**Food and Agriculture Organization of the United Nations**

**World Health Organization**

# JOINT FAO/WHO MEETING ON PESTICIDE RESIDUES

**Geneva, 16-25 September 2009**

**SUMMARY REPORT**

## ACCEPTABLE DAILY INTAKES, ACUTE REFERENCE DOSES, SHORT-TERM AND LONG-TERM DIETARY INTAKES, RECOMMENDED MAXIMUM RESIDUE LIMITS AND SUPERVISED TRIALS MEDIAN RESIDUE VALUES RECORDED BY THE 2009 MEETING

*Issued October 2009*

The following extracts of the results of the annual Joint FAO/WHO Meeting on Pesticide Residues (JMPR) are provided to make them accessible to interested parties at an early date.

The Meeting evaluated 24 pesticides, of which 3 were new compounds, and 8 were re-evaluated within the periodic review programme of the Codex Committee on Pesticide Residues (CCPR). The Meeting established acceptable daily intakes (ADIs) and acute reference doses (ARfDs).

The Meeting estimated maximum residue levels, which it recommended for use as maximum residue limits (MRLs) by the CCPR. It also estimated supervised trials median residue (STMR) and highest residue (HR) levels as a basis for estimation of the dietary intake of residues of the pesticides reviewed. Application of HR levels is explained in the report of the 1999 Meeting (section 2.4). The allocations and estimates are shown in the table.

Pesticides for which the estimated dietary intakes might, on the basis of the available information, exceed their ADIs are marked with footnotes, as explained in detail in the report of the 1999 Meeting (section 2.2). Footnotes are also applied to specific commodities when the available information indicated that the ARfD of a pesticide might be exceeded when the commodity was consumed. It should be noted that these distinctions apply only to new compounds and those re-evaluated within the CCPR periodic review programme.

The table includes the Codex reference numbers of the compounds and the Codex classification numbers (CCNs) of the commodities, to facilitate reference to the Codex maximum limits for pesticide residues (*Codex Alimentarius,* Vol. 2B) and other documents and working documents of the Codex Alimentarius Commission. Both compounds and commodities are listed in alphabetical order.

Apart from the abbreviations indicated above, the following qualifications are used in the Table.
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| | |
|---|---|
| * (following name of pesticide) | New compound |
| ** (following name of pesticide) | Compound reviewed within CCPR periodic review programme |
| * (following recommended MRL) | At or about the limit of quantification |
| HR-P | Highest residue in a processed commodity, in mg/kg, calculated by multiplying the HR in the raw commodity by the processing factor |
| Po | The recommendation accommodates post-harvest treatment of the commodity. |
| PoP (following recommendation for processed foods (classes D and E in the Codex classification) | The recommendation accommodates post-harvest treatment of the primary food commodity. |
| STMR-P | An STMR for a processed commodity calculated by applying the concentration or reduction factor for the process to the STMR calculated for the raw agricultural commodity. |
| W (in place of a recommended MRL) | The previous recommendation is withdrawn, or withdrawal of the recommended MRL or existing Codex or draft MRL is recommended. |

More information on the work of the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is available at:

**http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/en/**

**http://www.who.int/ipcs/food/jmpr/en/index.html**

## Established ADI and ARfD values and recommended MRL, STMR and HR values

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| **Benalaxyl (155)**** | VC 0424 | Cucumber | W | 0.05 | | |
| ADI: 0–0.07 mg/kg bw | FB 0269 | Grapes | 0.3 | 0.2 | 0.12 | 0.17 |
| ARfD: 0.1 mg/kg bw | DH 1100 | Hops, dry | W | 0.2 | | |
| (women of childbearing age) | VL 0482 | Lettuce, Head | 1 | | 0.07 | 0.43 |
| | VC 0046 | Melons, except watermelon | 0.3 | 0.1 | 0.02 | 0.05 |
| ARfD: Unnecessary | VA 0385 | Onion, Bulb | 0.02 * | 0.2 | 0 | 0 |
| (general population) | HS 0444 | Peppers Chili, dried | W | 0.5 | | |
| | VO 0445 | Peppers, Sweet (including pimento or pimiento) | W | 0.05 | | |
| | VR 0589 | Potato | 0.02 * | 0.02 * | 0 | 0 |
| | VO 0448 | Tomato | 0.2 | 0.5 | 0.035 | 0.05 |
| | VC 0432 | Watermelon | 0.1 | | 0.02 | 0.02 |
| | JF 0269 | Grape juice | | | 0.018 | |
| | JF 0448 | Tomato juice | | | 0.005 | |
| | | Tomato preserve | | | 0.006 | |
| | | Tomato pureé | | | 0.012 | |
| | | Wine | | | 0.035 | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* benalaxyl. | | | | | | |
| **Bifenthrin (178)**** | | | | | | |
| ADI: 0–0.01 mg/kg bw | | | | | | |
| ARfD: 0.01 mg/kg bw | | | | | | |
| **Boscalid (221)** | AM 0660 | Almond hulls | 15 | 15 | 4.1 | 13 |
| ADI: 0–0.04 mg/kg bw | FP 0226 | Apple | 2 | 2 | 0.365 | |
| ARfD: Unnecessary | FI 0327 | Banana | 0.2 | 0.2 | 0.05 | |
| | GC 0640 | Barley | 0.5 | | 0.075 | |
| | FB 0018 | Berries and other small fruits (*except strawberries and grapes*) | 10 | 10 | 2.53 | |
| | VB 0040 | Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas | 5 | | 1.52 | 2.7 |
| | VA 0035 | Bulb vegetables | 5 | | 1.02 | |
| | GC 0080 | Cereal grains (*except barley, oats, rye and wheat*) | 0.1 | | 0.05 | |
| | SB 0716 | Coffee beans | 0.05 * | 0.05 * | 0.05 | |
| | DF 0269 | Dried grapes (= currants, Raisins and Sultanas) | 10 | 10 | 2.6 | |
| | MO 0105 | Edible offal (Mammalian) | 0.2 | | 0.16 | |
| | PE 0112 | Eggs | 0.02 | | 0.02 | |
| | VC 0045 | Fruiting vegetables, Cucurbits | 3 | | 0.565 | |
| | VO 0050 | Fruiting vegetables, other than Cucurbits (*except fungi, mushroom and sweet corn*) | 3 | | 0.565 | |
| | FB 0269 | Grapes | 5 | 5 | 1.09 | |
| | FI 0341 | Kiwifruit | 5 | 5 | 0.073 | |
| | VL 0053 | Leafy vegetables | 30 | | 2.95 | |
| | VP 0060 | Legume vegetables | 3 | | 0.5 | |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.7 (fat) | | 0.18 (fat)<br>0.035 (muscle) | |
| | FM 0183 | Milk fats | 2 | | 0.64 | |
| | ML 0106 | Milks | 0.1 | | 0.066 | |
| | GC 0647 | Oats | 0.5 | | 0.075 | |
| | SO 0088 | Oilseed | 1 | | 0.145 | |
| | HS 0444 | Peppers Chili, dried | 10 | | 1.4 | |
| | TN 0675 | Pistachio nut | 1 | 1 | 0.27 | |
| | PO 0111 | Poultry, Edible offal of | 0.02 | | 0.02 | |
| | PF 0111 | Poultry fats | 0.02 | | 0.02 | |
| | PM 0110 | Poultry meat | 0.02 | | 0.02 | |
| | DF 0014 | Prunes [c] | 10 | | 3.39 | |
| | VD 0070 | Pulses | 3 | | 0.12 | |
| | VR 0075 | Root and tuber vegetables | 2 | | 0.305 | 0.71 |
| | GC 0650 | Rye | 0.5 | | 0.075 | |
| | FS 0012 | Stone fruits | 3 | 3.0 | 1.21 | |
| | AS 0081 | Straw and fodder (dry) of cereal grains [(*except straw and fodder of barley, oats, rye and wheat*)] Note for DB | 5 [b] | | 1.25 [b] | 3.2 [a, b] |
| | AS 0640 | Barley straw and fodder, dry | 50 [b] | | 9 [b] | 30.7 [a, b] |
| | AS 0647 | Oats straw and fodder, dry | 50 [b] | | 9 [b] | 30.7 [a, b] |
| | AS 0650 | Rye straw and fodder, dry | 50 [b] | | 9 [b] | 30.7 [a, b] |
| | AS 0654 | Wheat straw and fodder, dry | 50 [b] | | 9 [b] | 30.7 [a, b] |
| | FB 0275 | Strawberry | 3 | | 0.555 | |
| | TN 0085 | Tree nuts [(*except pistachio*)] Note for DB | 0.05 * | 0.05 * | 0.05 | |
| | GC 0654 | Wheat | 0.5 | | 0.075 | |
| | JF 0269 | Grape juice | | | 0.46 | |
| | | Pot barley | | | 0.026 | |
| | OR 0541 | Soya bean oil, refined | | | 0.061 | |
| | JF 0048 | Tomato juice | | | 0.085 | |
| | VW 0448 | Tomato paste | | | 0.413 | |
| | | Tomato puree | | | 0.136 | |
| | CF 0654 | Wheat bran, processed | | | 0.32 | |
| | CF 1210 | Wheat germ | | | 0.1 | |
| | CF 1211 | Wheat, flour | | | 0.026 | |
| | CF 1212 | Wheat wholemeal | | | 0.092 | |
| | | Wine | | | 0.38 | |

*Definition of the residue (for compliance with the MRL for plant and animal commodities and for estimation of dietary intake for plant commodities):* boscalid.
*Definition of the residue (for estimation of dietary intake for animal commodities):* sum of boscalid, 2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide including its conjugate, expressed as boscalid.

*The residue is fat-soluble.*

[a] Highest residue. [b] Calculated on a dry weight basis. [c] The dried fruit.

| | | | | | | |
|---|---|---|---|---|---|---|
| **Buprofezin (173)**<br>ADI: 0–0.009 mg/kg bw<br>ARfD: 0.5 mg/kg bw | AM 0660 | Almond hulls | 2 | | 0.23 | 1.76 |
| | TN 0660 | Almonds | 0.05 * | | 0.05 | 0.05 |
| | FP 0226 | Apple | 3 | | 0.28 | 0.99 |
| | FS 0013 | Cherries | 2 | | 0.73 | 1.32 |
| | VC 0424 | Cucumber | W [b] | 0.2 | | |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| | MO 0105 | Edible offal (Mammalian) | 0.05 * | 0.05 * | 0 | 0 |
| | VC 0045 | Fruiting vegetables, Cucurbits | 0.7 | | 0.19 | 0.41 |
| | FB 0269 | Grapes | 1 | | 0.17 | 0.74 |
| | DF 0269 | Dried grapes (= currants, Raisins and Sultanas) | 2 | | 0.37 | 1.63 |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.05 * | 0.05 * | 0 | 0 |
| | ML 0106 | Milks | 0.01 * | 0.01 * | 0 | 0 |
| | FS 0245 | Nectarine | 9 | | 1.355 | 8.13 |
| | FT 0305 | Olives | 5 | | 1.125 | 1.66 |
| | FS 0247 | Peach | 9 | | 1.355 | 8.13 |
| | FP 0230 | Pear | 6 | | 1.09 | 3.64 |
| | VO 0051 | Peppers | 2 | | 0.33 | 1.1 |
| | HS 0444 | Peppers chili, dried | 10 | | 2.31 | 7.7 |
| | FS 0014 | Plums (including Prunes) | 2 | | 0.155 | 0.55 |
| | FB 0275 | Strawberry | 3 | | 0.44 | 1.24 |
| | JF 0226 | Apple juice | | | 0.16 | |
| | JF 0269 | Grape juice | | | 0.098 | |
| | | Olive oil | | | 3.49 | |
| | DF 0014 | Prunes [c] | | | 0.465 | 1.65 |
| | | White wine | | | 0.15 | |
| | | Red wine | | | 0.1 | |

*Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* buprofezin.

[a] Dry weight basis

[b] Replaced by a new maximum residue level for fruiting vegetables, Cucurbits.

[c] The dried fruit.

**Cadusafos (174)****
ADI: 0–0.0005 mg/kg bw
ARfD: 0.001 mg/kg bw

**Carbofuran (096)**

| | | | | |
|---|---|---|---|---|
| ADI: 0–0.001 mg/kg bw | FI 0327 | Banana | 0.02 | |
| ARfD: 0.001 mg/kg bw | FC 0001 | Citrus fruits | | 0.01 |

*Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* sum of carbofuran, 3-hydroxycarbofuran and conjugated 3-hydroxycarbofuran, expressed as carbofuran.

