

**47th Session of the Codex Committee on Pesticide Residues
Beijing, China, 13 - 18 April 2015**

European Union Comments

Agenda Item 6 a

Draft and proposed draft maximum residue limits for pesticides in foods and feeds at Steps 7 and 4
Comments at steps 6 and 3

(CX/PR 15/47/5 and CX/PR 15/47/5-Add. 1)

European Union Competence

European Union Vote

5.22 Phosmet (103)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Cranberry

5.9 Dithiocarbamates (105)/Mancozeb (050)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Cardamom, seed

- Coriander, seed
- Fennel, seed
- Ginseng, dried
- Pepper, black, white
- Peppers, Chili

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Cumin, seed**

The origin of the residues is unknown. Therefore it would be more appropriate to assume the presence of the most toxic dithiocarbamate (i.e. ziram). The risk assessment should be revised accordingly.

5.33 Triforine (116) (T, R) **

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Blueberries
- Egg plant
- Tomato
- Edible offal (mammalian)
- Mammalian fat (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks

From the short documentation of the studies in the JMPR report it is not possible to decide whether the quality of the metabolism studies is sufficient to derive reliable residue definitions. For blueberries, the residue data indicate that a proposed draft MRL of 0.02 mg/ kg is sufficient according to the OECD calculator.

5.23 Propamocarb (148)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Broccoli**
- **Brussels sprouts**

- **Cauliflower**

The residue data indicate that a proposed draft MRL of 1.5 mg/ kg is sufficient according to the OECD calculator.

- **Onion, bulb**

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Eggs**
- **Poultry, meat**
- **Poultry, fat**
- **Poultry, Edible offal of**

The proposed draft MRLs are expressed on a different enforcement residue definition than the one applicable in the EU.

- **Leek**

An acute consumer risk has been identified for a European consumer group, based on the ARfD agreed in the EU, which is lower than the ARfD used by JMPR.

- **Cabbages, Head**

The residue data indicate that a proposed draft MRL of 0.7 mg/ kg is sufficient according to the OECD calculator.

The new uses for cabbages and kale, in addition to the existing use on potatoes leads to a dietary exposure of livestock which exceeds the dosing levels of the feeding study and the metabolism study. Without appropriate feeding studies, the MRL proposals for kale and cabbage head are not supported.

- **Kale**

The new uses for cabbages and kale, in addition to the existing use on potatoes lead to a dietary exposure of livestock which exceeds the dosing levels of the feeding study and the metabolism study. Without appropriate feeding studies, the MRL proposals for kale and cabbage head are not supported.

5.24 Propiconazole (160)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Edible offal (mammalian)**
- **Eggs**
- **Mammalian fat (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Poultry fat**
- **Poultry meat**

5.32 Triadimenol (168)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Grapes**

This MRL proposal should be also introduced for triadimefon (133), because the residue definitions are overlapping.

5.3 Buprofezin (173) (R)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRL for the following commodity:

- Coffee beans

Hydrolysis studies assessed in the EU revealed potentially harmful degradation products which were not present or at very low amounts in RACs (aniline (up to 19% TRR), BF11 (N-tert-butyl-N'-phenyl-N-propan-2-ylidicarbonyimidic diamide) and BF25 (N-tert-butyl-N'-phenyl-N-propan-2-ylidicarbonyimidothioic diamide). Further investigation is needed to decide whether it is necessary to include them in the risk assessment.

Since coffee is subject to processing, involving roasting and extraction with hot water, the formation of toxicological relevant degradation products cannot be excluded. Thus, the potential formation of toxicological relevant degradation products in coffee has to be further investigated.

5.17 Glufosinate-ammonium (175)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodity:

- Soy bean dry

It is noted that in the description of the GAP the specification of the trait of glufosinate-tolerant soya bean plants is required as well as the specification of the variety used in the supervised residue trials.

5.21 Myclobutanil (181)(T, R) **

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Beans except broad bean and soya bean

- Brassica (cole or cabbage) vegetables, head cabbage, flowerhead brassicas

Noting that as myclobutanil may be a persistent pesticide, the soil plateau level including accumulated residues in the soil due to consecutive years of treatment should be considered.

