

## 5.10 CYPRODINIL (207)

### RESIDUE AND ANALYTICAL ASPECTS

Cyprodinil was first evaluated for residues and toxicological aspects by the 2003 JMPR. The 2003 Meeting established an ADI of 0–0.03 mg/kg bw for cyprodinil and concluded that an ARfD was not necessary. The 2003 Meeting recommended a number of maximum residue levels for cyprodinil. The residue definition was established as cyprodinil for both compliance with MRLs and dietary risk assessment, for both plant and animal commodities. The residue is fat soluble.

Cyprodinil was scheduled by the Forty-fourth CCPR meeting in 2012 for evaluation of residue data for additional crops by the 2013 JMPR.

#### *Methods of analysis*

The Meeting received two analytical methods for determination of cyprodinil residues in plant matrices which were relevant to this evaluation. The LOQ for the HPLC-UV and HPLC-MS/MS methods was 0.01 mg/kg.

#### *Stability of residues in stored analytical samples*

The Meeting received information on the storage stability of cyprodinil residues in plant matrices from trials conducted in conjunction with the residue studies submitted to the Meeting. These data and stability data from JMPR 2003 cover the maximum storage period for samples in the residue studies submitted to the Meeting.

#### *Results of supervised residue trials on crops*

The Meeting received supervised trial data for application of cyprodinil to dry beans, lima beans, common beans (snap beans), berry fruit (blueberries, caneberries and strawberries), brassica vegetables (broccoli and cabbage), cucurbit fruiting vegetables (cantaloupe, cucumber and squash), other fruiting vegetables (sweet pepper, chili pepper, and tomato), herbs (parsley, basil and chives), leafy vegetables (mustard greens, lettuce, spinach and watercress), lemons (including processing data), pome fruit (apples and pears), root vegetables (carrot and radish), and tropical fruits-inedible peel (avocado, kiwifruit and litchi).

#### *Citrus fruits*

Cyprodinil is registered in the USA for use on lemons and limes at a GAP of  $1 \times 0.37$  kg ai/ha, and a 0-day PHI.

Three residue trials were conducted in lemons at GAP in the USA. Residues in lemons at the 0-day PHI were 0.19, 0.31 and 0.34 mg/kg.

The Meeting determined that there were insufficient data for the estimation of a maximum residue level in lemons.

#### *Pome fruits*

The 2003 JMPR estimated a maximum residue level of 0.05 mg/kg in apple based on a previous GAP in the USA of  $4 \times 0.26$  kg ai/ha, with applications only until the end of flowering. The 2003 JMPR estimated a maximum residue level of 1 mg/kg in pear based on the European GAP of  $3 \times 0.38$  kg ai/ha, with a 14-day PHI.

The Meeting received new residue data from the USA for both apples and pears at a different GAP from those previously considered. Cyprodinil is registered in the USA for use in apples and pears at a GAP of  $6 \times 0.26$  kg ai/ha, and a 0-day PHI.

Nine residue trials were conducted in apples at GAP in the USA. Residues in apples at the 0-day PHI were 0.20, 0.28, 0.40, 0.50, 0.51, 0.52, 0.70, 0.94, and 1.3 mg/kg.

Five residue trials were conducted in pears at GAP in the USA. Residues in pears at the 0-day PHI were 0.17, 0.35, 0.36, 0.46, and 0.65 mg/kg.

The Meeting noted that the USA GAP is for the pome fruits group, and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5 $\times$ ). The Meeting agreed to estimate a maximum residue level for the crop group Pome fruits. In deciding whether to combine the datasets for apple and pear for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting recognized the similarity of the datasets (confirmed by the Mann-Whitney U test), and decided to combine the datasets for apples and pears for the purposes of determining a group maximum residue level for pome fruit. Residues found were: 0.17, 0.20, 0.28, 0.35, 0.36, 0.40, 0.46, 0.50, 0.51, 0.52, 0.65, 0.70, 0.94 and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for pome fruit, and a STMR of 0.48 mg/kg. The Meeting withdrew its previous maximum residue level recommendations of 0.05 mg/kg for apple and 1 mg/kg for pear.

#### *Berries and other small fruits*

Cyprodinil is registered in the USA for use in bushberries at a GAP of  $4 \times 0.37$  kg ai/ha with a 0-day PHI.

Five residue trials were conducted at GAP in blueberries in the USA. Residues in blueberries at the 0-day PHI were 0.50, 0.62, 1.0, 1.4 and 1.9 mg/kg.

The 2003 JMPR estimated a maximum residue level of 0.5 mg/kg in raspberries, red, black based on the Swiss GAP of  $2 \times 0.45$  kg ai/ha, with a 14-day PHI.

The Meeting received residue data from the USA for raspberries. Cyprodinil is registered in the USA for use in caneberries at a GAP of  $4 \times 0.37$  kg ai/ha, with a 0-day PHI.

Five residue trials were conducted in raspberries in the USA. Residues in raspberries at the 0-day PHI were 1.5, 1.6, 2.2, 2.5, and 5.9 mg/kg.

The 2003 JMPR estimated a maximum residue level of 2 mg/kg in strawberries, based on various GAPs in Europe.

The Meeting received residue data from the USA in strawberries. Cyprodinil is registered in the USA for use in strawberries at a GAP of  $4 \times 0.37$  kg ai/ha, with a 0-day PHI.

Eight residue trials were conducted in strawberries in the USA. Residues in strawberries at the 0-day PHI were 0.10, 0.30, 0.68, 0.91, 1.1, 1.5, 1.6, and 2.0 mg/kg.

The Meeting noted that the USA GAP is the same for all berry fruit (except grapes) and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5 $\times$ ). The Meeting agreed to estimate a maximum residue level for the group Berry fruit (except grapes). In deciding whether to combine the datasets for blueberries, raspberries and strawberries for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). Therefore, recommendations on berry fruit will be based on raspberries, as the commodity with the highest residues. Based on the data set for raspberries, the Meeting estimated a maximum residue level of 10 mg/kg for Berries and other small fruits, except grapes, together with an STMR of 2.2 mg/kg. The Meeting withdrew its previous

maximum residue level recommendations of 0.5 mg/kg for raspberries, red, black and 2 mg/kg for strawberry.

#### *Assorted tropical and sub-tropical fruits – inedible peel*

##### *Avocado*

Cyprodinil is registered in the USA for use in avocado at a GAP of  $4 \times 0.37$  kg ai/ha, with a 0-day PHI.

Six trials were conducted in avocados in the USA. Residues in avocados at the 0-day PHI were 0.08, 0.18, 0.23, 0.30, 0.35, and 0.60 mg/kg.

The Meeting estimated a maximum residue level of 1 mg/kg for avocados, along with an STMR of 0.265 mg/kg.

##### *Kiwifruit*

Cyprodinil is registered in the USA for use in kiwifruit at a GAP of  $2 \times 0.53$  kg ai/ha, with a 0-day PHI.

Three residue trials were conducted in kiwifruit in the USA. Residues in kiwifruit at the 0-day PHI were 0.61, 0.99, and 1.1 mg/kg.

The Meeting determined that there were insufficient data for the estimation of a maximum residue level in kiwifruit.

##### *Litchi (lychee)*

Cyprodinil is registered in the USA for use in litchi at a GAP of  $4 \times 0.37$  kg ai/ha, with a 0-day PHI.

One residue trial was conducted in litchi in the USA. Residues in litchi at the 0-day PHI were 1.3 mg/kg.

The Meeting determined that there were insufficient data for estimation of a maximum residue level in litchi.

#### *Brassica vegetables*

##### *Cabbages, Head*

Cyprodinil is registered in the USA for use in brassica vegetables at a GAP of  $4 \times 0.37$  kg ai/ha, with a 7-day PHI.

Six trials were conducted in cabbage in the USA. Residues in cabbages (with wrapper leaves) at a PHI of 6–8 days were < 0.02, 0.02 (s), 0.02, 0.04, 0.19, and 0.36 mg/kg, where (s) indicates a result scaled to account for application rates outside  $\pm 25\%$  of GAP. Residues in cabbages (without wrapper leaves) were < 0.02 (5), and 0.08 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg for head cabbages, along with an STMR of 0.03 mg/kg.

##### *Flowerhead Brassicas*

Six trials were conducted in broccoli in the USA and Canada. Residues in broccoli at a PHI of 6–8 days were 0.02, 0.15, 0.20, 0.34, 0.43 and 1.1 mg/kg.

The Meeting estimated a maximum residue level of 2 mg/kg for broccoli, along with an STMR of 0.27 mg/kg and agreed to extend the MRL and STMR to the subgroup Flowerhead brassicas.

#### *Fruiting vegetables, Cucurbits*

The 2003 JMPM estimated maximum residue levels of 0.2 mg/kg for both cucumber and summer squash, based on data matching Spanish and Italian GAPs of  $4 \times 0.038$  kg ai/hL with a 7-day PHI, and  $3 \times 0.30$  kg ai/ha with a 7-day PHI respectively.

The Meeting received residue data from the USA in melon, cucumber and summer squash.

Cyprodinil is registered in the USA for use in fruiting vegetables, other than cucurbits at a GAP of  $4 \times 0.37$  kg ai/ha, with a 1-day PHI.

Five residue trials were conducted in melons in the USA. Residues in melons at the 1-day PHI were 0.05, 0.06, 0.10, 0.17 and 0.33 mg/kg.

Seven residue trials were conducted in cucumber in the USA. Residues in cucumber at the 1-day PHI were 0.04, 0.05, 0.09 (2), 0.11, 0.15, and 0.24 mg/kg.

Five residue trials in were conducted summer squash in the USA. Residues in summer squash at the 1-day PHI were 0.02, 0.03, 0.07 (2), and 0.09 mg/kg.

The Meeting noted that the USA GAP is for all cucurbit fruiting vegetables, and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5 $\times$ ). The Meeting agreed to estimate a maximum residue level for the group Fruiting vegetables, Cucurbits. In deciding whether to combine the datasets for melons, cucumbers and summer squash for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting recognized the similarity of the datasets (confirmed by the Kruskal-Wallis test), and decided to combine the datasets.

Combines residues were: 0.02, 0.03, 0.04, 0.05 (2), 0.06, 0.07 (2), 0.09 (3), 0.10, 0.11, 0.15, 0.17, 0.24, and 0.33 mg/kg.

The Meeting estimated a maximum residue level of 0.5 mg/kg for Fruiting vegetables, Cucurbits, together with an STMR of 0.09 mg/kg. The Meeting withdrew the previous maximum residue level recommendations of 0.2 mg/kg for cucumber and summer squash.

#### *Fruiting vegetables, other than Cucurbits*

The 2003 JMPM estimated a maximum residue level of 0.2 mg/kg for eggplant, based on data matching the Italian GAP of  $3 \times 0.30$  kg ai/ha, with a 7-day PHI, and the Spanish GAP of  $3 \times 0.038$  kg ai/hL, with a 7-day PHI. Based on a combined data set from three European GAPs (Italy:  $3 \times 0.30$  kg ai/ha, with a 7-day PHI, Spain:  $3 \times 0.038$  kg ai/hL, with a 7-day PHI, and Switzerland: 0.30 kg ai/ha, with a 3-day PHI), the 2003 JMPM estimated a maximum residue level of 0.5 mg/kg for tomatoes. The 2003 JMPM estimated a maximum residue level of 0.5 mg/kg for peppers, sweet, based on data matching the Italian GAP of  $3 \times 300$  g ai/ha, with a 7-day PHI, and the Spanish GAP of  $3 \times 38$  g ai/hL, with a 7-day PHI.

The Meeting received residue data from the USA and Canada in tomatoes, sweet peppers and chili peppers. Both field and greenhouse trial data were supplied for all three crops.

Cyprodinil is registered in the USA for use in fruiting vegetables, other than cucurbits, at a GAP of  $4 \times 0.37$  kg ai/ha, with a 0-day PHI.

Eleven residue trials were conducted in sweet pepper in the USA and Canada. Residues in sweet pepper at the 0-day PHI were 0.04, 0.10, 0.13, 0.15, 0.19, 0.21 (GH), 0.23, 0.23 (G), 0.25, 0.27 (GH), and 0.68 mg/kg. 'GH' indicates a trial conducted in a greenhouse, all other trials were conducted in the field.

Five trials were conducted in chili pepper in the USA. Residues in chili pepper at the 0-day PHI were 0.20, 0.27, 0.28, 0.59 (GH), and 0.67 mg/kg.

Sixteen trials were conducted in tomatoes in the USA. Residues in tomatoes at the 0-day PHI were 0.02, 0.03 (GH), 0.06, 0.09, 0.11, 0.13, 0.14 (2), 0.16, 0.17 (GH), 0.20, 0.22 (GH), 0.24, 0.26, 0.30, and 0.32 (GH) mg/kg.

A series of residue trials in fruiting vegetables (eggplant, sweet pepper and tomato), was considered by the 2003 JMPR. Most of the trials were conducted in greenhouse crops, and in accordance with a GAP of  $3 \times 0.38$  kg ai/ha applications, with a 7-day PHI. The majority were conducted as decline trials and have data for the USA PHI of 0 days. The application rates from the 2003 trials are within  $\pm 25\%$  of the USA GAP ( $4 \times 0.37$  kg ai/ha).

At a PHI of 0 days, residues of cyprodinil in greenhouse grown eggplant from trials from Italy and Spain relevant to USA GAP were 0.07, 0.14, and 0.23 (2) mg/kg.

At a PHI of 0 days, residues of cyprodinil in greenhouse grown tomato from trials from Greece, Italy, Spain, Switzerland and the UK, relevant to USA GAP were 0.08, 0.12, 0.13, 0.20, 0.21 (2), 0.22 (3), 0.23, 0.25 (3), 0.36, 0.41 mg/kg.

At a PHI of 0 days, residues of cyprodinil in field and greenhouse grown sweet pepper from Spanish and Italian trials relevant to USA GAP were 0.02, 0.26 (G), 0.27, 0.41 (GH), 0.73 (GH), 1.0 (GH), and 1.2 (GH) mg/kg. (GH) indicates a result from a greenhouse trial.

The Meeting agreed to combine the datasets for the USA (field and greenhouse) and European (greenhouse) to give a larger dataset for the purposes of estimation of dietary parameters and a maximum residue level for fruiting vegetables, other than cucurbits.

Residues in field and greenhouse grown tomatoes from trials carried out in the USA, Greece, Italy, Spain, Switzerland and the UK relevant to USA GAP were 0.02, 0.03 (G), 0.06, 0.08 (G), 0.09, 0.11, 0.12 (GH), 0.13, 0.13 (GH), 0.14 (2), 0.16, 0.17 (G), 0.20, 0.20 (GH), 0.21 (GH) (2), 0.22 (GH) (4), 0.23 (GH), 0.24, 0.25 (GH) (3), 0.26, 0.30, 0.32 (GH), 0.36 (GH), 0.41 (GH) mg/kg.

Residues in field and greenhouse grown sweet pepper from trials carried out in the USA, Spain and Italy relevant to USA GAP were 0.02, 0.04, 0.10, 0.13, 0.15, 0.19, 0.21 (GH), 0.23, 0.23 (GH), 0.25, 0.26 (GH), 0.27, 0.27 (GH), 0.41 (GH), 0.68, 0.73 (GH), 1.0 (GH), and 1.2 (GH) mg/kg.

The Meeting considered that the USA GAP is for all fruiting vegetables, other than cucurbits, except mushroom and sweet corn, and considered a group maximum residue level. To consider a group MRL, residues in individual crops should be similar (e.g. medians should not differ by more than 5 $\times$ ). The Meeting agreed to estimate a maximum residue level for the group fruiting vegetables, other than cucurbits, except mushroom and sweet corn. In deciding whether to combine the datasets for sweet peppers, chili peppers, tomatoes and eggplants for use in the statistical calculator or to only utilize the data from the commodity with the highest residues, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). Therefore, recommendations on fruiting vegetables, other than cucurbits, except mushroom and sweet corn will be based on the 2003 data set for sweet peppers, as the commodity with the highest residues.

Based on the combined data set for sweet pepper, the Meeting estimated a maximum residue level of 2 mg/kg for fruiting vegetables, other than cucurbits, except sweet corn and mushrooms, together with an STMR of 0.24 mg/kg. The Meeting agreed to withdraw the previous maximum residue level recommendations of 0.2 mg/kg for eggplant, 0.5 mg/kg for tomatoes, and 0.5 mg/kg for peppers, sweet.

The Meeting noted that the residues in chili pepper and other commodities within the group of fruiting vegetables differed significantly. Using the default dehydration factor of 7 for peppers, the following data set was obtained for dried chili peppers: 1.4, 1.9, 2.0, 4.1, and 4.7 mg/kg. The Meeting estimated a maximum residue level of 9 mg/kg for dried chili peppers, together with an STMR-P of 2.0 mg/kg.

*Brassica leafy vegetables*

Cyprodinil is registered in the USA for use in brassica leafy vegetables (including mustard greens), at a GAP of  $4 \times 0.37$  kg ai/ha, with a 7-day PHI.

Seven trials were conducted in mustard greens in the USA in accordance with GAP. Residues in mustard green leaves at the 7-day PHI were 0.23, 0.36, 0.36 (s), 0.37, 0.71, 5.4, and 8.0 mg/kg, where (s) indicates a result scaled to account for application rates outside  $\pm 25\%$  of GAP.

The Meeting estimated a maximum residue level of 15 mg/kg for mustard greens, together with an STMR of 0.37 mg/kg. The Meeting agreed to extrapolate to estimate a maximum residue level of 15 mg/kg for brassica leafy vegetables.

*Leafy vegetables, except brassica leafy vegetables*

The 2003 JMPM estimated maximum residue levels of 10 mg/kg for lettuce, head and lettuce, leaf, based on data matching GAP for France ( $2 \times 0.19$  kg ai/ha, with a 14-day PHI) and Italy ( $3 \times 0.26$  kg ai/ha, with a 14-day PHI).

The Meeting received residue data from the USA and Canada in head lettuce, leaf lettuce, spinach, and watercress.

Cyprodinil is registered in the USA for use in leafy vegetables, other than brassica leafy vegetables, at a GAP of  $4 \times 0.37$  kg ai/ha, with a 0-day PHI.

Eight trials were conducted in lettuce, head in accordance with the USA GAP. Residues in lettuce heads, with wrapper leaves at the 0-day PHI were 1.6, 2.0, 2.2, 2.3, 2.7, 2.9, 5.1, and 21 mg/kg. Residues in lettuce head with wrapper leaves removed were 0.07, 0.15, 0.31, 0.32, 0.63, 0.69, 1.6, and 3.2 mg/kg.

Six trials were conducted in leaf lettuce, in accordance with the USA GAP. Residues in lettuce leaves at the 0-day PHI were: 8.5, 10 (2), 11, 14, and 24 mg/kg.

Ten trials were conducted in spinach in accordance with the USA GAP. Residues in spinach at the 0-day PHI were 5.6, 6.1, 6.6, 8.3, 11 (2), 12, 13, 14, and 32 mg/kg.

One trial was conducted in watercress in accordance with the USA GAP. Residues in watercress at the 0-day PHI were 12 mg/kg.

The Meeting noted that the USA GAP is the same for all leafy vegetables other than brassica leafy vegetables and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5 $\times$ ). However, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). TAs a result recommendations on leafy vegetables other than brassica leafy vegetables were based on the spinach dataset, as the commodity with the highest residues. Based on the dataset for spinach, the Meeting estimated a maximum residue level of 50 mg/kg for leafy vegetables, except brassica leafy vegetables, together with an STMR of 11 mg/kg. The Meeting agreed to withdraw the previous maximum residue level recommendations of 10 mg/kg for lettuce, head and lettuce, leaf.

*Legume vegetables*

The 2003 JMPM estimated a maximum residue level of 0.5 mg/kg for beans (in pods), except broad bean and soya bean, based on data matching the GAPs of Spain ( $3 \times 0.038$  kg ai/hL, with a 14-day PHI) and ( $2 \times 0.38$  kg ai/ha, with a 14-day PHI).

The Meeting received residue data from the USA in common beans (snap beans, pods and succulent seed) and lima beans (succulent shelled seeds).

Cyprodinil is registered in the USA for use in beans (succulent), including chickpea, lupin, kidney, lima, mung, navy, pinto, snap, wax, and broad bean, asparagus bean and blackeyed pea, with a GAP of  $4 \times 0.37$  kg ai/ha, with a 7-day PHI.

Eight trials were conducted in common beans (pods and succulent seeds) in accordance with the USA GAP. Residues in pod and seed samples at the 7-day PHI were 0.10, 0.12, 0.13, 0.16, 0.17, 0.18, 0.23, and 0.49 mg/kg.

The Meeting estimated a maximum residue level of 0.7 mg/kg in beans, except broad bean and soya bean (green pods and immature seeds), together with an STMR of 0.165 mg/kg. The Meeting agreed to withdraw the previous maximum residue level recommendation of 0.5 mg/kg for beans, except broad bean and soya bean (green pods and immature seeds).

Six trials were conducted in lima beans (seeds without pods) in accordance with the USA GAP. Residues in succulent seeds at the 7-day PHI were < 0.02 (3), 0.02, 0.03 and 0.04 mg/kg.

The Meeting estimated a maximum residue level of 0.06 mg/kg for beans, shelled, together with an STMR of 0.02 mg/kg.

#### *Beans (dry)*

Cyprodinil is registered in the USA for use in beans (dry) at a GAP of  $4 \times 0.37$  kg ai/ha, with a 7-day PHI.

Nine trials in beans (dry) were conducted in accordance with the USA GAP. Residues in beans at the 7-day PHI were < 0.02, 0.02 (3), 0.03, 0.04 (3), and 0.15 mg/kg.

The Meeting estimated a maximum residue level of 0.2 mg/kg for beans, dry, together with an STMR of 0.03 mg/kg.

#### *Carrots*

Cyprodinil is registered in the USA for use in carrots at a GAP of  $4 \times 0.37$  kg ai/ha, with a 7-day PHI.

Ten trials in carrots were conducted in the USA and Canada in accordance with the USA GAP. Residues in carrots at the 7-day PHI were: 0.02, 0.05 (2), 0.06 (s), 0.08 (s) 0.10, 0.12, 0.18, 0.39, and 0.40 mg/kg, where (s) indicates a result scaled to account for application rates outside  $\pm 25\%$  of GAP.

The Meeting estimated a maximum residue level of 0.7 mg/kg for carrots, together with an STMR of 0.09 mg/kg.

The Meeting noted that the US GAP for parsnips is the same as that for carrots, and agreed to extrapolate the residue data for carrots and estimated a maximum residue level of 0.7 mg/kg for parsnips, together with an STMR of 0.09 mg/kg.

#### *Radish*

Cyprodinil is registered in the USA for use in radish at a GAP of  $2 \times 0.37$  kg ai/ha, with a 7-day PHI.

Five trials in radish were conducted in accordance with the USA GAP. Residues in radish roots at the 7-day PHI were < 0.01 (3), 0.03, and 0.14 mg/kg.

Residues in radish tops at the 7-day PHI were 0.13, 0.17, 0.40, 0.45, and 1.3 mg/kg.

The Meeting estimated a maximum residue level of 0.3 mg/kg for radish, together with an STMR of 0.01 mg/kg.

The Meeting agreed that residues of cyprodinil arising in radish tops would be covered by the proposed maximum residue level of 15 mg/kg for brassica leafy vegetables.

### *Herbs*

Cyprodinil is registered in the USA for use in herbs at a GAP of  $4 \times 0.37$  kg ai/ha, with a 7-day PHI.

Three trials in basil were conducted in accordance with the USA GAP. Residues in fresh basil leaves at the 7-day PHI were 1.5, 1.7 and 2.1 mg/kg. Residues in dried basil leaves at the 7-day PHI were 8.8 mg/kg.

Three trials in chives were conducted in accordance with the USA GAP. Residues in fresh chives at the 7-day PHI were 0.62, 1.0, and 1.1 mg/kg. Residues in dried chives at the 7-day PHI were 2.9 mg/kg.

Four trials in parsley were conducted in accordance with the USA GAP. Residues in fresh parsley at the 7-day PHI were 2.9, 3.0, 7.1, and 16 mg/kg. Residues in dried parsley at the 7-day PHI were 20 (2), 30, and 112 mg/kg.

The Meeting noted that the USA GAP is for all herbs and considered a group maximum residue level. To consider a group maximum residue level, residues in individual crops should be similar (e.g., medians should not differ by more than 5 $\times$ ). The Meeting agreed to estimate a maximum residue level for the group herbs. In deciding whether to combine the datasets for basil, chives and parsley for use in the statistical calculator, or to only utilize the data from the commodity with the highest residues, the Meeting agreed not to combine the data sets (Kruskal-Wallis test). Therefore, recommendations on herbs were based on parsley, as the commodity with the highest residues. Based on the data set for fresh parsley, the Meeting estimated a maximum residue level of 40 mg/kg for herbs, together with an STMR of 5.05 mg/kg.

The Meeting estimated a maximum residue level of 300 mg/kg for dried herbs except hops, dry, based on the data set for dried parsley, together with an STMR of 25 mg/kg.

### *Processing studies*

A processing study for lemons was evaluated by the current Meeting; however as the residue data set for lemons was insufficient for the estimation of a maximum residue level or STMR, STMR-P values for citrus processed products were not estimated.

Some processing data for tomatoes was generated as part of the residue trial in tomatoes provided to the Meeting. Processing studies for apples, barley, grapes, plums, tomatoes and wheat were considered by the 2003 JMPR. The studies in apples and tomatoes are relevant to the crops being considered by the current Meeting. Processing factors are tabulated below.

RAC	Processed product	PF
Apples	Wet pomace	3.5
	Juice	0.03
Tomatoes	Juice	0.17
	Purée	0.52
	Paste	0.86, 2.3

The processing factors were applied to the STMRs for the raw commodities to produce the following STMR-P values: wet apple pomace 1.8 mg/kg; apple juice 0.015 mg/kg; tomato juice 0.036 mg/kg; tomato purée 0.11 mg/kg; and tomato paste 0.48 mg/kg.

### **Residues in animal commodities**

#### *Farm animal dietary burden*

Dietary burden calculations incorporating all commodities considered by the current and 2003 Meetings for beef cattle, dairy cattle, broilers and laying poultry are presented in Annex 6. The calculations are made according to the livestock diets of the USA/Canada, the European Union, Australia and Japan as laid out in the OECD table.

	US/CAN		EU		AU		Japan	
	Max.	Mean	Max.	Mean	Max.	Mean	Max.	Mean
Beef cattle	0.91	0.37	13.9	1.8	5.8	1.4	0.46	0.46
Dairy cattle	1.7	0.87	13.5	1.4	<u>23.3</u> <sup>a</sup>	<u>1.8</u> <sup>b</sup>	0.26	0.26
Poultry – broiler	0.49	0.49	0.80	0.54	0.12	0.12	0.066	0.066
Poultry – layer	0.49	0.49	<u>4.1</u> <sup>c</sup>	<u>0.76</u> <sup>d</sup>	0.12	0.12	-	-

<sup>a</sup> Highest maximum dairy cattle dietary burden suitable for HR and MRL estimates for mammalian milk

<sup>b</sup> Highest mean dairy cattle dietary burden suitable for STMR estimates for mammalian milk

<sup>c</sup> Highest maximum poultry dietary burden suitable for HR and MRL estimates for poultry meat and eggs

<sup>d</sup> Highest mean poultry dietary burden suitable for STMR estimates for poultry meat and eggs

#### **Animal commodity maximum residue levels**

##### *Mammals*

A feeding study on lactating dairy cattle was considered by the 2003 JMPR.

Lactating Holstein dairy cows were dosed daily by gelatin capsule with cyprodinil at the equivalent of 5, 15 and 50 ppm in the dry-weight diet for 28 consecutive days. Milk was collected throughout and on days 28, 29, and 30, a cow from each dosing group was slaughtered for tissue collection. Cyprodinil residues were not detected (LOQ 0.01 mg/kg) in the milk (days 0, 1, 3, 7, 14, and 21), kidney, or fat of cows from the highest dose group (50 ppm), nor in milk (day 26) or muscle from any dose groups. Cyprodinil was present in liver (highest residue 0.013 mg/kg) from the highest dose group but not from the other groups.

The 2003 JMPR estimated a maximum residue level of 0.0004\* mg/kg (F) for milk, together with an STMR of 0 mg/kg, based on a maximum dietary burden for dairy cattle of 8.2 ppm, and a mean dietary burden of 0.53 ppm.

The highest dietary burden for dairy cattle is for Australia (max. dietary burden of 23.3 ppm and mean dietary burden of 1.8 ppm). The Meeting noted that no residues of cyprodinil were quantified in milk above the LOQ (0.01 mg/kg) at feeding levels up to 50 ppm in cattle. The Meeting concluded that the existing maximum residue level and STMR for milk remain appropriate.

The 2003 JMPR estimated maximum residue levels of 0.01\* mg/kg (fat) and STMRs of 0 mg/kg for meat (from mammals other than marine mammals), and edible offal (mammalian). These limits were based on a maximum dietary burden of 8.2 ppm, and a mean dietary burden of 0.53 ppm.

As for dairy cattle, the highest dietary burdens for calculation of meat MRLs are 23.3 ppm (max.) and 1.8 ppm (mean), considering all the use patterns evaluated by the 2003 JMPR and the present Meeting. Given that no residues of cyprodinil were found above the LOQ in muscle or fat of cattle at a feeding level of 50 ppm, the Meeting considers that the existing maximum residue level for meat (from mammals other than marine mammals), and the STMR values remain appropriate. No residues were found above the LOQ in kidney even at the highest dose of 50 ppm. In liver, no

residues were found above the LOQ in liver at feeding levels of 5 and 15 ppm, while at 50 ppm, low residues up to 0.013 mg/kg were found. The Meeting estimated a maximum residue level of 0.01 mg/kg for edible offal (mammalian), together with an STMR of 0 mg/kg. The Meeting agreed to withdraw the previous recommendation of 0.01\* mg/kg for edible offal (mammalian).

#### *Poultry*

A feeding study in poultry was not presented to the 2003 JMPR or to the present Meeting.

The 2003 JMPR estimated maximum residue levels of 0.01\* mg/kg for eggs and poultry, edible offal of, and 0.01\* mg/kg (fat) for poultry meat and STMRs of 0 mg/kg. These limits were based on a maximum dietary burden of 2.6 ppm and a mean dietary burden of 0.50 ppm, and consideration of the laying hen metabolism study.

Based on the use patterns considered by the 2003 JMPR and the present Meeting, the Meeting noted that the highest dietary burden for poultry (both for meat and egg producing birds) was the EU diet, with a maximum dietary burden of 4.1 ppm and a mean dietary burden of 0.76 ppm.

As noted by the 2003 JMPR, cyprodinil parent compound was not detected in poultry tissues in the laying hen metabolism study (except in kidney at 0.001 mg/kg), even at feeding levels of 215 and 226 ppm. Cyprodinil was detected in eggs at 0.002-0.011 mg/kg from birds dosed at 215 and 226 ppm. Given that these feeding levels are around 50 times the maximum dietary burden of 4.1 ppm estimated for poultry, the Meeting considers that the existing maximum residue levels, and STMR values for poultry commodities remain appropriate.

## **DIETARY RISK ASSESSMENT**

#### *Long-term intake*

The International Estimated Dietary Intakes (IEDIs) of cyprodinil were calculated for the 13 GEMS/food cluster diets using STMRs/STMR-Ps estimated by the current Meeting and by the 2003 JMPR. The ADI is 0–0.03 mg/kg bw and the calculated IEDIs were 5–40% of the maximum ADI (0.03 mg/kg bw). The Meeting concluded that the long-term intakes of residues of cyprodinil, resulting from the uses considered by the current Meeting and by the 2003 JMPR, are unlikely to present a public health concern.

#### *Short-term intake*

The 2003 JMPR decided that an ARfD was unnecessary and concluded that the short-term intake of cyprodinil is unlikely to present a public health concern.