**Chlorothalonil (081)****
ADI: 0–0.02 mg/kg bw
ARfD: 0.6 mg/kg bw

**4-Hydroxy-2,5,6-trichloroisophthalonitrile** [a]
ADI: 0–0.008 mg/kg bw
ARfD: 0.03 mg/kg bw

[a] Company Code **SDS-3701**

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| **Chlorpyrifos-methyl (090)**** | FP 0226 | Apple | W [a] | 0.5 | | |
| ADI: 0–0.01 mg/kg bw | VS 0620 | Artichoke, Globe | W | 0.1 | | |
| ARfD: 0.1 mg/kg bw | GC 0640 | Barley | 3 Po | | 2.1 | 2.2 |
| | VB 0041 | Cabbages, Head | W | 0.1 | | |
| | MF 0812 | Cattle fat | W [a] | 0.05 | | |
| | MM 0812 | Cattle meat | W [a] | 0.05 | | |
| | MO 0812 | Cattle, Edible offal of | W [a] | 0.05 | | |
| | PF 0840 | Chicken fat | W [a] | 0.05 | | |
| | PM 0840 | Chicken meat | W [a] | 0.05 | | |
| | PO 0840 | Chicken, Edible offal of | W [a] | 0.05 | | |
| | VL 0467 | Chinese cabbage (type Pe-tsai) | W | 0.1 | | |
| | FC 0001 | Citrus fruits | 2 | | 0.01 | 0.01 |
| | VP 0526 | Common bean (pods and/or immature seeds) | W | 0.1 | | |
| | FT 0295 | Date | W | 0.05 | | |
| | MO 0105 | Edible offal (Mammalian) | 0.01 | | 0 | 0 |
| | VO 0440 | Egg plant | 1 | 0.1 | 0.06 | 0.72 |
| | PE 0112 | Eggs | 0.01 * | 0.05 | 0 | 0 |
| | FB 0269 | Grapes | 1 | 0.2 | 0.02 | 0.53 |
| | AB 0269 | Grape pomace, dry | 5 | | 0.075 | |
| | VL 0482 | Lettuce, Head | W | 0.1 | | |
| | GC 0645 | Maize | 3 Po | | 2.1 | 2.2 |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.1 (fat) | | 0.03 (fat)<br>0 (muscle) | 0.055 (fat)<br>0 (muscle) |
| | ML 0106 | Milks | 0.01 * | 0.01 | 0.0006 | |
| | FM 0183 | Milk fats | 0.01* | 0.01 | 0.0006 | |
| | VO 0450 | Mushrooms | W | 0.01 * | | |
| | FC 0004 | Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars | W [a] | 0.5 | | |
| | JF 0004 | Orange juice | | | 0 | |
| | FS 0247 | Peach | W | 0.5 | | |
| | VO 0051 | Peppers | 1 | 0.5 | 0.06 | 0.72 |
| | HS 0444 | Peppers Chili, dried | 10 | 5 | 0.6 | |
| | FP 0009 | Pome fruits | 1 | | 0.06 | 0.56 |
| | VR 0589 | Potato | 0.01 * | | 0 | 0 |
| | PO 0111 | Poultry, Edible offal of | 0.01 * | | 0 | 0 |
| | PO 0110 | Poultry meat | 0.01 (fat) | | 0.004 (fat)<br>0 (muscle) | 0.004 (fat)<br>0 (muscle) |
| | VR 0494 | Radish | W | 0.1 | | |
| | GC 0649 | Rice | W | 0.1 | | |
| | GC 0651 | Sorghum | W [a] | 10 Po | | |
| | FS 0012 | Stone fruits | 0.5 | | 0.02 | 0.26 |
| | FB 0275 | Strawberry | 0.06 | | 0.01 | 0.04 |
| | DT 1114 | Tea, Green, Black (black, fermented and dried) | W | 0.1 | | |
| | VO 0448 | Tomato | 1 | 0.5 | 0.06 | 0.92 |
| | GC 0654 | Wheat | 3 Po | 10 Po | 2.1 | 2.2 |
| | CM 0654 | Wheat bran, unprocessed | 6PoP | 20 PoP | 5.14 | 5.39 |
| | CF 1211 | Wheat flour | W | 2 PoP | 0.525 | 0.55 |
| | CP 1211 | White bread | W | 0.5 PoP | 0.105 | 0.11 |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| | CF 1210 | Wheat germ | 5 PoP | | 3.99 | 4.18 |
| | CF 1212 | Wheat wholemeal | | | 3 | 4.7 |
| | CP 1212 | Wholemeal bread | W | 2 PoP | 1.01 | 1.06 |
| | | Beer | | | 0.002 | |
| | DF 5263 | Raisins | | | 0.001 | 0.001 |
| | JF 448 | Tomato juice | | | 0.002 | |
| | | Tomato puree | | | 0.016 | |
| | | Wine | | | 0.002 | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* chlorpyrifos-methyl.<br>*The residue is fat-soluble.*<br>[a] Replaced by commodity group MRL | | | | | | |
| **Cycloxydim (179) **** ADI: 0–0.07 mg/kg bw ARfD: 2 mg/kg bw for women of childbearing age unnecessary for general population | | | | | | |
| **Cyfluthrin (157)** Group ADI: 0–0.04 mg/kg bw Group ARfD: 0.04 mg/kg bw | VB 0400 | Broccoli | 2 | 2 | 0.2 | 1.5 [a] |
| | VB 0041 | Cabbages, Head | 0.5 | 4 | 0.09 | 0.2 |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* cyfluthrin (sum of isomers).<br>[a] The information provided to the JMPR precludes an estimate that the dietary intake would be below the ARfD. | | | | | | |
| **Cypermethrins (118)** Group ADI: 0–0.02 mg/kg bw Group ARfD: 0.04 mg/kg bw | GC 0640 | Barley | 2 [e] Po *C* [f] | | 1.38 | 1.5 |
| | GC 0080 | Cereal grains ( *except rice*) | W | 0.3 [g] | | |
| | GC 0080 | Cereal grains *( except rice, barley, oats, rye and wheat*) | 0.3 [e] *Acz* | | 0.035 | |
| | PE 0112 | Eggs | 0.01 * | 0.01 * | 0.0042 | 0.0060 |
| | GC 0647 | Oats | 2 [e] *Po C* | | 1.38 | 1.5 |
| | PM 0110 | Poultry meat | 0.1 (fat) | 0.05 * | 0.002 (muscle) 0.034 (fat) | 0.007 (muscle) 0.048 (fat) |
| | GC 0650 | Rye | 2 [e] Po *C* | | 1.38 | 1.5 |
| | GC 0654 | Wheat | 2 [e] Po *C* | | 1.38 | 1.5 |
| | CM 0654 | Wheat bran, unprocessed | 5 PoP *C* | | 3.45 | 3.75 |
| | | Beer | | | 0.04 | |
| | CF 1211 | Wheat flour | | | 0.48 *C* | 0.53 |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* cypermethrin (sum of isomers).<br>*The residue is fat-soluble.* | | | | | | |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| [e] Replacing previous MRL for Cereal grains, except rice. | | | | | | |
| [f] Source of data supporting the proposed MRL: *a: alpha-cypermethrin. c: cypermethrin. z: zeta-cypermethrin*. Capital letters show the source of data responsible for the MRL estimate. Small letters show the sources of other data for that commodity | | | | | | |
| [g] Replaced by Cereal grains, except rice, barley, oats, rye and wheat. | | | | | | |
| **Fenbuconazole (197)** | AM 0660 | Almond hulls | 3 | | 0.45 | |
| ADI: 0–0.03 mg/kg bw | AB 0226 | Apple pomace, dry | 1 | | 0.3 | |
| | FB 0020 | Blueberries | 0.5 | | 0.06 | 0.2 |
| | MF 0812 | Cattle fat | W [a] | 0.05 * | | |
| | MO 1280 | Cattle, Kidney | W [a] | 0.05 * | | |
| | MO 1281 | Cattle, Liver | W [a] | 0.05 | | |
| | MM 0812 | Cattle meat | W [a] | 0.05 * | | |
| | ML 0812 | Cattle milk | W [a] | 0.05 * | | |
| | FB 0265 | Cranberry | 1 | | 0.13 | 0.45 |
| | MO 0105 | Edible offal (Mammalian) | 0.1 | | 0.02 | 0.09 |
| | PE 0112 | Eggs | 0.01 * | 0.05 * | 0 | 0 |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.01 | | 0.003 | 0.01 |
| | ML 0106 | Milks | 0.01 * | | 0 | |
| | SO 0697 | Peanut | 0.1 | | 0.03 | 0.05 |
| | AL 0697 | Peanut fodder | 15 | | 2.3 | 7.1 |
| | TN 0672 | Pecan | W | 0.05 * | | |
| | VO 0051 | Peppers | 0.6 | | 0.15 | 0.21 |
| | HS 0444 | Peppers Chili, dried | 2 | | 1.5 | 2.0 |
| | FS 0014 | Plums (including Prunes) | 0.3 | | 0.08 | 0.17 |
| | FP 0009 | Pome fruits | 0.5 | 0.1 | 0.12 | 0.28 |
| | PF 0111 | Poultry fats | W | 0.05 * | | |
| | PM 0110 | Poultry meat | 0.01 * | 0.05 * | 0 | 0 |
| | PO 0111 | Poultry, Edible offal of | 0.01 * | 0.05 * | 0 | 0 |
| | TN 0085 | Tree nuts | 0.01 * | | 0 | 0 |
| | JF 0226 | Apple juice | | | 0.01 | |
| | OR 0697 | Peanut oil, edible | | | 0.04 | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* fenbuconazole. | | | | | | |
| *The residue is fat-soluble.* | | | | | | |
| [a] Replaced by commodity group MRL. | | | | | | |
| **Fluopicolide (235)*** | VB 0402 | Brussels sprouts | 0.2 | | 0.04 (0.01) [a] | 0.13 (0.01) |
| ADI: 0–0.08 mg/kg bw | VB 0041 | Cabbages, Head | 7 | | 1.2 (0.01) [a] | 4 (0.02) |
| ARfD: 0.6 mg/kg bw | VS 0624 | Celery | 20 | | 1.4 (0.01) [a] | 14 (0.04) |
| (women of childbearing age) | HS 0444 | Peppers Chili, dried | 7 | | 0.91 (0.01) | 7 (0.01) |
| | PE 0112 | Eggs | 0.01 * | | 0 (0) | 0 (0) |
| **2,6-dichlorobenzamide** | VB 0042 | Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower) | 2 | | 0.385 (0.01) [a] | 0.69 (0.01) |
| ADI: 0–0.02 mg/kg bw | VC 0045 | Fruiting vegetables, Cucurbits | 0.5 | | 0.07 (0.01) [a, b]<br>0.01 (0.01) [a, c] | 0.3(0.01) [b]<br>0.01(0.01) [c] |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| ARfD: 0.6 mg/kg bw (general population) | VO 0050 | Fruiting vegetables, other than Cucurbits (*except mushrooms and sweet corn*) | 1 | | 0.16 (0.01) [a] | 0.58 (0.01) |
| | FB 0269 | Grapes | 2 | | 0.38 (0.01) [a] | 1.2 (0.04) |
| | DF 0269 | Dried grapes (= currants, Raisins and Sultanas) | 10 | | 2.47 (0.045) [a] | 7.8 (0.06) |
| | AB 0269 | Grape pomace, dry | 7 | | | |
| | VL 0053 | Leafy vegetables | 30 | | 8.6 (0.07) [a] | 17 (0.19) |
| | MO 0105 | Edible offal (Mammalian) | 0.01 * | | 0 (0) [a] | 0 (0) |
| | ML 0106 | Milks | 0.02 | | 0 (0) [a] | |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.01 *(fat) | | 0 (0) [a] | 0 (0) |
| | VA 0385 | Onion, Bulb | 1 | | 0.07 (0.01) [a] | 0.58 (0.01) |
| | VA 0387 | Onion, Welsh | 10 | | 2.1 (0.01) [a] | 4.5 (0.01) |
| | PM 0110 | Poultry meat | 0.01 * | | 0 (0) [a] | 0 (0) |
| | PO 0111 | Poultry, Edible offal of | 0.01 * | | 0 (0) [a] | 0 (0) |
| | AS 0081 | Straw and fodder (dry) of cereal grains | 0.2 | | | |
| | JF 0448 | Tomato juice | | | 0.048 (0.01) [a] | |
| | | Tomato puree | | | 0.288 (0.01) [a] | |
| | VW 0448 | Tomato paste | | | 0.352 (0.01) [a] | |
| | | White wine | | | 0.16 (0.01) [a] | |
| | | Red wine | | | 0.12 (0.01) [a] | |
| *Definition of the residue (for compliance with the MRL) for plant and animal commodities:* fluopicolide. *Definition of the residue (for estimation of dietary intake) for plant and animal commodities:* fluopicolide and 2,6-dichlorobenzamide measured separately. *The residue is fat-soluble.* [a] Values in brackets are for residues of 2,6-dichlorobenzamide. [b] Values are for fruit with edible peel. [c] Values are for fruit with inedible peel. | | | | | | | |
| **Haloxyfop (194)**** | AL 1021 | Alfalfa forage (green) | W [a] | 5 [1] | | |
| ADI: 0–0.0007 mg/kg bw | FI 0327 | Banana | 0.02 * | 0.05 * | 0 | 0 |
| ARfD: 0.08 mg/kg bw | VD 0071 | Beans (dry) | 3 | | 0.335 | |
| | VP 0061 | Beans, except broad bean and soya bean | 0.5 | | 0.085 | 0.26 |
| | MO 1280 | Cattle, kidney | W [b] | 1 | | |
| | MO 1281 | Cattle, liver | W [b] | 0.5 | | |
| | MM 0812 | Cattle meat | W [b] | 0.05 | | |
| | ML 0812 | Cattle milk | W [b] | 0.3 | | |
| | PE 0840 | Chicken eggs | W [c] | 0.01 * | | |
| | PM 0840 | Chicken meat | W [c] | 0.01 * [2] | | |
| | PO 0840 | Chicken, Edible offal of | W [c] | 0.05 | | |
| | VD 0524 | Chick-pea (dry) | 0.05 | | 0.02 | |
| | FC 0001 | Citrus fruits | 0.02 * | 0.05 * | 0 | 0 |
| | SB 0716 | Coffee beans | 0.02 * | | 0 | 0 |

