

European Union Comments
CODEX COMMITTEE ON PESTICIDE RESIDUES

49th Session

Beijing, 24 – 29 April 2017

Agenda Item 6

**Draft and proposed draft maximum residue limits for pesticides in food and feed at steps 7 and 4
Comments at steps 6 and 3**

(CX/PR 17/49/5 and CX/PR 17/49/5-Add.1)

European Union Competence

European Union Vote

The EU would like to thank JMPR for the high scientific quality of its report and has the following comments:

5.6 Deltamethrin (135) (R)

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

-rape seed

5.15 Methoprene (147) (R)

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

- oilseed except peanut

A chronic risk for European consumers could not be excluded. Considering the significant background exposure from the existing EU MRLs, there is no scope to raise the MRLs. Further refinements of the chronic exposure calculation are possible; however the relevant data have not yet been assessed in the EU.

Studies investigating the metabolic behaviour after post-harvest treatment and on the nature and magnitude of residues in processed products are lacking.

It is noted that the dietary burden calculations should be added to the JMPR report to verify the statement that residues in oilseed do not impact on the dietary burden of farm animals.

5.4 Buprofezin (173) (R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities because a chronic risk for European consumers could not be excluded. Under high temperature processing conditions buprofezin degrades to several metabolites, including aniline. Aniline is a carcinogen for which a genotoxic mechanism cannot be excluded and therefore no threshold for acceptable exposure can be assumed.

- avocado
- basil
- soya bean, dry

5.18 Penconazole (182) (T,R)

The EU **reserves its position**, pending the outcome of an ongoing review of all existing MRLs and of the residue definition in the EU.

- strawberry.

At EU level, a different policy for merging datasets from protected and outdoor trials is in place.

5.8 Fenpropimorph (188) (T)

The EU has a different policy regarding the setting of toxicological reference values, following which different values are not set for

different subgroups of the population. Due to limited information provided in the JMPR report it could not be verified whether the proposed toxicological reference values are applicable for all components of the residue definition. The EU would like to ask JMPR for clarification on this point.

5.24 Teflubenzuron(190) (T,R)

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

- apples

The trials used for the calculation were not compliant with the GAP.

- meat from mammals (other than marine mammals)

- poultry meat

Concerning fat soluble residues, the MRLs for meat cannot be taken over in the EU legislation, due to the different policy to set MRLs for muscle.

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

- cauliflower

- coffee beans

- cucumber

- edible offal (Mammalian)

- eggs

- gherkin

- grapes

- maize

- mammalian fats (except milk fats)

- melons, except watermelon

- milk fats

- milk of cattle, goats and sheep

- papaya

- poultry fats

<ul style="list-style-type: none">- poultry, edible offal of- soya bean (dry)- lemons and limes (includes all commodities in this subgroup)- oranges, sweet and sour (includes all commodities in this subgroup)- sugar cane- sunflower seed- tomato
<p>5.9 Fipronil (202) (R)</p> <p>The EU introduces a <u>reservation to the advancement</u> of the proposed draft MRLs for basil. The proposed draft MRLs for commodities of plant origin cannot be taken over in EU legislation because they are derived for a different enforcement residue definition.</p>
<p>5.7 Dimethomorph (225) (R)</p> <p>The EU <u>supports the advancement</u> of the proposed draft MRL for the following commodity:</p> <p>-lettuce, leaf</p>
<p>5.5 Chlorantraniliprole (230) (R)</p> <p>The EU introduces a <u>reservation to the advancement</u> of the proposed draft MRLs for the following commodities:</p> <p>- poultry meat Concerning fat soluble residues, the MRLs for meat cannot be taken over in the EU legislation, due to the different policy to set MRLs for muscle.</p> <p>The EU <u>supports the advancement</u> of the proposed draft MRLs for the following commodities:</p> <p>- eggs</p>

- peanut
- poultry fat
- poultry, edible offal of

5.21 Saflufenacil (251)

The EU introduces a **reservation to the advancement** of proposed draft MRLs for the following commodities. The proposed draft MRLs cannot be taken over in EU legislation because they are derived for a different enforcement residue definition.

-pomegranate

-barley

The pre-harvest use in cereals is not sufficiently supported by metabolism data.

-triticale

The pre-harvest use in cereals is not sufficiently supported by metabolism data.

It is noted that the residue data indicate that according to the OECD calculator a proposed draft MRL of 0.5 mg/ kg is sufficient instead of 0.7 mg/kg.

-wheat

The pre-harvest use in cereals is not sufficiently supported by metabolism data.

It is noted that the residue data indicate that according to the OECD calculator a proposed draft MRL of 0.5 mg/ kg is sufficient instead of 0.7 mg/kg.

-sugar cane

-peanut

-sunflower seed

-edible offal (mammalian)

An acute consumer risk has been identified for a European consumer group.

-mammalian fats (except milk fats)

-meat (from mammals other than marine mammals)

-milks

-eggs

-poultry fats

-poultry meat

-poultry, edible offal of

-peanut

The EU would like to **comment** that in the EU the setting of an ARfD was considered necessary on the basis of the results of a rat developmental study.

5.23 Sulfoxaflor (252) (R)

-Tree nuts

In 2015 CCPR decided to retain the MRL proposal at step 4 awaiting JMPR evaluation in 2016. The **EU shares the view of JMPR** that no MRL can be proposed as no information on the authorised GAPs was provided. The proposed MRL should be withdrawn.

5.2 Benzovindiflupyr (261) (R)

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

-fruiting vegetables, cucurbits

The EU has a different policy on setting group MRLs for fruiting vegetables (cucurbits). The data would be sufficient to derive separate MRLs for cucurbits with edible peel (0.08 mg/kg) and cucurbits with inedible peel (0.3 mg/kg).

-mammalian fats (except milk fats)

From the feeding study and the dietary burden calculation it is concluded, that an MRL of 0.02 mg/kg would be sufficient instead of 0.03 m/kg.

-meat (from mammals other than marine mammals)

-poultry meat

At EU level, the residues are not considered fat soluble because the residues are not preferably located in fat tissue. The MRLs for meat cannot be taken over in the EU legislation, due to the different policy to set MRLs for muscle.

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

-pome fruits

-grapes

-fruiting vegetables other than cucurbits

- sweet corn
- beans (dry)
- peas (dry)
- soya bean (dry)
- potato
- barley
- oats
- wheat
- rye
- triticale
- sugar cane
- peanut
- rape seed
- coffee beans
- edible offal (mammalian)
- eggs
- milks
- poultry fats
- poultry, edible offal of

5.3 Bixafen (262) (R)

The EU introduces a reservation to the advancement of proposed draft MRLs for the following commodities:

- **meat (from mammals other than marine mammals)**
- **poultry meat**

Concerning fat soluble residues, the MRLs for meat cannot be taken over in the EU legislation, due to the different policy to set MRLs for muscle.

It is noted that according to the feeding study and the dietary burden calculation a proposed draft MRL of 1.5 mg/ kg would be sufficient for meat (from mammals other than marine mammals).

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

- barley
- barley, straw and fodder
- edible offal (Mammalian)
- eggs
- mammalian fats (except milk fats)
- milk fat
- milk

It is noted that according to the feeding study and the dietary burden calculation a proposed draft MRL of 0.15 mg/ kg would be sufficient.

- oats
- oats, straw and fodder
- poultry, edible offal of
- poultry fats
- rape seeds

5.11 Fluensulfone (265) (T, R)

The EU introduces a **reservation to the advancement** of proposed draft MRLs for the following commodities, as the residue definitions are questioned. The metabolism studies are not representative for the residue behaviour observed in the residue trials. In addition the EU is of the opinion that the genotoxic potential of MeS cannot be excluded and that further genotoxicity tests would be needed to follow up on the positive results in vitro.

- beetroot
- brassica (cole or cabbage) vegetables, Head cabbage

Noting that it should be clarified if the code is correctly assigned to the proposed MRL (VB 0400 refers to broccoli); the code corresponding with the description of the commodity is VB 0040.

- carrot
- celeriac
- celery
- chervil, turnip-rooted
- cucumber
- edible offal (mammalian)
- eggs

-fruiting vegetables, other than cucurbits, except sweetcorn and mushroom

-horseradish

-komatsuma

-leafy vegetables

-legume vegetables

-lettuce, head

Noting that the MRL proposal for VB 0053, derived from rotational crop studies, is higher than the MRL proposal for the use in lettuce following primary crop treatment. The footnote (R) for MRLs relating to rotational crops should be added.

-low-growing berries

-mammalian fats (except milk fats)

-meat (from mammals other than marine mammals)

-melons, except watermelon

-milks

-mustard greens

-parsnip

-potato

-poultry, edible offal of

-poultry fats

-poultry meat

-radish

-root and tuber vegetables

-spinach

-squash, summer

-swede

-sweet potato

-turnip greens (leaves)

-watermelon

5.25 Tolfenpyrad (269) (R)

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

- pecan
- potato

5.16 Metrafenone (278) (R)

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

- pome fruits
- cherries
- peaches
- fruiting vegetables, cucurbits
- peppers, sweet (including pimento or pimiento)
- peppers, Chili
- peppers Chili, dried
- tomato
- egg plant
- hops, dry

It is noted that the residue data indicate that according to the OECD calculator a proposed draft MRL of 80 mg/ kg would be derived.

5.10 Fluazifop-P-butyl (283) (T,R)

The EU **opposes to the advancement** of the proposed draft MRLs for the following commodities. A chronic risk for cluster diet 16 could not be excluded and therefore the proposed Codex MRL, which are higher than the LOQ, cannot be supported:

- strawberries
- onion, bulb
- garlic
- shallots
- cabagges, head

An acute consumer risk has been identified for a European consumer group.

- eggplant
- tomato

The trials were scaled to match a French GAP, which has been revoked in the meanwhile because of an acute exposure concern. Therefore the basis for the Codex MRL proposal is no longer valid.

An acute consumer risk has been identified for a European consumer group.

-beans, except broad bean and soya bean (green pods and immature seeds)

An acute consumer risk has been identified for a European consumer group.

-peas (pods and succulent immature seeds)

-peas, shelled (succulent seeds)

An acute consumer risk has been identified for a European consumer group.

-beans (dry)

An acute consumer risk has been identified for a European consumer group.

-field pea (dry)

-soya bean (dry)

-carrot

An acute consumer risk has been identified for a European consumer group.

-celeriac

-potato

An acute consumer risk has been identified for a European consumer group.

-sugar beet

-swede

An acute consumer risk has been identified for a European consumer group.

-turnip, garden

An acute consumer risk has been identified for a European consumer group.

-sweet potato

An acute consumer risk has been identified for a European consumer group.

-yams

An acute consumer risk has been identified for a European consumer group.

-cotton seed

-sunflower seed

Noting that the reason for the extremely high residues found in some of the residue trials used by JMPR to derive the MRL proposal should be examined.

-meat (from mammals other than marine mammals)

Noting that the proposed Codex MRL is derived from a feeding study where the highest dosing level was lower than the calculated

maximum dietary burden for beef cattle. The same comment goes for mammalian fats and edible offal.

-mammalian fats (except milk fats)

-edible offal (mammalian)

-milks

-poultry meat

Noting that the appropriateness of the MRL proposal cannot be verified because in the feeding study where the residues were analysed in “mixed tissues of fat and muscle” without specifying the ratio of fat and muscle. The same comment goes for poultry fats.

-poultry fats

-poultry, edible offal of

-eggs

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

-citrus fruits

-pome fruits

-stone fruits

-cane berries

-currant, black, red, white

-gooseberries

-grapes

-table olives

-olives for oil production

-banana

-lettuce, leaf

-sugar cane

-almonds

-macadamia nuts

-pecan

-walnuts

-coffee beans

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

- regarding the setting of the ARfD, some effects in rat developmental toxicity studies reported in the EU assessment (i.e. kinked ureters and/or dilated ureter) were not reported in the JMPR assessment. These effects were the basis for setting the ARfD of 0.017 mg/kg bw at EU level instead of the 0.4 mg/kg bw set by JMPR;

- since the analytical methods do not allow to discriminate between fluazifop-P and fluazifop-S (and the related metabolites), it would seem more appropriate to include the S-enantiomer in the JMPR residue definition, considering that the residue trials were also analysed for the total fluazifop residues (R- and S-isomer).

5.12 Flupyradifurone (285) (R)

The EU introduces a **reservation to the advancement** of proposed draft MRLs for the following commodities. The proposed draft MRLs cannot be taken over in EU legislation because they are derived for a different enforcement residue definition.

-beans, dry

-beans, shelled (succulent seeds)

-beans, except broad bean and soya bean (green pods and immature seeds)

-bulb vegetables, except fennel bulb

-bush berries

-cabbages, head

Noting that the approach of adding the mean and highest residue in rotational crops to the STMR and HR is not an agreed standard practice. This comment also applies to the proposed MRLs for cauliflower, celery, cotton seed, maize, melons, peanut, dry peas, peas (pods and succulent immature seeds), peas, shelled (succulent seeds), peppers, potato, root and tuber vegetables (except potato), soya bean (dry), strawberries, summer squash, sweet corn and tomato.

-cauliflower

-cereal grains (except maize and rice)

Noting that because the data sets are statistically different, separate MRLs should be set for wheat, barley and sorghum.

-cotton seed

-cucumber

Because in decline studies the residues did not reach a maximum, trials with sampling at longer PHIs would be required for deriving an HR and STMR. The same comment goes for tomatoes and summer squash.

- edible offal (mammalian)**
- eggs**
Noting that a lower MRL of 0.5 mg/kg would be sufficient.
- grapes**
- lemons and limes (including citron)**
- lettuce, head**
- mandarins**
- mammalian fats (except milk fats)**
- meat (from mammals other than marine mammals)**
- maize**
- melons, except watermelon**
- milks**
- oranges**
- peanut**
- peas (dry)**
- peas (pods and succulent immature seeds)**
- peas, shelled (succulent seeds)**
- pecan**
- peppers**
- pome fruits**
Noting that because the data sets for pears and apples are statistically different, separate MRLs should be set and for apples an MRL of 0.5 mg/kg would be sufficient.
- potato**
- poultry fats**
- poultry meat**
- poultry, edible offal of**
- pummelo and grapefruits**
- root and tuber vegetables (except potato)**
- soya bean dry**
- strawberry**
- squash, summer**
- sweet corn**

- sweet potato
- tomato

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

- mustard greens
- spinach
- lettuce leaf
- celery

An acute consumer risk has been identified for a European consumer group. JMPR also noted an exceedance of the ARfD.

The EU would like to **comment** that, even though not sufficient trials are available to set an MRL for broccoli, an MRL should be proposed to cover residues in rotational crops. The application rate in rotational crop studies should be at the level of the worst case GAP for primary crop treatment.

5.1 Acibenzolar-S-methyl (288)(T,R)

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

- **brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas**
- **brassica leafy vegetables**

An acute consumer risk has been identified for a European consumer group. The exceedance results from from the different EU variability factor used in the IESTI equation.

- **citrus fruits**

The EU notes that no metabolism studies representative of soil treatment are available. Residues in citrus fruits following soil treatment may increase over time. Thus, samples taken on the day of the treatment are most likely not leading to measurable residues.

- **fruiting vegetables, cucurbits**

An acute consumer risk has been identified for a European consumer group. The exceedance of the ARfD is related to the lower EU ARfD. It is noted that the residue data indicate that according to the OECD calculator a proposed draft MRL of 0.6 mg/ kg is sufficient.

- kiwi fruit**

The EU notes that no metabolism studies representative for soil treatment are available.

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

- apple
- banana
- edible offal (mammalian)
- eggs
- garlic
- lettuce, head
- lettuce, leaf
- low growing berries (including strawberries)
- mammalian fats
(except milk fats)
- meat
(from mammals other than marine mammals)
- milks
- onion, bulb
- peaches (including nectarines
and apricots)
- poultry fats
- poultry meat
- poultry, edible offal of
- shallot
- spinach
- tomato

5.13 Imazethapyr (289) (T,R)

The EU **reserves its position**, pending the outcome of the ongoing evaluation of an import tolerance request in the EU.

- edible offal (mammalian)

- eggs
 - lentil (dry)
 - maize
 - mammalian fats (except milk fats)
 - meat (from mammals other than marine mammals)
 - milks
 - peanut
 - poultry fats
 - poultry meat
 - poultry, edible offal of
 - rapeseed
- Noting that the trials were not analysed for all components of the risk assessment residue definition i.e. Glu-OH-imazetapyr).
- rice
 - soya bean (dry)

5.14 Isofetamid (290) (T,R)

The EU introduces 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
- poultry, edible offal of
- poultry fats
- poultry meat

For all these commodities, the proposed draft MRLs are expressed on an enforcement residue definition that is not compatible with the one applicable in the EU. For animal commodities, the EU residue definition for enforcement does not include the metabolite PPA, which is included in the corresponding JMPR definition.

Concerning edible offal (mammalian), the EU also notes that the HR/STMR/MRL derived by JMPR are calculated using an level of

isofetamid in liver of 0.10 mg/kg (JMPR report p.246), while the correct residue concentration in liver found in the goat metabolism study is 0.01 mg/kg (JMPR report p. 236). Considering the re-calculated results, a lower MRL for edible offal would be appropriate (i.e. 0.03 mg/kg).

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

- **almonds**
- **lettuce, head**
- **lettuce, leaf**
- **low growing berries (includes all commodities in this subgroup)**
- **rape seed**
- **small fruit vine climbing (includes all commodities in this subgroup)**

5.17 Oxathiapiprolin (291) (T,R)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities. For plant commodities no information on the residue concentration of the metabolites included in the residue definition for risk assessment is available. For commodities of animal origin, the presentation of the assessment of animal products does not allow to verify the validity of the proposed MRLs.

- broccoli,**
 - cabbages, head**
 - cauliflower**
 - edible offal (mammalian)**
 - eggs**
 - fruiting vegetables, cucurbits**
- Noting that sufficient data are available to set separate MRLs for cucurbits with and without edible peel.
- fruiting vegetables other than cucurbits (except sweetcorn and mushrooms)**
 - garlic**
 - ginseng, dried including red ginseng**
 - grapes**
 - leek**
 - lettuce, head**

- lettuce, leaf
- mammalian fats (except milk fats)
- meat (from mammals other than marine mammals)
- milks
- onions, bulb
- onions, Welsh
- peas (pods and succulent seeds)
- peas (shelled)
- potato
- poultry fats
- poultry meat
- poultry, edible offal of
- shallots
- spring onion
- spinach
- sweet potato

The EU would like to comment that clear guidance is needed for active substances that lead to residues in rotational crops due to their persistence.

5.19 Pendimethalin (292) (T,R)

The EU introduces a reservation to the advancement of the proposed draft MRLs for the following commodities:

- brassica leafy vegetables, except kale

The EU applied a different scientific methodology as regards the extrapolation from residue trials conducted on mustard greens to the whole group of brassica vegetables. The data are however sufficient to derive an MRL proposal for mustard greens.

- meat (from mammals other than marine mammals)

- poultry meat

Concerning fat soluble residues, the MRLs for meat cannot be taken over in the EU legislation, due to the different policy to set MRLs for

muscle.

- **onion, Welsh**
- **spring onions**

The proposed draft MRLs are based on an insufficient number of trials.

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

- **asparagus**
- **beans, except broad bean and soya bean (green pods and immature seeds)**
- **onion, bulb**
- **carrot**
- **celery**
- **citrus fruits**
- **edible offal (mammalian)**
- **eggs**
- **fennel bulb**
- **garlic**
- **hops, dry**
- **kale**
- **lettuce, leaf**
- **mammalian fats**
- **milks**
- **peas (dry)**
- **peas (pods and succulent = immature seeds)**
- **peas, shelled (succulent seeds)**
- **poultry, edible offal of**
- **poultry fats**
- **shallots**
- **tree nuts**

The EU **notes** that for the following commodities, the draft proposed MRL should be labelled with " * " to be consistent with the

recommendation of JMPR:

- beans, dry
- beans, except broad bean and soya bean (green pods and immature seeds)
- hops, dry
- peas (dry)
- peas (pods and succulent = immature seeds)
- peas, shelled (succulent seeds)

5.20 Pinoxaden (293) (T,R)

The EU introduces a **reservation to the advancement** of proposed draft MRLs for the following commodities. The proposed draft MRLs cannot be taken over in EU legislation because they are derived for a different enforcement residue definition.

-barley

As no appropriate feeding studies for ruminants are available and no MRL proposals for mammalian meat could be derived, no MRLs should be set for commodities, which can be used as feed, i.e. barley and wheat.

-wheat

-poultry meat

-poultry fats

-poultry, edible offal of

-eggs

5.22 Spiromefesin (294) (T,R)

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

- common bean(pods and/or immature seeds)
- brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas
- brassica leafy vegetables
- cassava
- coffee beans
- cotton seed
- cucumbers

- **edible offal (mammalian)**
- **eggplants**
- **eggs**
- **fruiting vegetables, cucurbits, except melon and cucumber**
- **leafy vegetables**
- **low-growing berries**
- **maize**
- **maize fodder (dry)**
- **mammalian fats (except milk fats)**
- **meat (from mammals other than marine mammals)**
- **melon, except watermelon**
- **milks**
- **okra**
- **pepino**
- **peppers**
- **peppers chili, dried**
- **popcorn processed – take out?**
- **potato**
- **poultry fats**
- **poultry meat**
- **poultry, edible offal of**
- **sweet corn (corn-on-the-cob)**
- **sweet potato**
- **tea, Green, black (black, fermented and dried)**
- **tomato**
- **tea (green and black infusion)**

For all these commodities, the proposed draft MRLs are expressed on an enforcement residue definition that is not compatible with the one applicable in the EU. The EU residue definition for enforcement does not include the metabolite M01, which is included in the corresponding JMPR definition.

- **eggs**

- **poultry fats**
- **poultry meat**
- **poultry, edible offal of**

The EU notes that the proposed draft MRL was derived from the poultry metabolism study performed at an exaggerated dose rate (35N). In the metabolism study the residues accounted:

- for eggs, in fat: 0.018 mg/kg;
- for poultry fats, in fat: 0.049 mg/kg;
- for poultry meat in muscle: 0.028 mg/kg
- for poultry, edible offal of, in liver, 0.3 mg/kg

These results would suggest under 1N condition no quantifiable residues would occur. Thus, the following proposed draft MRLs would be sufficient:

- 0.01*mg/kg for eggs, poultry fats, poultry meat; and
- 0.01*mg/kg or 0.02mg/kg for poultry, edible offal of.