REASONED OPINION

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

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance benalaxyl. In order to assess the occurrence of benalaxyl residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. Although no apparent risk to consumers was identified, some information required by the regulatory framework was found to be missing and the consumer risk assessment for benalaxyl is considered indicative only. Moreover, residues of benalaxyl may also be generated by the use of benalaxyl-M, which is the purified R-enantiomer of benalaxyl and which is currently stioll under assessment at EU level. Considering that EFSA was not yet in a position to include the use of benalaxyl-M in the above assessment and that most of the uses of benalaxyl evaluated in the framework of this review do not seem to require the setting of MRLs higher than those currently listed in Annexes II and III of Regulation (EC) No 396/2005 EFSA recommends that the existing EU MRLs for benalaxyl (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)), except for table grapes, are maintained until the review of MRLs for benalaxyl-M can be finalised. For table grapes, EFSA recommends to increase the existing EU MRL of 0.3 mg/kg to 0.6 mg/kg to cover the authorised use of benalaxyl on table grapes which is adequately supported by data and for which no risk to consumers was identified.

KEY WORDS

benalaxyl, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, phenylamide, fungicide, benalaxyl-M

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SUMMARY

Benalaxyl was included in Annex I to Directive 91/414/EEC on 01 March 2005, 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 Portugal, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 10 October 2008 and, after having considered several comments made by EFSA, the RMS provided on 22 June 2011 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 19 April 2013 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 21 June 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of benalaxyl was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.04 mg/kg bw/d. An ARfD was not deemed necessary. The ADI was established for benalaxyl, but it was concluded that benalaxyl-M (the purified R-enantiomer of benalaxyl) has a similar pattern of toxicity, toxicokinetics and metabolism as benalaxyl and the same ADI was established for both active substances.

Metabolism of benalaxyl was investigated in three different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the residue definition could be extended to all plants. The relevant residue for enforcement and risk assessment in plants could be defined as benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers). A validated analytical method for enforcement of the proposed residue definition is also available, with an LOQ of 0.01 mg/kg in acidic, dry, high water and high oil content commodities.

Regarding the magnitude of residues, a sufficient number of supervised residues trials is available for most 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 pepper and rape seed. In these two crops, no residue trials were available and no MRL or risk assessment values could be derived.

As the chronic exposure to benalaxyl does not exceed 10 % of the ADI, investigations on processed products are in principle not necessary. A study on the magnitude of residues was performed in grapes and tomatoes but the processing factors derived can only be considered as indicative as the nature of residues in processed commodities was not investigated. 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 processing factors for enforcement purposes, additional processing studies might be required.

Occurrence of benalaxyl residues in rotational crops was already investigated during the peer review of benalaxyl. On the basis of the reported data and considering the GAPs of benalaxyl reported in the framework of this review, it is concluded that significant residues of benalaxyl are not expected in rotational crops.

Based on the uses reported by the RMS, no significant intakes were calculated for all groups of livestock. However, metabolism studies on goats and hens were performed. These studies show that even if the compound is highly excreted, the remaining radioactivity consists mainly of hydroxymethyl metabolites, rather than of parent compound.

Chronic consumer exposure resulting from the MRLs derived in the framework of this review was 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 2 % of the ADI (WHO cluster diet B). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

However, residues of benalaxyl may also be generated by the use of benalaxyl-M, which is the purified R-enantiomer of benalaxyl. Considering that benalaxyl-M is currently under assessment at European level, and that no information supporting the review of MRLs for benalaxyl-M has been provided to EFSA so far, EFSA is not yet in a position to include the uses of benalaxyl-M in the current assessment. EFSA therefore assessed by means of a second calculation whether the existing EU MRLs for benalaxyl (including benalaxyl-M) might be of concern for European consumers. Noting that none of the MRLs derived in the framework of this review exceeds the existing EU MRLs for benalaxyl-M, except the one for table grapes, and assuming that current authorised uses of benalaxyl-M are also covered by the existing EU MRLs, this approach is expected to provide a tentative and conservative estimate of the combined exposure of European consumers to benalaxyl and benalaxyl-M residues, provided that the higher MRL proposal for table grapes is also included in the calculation. Based on this calculation, the highest chronic exposure represented 12.3 % of the ADI (WHO cluster diet B).

As the use of benalaxyl was previously assess by JMPR (FAO, 2009a), the CXLs resulting from this assessment should in principle also be taken into account for the intake calculation. However, these CXLs were already implemented at EU level by means of Regulation (EU) No 520/2011. Consequently, consumer exposure due to CXLs is already taken into account in the second intake calculation and no additional calculation is necessary.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. Considering that EFSA was not yet in a position to include the use of benalaxyl-M in the above assessment and that most of the uses of benalaxyl evaluated in the framework of this review do not seem to require the setting of MRLs higher than those currently listed in Annexes II and III of Regulation (EC) no 396/2005 EFSA recommends that the existing EU MRLs for benalaxyl (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)), except for table grapes, are maintained until the review of MRLs for benalaxyl-M can be finalised. For table grapes, EFSA recommends to increase the existing EU MRL of 0.3 mg/kg to 0.6 mg/kg to cover the authorised use of benalaxyl on table grapes which is adequately supported by data and for which no risk to consumers was identified.

It is noted however that during the assessment of benalaxyl the following data gaps have been identified for other crops:

- 8 residue trials supporting the northern outdoor GAP on wine grapes;
- 8 residue trials supporting the northern outdoor GAP tomatoes;
- 8 residue trials supporting the southern outdoor GAP and 8 residue trials supporting the indoor GAP on peppers;
- 6 additional residue trials supporting the indoor GAP on melon and watermelon;
- 8 residue trials supporting the northern outdoor GAP and 8 residue trials supporting the indoor GAPs on lettuce;
- 8 residue trials supporting the northern outdoor GAP on rapeseed;

- Storage stability data on high oil content commodities.

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. Regardless of the data gaps identified, Member States are in any case strongly recommended to reconsider any indoor GAP on melons and watermelons in order not to have exceedances of the EU MRL.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact on the national authorisations. The following data are therefore considered desirable but not essential:

- 1 additional residue trial supporting the southern outdoor GAP on melon and watermelon.

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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 benalaxyl was included in Annex I to the above mentioned directive on 01 March 2005, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-494 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, and 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 gain an overview of 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 inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

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

Portugal, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for benalaxyl. The requested information was submitted to EFSA on 10 October 2008 and subsequently checked for completeness. On 22 June 2011, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 19 April 2013 and submitted to Member States (MS) for commenting. All MS comments received by 21 June 2013 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.

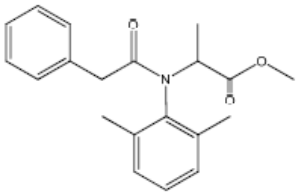
TERMS OF REFERENCE

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

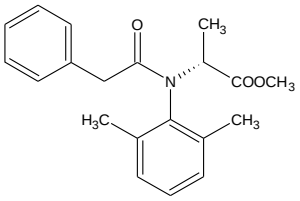
- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Benalaxyl is the ISO common name for methyl *N*-(phenylacetyl)-*N*-(2,6-xylyl)-DL-alaninate (IUPAC). Benalaxyl is a racemic mixture of two enantiomers. The purified R-enantiomer may also be available on the market, its ISO common name being benalaxyl-M.



Benalaxyl



Benalaxyl-M

Benalaxyl and benalaxyl-M belong to the group of phenylamide compounds which are used as fungicide for the control of oomycete pathogens. They are systemic compounds with apoplastic translocation. Both compounds inhibit mycelial growth of fungi and germination of zoospores, disrupting fungal nucleic acid synthesis.

Benalaxyl was evaluated in the framework of Directive 91/414/EEC with Portugal being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were outdoor treatments on a wide range of crops. The maximum rate of application was 0.24 kg a.s./ha. 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 2004/58/EC[6], which entered into force on 01 March 2005. According to Regulation (EU) No 540/2011[7], benalaxyl is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as fungicide only. As EFSA was not yet involved in the peer review of benalaxyl, a conclusion of EFSA on this active substance is not available.

Benalaxyl-M is currently being evaluated in the framework of Regulation (EC) No 1107/2009, also with Portugal being the designated rapporteur Member State. The representative uses supported for

[6] Commission Directive 2004/58/EC of 23 April 2004 amending Council Directive 91/414/EEC to include alpha-cypermethrin, benalaxyl, bromoxynil, desmedipham, ioxynil and phenmedipham as active substances, OJ L 120, 24.4.2004, p. 26-29.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1-50.

this peer review process is the outdoor foliar treatment of grapes with a maximum application rate of 0.1 kg a.s./ha. The Draft Assessment Report (DAR) and its addenda were peer reviewed by EFSA and a conclusion on benalaxyl-M is already available. However, a final decision on the approval of benalaxyl-M by the Standing Committee of the Food Chain and Animal Health has not yet been taken.

As benalaxyl and benalaxyl-M are mixtures of the same enantiomers but at different ratios, the MRLs of these active substances are closely related. The EU MRLs for benalaxyl and benalaxyl-M are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers), are summarised in Appendix C to this document. CXLs for benalaxyl were also established by the Codex Alimentarius Commission and are reported in Appendix C to this reasoned opinion. These CXLs refer to benalaxyl.