[1] Fresh weight basis.
[2] With adhering skin.

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| | SO 0691 | Cotton seed | 0.7 | 0.2 | 0.1 | |
| | OC 0691 | Cotton seed oil, crude | W | 0.5 | | |
| | MO 0105 | Edible offal (Mammalian) | 2 | | 0.27 | 1.42 |
| | PE 0112 | Eggs | 0.1 | | 0.022 | 0.05 |
| | AM 1051 | Fodder beet | 0.4 | 0.3 | 0.02 | 0.30 |
| | AV 1051 | Fodder beet leaves or tops | W [a] | 0.3 [l] | | |
| | FB 0269 | Grapes | 0.02 * | 0.05 * | 0 | 0 |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.5 (fat) | | 0.035 (fat)<br>0.006 (muscle) | 0.33 (fat)<br>0.041 (muscle) |
| | FM 0183 | Milk fats | 7 | | 0.87 | |
| | ML 0106 | Milks | 0.3 | | 0.033 | |
| | VA 0385 | Onion, Bulb | 0.2 | | 0.035 | 0.12 |
| | SO 0697 | Peanut | W | 0.05 | | |
| | AL 0697 | Peanut fodder | 5 | | 2.1 | 3.0 |
| | VD 0072 | Peas (dry) | 0.2 | | 0.04 | |
| | VP 0063 | Peas (pods and succulent = immature seeds) | 0.7 | 0.2 | 0.11 | 0.53 |
| | VP 0064 | Peas, shelled (succulent seeds) | 1 | | 0.08 | 0.75 |
| | FP 0009 | Pome fruits | 0.02 * | 0.05 * | 0 | 0 |
| | VR 0589 | Potato | W | 0.1 | | |
| | PM 0110 | Poultry meat | 0.7 (fat) | | 0.13 (fat)<br>0.032 (muscle) | 0.52 (fat)<br>0.11 (muscle) |
| | PO 0111 | Poultry, Edible offal of | 0.7 | | 0.21 | 0.61 |
| | VD 0070 | Pulses | W [d] | 0.2 | | |
| | SO 0495 | Rape seed | 3 | 2 | 0.07 | |
| | OC 0495 | Rape seed oil, crude | W [e] | 5 | 0.17 | |
| | OR 0495 | Rape seed oil, edible | W [e] | 5 | 0.16 | |
| | CM 1206 | Rice bran, unprocessed | W | 0.02 * | | |
| | CM 0649 | Rice, husked | W | 0.02 * | | |
| | CM 1205 | Rice, polished | W | 0.02 * | | |
| | VD 0541 | Soya bean (dry) | 2 | | 0.055 | |
| | OC 0541 | Soya bean oil, crude | W [f] | 0.2 | 0.044 | |
| | OR 0541 | Soya bean oil, refined | W [f] | 0.2 | 0.041 | |
| | FS 0012 | Stone fruits | 0.02 * | | 0 | 0 |
| | VR 0596 | Sugar beet | 0.4 | 0.3 | 0.02 | 0.30 |
| | AV 0596 | Sugar beet leaves or tops | W [a] | 0.3 | | |
| | SO 0702 | Sunflower seed | 0.3 | 0.2 | 0.05 | |

*Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:*

sum of haloxyfop (including haloxyfop-P), its esters and its conjugates expressed as haloxyfop.

[a] The current policy is not to recommend maximum residue levels for fresh animal forages, but to use the data in livestock dietary burden calculations.

[b] Recommendations for Cattle kidney and Cattle liver are withdrawn, to be replaced by a recommendation for mammalian edible offal. Recommendations for Cattle meat and Cattle milk are withdrawn and replaced by recommendations for mammalian meat and milks.

[c] Recommendations for Chicken eggs, meat and edible offal are withdrawn, to be replaced by recommendations for poultry commodities.

[d] The recommendation for Pulses is withdrawn to be replaced by recommendations for individual commodities.

[e] The recommendations for maximum residue levels for rape seed oils are withdrawn, because they are covered by the recommendation for Rape seed.

[f] The recommendations for maximum residue levels for Soya bean oils are withdrawn, because they are covered by the

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| recommendation for soya bean (dry). | | | | | | |
| **Hexythiazox (176)**** | FP 0226 | Apple | W [a] | 0.5 | | |
| ADI: 0–0.03 mg/kg bw | FS 0013 | Cherries | W [a] | 1 | | |
| ARfD: Unnecessary | FC 0001 | Citrus fruits | 0.5 | 0.5 | 0.074 (pulp) | |
| | VP 0526 | Common bean (pods and/or immature seeds) | W | 0.5 | | |
| | VC 0424 | Cucumber | W | 0.1 | | |
| | FB 0279 | Currant, Red, White | W | 0.2 | | |
| | FT 0295 | Date | 2 | | 0.26 | |
| | DF 0269 | Dried grapes (= currants, Raisins and Sultanas) | 1 | | 0.32 | |
| | MO 0105 | Edible offal (Mammalian) | 0.05 | | 0.01 | |
| | VO 0440 | Egg plant | 0.1 | | 0.05 | |
| | PE 0112 | Eggs | 0.05 | | 0.002 | |
| | VC 0045 | Fruiting vegetables, Cucurbits (*except watermelon*) | 0.05 | | 0.05 | |
| | AB 0269 | Grape pomace, dry | 15 (dry) | | | |
| | FB 0269 | Grapes | 1 | 1 | 0.2 | |
| | DH 1100 | Hops, dry | W | 2 | | |
| | MF 0100 | Mammalian fats (except milk fats) | 0.05 | | 0.01 | |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.05 | | 0.01 (fat)<br>0 (muscle) | |
| | FM 0183 | Milk fats | 0.05 | | 0.01 | |
| | ML 0106 | Milks | 0.05 | | 0.01 | |
| | FS 0247 | Peach | W [a] | 1 | | |
| | FP 0230 | Pear | W [a] | 0.5 | | |
| | FS 0014 | Plums (including Prunes) | W [a] | 0.2 | | |
| | FP 0009 | Pome fruits | 0.4 | | 0.11 | |
| | PM 0110 | Poultry meat | 0.05 * (fat) | | 0.002 (fat)<br>0 (muscle) | |
| | PO 0111 | Poultry, Edible offal of | 0.05 | | 0.01 | |
| | DF 0014 | Prunes [b] | 1 | | 0.41 | |
| | FS 0012 | Stone fruits | 0.3 | | 0.09 | |
| | FB 0275 | Strawberry | W | 0.5 | | |
| | VO 0448 | Tomato | 0.1 | 0.1 | 0.05 | |
| | TN 0085 | Tree nuts | 0.05 * | | 0 | |
| | JF 0269 | Grape juice | | | 0.084 | |
| | JF 0004 | Orange juice | | | 0.024 | |
| | | Wine | | | 0.01 | |

*Definition of the residue (for compliance with the MRL) for plant commodities:* hexythiazox.

*Definition of the residue (for estimation of dietary intake) for plant commodities:* sum of hexythiazox and all metabolites containing the *trans*-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3-), expressed as hexythiazox.

*Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for animal commodities:* sum of hexythiazox and all metabolites containing the trans-5-(4-chlorophenyl)-4-methyl-2-oxothiazolidine-moiety (PT-1-3-), expressed as hexythiazox.

*The residue is fat-soluble.*

[a] Replaced by commodity group MRL. [b] The dried fruit

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| **Indoxacarb (216)** | VD 0527 | Cowpea, dry | 0.1 | | 0.02 | |
| ADI: 0–0.01 mg/kg bw | FB 0265 | Cranberry | 1 | | 0.15 | 0.69 |
| ARfD: 0.1 mg/kg bw | VC 0424 | Cucumber | W [a] | 0.2 | | |
| | MO 0105 | Edible offal (Mammalian) | 0.05 | 0.05 | 0.014 | 0.030 |
| | PE 0112 | Eggs | 0.02 | 0.01 * | 0.01 | 0.02 |
| | VC 0045 | Fruiting vegetables, Cucurbits | 0.5 | | 0.06 [b] (0.02[c]) | 0.39 [b] (0.02[c]) |
| | MM 0095 | Meat (from mammals other than marine mammals) | 2 (fat) | 1 (fat) | 0.01 (muscle) 0.38 (fat) | 0.039 (muscle) 1.07 (fat) |
| | VC 0046 | Melons, except watermelons | W [a] | 0.1 | | |
| | FM 0183 | Milk fats | 2 | 2 | 0.78 | |
| | ML 0106 | Milks | 0.1 | 0.1 | 0.037 | |
| | HH 0738 | Mints | 15 | | 3.5 | 6.8 |
| | FS 0247 | Peach | W [a] | 0.3 | | |
| | PM 0110 | Poultry meat | 0.01 * (fat) | 0.01 * (fat) | 0 (muscle) 0.025 (fat) | 0 (muscle) 0.05 (fat) |
| | PO 0111 | Poultry, Edible offal of | 0.01 * | 0.01 * | 0 | 0 |
| | DF 0014 | Prunes [d] | 3 | | 0.68 | 2.6 |
| | FS 0012 | Stone fruits | 1 | | 0.17 | 0.64 |
| | | Mint oil | | | 0.05 | |
| | | Plum jam | | | 0.17 | |
| | | Plum juice | | | 0.06 | |
| | | Plum pomace, wet | | | 0.14 | |
| | | Plum puree | | | 0.22 | |
| | | Plums, canned | | | 0.11 | |

*Definition of the residue for compliance with the MRL for all commodities and for estimation of dietary intake for plant commodities:* sum of indoxacarb and its R enantiomer.

*Definition of the residue for estimation of dietary intake for animal commodities:* sum of indoxacarb, its R enantiomer and methyl 7-chloro-2,5-dihydro-2-[[[4-(trifluoromethoxy)phenyl] amino]carbonyl]ind*eno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate, expressed as indoxacarb.*

*The residue is fat-soluble.*

[a] Replaced by commodity group MRL.

[b] STMR and HR values in whole fruit

[c] STMR and HR values in edible portion (pulp).

[d] The dried fruit.

| | | | | | | |
|---|---|---|---|---|---|---|
| **Metaflumizone (236)*** | VB 0402 | Brussels sprouts | 0.8 | | 0.125 | |
| ADI: 0–0.1 mg/kg bw | VL 0467 | Chinese cabbage, (type Pe-tsai) | 3 | | 0.49 | |
| ARfD: Unnecessary | MO 0105 | Edible offal (Mammalian) | 0.02 * | | 0.013 | |
| | VO 0440 | Egg plant | 0.6 | | 0.18 | |
| | VL 0482 | Lettuce, Head | 7 | | 2.0 | |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.02 * (fat) | | 0.013 (muscle) 0.013 (fat) | |
| | ML 0106 | Milks | 0.01 * | | 0.007 | |
| | FM 0183 | Milk fats | 0.02 | | 0.013 | |
| | VO 0051 | Peppers | 0.6 | | 0.18 | |
| | HS 0444 | Peppers Chili, dried | 6 | | 1.8 | |
| | VR 0589 | Potato | 0.02 * | | 0 | |
| | VO 0448 | Tomato | 0.6 | | 0.12 | |

*Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities*: metaflumizone, sum of metaflumizone *E*-isomer and metaflumizone *Z*-isomer.

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| *The residue is fat-soluble.* | | | | | | |
| **Methoxyfenozide (209)** | FI 0326 | Avocado | 0.7 | | 0.13 | 0.41 |
| | VP 0526 | Common bean (pods and/or immature seeds) | 2 | | 0.065 | 0.99 |
| ADI: 0–0.1 mg/kg bw | VP 0062 | Beans, shelled | 0.3 | | 0.05 | 0.18 |
| ARfD: 0.9 mg/kg bw | VD 0071 | Beans, dry | 0.5 | | 0.05 | |
| | FB 0020 | Blueberries | 4 | | 1.25 | 2 |
| | VR 0577 | Carrot | 0.5 | | 0.13 | 0.31 |
| | FC 0001 | Citrus fruits | 0.7 | | 0.05 | 0.05 |
| | VD 0527 | Cowpea (dry) | 5 | | 0.56 | |
| | FB 0265 | Cranberry | 0.7 | 0.7 | 0.1 | 0.39 |
| | MO 0105 | Edible offal (Mammalian) | 0.1 | 0.02 | 0.051 | 0.057 |
| | MF 0100 | Mammalian fats (except milk fats) | 0.2 | | 0.094 | 0.162 |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.2 (fat) | 0.05 | 0.094 (fat)<br>0.019 (muscle) | 0.162 (fat)<br>0.025 (muscle) |
| | ML 0106 | Milks | 0.05 | | 0.030 | |
| | FI 0350 | Papaya | 1 | | 0.31 | 0.33 |
| | SO 0697 | Peanut | 0.03 | | 0.01 | 0.016 |
| | AL 0697 | Peanut fodder | 80 | | 13.5 | 51 |
| | OR 0697 | Peanut oil, edible | 0.1 | | 0.029 | |
| | VP 0064 | Peas, shelled (succulent seeds) | 0.3 | | 0.05 | 0.18 |
| | VR 0494 | Radish | 0.4 | | 0.08 | 0.1 |
| | VL 0494 | Radish leaves (including Radish tops) | 7 | | 0.75 | 4.0 |
| | FB 0275 | Strawberry | 2 | | 0.24 | 1.2 |
| | VR 0596 | Sugar beet | 0.3 | | 0.11 | 0.18 |
| | VR 0508 | Sweet potato | 0.02 | | 0.01 | 0.012 |
| | JF 0001 | Citrus juice | | | 0.011 | |
| | DM 0596 | Sugar beet molasses | | | 0.126 | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* methoxyfenozide. *The residue is fat-soluble, but is not classed as fat-soluble with respect to its distribution in milk.* | | | | | | |
| **Paraquat (057)** | GC 0649 | Rice | 0.05 | W | 0 | 0 |
| ADI: 0–0.005 mg/kg bw | AS 0649 | Rice straw and fodder, dry | 0.05 | — | 0.01 | 0.04 |
| ARfD: 0.006 mg/kg bw | | | | | | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities*: paraquat cation. | | | | | | |
| **Prochloraz (142)** | VO 0450 | Mushrooms | 3 | 40 | 0.71 | 1.4 |
| ADI: 0–0.01 mg/kg bw | | | | | | |
| ARfD: 0.1 mg/kg bw | | | | | | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* sum of prochloraz and its metabolites containing the 2,4,6-trichlorphenol moiety, expressed as prochloraz. *The residue is fat-soluble*. | | | | | | |
| **Prothioconazole (232)** | GC 0640 | Barley | 0.2 | 0.05 | 0.035 | |
| ADI: 0–0.05mg/kg bw | | Barley forage (fresh) | | | 1.2 | 5.4 |
| ARfD: 0.8 mg/kg bw (women of childbearing age) | AS 0640 | Barley straw and fodder, dry | W [a] | 2 | | |
| ARfD: Unnecessary | MO 0105 | Edible offal (Mammalian) | 0.5 | 0.02 | 0.05 | 0.23 |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| (general population) | | | | | (liver) 0.025 (kidney) | (liver) 0.15 (kidney) |
| | AS 0164 | Fodder (dry) of cereal grains | 5 | | 1.5 | 4.8 |
| | MF 0100 | Mammalian fats (except milk fats) | W | 0.01 | 0.01 | 0.02 |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.01 | 0.01 | 0.01 | 0.01 |
| **Prothioconazole-desthio** | ML 0106 | Milks | 0.004* | 0.004* | 0.004 | |
| ADI: 0–0.01 mg/kg bw | AS 0647 | Oat straw, and fodder, dry | W [a] | 2 | | |
| | VD 0070 | Pulses (*except Soya bean, dry*) | 1 | | 0.05 | |
| ARfD: 0.01 mg/kg bw | SO 0495 | Rape seed | 0.1 | 0.05 | 0.02 | |
| (women of childbearing age) | AS 0650 | Rye straw and fodder, dry | W [a] | 2 | | |
| ARfD: 1 mg/kg bw | VR 0596 | Sugar beet | 0.3 | | 0.05 | |
| (general population) | AS 0081 | Straw and fodder (dry) of cereal grains | 4 | | 0.65 | 1.9 |
| | OS 0653 | Triticale straw | W [a] | 2 | | |
| | GC 0654 | Wheat | 0.1 | 0.05 | 0.02 | |
| | CF 1211 | Wheat flour | W | 0.05 | 0.008 | |
| | OS 0654 | Wheat straw | W [a] | 2 | 0.65 | 1.9 |
| | OR 0495 | Rape seed oil, edible | | | 0.014 | |
| | CM 0654 | Wheat bran, unprocessed | | | 0.048 | |
| | CF 1210 | Wheat germ | | | 0.04 | |
| *Definition of the residue (for compliance with MRL and estimation of dietary intake) for plant commodities*: prothioconazole-desthio. | | | | | | |
| *Definition of the residue (for compliance with MRL) for animal commodities*: prothioconazole-desthio. | | | | | | |
| *Definition of the residue (for the estimation of dietary intake) for animal commodities:* the sum of prothioconazole-desthio, prothioconazole-desthio-3-hydroxy, prothioconazole-desthio-4-hydroxy and their conjugates expressed as prothioconazole-desthio. | | | | | | |
| [a] Replaced by commodity group MRL. | | | | | | |
| **Spirodiclofen (237)*** | AM 0660 | Almond hulls | 15 | | 3.5 | |
| ADI: 0–0.01 mg/kg bw | AB 0226 | Apple pomace, dry | 4 [a] | | 3.4 | |
| ARfD: Unnecessary | FC 0001 | Citrus fruits | 0.4 | | 0.13 [b] 0.02 [c] | |
| | SB 0716 | Coffee beans | 0.03 * | | 0.03 | |
| | VC 0424 | Cucumber | 0.07 | | 0.03 | |
| | FB 0021 | Currants, Black, Red, White | 1 | | 0.040 | |
| | DF 0269 | Dried grapes (= Currants, Raisins and Sultanas) | 0.3 [a] | | 0.13 | |
| | MO 0105 | Edible offal (Mammalian) | 0.05 * | | 0 | |
| | FB 0269 | Grapes | 0.2 | | 0.059 | |
| | VC 0425 | Gherkin | 0.07 | | 0.03 | |
| | DH 1100 | Hops, dry | 40 | | 11 | |
| | ML 0106 | Milks | 0.004 * | | 0 | |
| | MM 0095 | Meat (from mammals other than marine mammals) | 0.01 * (fat) | | 0 | |
| | FI 0350 | Papaya | 0.03 * | | 0.03 | |
| | VO 0445 | Peppers, Sweet (including pimento or pimiento) | 0.2 | | 0.08 | |
| | FP 0009 | Pome fruits | 0.8 | | 0.20 | |
| | FS 0012 | Stone fruits | 2 | | 0.315 | |
| | FB 0275 | Strawberry | 2 | | 0.0615 | |

| **Pesticide** (Codex reference number) | **CCN** | **Commodity** | **Recommended MRL mg/kg** | | **STMR or STMR-P mg/kg** | **HR or HR-P mg/kg** |
|---|---|---|---|---|---|---|
| | | | New | Previous | | |
| | VO 0448 | Tomato | 0.5 | | 0.08 | |
| | TN 0085 | Tree nuts | 0.05 | | 0.0155 | |
| | JC 0001 | Citrus juice | | | 0.0065 | |
| | JF 0226 | Apple juice | | | 0.004 | |
| | DF 0226 | Apples, dried | | | 0.018 | |
| | JF 0269 | Grape juice | | | 0.00051 | |
| | - | Wine | | | 0.018 | |
| | | Beer (from hops) | | | 0.011 | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant commodities:* spirodiclofen. | | | | | | |
| *Definition of the residue for compliance with the MRL for animal plant commodities*: spirodiclofen. | | | | | | |
| *Definition of the residue for estimation of dietary intake for animal commodities:* the sum of spirodiclofen and spirodiclofen-enol, expressed as spirodiclofen. | | | | | | |
| *The residue is fat-soluble.* | | | | | | |
| [a] Dry weight basis. [b] Whole fruit. [c] Edible portion. | | | | | | |
| **Zoxamide (227)** | VC 0424 | Cucumber | W [a] | 1 | | |
| ADI: 0–0.5 mg/kg bw | VC 0045 | Fruiting vegetables, Cucurbits | 2 | — | 0.225 | - |
| ARfD: Unnecessary | | | | | | |
| *Definition of the residue (for compliance with the MRL and for estimation of dietary intake) for plant and animal commodities:* zoxamide. | | | | | | |
| [a] Replaced by commodity group MRL. | | | | | | |

Edited versions of these general considerations will be published in the report of the 2009 JMPR. They are reproduced here so that the information is disseminated quickly. These drafts are subject to technical editing.

## *1. Response to specific concerns raised by CCPR*

### *1.1 BOSCALID*

Chlorpyrifos-methyl is registered to be used in peppers and egg plant in Italy at a rate of 0.34–0.45 kg ai/ha (PHI of 15 days) and 0.068–0.09 kg ai/hL in Spain for peppers (PHI of 5 days). Twenty four trials were conducted in Europe from 1999 to 2007 in the field and protected cropping.

Three trials were conducted in southern France, with one in protected cropping matching Spanish GAP, with residues of 0.14 mg/kg at a 5 day PHI.

Boscalid is a systemic fungicide first evaluated by JMPR in 2006 for residues and toxicology as a new active substance. For boscalid an ADI of 0-0.04 mg/kg bw was established while no ARfD was considered necessary. Due to an incomplete data submission for residues in follow crops the Meeting decided that a chronic risk assessment under consideration of residues in rotational crops could not be finalized during the 2006 Meeting. In 2008 additional uses involving banana and kiwifruit were review for residues. In response to the request of the 41st CCPR (ALINORM 09/32/24, para 124) the Meting reconsidered all data available for a finalization of the dietary risk assessment for boscalid.

New data were submitted for metabolism and degradation of boscalid in soil, uptake in follow up crops and livestock feeding to the 2009 JMPR. Further studies, GAP information and supervised residue trials referred to in this document are described in the evaluation of boscalid as a new active substance by the 2006 JMPR.

*Overview on the evaluation procedure for boscalid in rotational crops applied by JMPR*

The Meeting followed the general procedure outlined under point 2.9 in the JMPR Report of 2008. In the first step field decline studies were used to estimated half-live times of boscalid in soil under the assumption of 1st order kinetics. The Meeting identified DT50 values of 208, 365 and 746 days as values representing the total range of possible half-live times of boscalid in soil.

After the estimation of half-live times highest plateau level concentrations of boscalid in soil following annual application according to GAPs reported in 2006 were estimated. The calculation indicated that all uses reported globally, except uses involving 4.5 kg ai/ha and year, resulted in boscalid plateau level residues in soil equivalent to rate of 2.1 kg ai/ha or less.

In the next step field rotational crop studies on various commodities conducted at rates of 2.1 kg ai/ha and year were reviewed to estimate mean, median and highest residues expected following an uptake of boscalid via the roots. These additional residues were compared to boscalid levels found in the corresponding commodities after direct treatment according to GAPs described in the 2006 Report. In case of a significant contribution of residues arising after crop rotation to residues following direct treatment both pathways were taken into account simultaneously for an overall estimation of maximum residue levels as well as for STMR and highest residue values. Whenever appropriate, the Meeting decided to extrapolate its recommendations to whole commodity groups to included as many minor crops as possible probably being subject to crop rotation also.

*Example 1:* Root and tuber vegetables
Based on the use on carrots the following boscalid residues following direct treatment were identified in the roots: < 0.05, 0.06, 0.12, <u>0.17</u>, <u>0.18</u>, 0.19, 0.28, 0.34 mg/kg.

For carrot roots residues were found with mean, median and highest residues of 0.13 mg/kg, 0.065 mg/kg and 0.37 mg/kg, respectively. The Meeting concluded that root and tuber vegetables may be influenced significantly by an additional uptake of boscalid via the roots. It was decided to add the mean residue found in field studies on carrots roots of 0.13 mg/kg to the median residue obtained from supervised field trials on carrot roots of 0.175 mg/kg for an overall STMR for boscalid in carrot roots of 0.305 mg/kg. In addition the Meeting recommends a maximum residue level of 2 mg/kg for the group of root and tuber vegetables, based on the use of boscalid on carrot roots.

*Example 2: Oilseeds*

Based on the use on sunflowers the following boscalid residues following direct treatment were identified in the seeds: < 0.05, 0.08, 0.09, 0.13, 0.16, 0.16, 0.23, 0.45 mg/kg.

In field studies on succeeding crops mean, median and highest residues in alfalfa, soybean and cotton seeds were 0.05 mg/kg, 0.05 mg/kg and 0.06 mg/kg, respectively with most of the values below the LOQ of 0.05 mg/kg. The Meeting concluded that residues in oilseeds due to an additional uptake of boscalid via the roots are insignificant in comparison to residue levels following direct treatment. The Meeting estimated a maximum residue level and an STMR value for boscalid in oilseeds of 1 mg/kg and 0.145 mg/kg respectively based on sunflower seeds.

Due to the high number of commodities subject to crop rotation and new studies submitted to JMPR 2009 a detailed report, a long-term dietary risk assessment and a recommendation table are presented in Chapter 5.

### *1.2 CARBOFURAN--EC Concerns*

At the Forty-first Session of the CCPR (ALINORM 09/32/24, para 85), the delegation of the European Community (EC) raised concerns regarding the ADI and ARfD for carbofuran established by the JMPR in 2008, both these values being higher than those established by the EC.

*Evaluation of carbofuran by the JMPR*

In 2008, the Meeting established an ARfD of 0.001 mg/kg bw based on the "overall NOAEL" (see JMPR Report 2004, p. 9) of 0.03 mg/kg bw per day identified on the basis of inhibition of brain acetylcholinesterase activity in rat pups aged 11 days. This NOAEL was supported by the $BMD_{10}$ (benchmark dose at the 10% effect level) of 0.04 mg/kg bw and the $BMDL_{10}$ (lower 95% confidence limit for the $BMD_{10}$) of 0.03 mg/kg bw extrapolated by the United States EPA (US EPA, 2008a, 2008b) from data on inhibition of brain acetylcholinesterase activity in pups aged 11 days from three studies (Tyl et al., 2005c; Moser et al., 2007b; Hoberman, 2007c). A safety factor of 25 was considered to be appropriate because the acute toxic effects of carbofuran are dependent on $C_{max}$ rather than AUC and data indicated that the sensitivity of acetylcholinesterase activity to inhibition by carbofuran was similar in humans and laboratory animals (rats, dogs) (see JMPR Report 2008, p. 7). The ARfD was considered to be adequately protective of infants and children since it was based on the NOAEL identified in studies in pups aged 11 days.

The 2008 Meeting noted that this ARfD was lower than the ADI of 0–0.002 mg/kg bw. This is plausible in view of the toxicological characteristics of inhibition of acetylcholinesterase activity by carbofuran, which shows very rapid recovery; long-term exposure can thus be likened to a series of acute exposures. The 2008 Meeting therefore concluded that the ADI and ARfD for carbofuran should be based on the same NOAEL and revised the ADI to 0–0.001 mg/kg bw based on the overall NOAEL of 0.03 mg/kg bw from the new studies of acute toxicity in rats and using a safety factor of 25.

*Evaluation of carbofuran by the EC*

The EC also considered the studies of acute toxicity in rats, except for the study by Moser et al. (2007b), as key studies for establishing reference doses. However, the EC emphasized that they did

not consider either the ARfD of 0.001 mg/kg bw or the ADI of 0–0.001 mg/kg bw to be sufficiently protective for neurotoxicity in children. On the basis of the information provided by the EC, the concerns raised by the EC centred on the following issues:

- In the study of Hoberman (2007c), the lowest dose of 0.03 mg/kg bw was considered to be a LOAEL rather than a NOAEL, since brain acetylcholinesterase activity in female pups aged 11 days was inhibited by 20% ($p < 0.01$).
- On the basis of the studies from Tyl (2005c) and Hoberman (2007c), the EC calculated a $BMD_{10}$ of 0.014–0.016 mg/kg bw. This $BMD_{10}$ was considered to be supportive of an extra two-fold safety factor to extrapolate the LOAEL for pups (0.03 mg/kg bw) to a NOAEL (0.015 mg/kg bw).
- The EC noted that a safety factor of 100 should be maintained to derive the ADI and ARfD for carbofuran. EC considered it insufficiently proven that a lower safety factor should be applied based upon the assumption that *N*-methyl carbamate toxicity, which is dependent on a $C_{max}$ rather than an AUC effect, would exhibit lower inter- or intraspecies variability.

In conclusion, the EC concluded that an ADI of 0–0.00015 mg/kg bw and an ARfD of 0.00015 mg/kg bw should be established, based on an extrapolated NOAEL of 0.015 mg/kg bw and a safety factor of 100.

*Comments by the JMPR*

After consideration of the EC concerns and after reviewing the conclusions of the 2008 JMPR, the present Meeting highlighted the following points:

- In one study (Hoberman, 2007c), inhibition of brain acetylcholinesterase activity was 20% in female pups at a dose of 0.03 mg/kg bw. In male pups, however, inhibition was only 13% and data indicated no evidence for a sex-specific difference in sensitivity to inhibition of brain acetylcholinesterase activity by carbofuran. Also, in the corresponding dose range-finding study (Hoberman, 2007a), inhibition of brain acetylcholinesterase activity at a dose of 0.03 mg/kg bw was only 10% or 11% in male and female pups, respectively. Thus, based on data from both studies and for both sexes, the present Meeting considered the dose of 0.03 mg/kg bw to be an overall NOAEL for pups aged 11 days, since inhibition of brain acetylcholinesterase activity was clearly less than 20%.
- The overall NOAEL of 0.03 mg/kg bw is supported by the benchmark-dose analysis of data on brain acetylcholinesterase activity from the three studies in rat pups aged 11 days (Tyl et al., 2005c; Hoberman, 2007c; Moser et al., 2007b). The estimated $BMD_{10}$ for brain acetylcholinesterase activity was 0.04 mg/kg bw, while the $BMDL_{10}$ was 0.03 mg/kg bw. The Meeting considered that the $BMD_{10}$ used by the JMPR was more reliable than that calculated by the EC as it used data from three studies (Moser et al., 2007b; Tyl *et al*., 2005c; Hoberman, 2007c) rather than two (Tyl *et a*l., 2005c; Hoberman, 2007c).
- For carbofuran, the acute toxic effects are dependent on $C_{max}$ rather than AUC and data indicated that the sensitivity of humans and laboratory animals (rats, dogs) to inhibition of acetylcholinesterase activity was similar. Thus the Meeting considered that a safety factor of 25 was appropriate. A detailed rationale for this position is included in the 2008 JMPR Report, page *7: Safety factors for acute Cmax-dependent effects: specific considerations with respect to carbamates such as carbofuran.*

Therefore, the Meeting reaffirmed both the ARfD of 0.001 mg/kg bw and the ADI of 0–0.001 mg/kg bw based on an overall NOAEL of 0.03 mg/kg bw for inhibition of brain acetylcholinesterase activity in rat pups aged 11 days and with a safety factor of 25. Also, the Meeting confirmed that both the ADI and the ARfD are adequately protective of infants and children.

### *1.3 CHLORANTRANILIPROLE*

At the 41st Session of the CCPR, the delegation of the USA raised concerns regarding the reasoning for the maximum residue levels for chlorantraniliprole in grapes and leafy vegetables (spinach) differing from estimates made using the NAFTA calculator (ALINORM 09/32/24, para 126). A concern form was submitted.

The Meeting noted there are many approaches to estimating MRLs including experience, modelling and the use of statistics to evaluate sets of numbers. Experience takes into account the crop varieties used in residue trials and their potential for residues, the number of trials, distribution of trial locations, size of trial plots, timing of spray applications, spray volumes, use of spray additives such as adjuvants, range of half-times for residue decline, the large database of residue of data for other pesticides on the same or similar crops etc. These factors cannot be taken into account in the use of the NAFTA calculator (see General Item 1 this meeting).

Statistical methods use well established mathematical approaches to estimate a number. The NAFTA calculator used by the JMPR uses a decision tree to estimate one of:

- the upper 95% confidence limit for the 95th percentile residue
- the point estimate of the 99th percentile residue
- the mean + 3 × standard deviation

The JMPR has previously suggested that greater than 15 data points are required for application of the above statistical approaches though the NAFTA White paper acknowledges the accuracy of NAFTA estimates for smaller datasets diminishes as sample size decreases (JMPR 2008). The JMPR considered a combination of experience of historical data and statistical methods to arrive at the MRL recommendations.

*Grapes*

Data from seventeen residue trials matching GAP were available with a highest residue of 0.52 mg/kg. The NAFTA calculator estimate was 1.4 mg/kg however, the Meeting noted the data in the Q-Q plot for the data departs from the trend line at the high end of the plot where extrapolation to provide the NAFTA estimate occurs. The Meeting could not conclude the data follow a lognormal distribution. The range of estimates provided by the different options in the NAFTA calculator, prior to rounding, were:

- Assuming the data follow a normal distribution:
- 95% upper confidence level for the 95th percentile 0.61 mg/kg
- 99th percentile (point estimate) 0.59 mg/kg
- Assuming the data follow a lognormal distribution:
- 95% upper confidence level for the 95th percentile 1.64 mg/kg
- 99th percentile (point estimate) 1.39 mg/kg
- Upper prediction level for the 95th percentile assuming a coefficient of variation of 1 0.77 mg/kg
- Non-parametric methods
- Mean plus 3 times the standard deviation 0.70 mg/kg
- EU method II 0.66 mg/kg.

The 2008 JMPR took into account experience of likely high residues at the day of the last spray and use of decline half-lives obtained from the reported residue decline trials (assuming a DT50 of 34 days). Noting the above and the complete range of estimates from the calculator the Meeting recommended a value of 1 mg/kg for grapes.

The Meeting confirmed its previous recommendation of 1 mg/kg for grapes.

*Leafy vegetables (spinach)*

The 2008 JMPR estimated a maximum residue level for leafy vegetables based on a dataset of seven residue trials for spinach with a highest observed residue of 8.9 mg/kg. The NAFTA calculator estimated 15 mg/kg. Visual inspection of the Q-Q plot in the NAFTA calculator did not enable the Meeting to conclude the data follow a lognormal distribution. The range of estimates provided by the different options in the NAFTA calculator, prior to rounding, were:

- Assuming the data follow a normal distribution:
- 95% upper confidence level for the 95$^{th}$ percentile 13.1 mg/kg
- 99$^{th}$ percentile (point estimate) 11.31 mg/kg
- Assuming the data follow a lognormal distribution:
- 95% upper confidence level for the 95$^{th}$ percentile 19.98 mg/kg
- 99$^{th}$ percentile (point estimate) 14.5 mg/kg
- Upper prediction level for the 95$^{th}$ percentile assuming a coefficient of variation of 1 64 mg/kg
- Non-parametric methods:
- Mean plus 3 times the standard deviation 12.7 mg/kg
- EU method II 16.6 mg/kg.

As with grapes, the 2008 JMPR took into account experience of likely high residues at the day of the last spray the decline half-lives obtained from the reported residue decline trials (DT50 time of 14 days). Noting the range of estimates available using the NAFTA calculator, the small dataset and the results based on an estimate from the day of the last spray, the 2008 JMPR estimated a maximum residue level of 20 mg/kg.

The Meeting confirmed its previous recommendation of 20 mg/kg for leafy vegetables.

The current Meeting also reiterated that for small datasets the NAFTA White paper and reviews of the performance of the calculator suggest a large uncertainty in such estimates of high percentiles (JMPR 2008). Use of other tools and experience is needed to ensure the MRL estimates are realistic.

### *1.4 CYFLUTHRIN (157)/BETA-CYFLUTHRIN (228) – ALTERNATIVE GAP*

Cyfluthrin and beta-cyfluthrin were evaluated for toxicology (JMPR 2006) and residues (JMPR 2007) under the periodic review programme, and maximum residue levels for cyfluthrin, arising from the use of either cyfluthrin or beta-cyfluthrin on a number of commodities, were recommended.

The 2007 JMPR estimated short-term intakes for children that exceeded the ARfD of 0.04 mg/kg bw for broccoli and head cabbage and noted that there was insufficient data to support an estimation of lower maximum residue levels based on alternative GAPs for these commodities.

At the 41st Session of the CCPR in 2009, the Committee agreed that if no data were available to support lower MRLs for broccoli and head cabbage (based on alternative GAP), the draft MRLs would be considered for withdrawal at the 2010 session (ALINORM 09/32/24, para 106-107).

Information on current GAP and new supervised trials data from Indonesia were provided to the 2009 JMPR for cabbages but no new residue data or information was available for broccoli.

***Results of supervised trials on crops***

Based on US GAP and residue data for cyfluthrin, the 2007 JMPR estimated a maximum residue level of 4 mg/kg, an STMR of 0.25 mg/kg and an HR of 2.1 mg/kg for cyfluthrin in cabbage (head) but estimated that the short-term intake for children was 240% of the ARfD (0.04 mg/kg bw).

*Cabbage (Head) – beta-cyfluthrin*

Residue trials conducted in Germany matching the GAP of Sweden and Poland (10 g ai/ha, PHI 7 days) and evaluated by the 2007 JMPR, reported residues of < 0.01, < 0.01, 0.06 and 0.08 mg/kg.

New trials with beta-cyfluthrin reported to the Meeting from Indonesia (GAP 15 g ai/ha, PHI 7 days) reported residues of < 0.01, 0.02 and 0.05 mg/kg.

The Meeting agreed that the data were insufficient to estimate a maximum residue level to support an alternative GAP for beta-cyfluthrin on cabbage (head).

*Cabbage (Head) – cyfluthrin*

Residue trials with cyfluthrin conducted in Portugal and Spain, matching the GAP of Italy (25 g ai/ha, PHI 3 days) reported residues of 0.01 and 0.09 mg/kg.

Trials conducted in Germany, matching the GAP of Belgium (max 2 applications, 25 g ai/ha, PHI 14 days) reported residues of < 0.01, 0.02 and 0.06 mg/kg.

The Meeting agreed that the data were insufficient to estimate a maximum residue level to support an alternative GAP for cyfluthrin on cabbage (head).

Alternative GAP was considered by the present Meeting, but the previous HR recommendation was confirmed because of insufficient residue data. Hence, a refinement of the IESTI is not possible with the current data. The Meeting established a group ARfD for cyfluthrin and beta-cyfluthrin in 2006 based on acute neurotoxicity observed in a 4 week study in rats and a safety factor of 25 and it is unlikely that it could be refined.

## 1.5 FENTHION (39)

Fenthion is an insecticide used since 1957 for the control of a wide range of insect pests in fruit, vines, olives, vegetables, cotton, tea, sugar cane, beet, and rice. The use pattern also includes the postharvest disinfestation of fruit, the control of insect pests (e.g. mosquitoes, fleas) for public health purposes and animal houses and for the control of animal ectoparasites.

*Evaluation of fenthion by the JMPR*

Fenthion was first evaluated by the Joint Meeting in 1971 and has been reviewed several times since, in 1995 within the periodic review programme of the CCPR. An ADI of 0-0.007 mg/kg bw was established.

JMPR 2000 could not evaluate studies of residues in peaches, cherries and olives, since the trials were performed in EU countries and the related GAP in the European Union was pending.

*Consideration of fenthion by CCPR and the EU*

The 34th session of CCPR in 2003 noted that the current CXLs are mainly based on EU uses, and that fenthion was under evaluation in the EU (ALINORM 03/24, para 80-81).

In 2004, the EU decided not to include fenthion in Annex I of Directive EC/ 91/414, implicating that all fenthion uses within the EU would stop. Since the current CXLs are based on European use labels and European supervised field trials, CCPR considered to revoke all existing CXLs.

The 40th session of CCPR in 2008 noted that GAP information for cherries; citrus fruit and olives would be provided by Australia and decided to maintain the CXLs for cherries; citrus fruits;

olives and olive oil, virgin for 4 years under the periodic review procedure. The Committee also decided to delete the proposed MRLs for olive oil, virgin; mandarins and orange, sweet, sour, since they were based on European uses (ALINORM 08/31/24, para 50-51).

*Comments by JMPR*

The current meeting did not receive any data to evaluate, and noted that fenthion is not scheduled for periodic re-evaluation until 2017.

### *1.6 METHOMYL*

At the 41st session of CCPR in 2008 (ALINORM 09/32/24 para 78), the Committee noted the acute dietary intake concerns expressed by the EC and Norway for grape and tomato, based on the EC Acute Reference Dose established. The Delegation of the EC informed the Committee that they would submit a concern form for apple.

*Evaluation of methomyl by the JMPR*

Methomyl is a carbamate insecticide which is registered throughout the world for foliar application on numerous agricultural crops. JMPR has evaluated the compound several times since 1978. In 1989, an ADI of 0-0.03 mg/kg bw was established and in 2001, the Meeting was requested to establish an ARfD. The Meeting allocated an ARfD of 0.02 mg/kg bw based on a human volunteer study. The Meeting noted that this ARfD was lower than the ADI, and concluded that the ADI and ARfD should be based on the same NOAEL. The ADI was revised to 0-0.02 mg/kg bw accordingly.

Methomyl was evaluated for residues under the periodic review programme in 2001. Maximum residue levels for methomyl, arising from the use of either methomyl or thiodicarb, were recommended for a number of crops. The 2001 JMPR estimated short-term intakes that exceeded the ARfD of 0.02 mg/kg bw for apples, broccoli, Brussels sprouts, head cabbage, cauliflower, celery, water melon, grapes, kale, head lettuce, leaf lettuce, spinach, sweet corn and tomato.

The 38th Session of the CCPR in 2006 (ALINORM 06/29/24 para 80-81) requested JMPR to consider using alternative GAPs to recommend lower MRLs for apples, brassica vegetables, celery, fruiting vegetables, cucurbits, grapes, leafy vegetables and pears. JMPR 2008 was able to recommend maximum residue levels for apple, pear, cucurbits (cucumbers, courgettes and melons), grapes, lettuce and tomatoes. Most of the recommendations were based on European data. No new residue data or information was available for brassica vegetables and celery and the 2008 Meeting withdrew its previous recommendations for those commodities.

The International Estimated Daily Intakes in the 13 GEMS/Food cluster diets, based on the estimated STMRs as estimated by the 2008 JMPR were in the range 0–3% of the maximum ADI of 0.02 mg/kg bw. The IESTI varied from 0–50% of the ARfD (0.02 mg/kg bw) for the general population. The IESTI varied from 0–100% of the ARfD for children 6 years and below. The highest percentages (50% of the ARfD for general population, 100% of the ARfD for children) were found for tomatoes. The Meeting concluded that the long-term nor the short-term intake of residues of thiodicarb and methomyl from uses that have been considered by the JMPR is unlikely to present a public health concern.

*Evaluation of methomyl by the EU*

The present Meeting received the EC concern form, together with the EU dietary intake calculation results. The following information was presented: 'Using EC endpoints (ARfD 0.0025mg/kg bw/day) and risk assessment methodologies (EFSA model PRIMo rev2), apples are 666% of the ARfD[3], using an HR value of 0.17 mg/kg (15 trials). It is acknowledged that a higher ARfD of 0.01 mg/kg bw/day is accepted by JMPR, based on a human volunteer study. Even using the JMPR ARfD with EC risk assessment methodologies, apples are 167% of the ARfD.'

[3] For children

*Comments by JMPR*

The Meeting noted that the JMPR ARfD is 0.02 mg/kg bw, not 0.01 mg/kg bw as was incorrectly reported in the EC concern form. Furthermore, the Meeting noted that using the JMPR ARfD with the EC risk assessment methodologies, the short-term intake (children; Large Portion for UK infant 180 g/person) for apples was 83% when using a variability factor of 7, while it was 61% of the ARfD when using a variability factor of 5. The Meeting, using a variability factor of 3, calculated a short-term intake of 60% of the ARfD for children, based on a Large Portion size for children from the USA of 680 g/person.

Te Meeting confirmed that the short-term intake of residues of thiodicarb and methomyl from uses on apple is unlikely to present a public health concern.

### *1.7 PHORATE*

Phorate is a systemic organophosphate contact insecticide and acaricide that inhibits acetylcholinesterase activity. Residue and analytical aspects of phorate were evaluated by the JMPR in 1977, 1984, 1990, 1991, 1992, and 2005. The evaluation in 2005 was a periodic review. The toxicological periodic review was conducted in 2004, when an ADI of 0–0.0007 mg/kg bw and an ARfD of 0-0.003 mg/kg bw were established.

The residue definition for phorate, both for enforcement and for risk assessment for animal and plant commodities, is: Sum of parent, its oxygen analogue, and their sulfoxides and sulfones, expressed as phorate. The analytical methodology available relies on the oxidation of all phorate-related residues to the common moiety metabolite, phoratoxon sulfone.

JMPR 2005 noted that the acute dietary intake of potato by children up to 6 years amounted to 120% of the ARfD. The value of 120% represents the IESTI for potato, microwaved with peel. CCPR 2006 therefore decided not to advance the maximum residue level in the Codex step system. CCPR 2007 was informed that the manufacturers would provide additional data for processed potato in 2008 for evaluation by the 2009 JMPR.

The present Meeting received a new processing study in potatoes to enable a refinement of the risk assessment.

#### *Methods of analysis*

Total phorate-related residues (oxidizable to phoratoxon sulfone) were determined by GC-FPD, following method M-1620 (see JMPR 2005 evaluation). The reported LOQ was 0.049 mg/kg eq, the LOD was 0.003 mg/kg eq. Method verification recoveries at 0.049; 0.25 and 2.0 mg/kg eq. were for each fortification level above 90% (n=3, RSD < 4%).

#### *Fate of residues in storage and during processing*

The Meeting received new information on the fate of incurred residues of phorate during washing and microwave cooking of potatoes. The samples from the field studies were analysed twice, due to the variable results in the first experiment. The reason for this was thought to be as follows. The application of phorate in this study was as an in-furrow granule. As a result, it is possible that potatoes formed directly in the furrow accumulated more phorate, both on the surface, including adhered soil, and internally, than potatoes formed outside the treated furrow. In order to get a representative field sample, the potatoes were sampled from directly in the row (in the furrow where the insecticide was applied) as well as from the sides of the row. Each collected treated sample contained random potatoes from both areas, with potentially great variability in residue content between potatoes used in each processing step. The Meeting considered this to be a plausible explanation for the variable results.

The second experiment was modified to reduce this potential variability between potatoes used in each processing step, by direct pairing of potatoes/ potato parts across the unwashed versus washed and cooked samples. For the second processing set, the frozen whole potato retain samples held by the processing facility were utilized for processing.

Mean weight loss for the potatoes during cooking in processing experiment 2 (66%, mean of treated samples) was significantly higher than the weight loss in processing experiment 1 (15%). For microwaving, 15–20% is the commercial norm. Projected residues at 15% weight loss to correct for excess weight loss due to frozen storage of potatoes before processing were reported by the study director.

The Meeting decided that the experiment where frozen potatoes with peel were microwaved does not reflect common practices. The Meeting could not confirm that the extensive weight loss did not result in an unusual loss of phorate residues. The Meeting decided not to use the results of the new processing study, and confirmed its previous recommendations.

Using the HR for potato (0.27 mg/kg,) the 2005 Meeting estimated HR-Ps for the processed commodities as listed below. Furthermore, using the STMR for potato (0.05 mg/kg) the Meeting estimated STMR-Ps for these commodities.

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| Commodity | Processing factors | Processing factor (median or best estimate) | STMR-P | HR-P |
|---|---|---|---|---|
| Potatoes boiled with peel | 0.13 | | 0.0065 | 0.0351 |
| Potatoes boiled without peel | 0.11 | | 0.0055 | 0.0287 |
| Potatoes baked with peel | 0.28 | | 0.014 | 0.0756 |
| Potatoes baked without peel | 0.27 | | 0.0135 | 0.0729 |
| French fries | 0.38 | | 0.019 | 0.1026 |
| Potatoes microwaved with peel | 0.36 | | 0.018 | 0.0972 |

The 2005 Meeting decided to use the HR-P and STMR-P on potatoes, microwaved with peel in the dietary intake calculations for potatoes since this represented the worst-case situation.

The present Meeting noted that the dietary intake of French fries would also be critical.

## DIETARY RISK ASSESSMENT

### *Long-term intake*

*Conclusion from JMPR 2005:*

The International Estimated Daily Intakes (IEDI) of phorate, based on the STMRs estimated for 18 commodities, for the five GEMS/Food regional diets were in the range of 9 to 20% of the maximum ADI (0-0.0007 mg/kg bw). The Meeting concluded that the long-term intake of residues of phorate resulting from its uses that have been considered by JMPR is unlikely to present a public health concern.

### *Short-term intake*

The International Estimated Short Term Intake (IESTI) for phorate was calculated for potatoes, both by using the HR for potatoes, microwaved with peel and for French fries.

The IESTI represented 70% of the ARfD (0.003 mg/kg bw) for the general population (both for potatoes, microwaved with peel and for French fries ) and 170% and 180% of the ARfD for children, from consumption of potatoes, microwaved with peel and French fries, respectively. The information provided to the JMPR precludes an estimate that the dietary intake of potatoes by children 6 and below would be below the ARfD.

The Meeting noted that the intake estimation is already based on residues in processed potatoes, leaving little room for refinement. Furthermore, the ARfD is based on a single-dose study and therefore it is unlikely that it could be refined.

### *1.8 PROCYMIDONE – EC Concerns*

At the 40th Session of the CCPR, the delegation of the European Community (EC) raised concerns regarding the ADI and ARfD for procymidone established by the JMPR in 2007, which were higher than those established by the EC.(Alinorm 08/31/24, para 73)

*Evaluation of procymidone by the JMPR*

In 2007, the Meeting established an ADI of 0–0.1 mg/kg bw for procymidone based on the overall NOAEL of 12.5 mg/kg bw per day identified on the basis of hypospadias and alterations in testes, prostate and epididymis weights in two studies of reproductive toxicity in rats and a study of developmental toxicity in rats, with a safety factor of 100. The ADI was supported by NOAELs of 14 mg/kg bw per day in a long-term study in rats and 17 mg/kg bw per day in a long-term study in mice. An ARfD of 0.1 mg/kg bw was established based on the NOAEL of 12.5 mg/kg bw per day identified on the basis of hypospadias in a study of developmental toxicity in rats, with a safety factor of 100. The 2007 Meeting concluded that the effects on organ weights seen in studies of reproductive toxicity were largely a consequence of postnatal exposure over a period of time and therefore not appropriate for the establishment of an ARfD.

*Evaluation of procymidone by the EC*

The concern raised by the EC, as stated on the concern form, was that procymidone and its metabolite (PCM-CH2OH) bind to the human androgen receptor in vitro, indicating that procymidone has antiandrogenic activity in humans. Since data on toxicokinetics in humans still do not exist, it was concluded that it cannot be excluded that human exposure to procymidone would not lead to teratogenic effects. The EC also noted that procymidone is classified as "Repr. Cat. 2 R61[4]" in the EC.

The documentation submitted by the EC cited two sets of reference doses for procymidone. The first set of reference doses was agreed following an expert toxicology meeting and are the agreed values cited in the 'Review Report' supporting the authorization of procymidone (EC 2006). These values comprise an ADI of 0.025 mg/kg bw based on a NOAEL of 2.5 mg/kg bw per day from a study of reproductive toxicity in rats, with a safety factor of 100, and an ARfD of 0.035 mg/kg bw based on the NOAEL of 3.5 mg/kg bw from a study of developmental toxicity in rats, with a safety factor of 100.

The second set of reference doses was proposed in an addendum produced by the rapporteur member state (France) in 2007, which had not been discussed by EC toxicologists at any peer review meetings. The ADI of 0.0028 mg/kg bw was based on a LOAEL of 2.5 mg/kg bw per day from a study of reproductive toxicity in rats, with a safety factor of 900 (3 for moving from a LOAEL to a NOAEL; 3 for interspecies variability; 10 for intraspecies variability and 10 for severity of effect). The ARfD of 0.012 mg/kg bw based on the NOAEL of 3.5 mg/kg bw from a study of developmental toxicity in rats, with a safety factor of 300 (3 for interspecies variability; 10 for intraspecies variability and 10 for severity of effect).

The available information provided by the EC gave no detailed rationale for:

- the effects seen at the LOAELs used in the first evaluation;
- changing from a NOAEL to a LOAEL in the study of reproductive toxicity;
- the reduction of the default interspecies safety factor;
- the additional safety factor for severity.

[4] May cause harm to the unborn child. Toxic to reproduction, Category 2 - i.e. likely to be relevant to humans.

*Comments by the JMPR*

In order to respond as thoroughly as possible to the concerns raised, the 2009 JMPR went to considerable lengths to obtain more detailed information on the basis for the EC concerns, as these were not clearly described or justified on the concern form or submitted documents. The Meeting requested that any future concerns submitted to JMPR are accompanied by comprehensive and transparent supporting information.

The 2007 JMPR and 2007 EC appear to have had access to the same supporting databases. The 2007 JMPR discussed the reproductive effects of procymidone in great depth (performing its own benchmark-dose calculations for some end-points) and concluded that procymidone was a reproductive toxicant and could bind to the human androgen receptor in vitro. The 2007 JMPR also considered in depth the data on the toxicity of procymidone metabolites and the data on toxicokinetics in rats, rabbits and monkeys and their relevance to human exposures.

The main differences between the evaluations made by the 2007 JMPR and the EC are the NOAELs identified, and in the 2007 EC proposals, the safety factors chosen. The present Meeting reviewed tabulated data on a number of end-points, including all those identified in additional EC documents as being the basis for identifying the NOAELs used to set the EC reference doses. These end-points included anogenital distances, testes, prostate, epididymis and seminal vesicle weights, hypospadias, undescended testes and histopathology of testes, epididymides, coagulating glands, prostate and seminal vesicles. The present Meeting also reviewed the publications describing the 2007 JMPR decisions.

The present Meeting noted that the monograph produced by the 2007 JMPR described some effects at the intermediate dietary concentration of 250 ppm (17 mg/kg bw per day), which would give a NOAEL of 3.0 mg/kg bw per day (50 ppm) identified in the first study of reproductive toxicity. However, these findings were not evident at the NOAEL of 14 mg/kg bw per day in the long-term study in rats, for the parental effects, nor at the NOAEL of 12.5 mg/kg bw per day in the subsequent study of reproductive toxicity, for the pup effects. The present Meeting confirmed that the overall NOAEL from the studies of reproductive toxicity in rats was 12.5 mg/kg bw per day based on the NOAELs that were between the LOAEL and NOAEL for the first study of reproductive toxicity. The present Meeting noted that most of the findings mentioned in EC documents were not seen below doses of 37 mg/kg bw per day.

In the study of developmental toxicity in rats, the only finding at 12.5 mg/kg bw per day was a statistically significant (but < 10%) change in anogenital distance in male fetuses removed by caesarean section. However, in the part of this study where dams were allowed to deliver naturally, there were no significant effects on anogenital distance at postnatal days 1 or 21 in the group at 12.5 mg/kg bw per day. The present Meeting confirmed that the findings at 12.5 mg/kg bw per day were not adverse and identified this dose as the NOAEL.

The EC addendum gives no explanation for the choice of the non-default safety factors for interspecies (3) and severity (10). The 2007 JMPR discussed the use of a data-derived safety factor when deriving the ARfD for procymidone, but concluded that the uncertainties were such that this was not justifiable. The 2007 JMPR considered that the findings at the LOAELs were such that no additional safety factors were needed to derive the ARfD and ADI. The present Meeting confirmed that a safety factor of 100 was appropriate for deriving both the ADI and the ARfD for procymidone.

The present Meeting reaffirmed the ADI for procymidone of 0–0.1 mg/kg bw based on the overall NOAEL of 12.5 mg/kg bw per day from two studies of reproductive toxicity in rats and an ARfD for procymidone of 0.1 mg/kg bw based on the NOAEL of 12.5 mg/kg bw per day in a study of developmental toxicity in rats, both with a safety factor of 100.

European Commission (2006) Review report for the active substance procymidone. Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 27 January 2006 in view of the inclusion of procymidone in Annex 1 of Directive 91/414/EEC. SANCO/4064/2001 rev 1, dated 19 January 2006. European Commission Health and Consumer Protection Directorate-General. Draft working document.

### *1.9 Spirotetramat*

At the 41st Session of the CCPR the Delegation of the USA expressed concern over the maximum residue level estimation of 0.5 mg/kg made by the 2008 JMPR and submitted a Concern Form. The USA noted that there were 11 trials (USA) and that the NAFTA calculator produced an estimate of 0.3 mg/kg in the USA from the same data set. An explanation of the derivation of the JMPR estimate was requested and a request was made to consider 0.3 mg/kg as a revised estimate.

*Consideration and Response*

The supervised field trial data were from US trials conducted on almonds and pecans. The results in ranked order were: 0.020 (3), 0.031, 0.048, 0.054, 0.082, 0.089, 0.094, 0.13, 0.25 mg/kg (2008 JMPR Report, page 333).

The high residue (HR) is 0.25 mg/kg, and thus the MRL would be somewhat greater than 0.25 mg/kg. The median was 0.05 mg/kg. All values exceed the limit of quantitation.

The Meeting noted that only 11 sample values were available for combined almond and pecan field trial sample results. The value of 0.5 mg/kg was based upon the consideration of a relatively small number of trials, meaning that one or more high residue values may have been missed in the limited crop field trials conducted, and on the need to cover possible residues from nut varieties of the tree nut group that were not included in the limited trials on pecans and almonds only.

The Meeting considered the results of the NAFTA statistical calculation spreadsheet. It provided estimates in the range of 0.3–0.6 mg/kg depending on the distribution selected. The spreadsheet selected UPL median 95th value (0.3 mg/kg). This reflects the spreadsheet decision that the distribution is log normal, but *due to the small number of data points* a diversion from the log normal 99 estimate (0.4 mg/kg) and the log normal 95/95 value (0.6 mg/kg) is made.

The Meeting also noted that while the JMPR used the same data set as used in the USA there are differences in the treatment of that data that could lead to different estimates from the NAFTA calculator. The USA would have 22 residue values because of the procedure of using two data points per trial location. This inclusion of duplicate points no doubt would result in the use of the log normal 99 or log normal 95/95 value. The Meeting has rejected this approach, as it believes that samples from the same plot at the same site are not independent. It uses the highest residue from each trial site.

Furthermore, the Meeting decided that statistical methods may not be appropriate for data sets of less than 15 values (2008 JMPR Report, General Consideration 2.8, page 40). Examples show the uncertainty of the estimation based on a small number of residue data points, and this uncertainty and likelihood of underestimating the maximum residue limit is clearly explained in the *Canada/US White Paper* for the NAFTA Calculator.

The Meeting considered that given the small data set with HR of 0.25 mg/kg and the need to extrapolate pecan and almond data to all nuts, the maximum residue level should be estimated at 0.5 mg/kg. The lowest possible estimate could not be 0.3 mg/kg, as this was seen as too restrictive based on the few trial results available and the extrapolation to nut varieties with no trial data.

The Meeting confirmed its previous recommendation of 0.5 mg/kg for spirotetramat on tree nuts.

### *1.10 Triadimefon (133) and Triadimenol (168)*

Triadimefon and triadimenol were evaluated by the JMPR in several years from 1978 to 2007. The compounds were re-evaluated for periodic review in 2007 for residues and in 2004 for toxicology. The Meeting recommended a number of MRLs and established an ADI of 0-0.03 mg/kg bw and an ARfD of 0.08 mg/kg bw for both compounds. In 2008 the 40th session of the CCPR the Committee requested JMPR to consider using alternative GAPs because of dietary intake concerns to recommend a lower MRL for grapes.

Information on current GAPs submitted to the 2008 JMPR included a companies statement that the GAP from Taiwan is no longer supported.

*Results of supervised residue trials on crops*

For triadimefon and triadimenol GAP information on grapes were submitted to the Meeting being similar to the GAPs the re-evaluation for periodic review in 2007 was based on. Although the GAP from Taiwan no longer supported by the company was available in 2007, the evaluation of supervised residue trial data were based on uses reported from Belarus, Croatia, Kazakhstan, Macedonia, Russia, South Africa and the United States (triadimefon) as well as Australia, Bulgaria, Cyprus, France, Georgia, Italy, Moldavia, New Zealand, South Africa and the Ukraine (triadimenol). None of these GAPs have be revised to allow a re-evaluation in view of an alternative GAP approach.

The 2007 Meeting considered all supervised field trials available for grapes and decided to combine all residue data, since due to the high variability within the crop field trial data could not be attributed to one specific GAP. Residue data selected in 2007 were: < 0.02(3), 0.03, < 0.04, < 0.04, 0.04(3), < 0.05(5), 0.05, 0.05, 0.06, 0.06, 0.07(4), 0.08, 0.08, 0.09(3), 0.1, 0.1, 0.11, 0.11, 0.15(4), 0.16, 0.17, 0.18, 0.21, 0.25, 0.27, 0.27, 0.28, 0.3, 0.32, 0.33, 0.36, 0.37, 0.43, 0.46, 0.54, 0.58, 0.59, 0.6, 0.6, 0.69, 0.78, 0.78, 0.8, 1.4, 1.7, 1.9 and 3.2 mg/kg (sum of triadimefon and triadimenol).

The HR of 3.2 mg/kg was based on one supervised field trial conducted with triadimefon according to the GAPs reported for Croatia and Macedonia using an application rate of 0.0025 kg ai/hl with a PHI of 35 days. This GAP represents the lowest application rate in combination with the highest PHI reported for all uses of triadimefon and triadimenol on grapes.

The second highest residue found in grapes of 1.9 mg/kg followed the use of triadimenol according to GAP reported from South Africa using 0.12 kg ai/ha (0.0075 kg ai/hl) with a PHI of 14 days.

The third highest residue of 1.7 mg/kg is based on a supervised field trial conducted with triadimefon according to the GAP reported from Belarus and Kazakhstan (0.0075 kg ai/hl, PHI: 30 days).

In view of this consideration the Meeting concluded in 2007 that an alternative GAP approach is not applicable to uses of triadimefon and triadimenol on grapes. Based on the uses of both triadimefon and triadimenol the Meeting confirms its previous recommendation and estimated an STMR value of 0.15 mg/kg, an HR value of 3.2 mg/kg and a maximum residue level of 5 mg/kg for the sum of triadimefon and triadimenol in grapes.

*Comment by the JMPR*

The Meeting concluded that an alternative GAP approach for the use of triadimefon and triadimenol on grapes is not possible since high residues would arise from all available GAPs, and confirmed the dietary risk assessment already presented in the re-evaluation in 2007.

The Meeting noted that the IESTI calculation for grapes at the HR level of 3.2 mg/kg, as well as the consumption of grapes at a level of 1.9 mg/kg and 1.7 mg/kg will lead to an exceedance of the ARfD.

The Meeting noted that although the ARfD is based on a study of acute neurotoxicity in rats given triadimefon and a safety factor of 25, the large dose spacing between the NOAEL and the LOAEL suggests possibility of a refinement of the ARfD (e.g. by benchmark dose calculations).

***2. Transparency in MRL estimation process - further considerations***

The 41st Session of the CCPR discussed transparency in the maximum residue level estimation process of the JMPR, as a response to 'General consideration 2.7' in the JMPR 2008 Report. JMPR 2008 had, in addition to its usual procedure, used the NAFTA MRL calculator to estimate maximum residue levels and had produced a summary table where it was explained when JMPR estimates differed from estimates derived by the NAFTA calculator.

CCPR recommended "that for the 2009 JMPR meeting the OECD statistical calculation method would be used, if available, and if not available the NAFTA calculator method would continue to be used and reported and, to the extent possible, brief explanations of derivation of the

MRLs would be provided when the calculator was not used" (ALINORM 09/32/24, para 30-45). The Meeting decided that, instead of producing a summary table for these cases, it would provide for each pesticide/commodity maximum residue level recommendation additional explanation on how the value was derived.

The 2009 JMPR noted that the MRL is the maximum residue anticipated in a commodity if produced following good agricultural practice. The process of estimation of a maximum residue level involves selection of residue trials conducted according a critical GAP. It is generally the highest observed residue value that has the greatest influence on the estimated MRL. Small datasets, those with less than 15 data points, represent a particular challenge in estimating maximum residue levels. The JMPR has previously noted that estimated 95$^{th}$ or 99$^{th}$ percentiles based on statistical methods are increasingly inaccurate with decreasing size of data sets below 15 and such estimates should not be automatically used. The Meeting agreed that for larger datasets the estimates provided using statistical methods are generally acceptable. Data available to the JMPR generally have additional limitations that can compromise the ability to use statistical approaches including whether the trials represent a random sample. Some of these limitations have previously been elaborated in reports of the JMPR, principally in 2008.

The JMPR employs expert judgement informed by available tools such as statistical approaches to estimate maximum residue levels. The following provides further discussion of factors the JMPR takes into account as part of its application of expert judgement.

Experience leads to an understanding of the uncertainties in the parameters involved in maximum residue level estimation. A range of information is considered and it is a question of finding the best value and making the best decision from all the available evidence. The initial deposit of a pesticide on a crop is the best indicator of the proper application of a pesticide when the edible part of the crop is present and well-developed at the time of application. For example, analysis of available data for pesticides enabled estimates to be made for the upper limits and ranges of initial deposits for many crops (Bates JAR. 1990. The prediction of pesticide residues in crops by the optimum use of existing data. Pure & Applied Chemistry 62:337-350). Various factors beyond those used in statistical calculation such as the examples listed below may be taken into account in the estimation of MRLs.

| **Issue or factor** | **Action or comment** |
|---|---|
| Accumulated data on the distribution of residues from supervised trials for residues of pesticides on a crop provide a reliable basis for the likely spread of residues within a dataset. It complements the limited information which can be obtained from small data sets usually available. | The Meeting regularly considers the typical distribution of residues between trials, including initial deposits, and where limited trial data are available for a particular pesticide crop combination, adjusts the estimated MRL appropriately. |
| Some of latitude is allowed in how close trials comply with GAP in selecting the dataset for maximum residue estimation (typically change in parameters leading to ±25% change in residues), if the majority of trials have been conducted at the lower or higher ends of the range used to select data this should be taken into account when recommending an MRL | The Meeting makes an allowance to account for how close the majority of selected residue trials match the critical GAP |
| Residues resulting from rates of application higher and lower than GAP as well as metabolism studies are taken into account in the context of the use to predict a pattern of likely residue concentrations, but are not used directly in the set of numbers that support an MRL or in the risk assessment. | These values may provide information on situations where no residues are expected or provide information as to whether residues scale with application rate. |
| Noting the effect of crop growth stage where this aspect is particularly important. Examples of this are the herbicides haloxyfop and glyphosate where data selection concentrates on the growth stages that might occur prior to the PHI rather than the time before harvest itself. | This example underlines the importance of expert judgement in selecting the suitable residue data for estimation of residue levels. |

| Issue or factor | Action or comment |
|---|---|
| Should greater weight be given to different data within a dataset to account for differences between commercial practice and available trial conditions, for example varieties or cultivars grown, crops grown under protected cover versus field grown crops? | The JMPR may take into account the varieties and cultivars used in the available residue dataset. Allowances may need to be made in MRL estimates depending on the range of varieties used in the trials. For example if no trials have been provided on small tomato varieties a higher MRL might be recommended. |
| Whether or not the trial data are representative of differences in cultural practices (orchard and vine crop production techniques, planting density, hedging versus spindal versus vase etc) | The JMPR may make an allowance for the unavoidable bias in the cultural practices observed in the residue trials available |
| Whether or not the trial data are representative of differences in application equipment | The JMPR may make an allowance for the unavoidable bias in the application equipment observed in the residue trials available |
| Data from trials on one crop are sometimes extrapolated to other members of a crop group or used to recommend an MRL for the entire group. | The JMPR may need to make allowances for differences in crops when making recommendations based on extrapolation or for group MRLs |
| For post-harvest use of grain protectants, the application rates of the active ingredient provide a precise estimate of expected residue levels at time of application. Additionally, the Meeting generally gives greater weight to commercial size trials over laboratory scale trials | The JMPR may recommend MRLs at the application rate as residues higher than the amount added are not expected |
| Foliar application of a non-systemic pesticide to certain crops (root and tuber, cotton, nuts) may result in occasional residues on the harvested commodity due to the commodity sometimes being exposed to direct spray (e.g. some cotton bolls open etc) | The Meeting may recognise this in estimating maximum residues. |
| Commercial shelling of nuts may give rise to low level residues in nutmeat that need to be taken into account | The Meeting may recognise this in estimating maximum residues for tree nuts |

It is possible that innovation will lead to new methods such as predictive models for residues on crops and derived commodities that might allow improved estimation of maximum residue levels.

*Conclusion*

The above examples of how the JMPR uses expert judgement indicate that evaluation of residue data is a complex task which requires the consideration of factors and parameters in addition to the numerical residue values. Consequently, MRL estimates cannot be based solely on automatic calculation using any currently available 'statistical' methods.

### *3. Guidance for data submission for estimation of residue levels in/on spices*

In response to the request of the 34th Session of the CCPR, the 2002 JMPR considered the options for estimating maximum residue levels for spices based on monitoring data (JMPR Report 2002 section 2.7.) and provided guidance on the format for reporting such data. As the 35th Session of the CCPR decided to elaborate MRLs based on monitoring data (Paras 187-200, ALINORM 03/24A, 2003), the 2003 Meeting (Report 2.5) gave further consideration to possible options for estimating maximum residue levels where sufficient monitoring data were not available and prepared guidelines for conducting selective surveys to generate pesticide residue data reflecting the field and post-harvest application of pesticides.

The 2004 JMPR (Report 2.6) considered the nature of monitoring results and defined the basic principles for evaluation of monitoring data to estimate maximum residue levels. The Meeting recommended maximum residue levels which encompasses at least 95% of the residues with 95% probability (in 95% of cases). To satisfy this requirement, a minimum of 59 residue data for each spice commodity pesticide residue combination is required.

The Meeting further recommended that monitoring results should not be used for estimating maximum residue levels that reflect post-harvest use, which results in much higher residue values than foliar application or exposure to spray drift.

The present Meeting noted that the guidance given in the previous reports might have been misinterpreted and, as a consequence, the residue data submitted were insufficient for evaluation.

In order to assist collection and submission of the appropriate information, the Meeting reemphasizes that:

(a) The minimum data required for each pesticide - spice commodity combination is 59.

(b) Where residue data are available for several spice commodities belonging to one spice group, the JMPR will evaluate the residue data and if the residue distributions can be considered similar, then the JMPR may recommend a MRL for the commodity group.

(c) The JMPR cannot make any recommendations for pesticide classes such as organophosphates, carbamates, pyrethroids. If it is claimed, for instance, that no organophosporous compounds were detected in 20 samples of a spice commodity, then it has to be specified what compounds had been looked for, what were their LOQ and recovery values. The method performance parameters indicated has to be supported with appropriate method validation data.

In addition, the supporting information should be provided as specified in the JMPR reports on actual agricultural, storage and processing practice, the need for post-harvest protection, etc.

Comprehensive information on data requirements will also be available in the second edition of the FAO Manual (section 3.6).