- Bulb vegetables

Noting that as myclobutanil may be a persistent pesticide, the soil plateau level including accumulated residues in the soil due to consecutive years of treatment should be considered.

- Cherries

Noting that the number of applications and the dose rate of the US GAP were not clearly reported.

- Currants, black, red, white

- Edible offal (mammalian)

- Eggs

- Fruiting vegetables, cucurbits

- Grapes

- Hops, dry

- Leafy vegetables

Noting that as myclobutanil may be a persistent pesticide, the soil plateau level including accumulated residues in the soil due to consecutive years of treatment should be considered.

- Mammalian fats (except milk fats)

- Meat (from mammals other than marine mammals)

- Milks

- Plums (including prune)

- Pome fruits

- Poultry fats

- Poultry meat

- Poultry, edible offal of

- Root and tuber vegetables

Noting that as myclobutanil may be a persistent pesticide, the soil plateau level including accumulated residues in the soil due to consecutive years of treatment should be considered.

- Strawberry

- Tomato

Noting that for the MRL for all the above mentioned commodities clarification is needed whether the results of the supervised residue trials were generated with analytical methods including the hydrolysis step to release conjugates.

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRL for the following commodities:

- Peaches

For apricots the extrapolation is not in line with the EU extrapolation rules. Sufficient data are available to support a lower MRL of 1 mg/kg for apricots.

- Peppers

Not sufficient trials on sweet peppers are available to allow deriving an MRL proposal or to conclude whether sweet and chili pepper trials reflect the same population.

The EU would like to **comment** that discrepancies between the proposed draft MRL listed in the Circular letter/JMPR summary report and the full JMPR report (p 284) were noted for the following commodities:

- Peppers chili, dried

5.12 Fenpropathrin (185)(T, R) **

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Cherries

- Citrus fruits

- Coffee beans

- Edible offal (mammalian)

- Eggs
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Peaches (including nectarine and apricots)
- Peppers
- Plums
- Pome fruits
- Poultry fats
- Poultry meat
- Poultry, edible offal of
- Soya bean (dry)
- Strawberry
- Tea, green, black (black fermented and dried)
- Tomato
- Tree nuts

The JMPR assessment referred to fenpropathrin with CAS Register number 39515-41-8 of unstated stereochemistry. Lacking data on the technical specification of the active substance and the unknown stereocomposition raised uncertainties about reliability of the toxicological data package that was used for the setting of reference values.

Specification of the technical material (including the purity and the isomer ratio), information on possible preferential degradation of the isomers of the racemic mixture, metabolism studies in rotational crops and standard hydrolysis study are needed for establishing the residue definition.

An acute risk for consumers was identified for the following commodities:

- Apricots
- Cherries
- Peaches
- Peppers
- Pome fruits
- Tomatoes

The EU would like to **comment** that:

Discrepancies were noted between the proposed draft MRL listed in the JMPR summary report and annex 1 of the full JMPR report on one side and the one proposed on p 163 of the full JMPR report on the other side for the following commodities:

- **Peppers chili, dried**

For the following commodities LOQ was proposed as the appropriate MRL, therefore it should be labelled with ‘*’:

- **Edible offal (mammalian)**

- **Mammalian fats (except milk fats)**

- **Meat (from mammals other than marine mammals)**

- **Milks**

5.27 Pyraclostrobin (210)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Cherries**

In the JMPR Report, a level of 0.3 mg/kg is erroneously mentioned. The JMPR Summary Report and CL 2014/36-PR correctly refer to the draft proposed MRL of 3 mg/kg.

- **Peaches**

- **Plums**

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Apricots**

The extrapolation is not in line with EU extrapolation rules. Two additional trials on apricots would be needed to obtain sufficient data for setting an MRL.

5.8 Dimethomorph (225) (R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Artichoke, globe- broccoli**
- **Cabbages, head**
- **Celery**
- **Garlic**
- **Grapes- leek**
- **Lettuce, head**
- **Onion, bulb**
- **Onion, welsh**

- **Peas, shelled (succulent seeds)**

Noting that with the OECD calculator a lower MRL proposal of 0.09 mg/kg is derived.

- **Shallots**
- **Spinach**
- **Spring onion**
- **Strawberry**

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Fruiting vegetables other than cucurbits**

For tomatoes and peppers, trial data are available that allow setting MRLs for the subgroups 12A (tomatoes) of 0.9 mg/kg and 12B (peppers) of 2 mg/kg, instead of applying the group MRL of 1.5 mg/kg. The MRL of 0.9 mg/kg for tomatoes can be extrapolated to subgroup 12C (eggplants).

- **Lettuce, leaf**

JMPR indicated that an acute risk for consumers could not be excluded.

- Lima bean (young pods and/or immature beans)

In the trials the succulent seeds without pods were analysed. The trials are not appropriate to derive an MRL proposal for lima beans (young pods and/or immature beans) as in the young pods higher residues are expected than the residues measured in the residue trials.

5.4 Chlorantraniliprole (230)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Citrus fruit
- Mammalian fats (except milk fats)
- Poultry fats

- Soya bean (dry)

noting that for soya bean (dry) two trials are missing.

The EU **shares the view of JMPR** that MRLs cannot be proposed in the absence of a sufficient number of residue trials and/or trials matching with the relevant GAP:

- Mungo beans
- Chickpeas
- Peanuts
- Green onions
- Cereals

5.25 Prothioconazole (232)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Cranberry**
- **Potato**

- **Maize**

The residue data indicate that a proposed draft MRL of 0.05 mg/ kg is sufficient according to the OECD calculator.

- **Sweet corn (corn-on-the-cob)**
- **Soya bean (dry)**

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Bush berries**

An acute consumer risk has been identified for currants and gooseberries for a European consumer group, based on the ARfD for prothioconazole-destho agreed in the EU, which for the general population is lower than the ARfD used by JMPR, and applying a presumptive conversion factor of 2.

- **Fruiting vegetables, Cucurbits (except watermelon)**

An acute consumer risk has been identified for melons, cucumbers and pumpkins for a European consumer group, based on the ARfD for prothioconazole-destho agreed in the EU, which for the general population is lower than the ARfD used by JMPR, and applying a presumptive conversion factor of 2. Note that an acute consumer risk for melons is identified even when no conversion factor is applied.

5.15 Fluopicolide (235)(R)

No comments necessary

5.29 Spirodiclofen (237)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Blueberries**

5.5 Clothianidin (238) (R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Beans, except broad bean and soya bean**
- **Hops, dry**
- **Mango**
- **Mints**

5.16 Fluopyram (243)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Asparagus**
- **Blackberries**
- **Broccoli**
- **Brussels sprouts**

- **Cabbages, head**
- **Cauliflowers**
- **Garlic**
- **Leek**

- **Lettuce, head**

Noting that fluopyram is a persistent pesticide and not enough studies to estimate a residue plateau level in the soil are available.

- **Lettuce, leaf**

Noting that fluopyram is a persistent pesticide and not enough studies to estimate a residue plateau level in the soil are available.

- **Onion, bulb**

- **Peaches (including nectarine and apricots)**

- **Plums (including prunes)**

- **Rape seed**

- **Raspberries, red, black**

5.31 Thiamethoxam (245)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Avocado**
- **Beans, except broad bean and soya bean**
- **Hops, dry**
- **Mango**
- **Mints**

5.10 Emamectin benzoate (247) (T,R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Cos lettuce
- Lettuce leaf
- Rape seed
- Tree nuts

The EU would like to **comment** that also the existing MRLs should be re-evaluated in view of the new acute reference dose that was established in 2014.

5.30 Sulfoxaflor (252)(R)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Cherries
- Lemon and limes (including citron)
- Mammalian fat
- Mandarins
- Oranges
- Peaches (including nectarines and apricots)
- Plums (including prunes)
- Pome fruits
- Poultry fats
- Pummelo and grapefruits

The EU wishes to maintain a general reservation pending the outcome of its own evaluation. Moreover, all residue data provided for stone fruits, i.e. cherries, peaches (including nectarines and apricots), and plums (including prunes), were based on fruits

without stone (pitted fruits). The MRLs however usually refer to whole fruits (with stone). The MRL proposals derived by JMPR for stone fruits should hence be recalculated to reflect residues in whole fruits (with stone).

5.28 Sedaxane (259)(R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Cereal grains
- Potato
- Pulses
- Sweet corn (corn-on-the-cob)

5.2 Benzovindiflupyr (261)(R)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Eggs
- Meat (from mammals other than marine mammals)
- Edible offal (mammalian)
- Mammalian fats (except milk fats)
- Milks
- Poultry, edible offal of
- Poultry fats
- Poultry meat
- Soya bean (dry)

As the approval procedure at EU level is still ongoing and might conclude on different toxicological reference values and residue definitions.

5.11 Fenamidone (264)(T,R)

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Beans, except broad bean and soya bean**
- **Beans, Shelled**

- **Cabbages, Head**
noting that for cabbages, head two trials are missing.

- **Carrots**
- **Celery**
- **Cotton seed**
- **Edible offal (mammalian)**
- **Eggs**
- **Fruiting vegetables, Cucurbits**
- **Garlic**
- **Grapes**
- **Leek**
- **Lettuce, Head**
- **Lettuce, Leaf**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Onion, Bulb**
- **Onion, Welsh**
- **Peppers, Chili**
- **Potato**
- **Poultry meat**
- **Poultry, Edible offal of**
- **Poultry fats**

- Shallot
- Spring onion
- Strawberry
- Sunflower seed
- Witloof chicory (sprouts)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Flowerhead brassicas

The extrapolation is not in line with EU extrapolation rules. The data are however sufficient to derive an MRL proposal for broccoli.

- Fruiting vegetables, other than Cucurbits (except chilli pepper, fungi, sweet corn)

For tomatoes and peppers, trial data are available that allow setting MRLs for the subgroups 12A (tomatoes) of 1.5 mg/kg and 12B (peppers, except chilli pepper) of 0.3 mg/kg, instead of applying the group MRL of 1.5 mg/kg. The MRL of 1.5 mg/kg for tomatoes can be extrapolated to subgroup 12C (eggplants).

- Mustard greens

JMPR noted an exceedance of the ARfD.

- Spinach

JMPR noted an exceedance of the ARfD.

5.13 Fluensulfone (265)(T,R)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Fruiting vegetables, cucurbits
- Fruiting vegetables, other than cucurbits (except sweet corn and mushrooms)

The decision on the toxicological relevance of the metabolites is based only on non-GLP studies (for TSA and BSA) and the use of the TTC approach (MeS) based on exposure calculations considering residues from primary crops only. Further clarifications are required why in the exposure assessment MeS residues expected in rotational crops were not included and why the exposure for melons was calculated based on a different HR than for the whole fruiting vegetables, cucurbits group.

5.1 Aminocyclopyrachlor (272) (T,R)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Edible offal (mammalian)**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**

Due to open issues on genotoxicity and metabolism for the metabolite cyclopropane carboxylic acid (CPCA), the risk assessment could not be finalised. Without further details, the proposed residue definitions cannot be supported.

5.6 Cyflumetofen (273) (T,R)**

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Citrus fruits**
- **Edible offal (mammalian)**
- **Grapes**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Pome fruits**
- **Strawberry**

- Tomato
- Tree nuts

5.7 Dichlobenil (274)(T,R)*

The EU would like to introduce a reservation to the advancement of the proposed draft MRLs for the following commodities:

- **Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas**
- **Cane berries**
- **Celery**
- **Cereal grains**
- **Fruiting vegetables, Cucurbits**
- **Fruiting vegetables, other than Cucurbits (except sweetcorn and mushrooms)**
- **Grapes**
- **Leafy vegetables**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Onion, Bulb**
- **Onion, Welsh**
- **Pulses**

The approach used to take into account residues of 2,6-dichlorobenzamide present in soil was not consistent. The risk assessment is affected by a high level of uncertainties.

- **Edible offal (mammalian)**

See above. Moreover, the results of the feeding study seem to be in contradiction to the livestock metabolism study with 2,6-dichlorobenzamide where 2,6-dichlorobenzamide was found as a minor metabolite in liver, while in the feeding study it was detected in concentrations that require the setting of an MRL above the LOQ.

- **Eggs**

- Poultry, Edible offal of
- Poultry fats
- Poultry meat

See above. Moreover, the MRL proposal was derived from the metabolism study in poultry which was scaled down by a factor of ca. 100.

5.14 Flufenoxuron (275)(T, R) *

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Edible offal (mammalian)
- Meat (from mammals other than marine mammals)
- Mammalian fats (except milk fats)
- Milks
- Oranges
- Tea, green, black (black, fermented and dried) tea infusion

For the residue definition for risk assessment for plant commodities 2,6-difluorobenzamide should be taken into account. For the residue definition for commodities of animal origin, further clarifications are needed regarding the metabolism studies in lactating goats.

For the commodities of animal origin a dietary burden calculation should be performed as there is evidence of a transfer of residues in animal products.

For tea, green, black (black, fermented and dried) tea infusion the more toxic degradation product Reg.No 4064702 might be generated during preparation of infusions.

5.18 Imazamox (276)(T, R) *

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- **Bean (dry)**
- **Beans, except broad bean and soya bean (green pods and immature seeds)**
- **Edible offal (mammalian)**
- **Eggs**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Peas (dry)**
- **Peanut**
- **Peas, Shelled (succulent seeds)**
- **Poultry fats**
- **Poultry meat**
- **Poultry, Edible offal of**
- **Rape seed**
- **Soya bean (dry)**
- **Wheat**

noting that for several commodities one or more trials are missing. However, given the no-residue situation in those crops, the CXL proposals are considered sufficiently supported.

- **Lentil (dry)**

noting that in contrast to other pulses, significant residues were observed in lentils, although the GAP seems to be less critical. An explanation should be provided. In its absence, it seems to be appropriate to revise the STMR values for soya beans, beans and peas to 0.05 mg/kg.

- **Rice**

- **Sunflower seed**

noting that for both commodities two trials (each) are missing.

5.19 Mesotrione (277)(T, R) *

The EU **supports the advancement** of the proposed draft MRLs for the following commodities:

- Linseed
- Maize
- Millet
- Oats
- Rice, husked
- Sorghum

- Soya bean (dry)

Noting that for the MRL proposal for soya bean dry, more details on the variety of transgenic soya would be desirable.

- Sweet corn (corn-on-the-cob)

The EU would like to introduce a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- Asparagus
- Bush berries
- Cane berries
- Cranberry
- Edible offal (mammalian)
- Eggs
- Meat (from mammals other than marine mammals)
- Milks
- Okra
- Poultry, edible offal of
- Poultry meat
- Rhubarb

- Sugar cane

The occurrence of the metabolites AMBA (2-amino-4-(methylsulfonyl)benzoic acid) and MNBA (4-methylsulfonyl-2-nitro benzoic acid) was not adequately addressed. This is reflected in the divergent residue definitions agreed by JMPR and the EU, respectively.

Feed items such as maize forage and soya bean dry, which are expected to contribute to the overall dietary burden, should be taken into account for the MRLs for animal origin commodities.

5.20 Metrafenone (278)(T, R) *

The EU supports the advancement of the proposed draft MRLs for the following commodities:

- Barley
- Cucumber
- Edible offal (mammalian)
- Eggs
- Gherkin
- Grapes
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Oats
- Peppers, Chili
- Poultry fats
- Poultry meat
- Poultry, Edible offal of
- Rye
- Squash, Summer (courgettes)
- Strawberry
- Tomato

- Wheat
- Mushrooms

5.26 Pymetrozine (279) (T, R) *

The EU would like to introduce a reservation to the advancement of the proposed draft MRLs for the following commodities:

- Citrus fruits
- Apricot
- Peach/ nectarins
- Cucumbers
- Peppers sweet
- Tomatoes
- Asparagus
- Cotton

JMPR could not conclude on the risk assessment residue definitions since no conclusion could be reached on the toxicological relevance of the CGA294849 and CGA300407 metabolites. As long as no reliable residue definitions can be derived, no new MRL proposals should be advanced.