For the purpose of this MRL review, the critical uses of benalaxyl currently authorised within the EU, have been collected by the RMS and reported in the PROFile (see Appendix A). They include a foliar outdoor treatment in grapevine, and foliar outdoor and indoor treatments in several vegetables, with application rates up to 200 g a.s./ha in northern Europe and up to 240 g a.s./ha indoor and in southern Europe. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

Although provisional authorisations for benalaxyl-M may have been issued in several Member States, a final decision on the approval of benalaxyl-M in the framework of Regulation (EC) No 1107/2009 has not yet been taken. The critical uses of benalaxyl-M have therefore not yet been collected by the RMS.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (Portugal, 2000), the Review Report on benalaxyl (EC, 2004), the JMPR Evaluation report (FAO, 2009a), the conclusion on the peer review of the pesticide risk assessment of the active substance benalaxyl-M (EFSA, 2013) as well as the evaluation report submitted during the consultation of Member States (France, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

It is highlighted that the present assessment is only based on the use of benalaxyl, while residues of benalaxyl may also be generated by the use of benalaxyl-M, which is the purified R-enantiomer of benalaxyl. Considering however that benalaxyl-M is not yet approved in the framework of Regulation (EC) No 1107/2009 and that the review of MRLs under Article 12 of Regulation (EC) No 396/2005 has not yet been triggered, EFSA is not yet in a position to include the uses of benalaxyl-M in the current assessment. EFSA will therefore review once again the MRLs of benalaxyl and benalaxyl-M as soon as a final decision on the approval of benalaxyl-M will have been taken

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

1. Methods of analysis

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

During the peer review of benalaxyl under Directive 91/414/EEC, an analytical method using GC-NPD and its ILV were evaluated in plant matrices for the determination of benalaxyl (sum of isomers) and validated with an LOQ of 0.02 mg/kg in high water content (lettuce) and acidic (grapes) commodities. However, the number of tested samples for lettuce is insufficient and no confirmatory method was available (Portugal, 2000).

The multi-residue QuEChERS method in combination with HPLC-MS/MS are also reported for the analysis of benalaxyl (sum of isomers) with an LOQ of 0.01 mg/kg in high water content, high oil content, dry and acidic commodities (EURL, 2013). A detailed description of the QuEChERS method is reported by CEN (2008). This method is not expected to distinguish between both enantiomers considering that a chiral column is normally not applied in the QuEChERS method.

Table 1-1: Recovery data for the analysis of benalaxyl in different crop groups using the QuEChERS method in combination with HPLC-MS/MS (EURL, 2013)

Commodity group	Spiking levels (mg/kg)	Recoveries			No of labs
		Mean (%)	RSD (%)	n	
Acidic	0.01 0.1	99.9 97.9	5.4 2.5	10 10	2
Dry (cereals, dry pulses)	0.01 0.10	101.1 100.3	3.9 3.1	10 10	2
Fatty (oils)	0.01 0.10	93.2 93.1	4.3 3.8	10 10	2
Watery	0.01 0.10	99.0 97.0	3.8 4.1	10 10	2

Hence, it is concluded that benalaxyl (sum of isomers) can be enforced in food of plant origin with an LOQ of 0.01 mg/kg in acidic, dry, high water content and high oil content commodities.

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

During the peer review of benalaxyl under Directive 91/414/EEC, an analytical method using GC-NPD and its ILV were evaluated in food of animal origin for the determination of benalaxyl (sum of isomers) and validated with an LOQ of 0.02 mg/kg in meat, milk and eggs. No confirmatory method was available (Portugal, 2000; FAO, 2009a). Moreover, no analytical method in fat, liver and kidney is available.

However, considering the fact that there is no significant intake of residues by livestock, no residue definitions and no MRLs are proposed for commodities of animal origin (section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary.

2. Mammalian toxicology

The toxicological assessment of benalaxyl was peer reviewed under Directive 91/414/EEC and an ADI value was established by the European Commission (2004b). The studies were performed on benalaxyl. The toxicological reference values are summarised in Table 2-1.

During the peer review of benalaxyl-M, it was concluded that benalaxyl-M has a similar pattern of toxicity, toxicokinetics and metabolism as benalaxyl and the same ADI was established for both active substances (EFSA, 2013).

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Benalaxyl					
ADI	EC	2004	0.04 mg/kg bw/d	2 year, rat	100
ARfD	EC	2004	Not established - not necessary		
Benalaxyl-M					
ADI	EFSA	2013	0.04 mg/kg bw/d	2 year, rat, benalaxyl	100
ARfD	EFSA	2013	Not established - not necessary		

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of benalaxyl was investigated for foliar treatment on fruits and fruiting vegetables (grape and tomato), on leafy vegetable (tobacco) and on root and tuber vegetables (potato) using ^{14}C-labelled benalaxyl (Portugal, 2000). The studies on grape, tomato and potato were also considered during the peer review on benalaxyl-M (EFSA, 2013). The characteristics of these studies are summarised in Table 3-1.

Based on these studies, benalaxyl was demonstrated to penetrate into the plants' aerial parts. In tobacco plants, 47 % of the TRR (7.78 mg eq/kg) was inside the leaves 16 days after treatment, in tomato 35 % of the TRR (0.069 mg eq/kg) was found inside the fruit 28 days after treatment, in grapes 88 % of the TRR (2.27 mg eq/kg) was found in the fruit 24 days after application, and in potato plants 93% of the TRR (10.21 mg eq/kg) was inside the leaves 16 days after treatment. However, absorption or translocation to the roots does not appear and no significant radioactivity was found in tubers (<0.005 mg eq/kg) after treatment on potato plant leaves.

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (g a.s./hL)	No	Sampling (DAT)	Remarks
Fruits and fruiting vegetable	Grape	n.r.	foliar treatment (F)	24	1	0, 3, 8, 15 and 24	-
		^{14}C in the alpha position of the ester group	foliar treatment	30	5	n.a.	-
		n.r.	foliar treatment (F)	24	4	22	-
		n.r.	foliar treatment	24	4	22	-
		n.r.	foliar treatment	n.r.	4	16	-
	Tomato	n.r.	foliar treatment (F)	25	1	1, 7, 14, 21, 28 and 35	-
Leafy vegetables	Tobacco	n.r.	foliar treatment (F)	25	2	7, 14 and 21	-
		n.r.	foliar treatment	n.r.	n.r.	16	-
Root and tuber vegetables	Potato	^{14}C in the alpha position of the ester group	foliar treatment (G)	30	1	0,1, 2, 3, 4, 7, 10 and 16	-
		n.r.	foliar treatment (F)	25	1	5, 12, 19 and 26	-

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

The level of metabolisation depends on the plant species, but parent benalaxyl remains the major compound found. In tobacco leaves, benalaxyl represents 83 % of TRR (11.94 mg eq/kg) 21 days after treatment, whereas it represents 67 % of TRR (0.132 mg eq/kg) in tomato fruits 28 days after application, 51.74 % of TRR (1.34 mg eq/kg) in grapes 24 days after treatment, and only 16 % of TRR (0.55 mg eq/kg) in potato leaves 26 days after treatment.

The other compounds identified in significant amount are gluco-benalaxyl[10] (25 % of the TRR in fruit at PHI 24, 63 % of the TRR in leaves at PHI 16) and digluco-benalaxyl[10] (10 % of the TRR in fruit at PHI 24) in grape, malo-gluco-benalaxyl[10] in tomato (15 % of the TRR at PHI 28) and potato leaves (21 % of the TRR at PHI 26). Those metabolites result of oxidization and linkage of the parent compound to one (gluco-benalaxyl) or more (digluco-benalaxyl) molecules of glucose or (malo-gluco-

[10] See appendix E

benalaxyl) molecules of glucose and malonic acid. The proportions of these conjugates increased with time. However, these plant metabolites were considered less toxic than the parent compound.

In addition, on the basis of peer reviewed public literature, it was demonstrated that significant stereo-selective degradation of racemic benalaxyl can occur on a variety of crops (fruiting vegetables, leafy and root crops), leading to relative enrichment of the benalaxyl R-isomer, i.e. benalaxyl-M (EFSA, 2013). Since benalaxyl-M was considered to have the same toxicological properties of racemic benalaxyl, no impact on the risk assessment is expected from this selective degradation.

Consequently, metabolism studies have been performed on three crop groups (fruits and fruiting vegetables, roots and tuber vegetables and leafy vegetables) and, as there is no clear evidence that benalaxyl can be considered as fat soluble and metabolism in all crops investigated was found to be similar, the residue definition should be applicable to all uses reported in the framework of this review, including rapeseed (oilseeds). Based on the available studies, and considering that the different mixtures of benalaxyl isomers are expected to have similar toxicities (see also section 2), the residue for both enforcement and risk assessment in all plant commodities is defined as benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers). This definition is also in line with the one proposed by JMPR (FAO, 2009a). Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1).

3.1.1.2. Magnitude of residues

According to the RMS, the active substance benalaxyl is authorised for outdoor foliar treatment in grape in northern and southern Europe, and several vegetables in northern and southern Europe both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of benalaxyl residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including those evaluated in the framework of the peer review of benalaxyl (Portugal, 2000) and additional data submitted during the consultation of Member States (France, 2013). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised 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:

- Wine grape: no residue trials are available in northern Europe. Although appropriate MRL and risk assessment values can be derived from the southern Europe data, 8 trials complying with the northern GAPs are still required as it is a major crop in northern Europe.

- Potato: the number of trials reported for southern Europe is not compliant with the data requirements but the reduced number was considered sufficient by EFSA because all available trial results were below the LOQ, indicating a no residue situation. Further residue trials are not required (see also section 3.1.1.3).

- Onion, shallots: only 4 residue trials are available in northern Europe, and only 2 are available in southern Europe, although it is a major crop in both northern and southern Europe. Considering the metabolism study on potato and considering that residues were demonstrated to be below the LOQ, the reduced number of trials in both northern and southern Europe was considered sufficient by EFSA to propose appropriate MRL and risk assessment values.

- Tomato and aubergines: no residue trials are available in northern Europe, while tomato is a major crop in this area. Although appropriate MRL and risk assessment values can be derived

from the indoor data, 8 trials on tomatoes complying with the northern outdoor GAP on tomatoes are still required.

- Pepper: no residue trials are available for southern Europe and indoor uses, although it is a major crop in Europe. 8 southern and 8 indoor trials complying with the GAP are therefore required. Meanwhile, no MRL or risk assessment values can be derived.

- Melon and watermelon: only 7 residue trials are available in southern Europe, although they are major crops in this area. One additional trial on melon would be required according to the guidance document, but this additional trial is not expected to significantly impact on the outcome of the assessment. Therefore this additional southern trial on melon is only considered desirable (minor deficiency). For the indoor use, only 2 residues trials are available and 6 trials complying with the indoor GAPs are still required as these are major crops in Europe. Although MRL and risk assessment values can be derived from the southern Europe data, the indoor use is considered as the critical one in this review because residue levels higher than the proposed MRL may occur when benalaxyl is used according to the indoor GAP. Member States are therefore strongly recommended to reconsider any indoor GAP for these crops in order not to have exceedances of the proposed MRL.

- Lettuce: no residue trials are available for northern and indoor uses while it is a major crop in Europe. Although appropriate MRL and risk assessment values can be derived from the southern Europe data, 8 trials complying with the northern outdoor GAP and 8 trials complying with the indoor GAP are still required.

- Rapeseed: no residue trials are available in northern Europe, although it is a major crop in this area. 8 trials complying with the GAP are therefore still required. Meanwhile, no MRL or risk assessment values are derived

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review of benalaxyl, storage stability of benalaxyl was demonstrated for a period of 36 months at -20°C in commodities with high water (potato and tomato) and high acid (grapes) content (Portugal, 2000). According to the RMS, all residue trials samples reported in the PROFile were stored in compliance with the above reported storage conditions. Degradation of residues during storage of the trial samples is not expected. However, storage stability data could be needed for high oil commodities (rapeseed) depending on the trials required.

Consequently, the available residue data are considered acceptable to derive adequate MRL proposals as well as risk assessment values for all crops under assessment, except for pepper and rapeseed where the number of residue trials was too limited for deriving MRL proposals and risk assessment values (see also Table 3-2). In cases were 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.

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 (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))	**Risk assessment (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))**					
Table grapes	NEU	Outdoor	0.11; 0.19; 0.19; 0.26; 0.28; 0.28	0.11; 0.19; 0.19; 0.26; 0.28; 0.28	**0.23**	**0.28**	**0.6**	**1.00**	Trials compliant with the GAP. R_{ber} = 0.56 R_{max} = 0.47
	SEU	Outdoor	0.02; 0.03; 0.03; 0.04; 0.04; 0.04; 0.05; 0.05	0.02; 0.03; 0.03; 0.04; 0.04; 0.04; 0.05; 0.05	0.04	0.05	0.1	1.00	Trials compliant with the GAP. R_{ber} = 0.1 R_{max} = 0.07
Wine grapes	NEU	Outdoor	-	-	-	-	-	-	No trial compliant with the GAP; extrapolation from table grapes is not possible as GAPs are different.
	SEU	Outdoor	0.02; 0.03; 0.03; 0.04; 0.04; 0.04; 0.05; 0.05	0.02; 0.03; 0.03; 0.04; 0.04; 0.04; 0.05; 0.05	0.04	0.05	0.1	1.00	Extrapolation from the southern oudoor GAP on table grapes is possible.

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 (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))	Risk assessment (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))					
Potatoes	NEU	Outdoor	13 x <0.01; 2 x 0.01	13 x <0.01; 2 x 0.01	**0.01**	**0.01**	**0.02**	**1.00**	Trials compliant with the GAP. R_{ber} = 0.02 R_{max} = 0.01
	SEU	Outdoor	4 x <0.01	4 x <0.01	0.01	0.01	0.01*	1.00	Trials compliant with the GAP.
Onions Shallots	NEU	Outdoor	4 x <0.01	4 x <0.01	0.01	0.01	0.01*	1.00	4 trials on onions compliant with the GAP, extrapolation to shallots is possible (France, 2013).
	SEU	Outdoor	2 x <0.01	2 x <0.01	0.01	0.01	0.01*	1.00	2 trials compliant with the GAP; not authorised in shallot in SEU outdoor.

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 (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))	Risk assessment (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))					
Tomatoes Aubergines	NEU	Outdoor	-	-	-	-	-	-	No trial compliant with the GAP; not authorised on aubergines in NEU outdoor.
	SEU	Outdoor	3x<0.01; 0.01; 2x<0.02; 5x0.02; 0.03; 4x0.04; 2x0.05	3x<0.01; 0.01; 2x<0.02; 5x0.02; 0.03; 4x0.04; 2x0.05	0.02	0.05	0.08	1.00	Trials on tomatoes compliant with GAP; extrapolation to aubergines is possible (France, 2013). R_{ber} = 0.08 R_{max} = 0.06
	EU	Indoor	0.032; 0.083; 0.092; 0.11; 0.17; 0.18; 0.23; 0.24	0.032; 0.083; 0.092; 0.11; 0.17; 0.18; 0.23; 0.24	**0.14**	**0.24**	**0.5**	**1.00**	Trials on tomatoes compliant with GAP; extrapolation to aubergines is possible. R_{ber} = 0.44 R_{max} = 0.38
Peppers	SEU	Outdoor	-	-	-	-	-	-	No trial compliant with the GAP.
	EU	Indoor	-	-	-	-	-	-	No trial compliant with the 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 (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))	Risk assessment (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers))					
Melons Watermelons	SEU	Outdoor	0.01; 0.01; 0.02; 0.02; 0.025; 0.038; 0.056	00.01; 0.01; 0.02; 0.02; 0.025; 0.038; 0.056	0.02	0.06	0.1	1.00	Trials on melons compliant with the GAP. R_{ber} = 0.08 R_{max} = 0.08
	EU	Indoor	0.06; 0.154	0.06; 0.154	-	-	-	-	2 trials on melons compliant with the GAP.
Lettuce	NEU	Outdoor	-	-	-	-	-	-	No trial compliant with the GAP.
	SEU	Outdoor	0.039; 0.058; 0.059; 0.059; 0.064; 0.064; 0.089; 0.105; 0.119; 0.154; 0.328;0.425	0.039; 0.058; 0.059; 0.059; 0.064; 0.064; 0.089; 0.105; 0.119; 0.154; 0.328;0.425	0.08	0.43	0.5	1.00	Trials compliant with the GAP. R_{ber} = 0.29 R_{max} = 0.46
	EU	Indoor	-	-	-	-	-	-	No trial compliant with the GAP.
Rape seed	NEU	Outdoor	-	-	-	-	-	-	No trial compliant with the GAP.

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(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.
(*): 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 benalaxyl residues was not investigated in the framework of the peer review. As the chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. Studies investigating the magnitude of residues in processed commodities of grape and tomato were reported in the framework of the peer review of benalaxyl (Portugal, 2000). An overview of all available processing studies is available in Table 3-3. These processing factors are however considered as indicative only considering that nature of the residue after processing was not investigated.

Further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, 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
Risk assessment residue definition: benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)				
Indicative processing factors (no residue defined in processed commodities)				
Wine grapes, juice	4	0.09	1.00	The residue levels in wine were lower or equal to 0.01 mg/kg and in juice lower or equal to 0.02 mg/kg (Portugal, 2000).
Wine grapes, must	4	0.09	1.00	
Wine grapes, red wine (unheated)	4	0.01	1.00	
Wine grapes, red wine (heated)	4	0.01	1.00	
Wine grapes, white wine	4	0.01	1.00	
Tomatoes, sauce	1	0.40	1.00	The residues in juice and sauce are <0.01 mg/kg (Portugal, 2000)
Tomatoes, juice	1	0.40	1.00	

(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

All crops under consideration, except permanent crops (grapes), may be grown in rotation within the EU. During the peer review of benalaxyl under Directive 91/414/EEC, it was also demonstrated in several degradation studies that benalaxyl is persistent in soil and that DT_{90} values exceed the trigger value of 100 days (DT_{90f} ranges from 67 to 326 days) (Portugal, 2000). A detailed assessment of the nature and magnitude of benalaxyl residues is therefore considered relevant.

3.1.2.2. Nature and magnitude of residues

In the peer review of benalaxyl, the metabolism of benalaxyl in rotational crops was studied in tomato, lettuce, carrot, wheat and tobacco with ^{14}C-labelled benalaxyl (Portugal, 2000). The same studies were also reported by JMPR (FAO, 2009a). The radiolabelled active substance was applied on a bare soil once at an application rate of 2.25 kg a.s./ha and crops were sown or planted at around 30, 120 and 365 DAT. Studies are summarised in Table 3-4.

TRRs for all plant-back intervals ranged between 0.02 and 0.11 mg-eq/kg in mature lettuce, 0.01 and 0.10 mg-eq/kg in tomato, 0.02 to 0.06 mg-eq/kg in the root parts of carrot, up to 0.16 mg-eq/kg in wheat grain and up to 0.24 mg-eq/kg in wheat straw. No data on tobacco was reported, but results were claimed to be in accordance with the other crops (Portugal, 2000). Despite the fact that TRR level is significant in most of the samples, no further characterisation or identification was conducted. Consequently, it is not possible to conclude on the comparability of the metabolic patterns in rotational and primary crops. Nevertheless, considering the overdosing factor of the above studies (3.1 to 10 times the reported application rates) and the fact that benalaxyl was applied to a bare soil (interception of benalaxyl by the plants is expected in practice), it is expected that residues of benalaxyl resulting from soil uptake will not exceed 0.01 mg/kg. Therefore, specific residue definitions for rotational crops are not considered necessary and specific plant-back restrictions related to the use of benalaxyl are not required, provided that benalaxyl is applied in compliance with the GAPs evaluated in the framework of this review (see Appendix A).

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
Fruits and fruiting vegetable	tomato	n.r.	Bare soil, G	2.25	33 111 363	84-98	-
Leafy vegetables	lettuce	n.r.	Bare soil, G	2.25	31 117 360	15-20, and n.r.	-
Root and tuber vegetables	carrot	n.r.	Bare soil, G	2.25	32 110 370	70-80 and 112-115	-
Cereals	wheat	n.r.	Bare soil, G	2.25	30 120 295	272	-

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

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Benalaxyl is authorised for use on a crop that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups 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, 2009b) and are summarised in Table 3-5.

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: benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)				
Potatoes	0.01	Median residue	0.01	Highest residue

The results of the calculations are reported in Table 3-6. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM/d, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary. It should be highlighted however that underestimation of the livestock dietary burden cannot be excluded because the possible impact of the authorisation on rapeseed could not be estimated (no residue trials available). It is therefore recommended to withdraw this authorisation unless further information is provided.

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/d)	Trigger exceeded (Y/N)
Risk assessment residue definition: benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)					
Dairy ruminants	0.0007	0.0007	Potatoes	0.0202	No
Meat ruminants	0.0017	0.0017	Potatoes	0.0399	No
Poultry	0.0008	0.0008	Potatoes	0.0134	No
Pigs	0.0016	0.0016	Potatoes	0.0400	No

3.2.2. Nature and magnitude of residues

Although the dietary burden is not triggered, the nature of benalaxyl residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (Portugal, 2000). Reported metabolism studies include one study in lactating goats and one in laying hens using ^{14}C- benalaxyl. The basic characteristics of the metabolism studies are summarised in Table 3-7.

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

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg diet)	Duration (days)	Commodity	Time
Lactating ruminants	Goat	n.r.	2	36.1 - 41.8	7	Milk	At specific intervals
						Urine and faeces	At specific intervals
						Expired carbon dioxide	Over a 10-hour period
						Tissues	At slaughter
Laying poultry	Hens	n.r.	10	59.6	14	Eggs	At specific intervals
						Excreta	At specific intervals
						Tissues	At slaughter

n.r.: not reported

The metabolism study on goat showed that the main part of the radioactivity was excreted (87 % and 79 % for goat 1 and 2 respectively). At slaughter, tissues contained only 4.6 % of the AR. The TRR level was relatively low in milk (up to 0.011 mg/kg), fat (up to 0.03 mg/kg) and muscle (up to 0.02 mg/kg) when compared to the TRR levels in liver (up to 1.14 mg/kg) and kidney (up to 0.37 mg/kg). For liver, the extraction efficiency was poor (65%TRR extracted). After enzymatic hydrolysis, 55% of TRR remained unidentified, no parent compound was detected and the most abundant single compound was an hydroxymethyl derivative of benalaxyl[11] (6.2%TRR; 0.04 mg-eq/kg). For kidney, extraction was more efficient (ca. 100%) but 58 % TRR remained unidentified. Hydroxymethyl derivatives of benalaxyl[13] were the most abundant single identified compounds (21.3 and 14.9% TRR; 0.07 mg-eq/kg and 0.05 mg-eq/kg).

In the hen metabolism study, 81 % of the administrated dose was found in excreta. The TRR levels was relatively low in egg white (up to 0.05 mg/kg), fat (up to 0.04 mg/kg) and muscle (up to 0.05 mg/kg) when compared to the TRR levels in liver (up to 1.4 mg/kg), kidney (up to 0.72 mg/kg) and egg yolk (up to 0.30 mg/kg). Liver and egg yolk were extracted and analysed to identify metabolites. Hydroxy-carboxy-benalaxyl[12] was the most abundant compound in egg yolk (20.5%TRR; 0.06 mg/kg). No compound was identified in liver. In all samples, parent compound was found at low level or even not found at all.

The metabolism in hen being similar to the one in goat, which is itself similar to the one in rat, a general metabolic pathway can be proposed. Benalaxyl is oxidised, giving hydroxymethyl derivatives.

[11] methyl {[2-(hydroxymethyl)-6-methylphenyl](phenylacetyl)amino}acetate. See appendix E.
[12] 3-(hydroxymethyl)-2-[(1-methoxy-1-oxopropan-2-yl)(phenylacetyl)amino]benzoic acid. See Appendix E.

Those compounds can be further oxidised to form carboxy benalaxyl[13]. Conjugation can occur with all compounds.

As the calculated dietary burden was shown to be below the trigger value, there is currently no need to derive a residue definition or to establish MRLs for commodities of animal origin. Moreover, in the reported metabolism studies, a high level of TRR remains unidentified. Further clarifications on the identity/characteristics of the radioactive residue would therefore still be required if a further increase of the livestock dietary burden would be observed in the future. Consequently EFSA cannot conclude on the residue definition in animal commodities and further discussion of the residue definition at the European level will be strongly recommended if a significant dietary burden occurred in the future because of additional uses.

4. Consumer risk assessment

In the framework of this review, only the uses of benalaxyl reported by the RMS in Appendix A were considered. A first intake calculation was therefore performed including the uses of benalaxyl only.

However, residues of benalaxyl may also be generated by the use of benalaxyl-M, which is the purified R-enantiomer of benalaxyl. Considering that benalaxyl-M is currently under assessment at European level, and that no information supporting the review of MRLs for benalaxyl-M has been provided to EFSA so far, EFSA is not yet in a position to include the uses of benalaxyl-M in the current assessment. EFSA therefore assessed by means of a second calculation whether the existing EU MRLs for benalaxyl (including benalaxyl-M) might be of concern for European consumers. Noting that none of the MRLs derived in the framework of this review exceeds the existing EU MRLs for benalaxyl-M, except the one for table grapes, and assuming that current authorised uses of benalaxyl-M are also covered by the existing EU MRLs, this approach is expected to provide a tentative and conservative estimate of the combined exposure of European consumers to benalaxyl and benalaxyl-M residues, provided that the higher MRL proposal for table grapes is also included in the calculation.

As the use of benalaxyl was previously assess by JMPR (FAO, 2009a), the CXLs resulting from this assessment should in principle also be taken into account for the intake calculation. However, these CXLs were already implemented at EU level by means of Regulation (EU) No 520/2011[14]. Consequently, consumer exposure due to CXLs is already taken into account in the second intake calculation and no additional calculation is necessary.

4.1. Consumer risk assessment based on the uses of benalaxyl only

Chronic 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 summarised in Table 4-1. 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 GAP was reported in the framework of this review, were not included in

[13] 2-[(1-methoxy-1-oxopropan-2-yl)(phenylacetyl)amino]-3-methylbenzoic acid. See appendix E

[14] Commission Regulation (EU) No 520/2011 of 25 May 2011 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for benalaxyl, boscalid, buprofezin, carbofuran, carbosulfan, cypermethrin, fluopicolide, hexythiazox, indoxacarb, metaflumizone, methoxyfenozide, paraquat, prochloraz, spirodiclofen, prothioconazole and zoxamide in or on certain products, OJ L 140, 27.5.2011, p. 2–47.

the calculation. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Table 4-1: Input values for the consumer risk assessment

Commodity	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Risk assessment residue definition: benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)		
Table grapes	0.23	Median residue[(a)]
Wine grapes	0.04	Median residue[(a)]
Potatoes	0.01*	Median residue[(a)]
Onions	0.01*	Median residue[(a)]
Shallots	0.01*	Median residue[(a)]
Tomatoes	0.14	Median residue[(a)]
Peppers	0.20	EU MRL[(b)]
Aubergines (egg plants)	0.14	Median residue[(a)]
Melons	0.02	Median residue[(a)]
Watermelons	0.02	Median residue[(a)]
Lettuce	0.08	Median residue[(a)]
Rape seed	0.05	EU MRL[(b)]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment value derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not supported by data; the existing EU MRL is used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for benalaxyl (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 WHO cluster diet B, representing 2 % of the ADI.

Based on the above calculations, EFSA concludes that the use of benalaxyl on crops fully supported by data (footnote a 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 the existing EU MRLs in the exposure calculation did not indicate a risk to consumers.

4.2. Consumer risk assessment based on the existing EU MRL for benalaxyl

European MRLs are defined for benalaxyl and benalaxyl-M (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)). As both benalaxyl and benalaxyl-M can be used in Europe, a second intake calculation was performed considering the existing EU MRLs presented in Appendix C.1, and the authorised use on table grapes reported in the framework of this opinion which leads to a higher MRL than the one currently established in legislation. Chronic exposure calculations were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007).

The calculated exposures were compared with the toxicological reference values derived for benalaxyl and benalaxyl-M (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.2. The highest chronic exposure was calculated for WHO cluster diet B, representing 12.3 % of the ADI.

Based on the above calculations, EFSA concludes that the existing EU MRLs for benalaxyl (including benalaxyl-M) are not expected to be of concern for the European consumers. These MRLs may therefore be maintained pending the review of MRLs for benalaxyl-M.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of benalaxyl was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.04 mg/kg bw/d. An ARfD was not deemed necessary. The ADI was established for benalaxyl, but it was concluded that benalaxyl-M (the purified R-enantiomer of benalaxyl) has a similar pattern of toxicity, toxicokinetics and metabolism as benalaxyl and the same ADI was established for both active substances.

Metabolism of benalaxyl was investigated in three different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the residue definition could be extended to all plants. The relevant residue for enforcement and risk assessment in plants could be defined as benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers). A validated analytical method for enforcement of the proposed residue definition is also available, with an LOQ of 0.01 mg/kg in acidic, dry, high water and high oil content commodities.

Regarding the magnitude of residues, a sufficient number of supervised residues trials is available for most 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 pepper and rape seed. In these two crops, no residue trials were available and no MRL or risk assessment values could be derived.

As the chronic exposure to benalaxyl does not exceed 10 % of the ADI, investigations on processed products are in principle not necessary. A study on the magnitude of residues was performed in grapes and tomatoes but the processing factors derived can only be considered as indicative as the nature of residues in processed commodities was not investigated. 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 processing factors for enforcement purposes, additional processing studies might be required.

Occurrence of benalaxyl residues in rotational crops was already investigated during the peer review of benalaxyl. On the basis of the reported data and considering the GAPs of benalaxyl reported in the framework of this review, it is concluded that significant residues of benalaxyl are not expected in rotational crops.

Based on the uses reported by the RMS, no significant intakes were calculated for all groups of livestock. However, metabolism studies on goats and hens were performed. These studies show that even if the compound is highly excreted, the remaining radioactivity consists mainly of hydroxymethyl metabolites, rather than of parent compound.

Chronic consumer exposure resulting from the MRLs derived in the framework of this review was 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 2 % of the ADI (WHO cluster diet B). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

However, residues of benalaxyl may also be generated by the use of benalaxyl-M, which is the purified R-enantiomer of benalaxyl. Considering that benalaxyl-M is currently under assessment at European level, and that no information supporting the review of MRLs for benalaxyl-M has been provided to EFSA so far, EFSA is not yet in a position to include the uses of benalaxyl-M in the current assessment. EFSA therefore assessed by means of a second calculation whether the existing EU MRLs for benalaxyl (including benalaxyl-M) might be of concern for European consumers. Noting that none of the MRLs derived in the framework of this review exceeds the existing EU MRLs for benalaxyl-M, except the one for table grapes, and assuming that current authorised uses of benalaxyl-M are also covered by the existing EU MRLs, this approach is expected to provide a tentative and conservative estimate of the combined exposure of European consumers to benalaxyl and benalaxyl-M residues, provided that the higher MRL proposal for table grapes is also included in the calculation. Based on this calculation, the highest chronic exposure represented 12.3 % of the ADI (WHO cluster diet B).

As the use of benalaxyl was previously assess by JMPR (FAO, 2009a), the CXLs resulting from this assessment should in principle also be taken into account for the intake calculation. However, these CXLs were already implemented at EU level by means of Regulation (EU) No 520/2011[15]. Consequently, consumer exposure due to CXLs is already taken into account in the second intake calculation and no additional calculation is necessary.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. Considering that EFSA was not yet in a position to include the use of benalaxyl-M in the above assessment and that most of the uses of benalaxyl evaluated in the framework of this review do not seem to require the setting of MRLs higher than those currently listed in Annexes II and III of Regulation (EC) no 396/2005 EFSA recommends that the existing EU MRLs for benalaxyl (benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)), except for table grapes, are maintained until the review of MRLs for benalaxyl-M can be finalised. For table grapes, EFSA recommends to increase the existing EU MRL of 0.3 mg/kg to 0.6 mg/kg to cover the authorised use of benalaxyl on table grapes which is adequately supported by data and for which no risk to consumers was identified.

It is noted however that during the assessment of benalaxyl the following data gaps have been identified for other crops:

- 8 residue trials supporting the northern outdoor GAP on wine grapes;
- 8 residue trials supporting the northern outdoor GAP tomatoes;
- 8 residue trials supporting the southern outdoor GAP and 8 residue trials supporting the indoor GAP on peppers;
- 6 additional residue trials supporting the indoor GAP on melon and watermelon;
- 8 residue trials supporting the northern outdoor GAP and 8 residue trials supporting the indoor GAPs on lettuce;

[15] Regulation (EU) No 520/2011 of 25 May 2011, OJ L 140, 27.5.2011, p. 2–47.

- 8 residue trials supporting the northern outdoor GAP on rapeseed;
- Storage stability data on high oil content commodities.

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. Regardless of the data gaps identified, Member States are in any case strongly recommended to reconsider any indoor GAP on melons and watermelons in order not to have exceedances of the EU MRL.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact on the national authorisations. The following data are therefore considered desirable but not essential:

- 1 additional residue trial supporting the southern outdoor GAP on melon and watermelon.

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on benalaxyl prepared by the rapporteur Member State Portugal in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 10 October 2008. Last updated on 22 June 2011.

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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 waiting 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.					
Table grapes	*Vitis euvitis*	NEU	Outdoor	SI					Foliar treatment - spraying					10	14		0,20	kg a.i./ha	42	
Wine grapes	*Vitis euvitis*	NEU	Outdoor	FR					Foliar treatment - spraying				3	10	14		0,15	kg a.i./ha	28	
Potatoes	*Tuber form Solanum Spp*	NEU	Outdoor	IE			8,0	% (w/w)	Foliar treatment - spraying				3				0,20	kg a.i./ha	7	
Onions	*Allium cepa*	NEU	Outdoor	FR					Foliar treatment - spraying				3	7	10		0,20	kg a.i./ha	28	
Shallots	*Allium ascalonicum (Allium cepa var. aggregatum)*	NEU	Outdoor	FR					Foliar treatment - spraying				3	7	10		0,20	kg a.i./ha	28	
Tomatoes	*Lycopersicum esculentum*	NEU	Outdoor	HU					Foliar treatment - spraying				3	7	10		0,20	kg a.i./ha	14	
Lettuce	*Lactuca sativa*	NEU	Outdoor	FR					Foliar treatment - spraying				4				0,08	kg a.i./ha	21	PHI reported for spring; in winter and autumn a PHI of 28 days is applicable.
Rape seed	*Brassica napus*	NEU	Outdoor	UK					Foliar treatment - spraying				1				0,16	kg a.i./ha	30	

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 waiting 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.					
Table grapes	*Vitis euvitis*	SEU	Outdoor	ES	Plasmopara viticola	WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	30	
Wine grapes	*Vitis euvitis*	SEU	Outdoor	ES	Plasmopara viticola	WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	30	
Potatoes	*Tuber form Solanum Spp*	SEU	Outdoor	FR					Foliar treatment - spraying								0,20	kg a.i./ha	7	
Onions	*Allium cepa*	SEU	Outdoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	15	
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	FR					Foliar treatment - spraying				4				0,24	kg a.i./ha	14	
Peppers	*Capsicum annuum, var grossum and var. longum*	SEU	Outdoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	15	
Aubergines (egg plants)	*Solanum melongena*	SEU	Outdoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	15	
Melons	*Cucumis melo*	SEU	Outdoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				1			0,16	0,24	kg a.i./ha	7	
Watermelons	*Citrullus lanatus*	SEU	Outdoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				1			0,16	0,24	kg a.i./ha	7	
Lettuce	*Lactuca sativa*	SEU	Outdoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				1			0,16	0,24	kg a.i./ha	15	

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or waiting 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.					
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				3			0,16	0,24	kg a.i./ha	15	
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU/SEU	Indoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	15	
Aubergines (egg plants)	*Solanum melongena*	NEU/SEU	Indoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying							0,16	0,24	kg a.i./ha	15	
Melons	*Cucumis melo*	NEU/SEU	Indoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				1			0,16	0,24	kg a.i./ha	7	
Watermelons	*Citrullus lanatus*	NEU/SEU	Indoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				1			0,16	0,24	kg a.i./ha	7	
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	ES		WP	8,0	% (w/w)	Foliar treatment - spraying				1			0,16	0,24	kg a.i./ha	15	

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario 1 based including the uses of benalaxyl only

Appendix B.2 – EU scenario 2 including the existing EU MRL for benalaxyl and the new MRL proposal on table grapes

APPENDIX B.1 – EU SCENARIO 1 BASED INCLUDING THE USES OF BENALAXYL ONLY

Benalaxyl			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

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)
2,0	WHO Cluster diet B	1,1	Tomatoes	0,2	Peppers	0,2	Table grapes	0,1
1,3	DE child	0,7	Table grapes	0,3	Tomatoes	0,1	Peppers	0,1
1,0	PT General population	0,3	Tomatoes	0,2	Wine grapes	0,2	Table grapes	0,1
0,9	NL child	0,4	Table grapes	0,2	Tomatoes	0,1	Potatoes	0,2
0,8	WHO regional European diet	0,4	Tomatoes	0,1	Potatoes	0,1	Peppers	0,1
0,7	IT kids/toddler	0,5	Tomatoes	0,1	Table grapes	0,1	Lettuce	0,0
0,7	WHO cluster diet D	0,4	Tomatoes	0,1	Table grapes	0,1	Potatoes	0,1
0,7	FR all population	0,4	Wine grapes	0,2	Tomatoes	0,1	Table grapes	0,0
0,7	IE adult	0,1	Table grapes	0,1	Tomatoes	0,1	Wine grapes	0,1
0,7	WHO cluster diet E	0,2	Tomatoes	0,2	Wine grapes	0,1	Potatoes	0,1
0,7	IT adult	0,4	Tomatoes	0,1	Table grapes	0,1	Lettuce	0,0
0,6	PL general population	0,3	Tomatoes	0,2	Table grapes	0,1	Potatoes	0,1
0,6	WHO Cluster diet F	0,2	Tomatoes	0,1	Potatoes	0,1	Table grapes	0,1
0,6	ES adult	0,3	Tomatoes	0,1	Lettuce	0,1	Peppers	0,0
0,6	ES child	0,3	Tomatoes	0,1	Lettuce	0,1	Peppers	0,1
0,5	FR toddler	0,3	Tomatoes	0,1	Potatoes	0,1	Table grapes	0,1
0,5	DK child	0,2	Tomatoes	0,1	Peppers	0,1	Table grapes	0,1
0,5	SE general population 90th percentile	0,3	Tomatoes	0,1	Potatoes	0,1	Peppers	0,1
0,5	NL general	0,1	Tomatoes	0,1	Table grapes	0,1	Potatoes	0,1
0,5	UK vegetarian	0,2	Tomatoes	0,1	Wine grapes	0,0	Table grapes	0,0
0,5	UK Toddler	0,2	Tomatoes	0,1	Table grapes	0,1	Potatoes	0,1
0,4	DK adult	0,1	Tomatoes	0,1	Wine grapes	0,1	Peppers	0,0
0,4	UK Adult	0,2	Tomatoes	0,1	Wine grapes	0,0	Potatoes	0,0
0,3	LT adult	0,2	Tomatoes	0,1	Potatoes	0,0	Lettuce	0,1
0,3	FI adult	0,1	Tomatoes	0,0	Potatoes	0,0	Wine grapes	0,0
0,2	UK Infant	0,1	Tomatoes	0,1	Potatoes	0,0	Table grapes	0,1
0,2	FR infant	0,1	Potatoes	0,1	Tomatoes	0,0	Table grapes	0,1

Conclusion:

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

APPENDIX B.2 – EU SCENARIO 2 INCLUDING THE EXISTING EU MRL FOR BENALAXYL AND THE NEW MRL PROPOSAL ON TABLE GRAPES

Benalaxyl			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,04**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2004**	Year of evaluation:	**2004**

Chronic risk assessment - refined calculations

	TMDI (range) in % of ADI minimum - maximum
	2 12
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)
12,3	WHO Cluster diet B	3,9	Tomatoes	1,3	Wine grapes	1,1	Wheat	
9,8	NL child	3,7	Milk and milk products: Cattle	0,8	Apples	0,8	Tomatoes	
8,7	DE child	1,8	Milk and milk products: Cattle	1,5	Apples	1,2	Tomatoes	
7,1	IE adult	0,9	Wine grapes	0,6	Melons	0,5	Tomatoes	
6,8	ES child	1,6	Milk and milk products: Cattle	1,2	Tomatoes	1,0	Lettuce	
6,2	WHO regional European diet	1,4	Tomatoes	0,9	Lettuce	0,6	Milk and milk products: Cattle	
6,1	UK Toddler	2,9	Sugar beet (root)	0,7	Tomatoes	0,5	Wheat	
5,8	FR infant	3,2	Milk and milk products: Cattle	0,5	Potatoes	0,3	Carrots	
5,7	FR all population	3,0	Wine grapes	0,5	Tomatoes	0,4	Wheat	
5,7	WHO cluster diet E	1,2	Wine grapes	0,7	Tomatoes	0,5	Wheat	
5,5	PT General population	1,9	Wine grapes	1,1	Tomatoes	0,7	Potatoes	
5,4	WHO cluster diet D	1,3	Tomatoes	0,8	Wheat	0,6	Milk and milk products: Cattle	
5,3	SE general population 90th percentile	1,5	Milk and milk products: Cattle	1,0	Tomatoes	0,5	Potatoes	
5,3	WHO Cluster diet F	0,9	Tomatoes	0,8	Lettuce	0,5	Milk and milk products: Cattle	
5,2	ES adult	1,3	Lettuce	1,0	Tomatoes	0,6	Milk and milk products: Cattle	
4,5	FR toddler	1,0	Tomatoes	0,6	Potatoes	0,3	Apples	
4,4	IT kids/toddler	1,8	Tomatoes	0,8	Wheat	0,7	Lettuce	
4,4	NL general	0,8	Milk and milk products: Cattle	0,5	Tomatoes	0,5	Wine grapes	
4,2	DK child	0,7	Wheat	0,7	Tomatoes	0,6	Rye	
3,9	UK Infant	1,3	Sugar beet (root)	0,5	Tomatoes	0,4	Potatoes	
3,9	IT adult	1,5	Tomatoes	0,9	Lettuce	0,5	Wheat	
3,5	UK vegetarian	0,8	Tomatoes	0,6	Wine grapes	0,5	Sugar beet (root)	
3,1	UK Adult	0,8	Wine grapes	0,5	Tomatoes	0,5	Sugar beet (root)	
2,9	LT adult	0,8	Tomatoes	0,5	Milk and milk products: Cattle	0,4	Potatoes	
2,8	DK adult	1,0	Wine grapes	0,5	Tomatoes	0,3	Wheat	
2,6	PL general population	1,1	Tomatoes	0,4	Potatoes	0,3	Apples	
1,9	FI adult	0,5	Tomatoes	0,2	Wine grapes	0,2	Lettuce	

Conclusion:

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

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 12/07/2011)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0.05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.05*
110030	Lemons (Citron, lemon)	0.05*
110040	Limes	0.05*
110050	Mandarins (Clementine, tangerine and other hybrids)	0.05*
110990	Others	0.05*
120000	(ii) Tree nuts (shelled or unshelled)	0.05*
120010	Almonds	0.05*
120020	Brazil nuts	0.05*
120030	Cashew nuts	0.05*
120040	Chestnuts	0.05*
120050	Coconuts	0.05*
120060	Hazelnuts (Filbert)	0.05*
120070	Macadamia	0.05*
120080	Pecans	0.05*
120090	Pine nuts	0.05*
120100	Pistachios	0.05*
120110	Walnuts	0.05*
120990	Others	0.05*
130000	(iii) Pome fruit	0.05*
130010	Apples (Crab apple)	0.05*
130020	Pears (Oriental pear)	0.05*
130030	Quinces	0.05*
130040	Medlar	0.05*
130050	Loquat	0.05*
130990	Others	0.05*
140000	(iv) Stone fruit	0.05*
140010	Apricots	0.05*
140020	Cherries (sweet cherries, sour cherries)	0.05*
140030	Peaches (Nectarines and similar hybrids)	0.05*
140040	Plums (Damson, greengage, mirabelle)	0.05*
140990	Others	0.05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	0.3
151010	Table grapes	0.3
151020	Wine grapes	0.3
152000	(b) Strawberries	0.05*
153000	(c) Cane fruit	0.05*
153010	Blackberries	0.05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0.05*
153030	Raspberries (Wineberries)	0.05*
153990	Others	0.05*
154000	(d) Other small fruit & berries	0.05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0.05*
154020	Cranberries	0.05*
154030	Currants (red, black and white)	0.05*
154040	Gooseberries (Including hybrids with other ribes species)	0.05*
154050	Rose hips	0.05*
154060	Mulberries (arbutus berry)	0.05*
154070	Azarole (mediteranean medlar)	0.05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.05*
154990	Others	0.05*
160000	(vi) Miscellaneous fruit	0.05*
161000	(a) Edible peel	0.05*
161010	Dates	0.05*
161020	Figs	0.05*
161030	Table olives	0.05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.05*
161050	Carambola (Bilimbi)	0.05*
161060	Persimmon	0.05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.05*
161990	Others	0.05*
162000	(b) Inedible peel, small	0.05*
162010	Kiwi	0.05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.05*
162030	Passion fruit	0.05*
162040	Prickly pear (cactus fruit)	0.05*
162050	Star apple	0.05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.05*
162990	Others	0.05*
163000	(c) Inedible peel, large	0.05*
163010	Avocados	0.05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.05*
163030	Mangoes	0.05*
163040	Papaya	0.05*
163050	Pomegranate	0.05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.05*
163070	Guava	0.05*
163080	Pineapples	0.05*
163090	Bread fruit (Jackfruit)	0.05*
163100	Durian	0.05*
163110	Soursop (guanabana)	0.05*
163990	Others	0.05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0.05*
211000	(a) Potatoes	0.05*
212000	(b) Tropical root and tuber vegetables	0.05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.05*
212020	Sweet potatoes	0.05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.05*
212040	Arrowroot	0.05*
212990	Others	0.05*
213000	(c) Other root and tuber vegetables except sugar beet	0.05*
213010	Beetroot	0.05*
213020	Carrots	0.05*
213030	Celeriac	0.05*
213040	Horseradish	0.05*
213050	Jerusalem artichokes	0.05*
213060	Parsnips	0.05*
213070	Parsley root	0.05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.05*
213100	Swedes	0.05*
213110	Turnips	0.05*
213990	Others	0.05*
220000	(ii) Bulb vegetables	
220010	Garlic	0.05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)
220020	Onions (Silverskin onions)	0.2
220030	Shallots	0.05*
220040	Spring onions (Welsh onion and similar varieties)	0.05*
220990	Others	0.05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0.5
231020	Peppers (Chilli peppers)	0.2
231030	Aubergines (egg plants) (Pepino)	0.5
231040	Okra, lady's fingers	0.05*
231990	Others	0.05*
232000	(b) Cucurbits - edible peel	0.05*
232010	Cucumbers	0.05*
232020	Gherkins	0.05*
232030	Courgettes (Summer squash, marrow (patisson))	0.05*
232990	Others	0.05*
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0.3
233020	Pumpkins (Winter squash)	0.05*
233030	Watermelons	0.1
233990	Others	0.05*
234000	(d) Sweet corn	0.05*
239000	(e) Other fruiting vegetables	0.05*
240000	(iv) Brassica vegetables	0.05*
241000	(a) Flowering brassica	0.05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.05*
241020	Cauliflower	0.05*
241990	Others	0.05*
242000	(b) Head brassica	0.05*
242010	Brussels sprouts	0.05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.05*
242990	Others	0.05*
243000	(c) Leafy brassica	0.05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.05*
243020	Kale (Borecole (curly kale), collards)	0.05*
243990	Others	0.05*
244000	(d) Kohlrabi	0.05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	0.05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	1
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0.05*
251040	Cress	0.05*
251050	Land cress	0.05*
251060	Rocket, Rucola (Wild rocket)	0.05*
251070	Red mustard	0.05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0.05*
251990	Others	0.05*
252000	(b) Spinach & similar (leaves)	0.05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0.05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0.05*
252030	Beet leaves (chard) (Leaves of beetroot)	0.05*
252990	Others	0.05*
253000	(c) Vine leaves (grape leaves)	0.05*
254000	(d) Water cress	0.05*
255000	(e) Witloof	0.05*
256000	(f) Herbs	0.05*
256010	Chervil	0.05*
256020	Chives	0.05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0.05*
256040	Parsley	0.05*
256050	Sage (Winter savory, summer savory,)	0.05*
256060	Rosemary	0.05*
256070	Thyme (marjoram, oregano)	0.05*
256080	Basil (Balm leaves, mint, peppermint)	0.05*
256090	Bay leaves (laurel)	0.05*
256100	Tarragon (Hyssop)	0.05*
256990	Others	0.05*
260000	(vi) Legume vegetables (fresh)	0.05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.05*
260030	Peas (with pods) (Mangetout (sugar peas))	0.05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.05*
260050	Lentils	0.05*
260990	Others	0.05*
270000	(vii) Stem vegetables (fresh)	0.05*
270010	Asparagus	0.05*
270020	Cardoons	0.05*
270030	Celery	0.05*
270040	Fennel	0.05*
270050	Globe artichokes	0.05*
270060	Leek	0.05*
270070	Rhubarb	0.05*
270080	Bamboo shoots	0.05*
270090	Palm hearts	0.05*
270990	Others	0.05*
280000	(viii) Fungi	0.05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0.05*
280990	Others	0.05*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0.05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.05*
300020	Lentils	0.05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0.05*
300040	Lupins	0.05*
300990	Others	0.05*
400000	4. OILSEEDS AND OILFRUITS	0.05*
401000	(i) Oilseeds	0.05*
401010	Linseed	0.05*
401020	Peanuts	0.05*
401030	Poppy seed	0.05*
401040	Sesame seed	0.05*
401050	Sunflower seed	0.05*
401060	Rape seed (Bird rapeseed, turnip rape)	0.05*
401070	Soya bean	0.05*
401080	Mustard seed	0.05*
401090	Cotton seed	0.05*
401100	Pumpkin seeds	0.05*
401110	Safflower	0.05*
401120	Borage	0.05*
401130	Gold of pleasure	0.05*
401140	Hempseed	0.05*
401150	Castor bean	0.05*
401990	Others	0.05*
402000	(ii) Oilfruits	0.05*
402010	Olives for oil production	0.05*
402020	Palm nuts (palmoil kernels)	0.05*
402030	Palmfruit	0.05*
402040	Kapok	0.05*
402990	Others	0.05*
500000	5. CEREALS	0.05*
500010	Barley	0.05*
500020	Buckwheat	0.05*
500030	Maize	0.05*
500040	Millet (Foxtail millet, teff)	0.05*
500050	Oats	0.05*
500060	Rice	0.05*

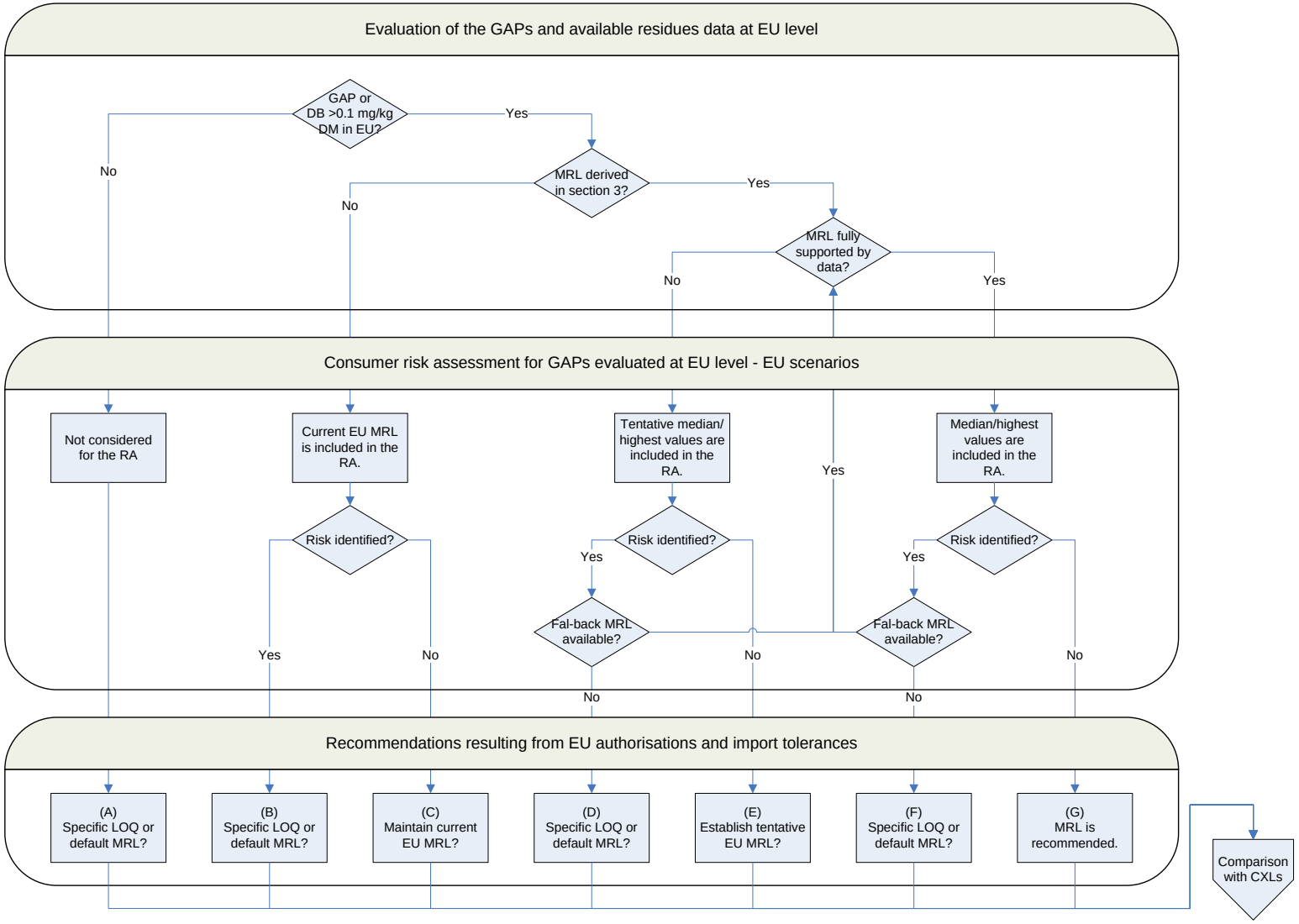
Code number	Groups and examples of individual products to which the MRLs apply (a)	Benalaxyl including other mixtures of constituent isomers including benalaxyl-M (sum of isomers)
500070	Rye	0.05*
500080	Sorghum	0.05*
500090	Wheat (Spelt Triticale)	0.05*
500990	Others	0.05*
600000	6. TEA, COFFEE, HERBAL 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	0.05*
900010	Sugar beet (root)	0.05*
900020	Sugar cane	0.05*
900030	Chicory roots	0.05*
900990	Others	0.05*
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	0.05*
	other processed products such as sausages and food preparations based on these	
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	0.05*
1020010	Cattle	0.05*
1020020	Sheep	0.05*
1020030	Goat	0.05*
1020040	Horse	0.05*
1020990	Others	0.05*
1030000	(iii) Birds' eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0.05*
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	

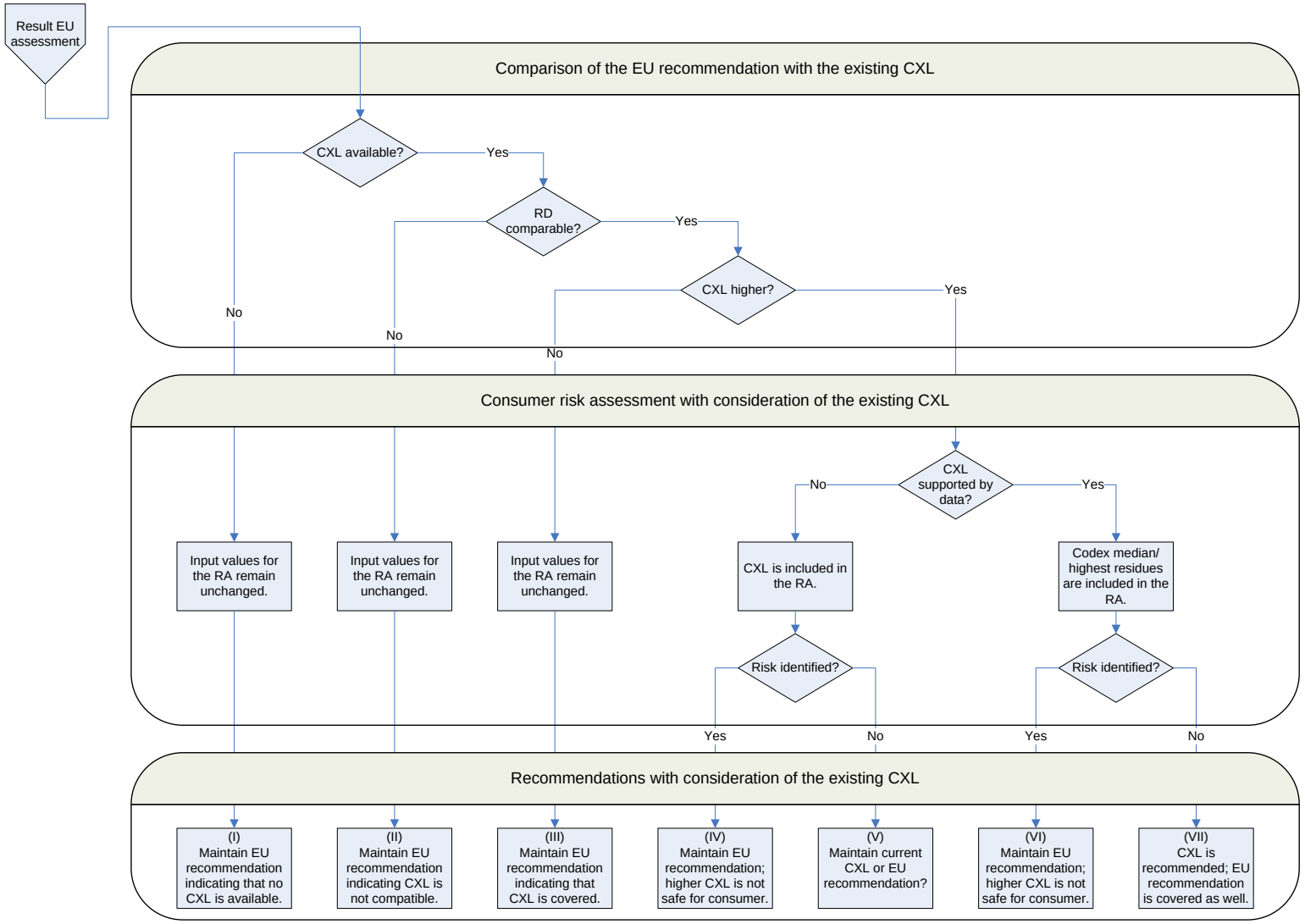
(*) Indicates lower limit of analytical determination

APPENDIX C.2 – EXISTING CXLS

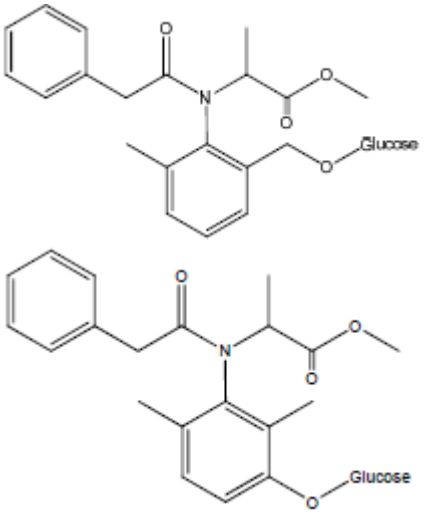
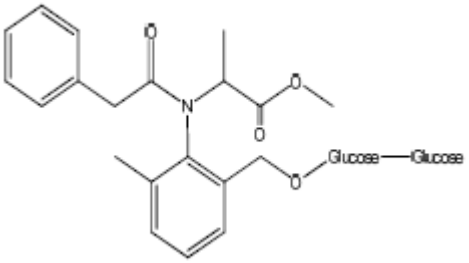
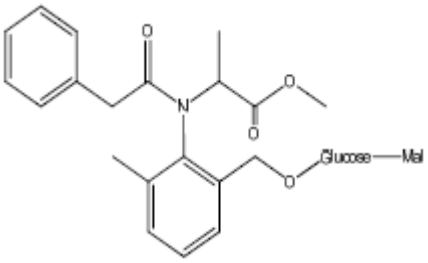
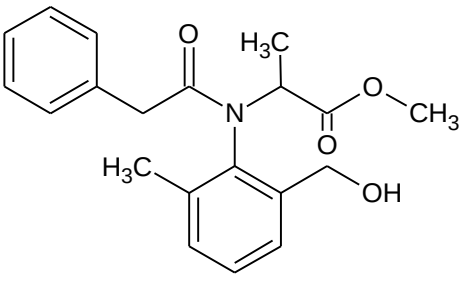
Summary of CXLs for benalaxyl in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	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
151010	Table grapes	Benalaxyl	0,3	Benalaxyl	0,12	0,17	3	n.c.	0,12	0,17	n.a.	1	2009	Yes	Trials were conducted in France and Italy according to the Italian GAP.
151020	Wine grapes	Benalaxyl	0,3	Benalaxyl	0,12	0,17	3	n.c.	0,12	0,17	n.a.	1	2009	Yes	
211000	Potatoes	Benalaxyl	0,02 *	Benalaxyl	0	0	n.k.	n.c.	0,02	0,02	n.a.	1	2009	Yes	Trials conducted in France and Italy had residues <0.02 mg/kg. This was supported by the metabolism data.
220020	Onions	Benalaxyl	0,02 *	Benalaxyl	0	0	n.k.	n.c.	0,02	0,02	n.a.	1	2009	Yes	All trials conducted in the EU according to GAP had residues <0.02 mg/kg when PHI was 0-30 days.
231010	Tomatoes	Benalaxyl	0,2	Benalaxyl	0,035	0,05	3	n.c.	0,04	0,05	n.a.	1	2009	Yes	All trials were conducted in the EU according to the French GAP.
233010	Melons	Benalaxyl	0,3	Benalaxyl	0,02	0,05	3	n.c.	0,05	0,15	0,9	1	2009	Yes	Trials were conducted in Italy and Spain according to Spanish GAP.
233030	Watermelons	Benalaxyl	0,1	Benalaxyl	0,02	0,02	3	n.c.	0,02	0,03	1	1	2009	Yes	Trials were conducted in Italy and Spain according to Spanish GAP.
251020	Lettuce	Benalaxyl	1	Benalaxyl	0,07	0,43	3	n.c.	0,07	0,43	n.a.	1	2009	Yes	Trials were conducted in Italy and Spain according to GAP.

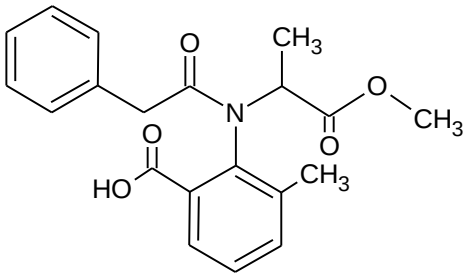
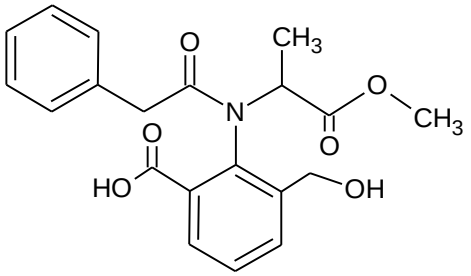
APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




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
Gluco-benalaxyl	n.r.	
Digluco-benalaxyl	n.r.	
Malo-gluco-benalaxyl	n.r.	
Hydroxymethyl benalaxyl	methyl {[2-(hydroxymethyl)-6-methylphenyl](phenylacetyl)amino}acetate	

Common name	IUPAC name	Structural formula
Carboxy metabolite	2-[(1-methoxy-1-oxopropan-2-yl)(phenylacetyl)amino]-3-methylbenzoic acid	
Hydroxy-carboxy-benalaxyl	3-(hydroxymethyl)-2-[(1-methoxy-1-oxopropan-2-yl)(phenylacetyl)amino]benzoic acid	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
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)
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	gas chromatography
GC-MS	gas chromatography with mass spectrometry detection
GC-NPD	gas chromatography with nitrogen/phosphorous detection
ha	hectare
hL	hectolitre

HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
ILV	independent laboratory validation
ISO	International Organisation for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
PF	processing factor
PHI	pre-harvest interval
PROFile	(EFSA) Pesticide Residue Overview File
PRIMo	(EFSA) Pesticide Residues Intake Model
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
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation