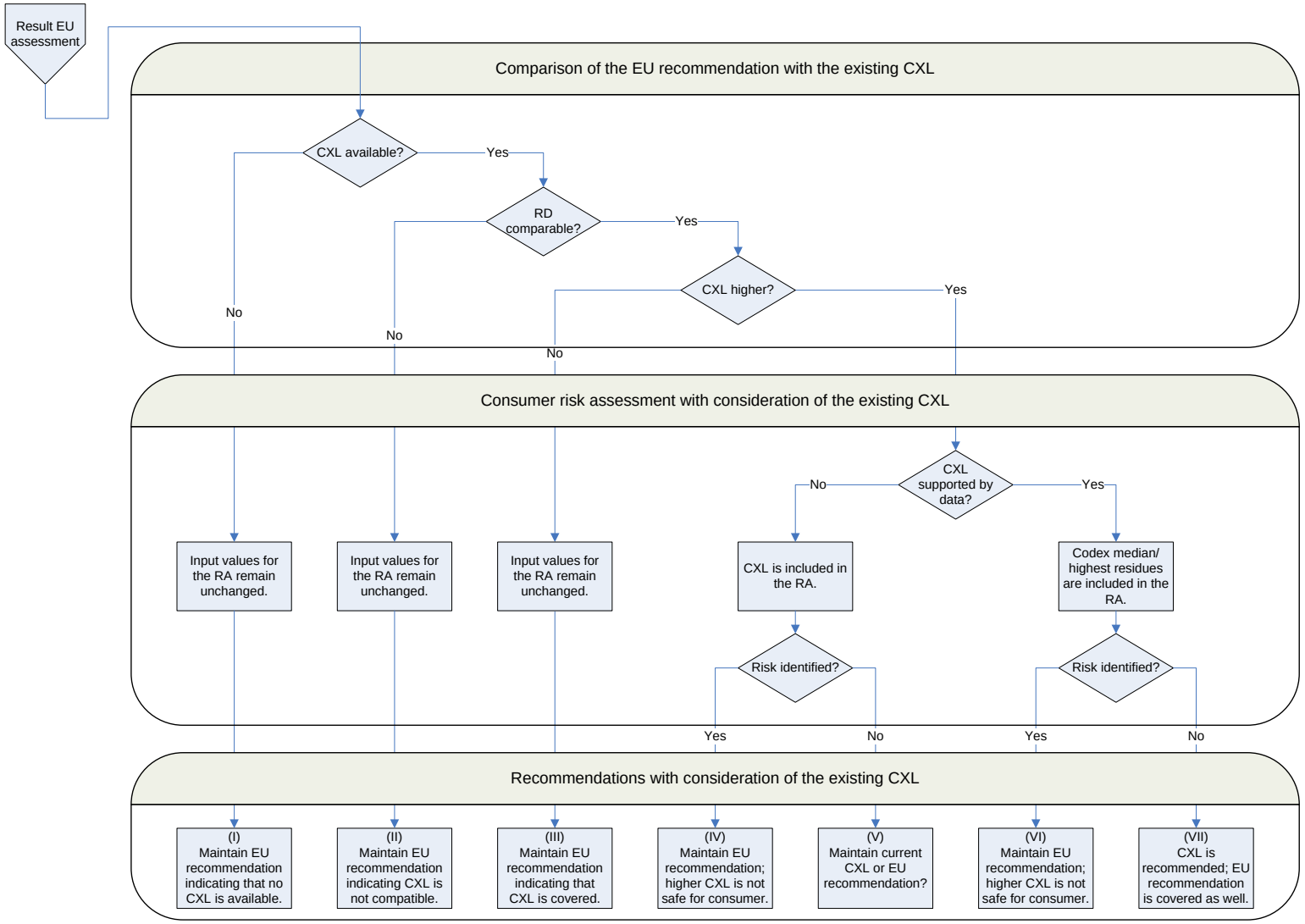
n.a.: not applicable

n.c.: not considered

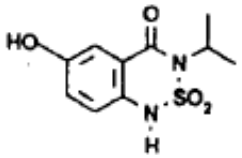
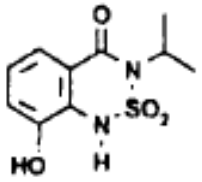
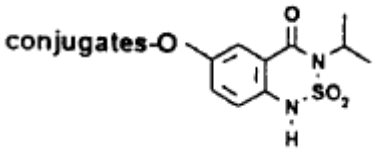
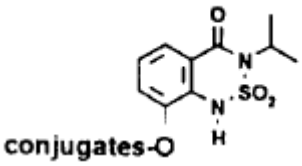
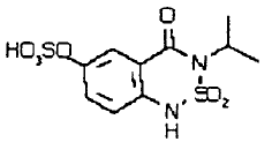
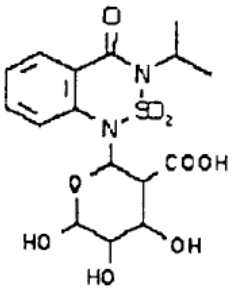
n.k.: not known

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
6-hydroxy bentazone	6-hydroxy-3-(propan-2-yl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide	
8-hydroxy bentazone	8-hydroxy-3-(propan-2-yl)-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one 2,2-dioxide	
bentazone-6-O-conjugates	Not reported	
bentazone-8-O-conjugates	Not reported	
sulfate of 6-hydroxy bentazone	Not reported	
glucuronide of bentazone	2-[2,2-dioxido-4-oxo-3-(propan-2-yl)-3,4-dihydro-1*H*-2,1,3-benzothiadiazin-1-yl]-4,5,6-trihydroxytetrahydro-2*H*-pyran-3-carboxylic acid	

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
CAC	Codex Alimentarius Commission
CEN	European Committee for Standardization (Comité Européen de Normalisation)
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
DT_{90lab}	period required for 90 percent dissipation (define method of estimation) - laboratory
EC	European Commission
EFSA	European Food Safety Authority
eq	equivalent
EU	European Union
EURLs	EU Reference Laboratories (former CRLs)
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-FPD	gas chromatography coupled with flame photometric detection

ha	hectare
HPLC-MS/MS	high performance liquid chromatography coupled with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
$P_{o/w}$	partition coefficient n-octanol/water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residue Overview File
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation