5. EVALUATION OF DATA FOR ACCEPTABLE DAILY INTAKE AND ACUTE DIETARY INTAKE FOR HUMANS, MAXIMUM RESIDUE LEVELS AND SUPERVISED TRIAL MEDIAN RESIDUE VALUES

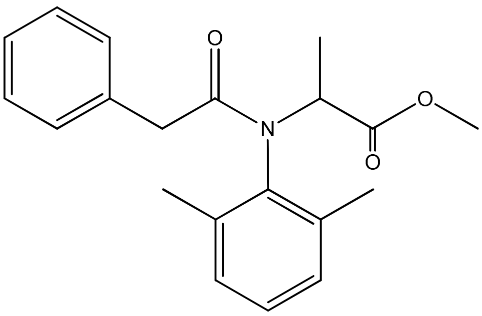
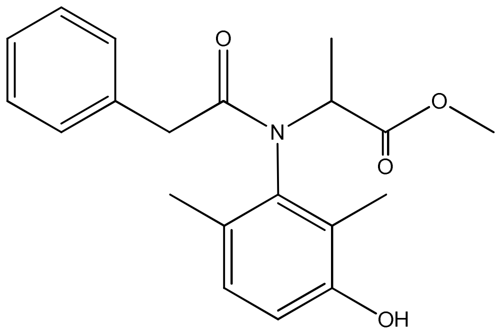
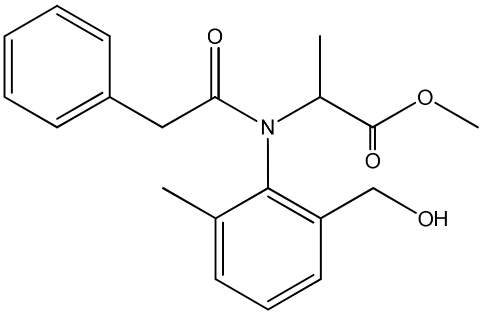
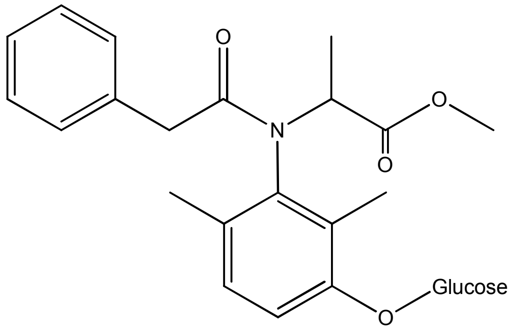
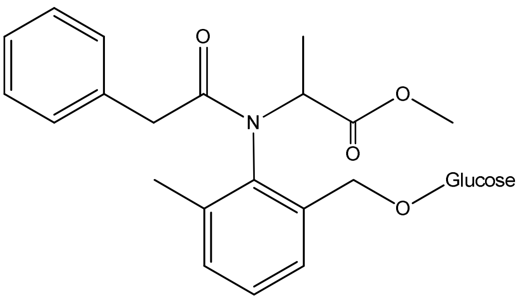
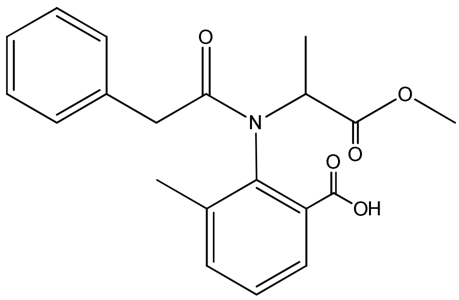
5.1 BENALAXYL (155)

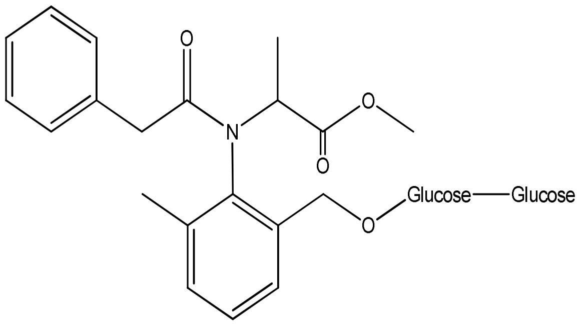
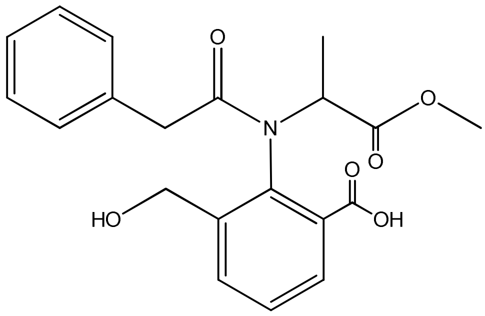
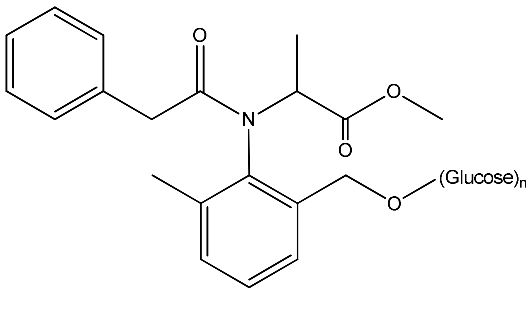
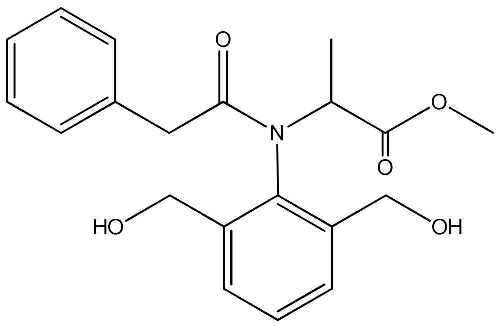
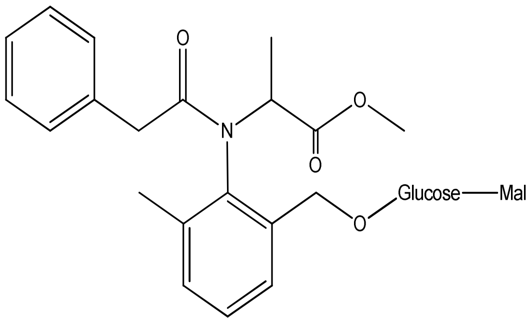
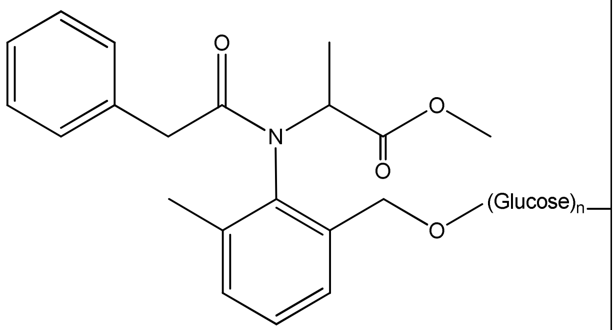
RESIDUE AND ANALYTICAL ASPECTS

Benalaxyl [methyl N-phenylacetyl-N-2,6-xylyl-DL-alaninate] is a broad-spectrum phenylamide fungicide. Residue and analytical aspects of benalaxyl were evaluated by the JMPR in 1986, 1988, 1992, and 1993. It was evaluated for toxicological review by JMPR 2005. The ADI for benalaxyl was established at 0-0.07 mg/kg bw and an ARfD of 0.1 mg/kg bw was established for women of childbearing age. This compound was listed in the Periodic Re-Evaluation Program at the Fortieth Session of the CCPR for periodic review by the 2009 JMPR.

Residue studies were submitted by the manufacturer to support the use of benalaxyl in or on a variety of fruits and vegetables.

Chemical codes and structures of Benalaxyl and its plant and animal metabolites:

 Benalaxyl [Galben]	 GX5c (Plants)
 GX5a and GX5b (Plants), G8 and G14 (Animals)	 GX1c (Plants)
 GX1a and GX1b (Plants)	 G7a and G7b (Animals)

 GX6 (Plants)	 G6 (Animals)
 GX4 (Plants)	 M4 (Plants and Animals)
 GX11 (Plants)	 GX16 (Plants)

Animal metabolism

The Meeting reviewed studies on the metabolism of ^{14}C-labelled benalaxyl in goats and hens. Two lactating goats received two daily oral administrations of benalaxyl at the equivalent of 40 ppm in the feed for seven consecutive days. The urine and faeces' contained about 80–90% of the administered dose of radioactivity. The maximum levels of radioactive residue in milk and tissues were as follows: milk, 0.011 mg/kg; muscle, 0.017 mg/kg; fat, 0.027 mg/kg; liver 1.1 mg/kg; and kidney 0.37 mg/kg. Minor amounts of benalaxyl (< 2% TRR) were identified in kidney or liver samples. The major metabolites identified in tissues were glucuronide and/or sulphate conjugates of the hydroxylated metabolites G8 and G14. However, poor extractability and analysis difficulties hampered metabolite identification, particularly in liver samples, resulting in 20–30% TRR being unidentified but characterized as polar species.

Ten laying hens were dosed once daily for fourteen days with capsules containing ^{14}C-labelled benalaxyl at a dose of approximately 60 mg/kg diet/day. The TRR levels were as follows: eggs, 0.35 mg/kg, fat, 0.04 mg/kg; kidney, 0.72 mg/kg; liver, 1.4 mg/kg; and muscle, 0.05 mg/kg. The residue profile was qualitatively similar to that of the goat. Benalaxyl was not found in any of the hen tissues except blood (9%). The major metabolite identified was the hydroxymethylcarboxy metabolite G6 at 21% TRR in egg yolk. As with the goat metabolism study, large portions of the TRR were characterized as a sum of polar metabolites each comprising less than 10% TRR, with 10–15% TRR unidentified.

The 2005 JMPR Toxicological Evaluation provides a description of the metabolic profile of benalaxyl in rats that is qualitatively similar to that discussed above for goats and hens.

Based on the results of the goat and hen metabolism studies, a metabolic profile for benalaxyl was proposed. Benalaxyl is oxidised giving the G8 and G14 hydroxymethyl derivatives. The G8 and G14 compounds are further oxidised to form the G7A and G7B carboxy derivatives. The G6 hydroxymethylcarboxy metabolite is a further oxidation product. Conjugation appears to occur with all the compounds. Enzymatic hydrolysis increased the levels of extractable ^{14}C-residue in the tissues and egg yolk. Thus, it is likely that oxidation followed by conjugation is the main route of benalaxyl metabolism in animals.

Plant metabolism

The studies on plant metabolism show that [^{14}C]benalaxyl penetrates into grape, tomato, and potato plants. In grapes, more than 75% of radioactivity applied was found in the fruit 8 days after application while in tomato 40% of radioactivity was inside the fruit 28 days after treatment. Benalaxyl sprayed on potato plant leaves or present in soil, due to dripping after spraying, doesn't transfer to tuber since no significant radioactivity was found in tubers (< 0.005 mg/kg).

The rate of degradation depends on the plant species. In grapes, more than 50% of existing radioactivity corresponds to the active ingredient itself, 24 days after application; in tomato fruit, more than 15% was found as benalaxyl 35 days after treatment; in potato leaves, the parent compound percentage was more than 25%, 10 days after treatment.

The metabolites identified in grapes are GX1, GX5a, GX5b, GX5c and GX6; only GX1 and GX6 were present in significant levels (25% and 10%, respectively). In wine, besides some of those metabolites, minor levels of metabolites GX4, GX7 and GX8 were found. In tomato, several metabolites were found in low concentrations, except for GX11 which is significant (> 10% TRR).

The most important component of residue is the parent compound. However, metabolites GX1 and GX6 in grapes, and GX11 in tomatoes comprise more than 10% TRR. These metabolites result from oxidation and linkage of the parent compound to one (GX1) or more (GX6) molecules of glucose or (GX11) molecules of glucose plus malonic acid. Although these glucoside metabolites were not identified in the rat metabolism study, these plant metabolites are more polar and likely less toxic than the parent compound.

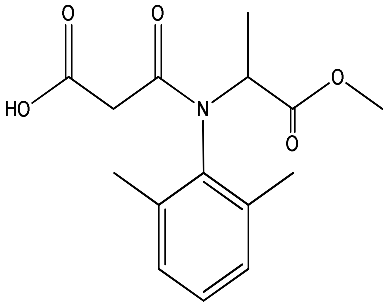
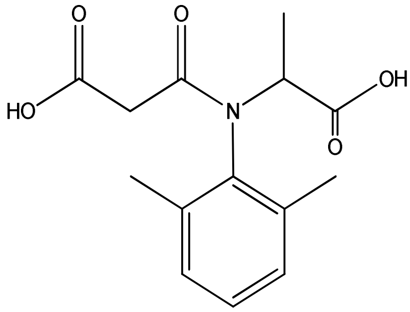
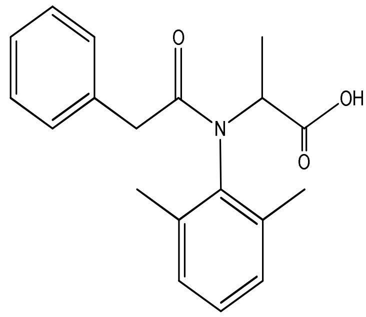
Environmental fate

Soil

The metabolism of [^{14}C-α position of the ester moiety] benalaxyl in aerobic conditions was investigated in previously sieved silt loam soil. Benalaxyl degraded very slowly in the first 28 days after treatment suggesting a lag phase followed by a steady degradation until the end of the incubation period (133 days after treatment). By this time the radioactivity associated with benalaxyl represented only 11.7% AR.

The DT_{50} of benalaxyl taking into account the lag period was estimated to be 77 days. Excluding the initial lag phase of 28 days acclimation/adaptation period during which very little benalaxyl degradation occurred, a shorter DT_{50} of approximately 42 days was estimated.

Chemical Codes and Structures of Benalaxyl Soil Metabolites:

		
Compound A: methyl-N-(2,6-xylyl)-N-malonyl alaninate	Compound B: N-(2,6-xylyl)-N-malonyl alanine	Benalaxyl acid: N-(2,6-xylyl)-N-(phenylacetyl) alanine

Two main degradation products were identified in soil extracts.

Compound A, identified as methyl-N-(2,6-xylyl)-N-malonyl alaninate and Compound B, identified as N-(2,6-xylyl)-N-malonyl alanine with maximum soil concentrations after treatment at 133 days (31% AR) and 98 days (34.1% AR), respectively.

Benalaxyl acid, identified as phenylacetyl-N-2,6-xylyl-DL-alanine was found with maximum soil concentration at 28 days (4.9% AR). In the first period (1–28 day) this is the only metabolite present in soil then from 56 to 133 day the other two metabolites (compound A and compound B) are detectable.

The results of a study of benalaxyl degradation rates in four different soil types (loam/sandy loam, loam, clay loam, and sandy loam) under identical incubation conditions demonstrated DT_{50} values ranging from 77–100 days. The same experiment with one-tenth the initial concentration of benalaxyl gave DT_{50} values of 36–85 days. These results demonstrate that benalaxyl is stable in most soils and show the range of half-life variability in four different soil types.

The degradation rate of benalaxyl in soil essentially depends on the presence of micro-organisms. The concentration and activity of these agents can vary significantly in different soils and account for the range of half-lives determined in the study cited above. The DT_{50} value in sterilized soil was reported as greater than 300 days. Evidence of microbial adaptation was also reported in this study.

Photolysis

Labelled [^{14}C]benalaxyl (≥ 98% radiochemical purity; 100 KBq/mg specific activity) was irradiated under natural sunlight conditions in a distilled sterilized buffer solution at pH 7 and test concentration of 10 mg ai/L for up to 64 days. After 64 days, 60% AR was still present as benalaxyl. At least 15 different compounds were recorded but none of them represented individually more than 5.0% of the applied radioactivity and therefore were not identified. No degradation of benalaxyl was observed under dark conditions. The study was conducted during June–August, 1984 in Milan, Italy.

In a separate experiment, the degree of photolytic degradation and the quantum yield of benalaxyl were determined by irradiation with xenon light at 306 + 12 nm at 20 °C. The absorption coefficients of benalaxyl in the relevant wavelength range around 300 nm were very low (approximately 5–10 mol/L^{-1} cm^{-1}). Just 2% benalaxyl degradation was found after 5 days and 3% degradation after 10 days. Degradation products could not be detected. The quantum yields of the photodegradation as estimated from the 5 days and 10 days irradiations were both 0.01. Thus, benalaxyl may be considered a photolytically stable compound.

Rotational Crops

Rotational crop studies using radiolabelled benalaxyl are available showing very low levels of residues in the following crops (lettuce, tomato, carrot, and wheat) even after application at highly exaggerated rates (approximately 10×). Based on the behaviour of benalaxyl in soil and the findings in the radio-labelled studies, it is unlikely that residues above the limit of quantitation would occur in succeeding crops.

Methods of analysis

The Meeting received description and validation data for a single-residue analytical method for benalaxyl in samples of plant and animal origin. The method is based on extraction with acetone, followed by liquid-liquid extraction using water and dichloromethane and an additional clean-up on an alumina column. The determination of benalaxyl residues is performed using GC-NPD. The method was validated for grapes, lettuce, bovine milk, bovine meat and poultry eggs with a LOQ of 0.02 mg/kg. The recoveries for plant and animal matrices were in the range of 81–102% and 73–110%, respectively, with RSDs < 10%. The method was used in the supervised trials on plant commodities evaluated by this Meeting (grapes, onions, melons, tomatoes, lettuce, and potatoes) with concurrent recoveries within the range of 80–120% and RSD < 10%.

The Meeting noted that there are several multiresidue methods available (e.g., the German DFG S19 or the QuEChERS methods) that are used in routine monitoring laboratories for the analysis of benalaxyl residues (using GC-MS or GC-NPD for determination).

Adequate multi- and single-residue methods exist for both gathering data in supervised trials and other studies and for monitoring and enforcing benalaxyl MRLs in samples of plant and animal origin.

Stability of pesticide residues in stored analytical samples

The Meeting received information on the stability of benalaxyl in freezer-stored samples of grapes, grape must and pomace, potatoes and tomatoes. The samples were fortified at different concentration levels and stored at –20° C for up to 3 years. The concurrent recoveries were in the range of 98–100%, with RSDs of 4.0–6.4%. The residues remaining after 3 years of storage were in the range of 95–106%, demonstrating very good freezer-storage stability of benalaxyl residues in the tested commodities during the period of 3 years, which well covers the storage intervals in the supervised trials evaluated by this Meeting.

Stability of benalaxyl residues in frozen livestock commodity samples was not demonstrated, but only livestock metabolism studies were conducted.

Definition of the residue

The plant metabolism studies indicate that significant portions of benalaxyl are oxidized and then converted to the corresponding glucoside in plant matrices. However, due to the low absolute levels of metabolites expected in crops at the label use rates and presumed lower toxicity of the polar conjugates formed, the Meeting concluded that the residue definition for plant commodities for purposes of enforcement is benalaxyl. The Meeting also concluded that for purposes of dietary intake considerations, the residue definition is also benalaxyl alone.

The ruminant and poultry metabolism studies showed an initial oxidation step as observed in plants. However, animal metabolism proceeds with further oxidation reactions to form carboxylic acids rather than the glucosides generated in plants. Noting the low levels of benalaxyl residues expected in animal tissues, the Meeting concluded that the residue definition for animal commodities for purposes of enforcement and dietary intake considerations is benalaxyl.

The octanol-water partition coefficient of benalaxyl (log K_{OW} = 3.5) implied that benalaxyl may be fat-soluble. However, the results of the goat metabolism study were inconclusive about the fat solubility issue since such low levels of benalaxyl were found. The Meeting agreed that insufficient information was available to reach a conclusion regarding the fat solubility of benalaxyl.

Results of supervised trials on crops

The NAFTA calculator was used as a tool in the estimation of the maximum residue level from the selected residue data set obtained from trials conducted according to GAP. As a first step, the Meeting reviewed all relevant factors related to each data set in arriving at a best estimate of the maximum residue level using expert judgement. Then, the NAFTA calculator was employed. If the statistical calculation spreadsheet suggested a different value from that recommended by the JMPR, a brief explanation of the deviation was supplied. Some common factors that may lead to rejection of the statistical estimate include when the number of data points is < 15 or when there are a large number of values < LOQ.

Grape

The Meeting received results from supervised trials with benalaxyl used on grapes in France, Italy, and Brazil.

The GAP in Italy specifies 0.20 kg ai/ha, four applications, and a 20 day PHI. There were four trials in Italy at the GAP with a PHI of 20–21 days and five trials in France conducted at the Italian GAP rate with four applications and a PHI of 15 days. Based on the decline results obtained in the same French trials, the benalaxyl residues at the GAP PHI of 20 days are expected to be within ± 25% of the residues obtained at a PHI of 15 days. The benalaxyl residues from trials in Italy and France, ranked order, were (n=9): 0.055, 0.092, 0.10, 0.11, 0.12, 0.14, 0.15, and 0.17 (2) mg/kg.

The GAP in Brazil specifies 0.24 kg ai/ha, four applications, and a 7 day PHI. Two trials in Brazil were conducted at the GAP. There were also two additional trials at a double rate. Benalaxyl residues were < 0.1 mg/kg in all four trials.

Based on the trials in France and Italy, the Meeting estimated a maximum residue level for benalaxyl in grapes of 0.3 mg/kg to replace the previous recommendation of 0.2 mg/kg, an STMR of 0.12 mg/kg, and an HR of 0.17 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.30 mg/kg, which was in agreement with the Meeting’s estimation.

Onion, bulb

The Meeting received results from supervised trials with benalaxyl used on onions in Brazil, France, Italy, Greece, and Spain.

The GAP in Brazil for onions specifies 0.24 kg ai/ha, four applications, and a 7 day PHI. Three trials in Brazil were conducted at the GAP. There were also three additional trials conducted at a double rate. Benalaxyl residues were < 0.1 mg/kg in all six trials.

In Europe, the GAP of Cyprus, Spain, Italy, and France specify 0.20 kg ai/ha, 3 applications, and a PHI of 14, 15, 20 and 28 days, respectively. Ten trials in Greece, France and Italy were conducted at the GAP rate of Cyprus with a PHI of 14 days. Benalaxyl residues were < 0.02 (10) mg/kg. The Meeting noted that the residues were < LOQ of 0.02 mg/kg at PHIs from 0 to 30 days, concluding that benalaxyl residues are unlikely to occur in onions.

The Meeting estimated a maximum residue level for benalaxyl in onion, bulb of 0.02(*) mg/kg to replace the previous recommendation of 0.2 mg/kg, an STMR of 0 mg/kg and an HR of 0 mg/kg.

Cucumber

No residue data were available for cucumber. The Meeting withdrew the previous benalaxyl maximum residue level recommendation of 0.05 mg/kg for cucumber.

Melons, except watermelon

The Meeting received results from supervised trials with benalaxyl used on melons in Italy and Spain. The GAP of Spain for melon specifies 0.20 kg ai/ha, 3 applications, and a 7-day PHI.

Benalaxyl residues in whole fruit, in ranked order, were (n=9): 0.02 (2), 0.03, 0.04, 0.05, 0.06 (2), 0.08, and 0.15 mg/kg. For melon pulp (n=7), the ranked order of residues was: < 0.02 (4), 0.02, and 0.05 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for melons, except watermelon to replace the previous recommendation of 0.1 mg/kg, an STMR of 0.02 mg/kg and an HR of 0.05 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.25 mg/kg, which when rounded up, was in agreement with the Meeting's estimation.

Watermelon

The Meeting received results from supervised trials with benalaxyl used on watermelon in Italy and Spain. The GAP of Spain for watermelon specifies 0.20 kg ai/ha, 3 applications, and a 7 day PHI.

Benalaxyl residues in whole fruit, in ranked order, were (n=5): < 0.02 (4) and 0.03 mg/kg. In two trials from Spain, benalaxyl residues in watermelon pulp were < 0.02 (2) mg/kg.

The Meeting estimated a maximum residue level of 0.1 mg/kg for watermelon, an STMR of 0.02 mg/kg and an HR of 0.02 mg/kg.

Peppers

No residue data were available for peppers. The Meeting withdrew the previous benalaxyl maximum residue level recommendations of 0.05 mg/kg for peppers, sweet and 0.5 mg/kg for chilli peppers, dry.

Tomato

The Meeting received results from supervised trials with benalaxyl used on tomato in Brazil, France, Italy and Spain. The GAPs of Spain, Italy and France for tomato specify 0.24 kg ai/ha, 4 applications, and a PHI 3, 7, and 14 days.

Four trials in Italy were conducted according to the GAP of Spain with a PHI of 3 days. Benalaxyl residues, in ranked order, were (n=4): 0.10, 0.11, and 0.14 (2) mg/kg. The Meeting agreed that four tomato trials were insufficient for a maximum residue level estimate.

Eight trials in France, Italy and Spain were conducted according to the GAP of France with a PHI of 14 days. Benalaxyl residues, in ranked order, were (n=8): < 0.02 (2), 0.02, 0.03, 0.04 (2), and 0.05 (2) mg/kg.

The GAP of Brazil for tomato specifies 0.24 kg ai/ha, 4 applications, and a 7-day PHI. Five trials in Brazil were conducted at the GAP. There were also four additional trials conducted at a double rate. Benalaxyl residues were < 0.1 mg/kg in all nine trials.

Based on the trials in France, Italy, and Spain according to the French GAP, the Meeting estimated a maximum residue level of 0.2 mg/kg for tomato to replace the previous recommendation of 0.5 mg/kg, an STMR of 0.035 mg/kg and an HR of 0.05 mg/kg.

The maximum residue level estimate derived from use of the NAFTA statistical calculator was 0.15 mg/kg (making use of Maximum Likelihood Estimate [MLE] procedures to fit data points below the LOQ to a lognormal distribution), which when rounded up was in agreement with the Meeting's estimation.

Lettuce, Head

The Meeting received results from supervised trials with benalaxyl used on head lettuce in Italy and Spain. The GAP of Italy and Spain specify 0.20 kg ai/ha, 3 applications, and a PHI 15 days.

The trials in Spain (n=8) were conducted with 2 applications but, based on the data from Italian trials, the benalaxyl residues determined prior to the last application were insignificant in comparison with the residues determined on day 0 of the last application. Therefore, the Meeting considered the Spanish trials together with the trials in Italy (n=7), which were conducted at the GAP of Italy with 3 applications.

The benalaxyl residues in head lettuce, in ranked order, were (n=15): < 0.02 (4), 0.06 (3), 0.07, 0.08, 0.09, 0.11, 0.12, 0.15, 0.33, and 0.43 mg/kg.

The Meeting estimated a maximum residue level for benalaxyl in lettuce, head of 1 mg/kg, an STMR of 0.07 mg/kg, and an HR of 0.43 mg/kg.

The maximum residue level estimate derived from the use of the NAFTA statistical calculator was 1.0 mg/kg (making use of MLE procedures), which was in agreement with the Meeting's estimation.

Potato

The Meeting received results from supervised trials with benalaxyl used on potato in Brazil, France, and Italy.

The GAP of Brazil for potato specifies 0.24 kg ai/ha, 2 applications, and a 7 day PHI. Five trials in Brazil were conducted at the GAP. There were also five additional trials conducted at a double rate. Benalaxyl residues were < 0.1 mg/kg in all 10 trials.

The GAPs of France and Italy for potato specify 0.24 kg ai/ha, 4 applications, and a 7-day PHI. Six trials in France and Italy were conducted at the GAP rate, with benalaxyl residues being < 0.02 (6) mg/kg.

Based on the results of the potato metabolism study, which showed no transfer of radioactivity to the tubers, the Meeting agreed that no benalaxyl residues are expected in potatoes.

The Meeting estimated a maximum residue level for benalaxyl in potato of 0.02(*) mg/kg to confirm its previous recommendation, an STMR of 0 mg/kg and an HR of 0 mg/kg.

Hops, dry

No residue data were available for dry hops. The Meeting withdrew the previous benalaxyl maximum residue level recommendation of 0.2 mg/kg for hops, dry.

Fate of residues during processing

The Meeting received processing studies for grape and tomato. The residue definition recommended for plant commodities will suffice for processed plant commodities (parent only).

The processing (or transfer) factors derived from the processing studies and the resulting recommendations for STMR-P values are summarized in the table below. The factors are the ratio of the total residue in the processed commodity divided by the total residue in the raw agricultural commodity (RAC).

Processing (Transfer) Factors from the Processing of Raw Agricultural Commodities (RACs) with Field-Incurred Residues from Foliar Treatment with Benalaxyl.

RAC	RAC STMR	Processed Commodity	Processing Factor[a]	Processed Commodity STMR-P
Grapes	0.12	Juice	0.11, 0.18, 0.15, 0.16 Median: 0.155	0.019
		Wet Pomace	3.3, 3.8 Mean: 3.5	0.42
		Bottled Wine	0.22, 0.36, 0.15, 0.16, Median:0.19	0.03
Tomato	0.035	Juice	0.22, 0.22 Mean: 0.22	0.0077
		Puree	0.21, 0.48 Mean: 0.344	0.012
		Preserve	0.10, 0.22 Mean: 0.16	0.0056

[a] Each value represents a separate study. The processing factor is the ratio of the total residue in the processed item divided by the total residue in the RAC.

Based on the STMR-P value of 0.42 mg/kg and dry-weight content of 15% for grape pomace, wet, the Meeting estimated an STMR-P value of 2.8 mg/kg and a maximum residue level of 3 mg/kg for benalaxyl in grape pomace, dry.

Estimated maximum and mean dietary burdens of farm animals

Dietary burden calculations for beef cattle and dairy cattle are provided below. The calculations were made according to the animal diets from Canada-USA, EU, and Australia in the Table of OECD Feedstuffs Derived from Field Crop (Annex 6 of the 2006 JMPR Report).

Grape pomace, dry is the only potential cattle feed item.

Animal dietary burden, benalaxyl residue, ppm of dry matter diet				
		US-Canada	EU	Australia
Beef/Dairy cattle	Max	0	0	0.56
	Mean	0	0	0.56

Animal commodity maximum residue levels

A bovine feeding study was not provided. However, there are no cattle feed items resulting from the RACs for which the 2009 Meeting made maximum residue level recommendations, except for wet grape pomace, which is a feed item only for Australia. Moreover, as indicated in the *FAO Manual* [Second Edition] (Section 3.9), a bovine feeding study is not necessary when a ruminant metabolism study with dosing at the equivalent of 10×, where 1× is the anticipated dietary burden, results in levels of the residue of concern below the limit of quantitation (LOQ) in all edible commodities. Accordingly, the Meeting determined that no bovine feeding study is necessary at this time.

The Meeting estimated maximum residue levels of 0.02(*) mg/kg and STMR and HR values of 0 mg/kg for benalaxyl in meat from mammals (other than marine mammals), edible offal (mammalian), and milks.

A poultry feeding study was not provided. However, as there are no poultry feed items resulting from the RACs for which the 2009 Meeting made maximum residue level recommendations, there was no need to recommend maximum residue levels for poultry commodities.

DIETARY RISK ASSESSMENT

Long-term intake

The evaluation of benalaxyl has resulted in recommendations for MRLs and STMRs for raw and processed commodities. These commodities were included at the appropriate levels in the dietary intake calculations. The International Estimated Daily Intakes (IEDI) for the 13 GEMS/Food Consumption Cluster Diets, based on estimated STMRs were in the range 0–1% of the maximum ADI of 0.07 mg/kg bw The results are shown in Annex 3.

The Meeting concluded that the long-term intake of residues of benalaxyl from uses that have been considered by the JMPR is unlikely to present a public health concern.

Short-term intake

The International Estimated Short-Term Intake (IESTI) for benalaxyl was calculated for the food commodities (and their processing fractions) for which maximum residue levels and HRs were estimated and for which consumption data were available. The results are shown in Annex 4. For benalaxyl, the IESTI varied from 0–4% of the ARfD (0.1 mg/kg bw) for women of childbearing age using the intake figures for the general population.

The Meeting concluded that the short-term intake of residues of benalaxyl from uses that have been considered by the JMPR is unlikely to present a public health concern.