

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
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World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES

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PROPOSED MAXIMUM RESIDUE LIMITS FOR PESTICIDES IN FOOD AND FEED

Comments at Step 3 in reply to CL 2018/97-PR submitted by European Union and Kenya

General comments

European Union

The EU would like to **comment** that the MRLs and also the currently taken positions for propiconazole, tebuconazole, difenoconazole and prothioconazole might be revised in future, pending an evaluation of triazole derivative metabolites in the EU.

Kenya

Kenya supports the proposed MRLs as outlined in the JMPR 2018 report. We further propose that these draft MRLs be advanced to the next codex step.

Specific comments

2, 4-D (020)

Kenya

Kenya supports the conclusion from the JMPR 2018

Diquat (031)

European Union

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities. A recent EU review identified the need for further toxicological information on several metabolites:

- Barley
- Chick-pea (dry)
- Dry beans, Subgroup of (includes all commodities in this subgroup)
- Dry peas, Subgroup of (except chick-pea (dry))
- Mammalian fats (except milk fats)
- Poultry fats
- Rye
- Triticale

The EU **notes** that 2013 JMPR recommended withdrawal of the CXL for **barley, oats, wheat, wheat bran, wheat flour and wheat wholemeal**. Since sufficiently supported alternative GAPs were only provided for barley, the other CXLs should be withdrawn in 2019 CCPR.

2018 JMPR confirmed the draft MRLs for **edible offal (mammalian), eggs, meat (from mammals other than marine mammals), milks, poultry meat, poultry edible offal** which were maintained at step 4. Thus, if these MRL proposals are advanced, the old CXLs for these commodities should be withdrawn.

Bromopropylate (070)**Kenya**

Kenya supports the recommendation by the JMPR that the critical drivers identified for a potential acute reference dose (ARfD) reduced body weight, was unlikely to represent a major, acute public health concern from dietary exposure to bromopropylate.

Imazalil (110)**European Union**

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

- Tomato
- Barley
- Triticale
- Meat (from mammals other than marine mammals)
- Mammalian fats (except milk fats)
- Poultry meat
- Poultry fats
- Poultry, edible offal
- Eggs
- Milks

The EU **notes** that the proposed CXL for tomato is based on an EU use. Since tomato is considered as a major crop in the EU, the applicant has submitted eight residue trials in support of the EU MRL. However, only six residue trials were submitted to JMPR in support of the proposed Codex MRL.

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing evaluation of toxicological properties of metabolites R014821, R061000 (FK-772) and R043449 (FK-284) in the EU:

- Lemons and limes (includes all commodities in this subgroup)
- Oranges, sweet, sour (includes all commodities in this subgroup)
- Banana
- Potato
- Edible offal (mammalian)

For potato, an acute consumer risk has been identified for European consumers.

Oxamyl (126)**Kenya**

Kenya supports the extrapolation of the maximum residue levels.

Propamocarb (148)**European Union**

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

The enforcement residue definition for animal commodities in the EU differs from the definition applied by JMPR.

Propiconazole (160)**European Union**

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

- Cherries (including all commodities in this subgroup)
- Lemons and Limes (including Citron) (including all commodities in this subgroup)
- Mandarins (including Mandarin-like hybrids) (including all commodities in this subgroup)
- Oranges, Sweet, Sour (including orange-like hybrids) (including all commodities in this subgroup)
- Peach
- Pineapple
- Plums (includes all commodities in this subgroup)
- Pumelo and grapefruit (including Shaddock-like hybrids)(including all commodities in this subgroup)

Following a recent EU evaluation, the active substance was not approved in the EU. In that framework, the consumer risk assessment could not be finalised due to data gaps, and no conclusion could be drawn on the genotoxicity and the general toxicity of several metabolites.

Moreover, for peaches, an acute consumer risk has been identified for European consumers.

Kenya

Kenya supports the recommendation of the JMPR 2018 for the proposed maximum residue levels for the Subgroup

Profenofos (171)

European Union

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

- Coffee bean

Bentazone (172)

European Union

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

- Dry beans (includes all commodities in this subgroup)
- Dry peas (includes all commodities in this subgroup)
- Edible offal (Mammalian)
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks

The enforcement residue definitions for plant and animal commodities in the EU differ from the definitions applied by JMPR.

The EU **notes** that for **dry beans** no residue trials were performed on soybeans.

Abamectin (177)

European Union

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

- Pineapple
- Soya bean (dry)
- Succulent beans without pods, subgroup of (includes all commodities in this subgroup)
- Sweet corns

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities. The EU residue definition for products of plant origin is not compatible with the residue definition derived by JMPR:

- Cane berries, subgroup of (includes all commodities in this subgroup)
- Grapes
- Green onions, subgroup of (includes all commodities in this subgroup)
- Herbs, subgroup of, except mint

The EU **notes** that for **grapes** the proportionality approach was applied despite deviation from the cGAP by more than one parameter.

Fenpyroximate (193)

European Union

The EU **supports 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
- Tomatoes, subgroup of (includes all commodities in this subgroup)

Kenya

Kenya supports the extrapolation of the maximum residue levels.

Kresoxim-methyl (199)

European Union

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

- Barley, subgroup of (includes all commodities in this subgroup)
- Beet root
- Currants, Black, Red, White
- Edible offal (mammalian)
- Eggs
- Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)
- Garlic
- Grape
- Leek
- Mammalian fats (except milk fats)
- Mango
- Meat (from mammals other than marine mammals)
- Milks
- Olives for oil production
- Peach
- Pecan nuts
- Peppers, sweet
- Poultry fats
- Poultry meat
- Poultry, Edible offal of
- Sugar beet
- Table olives
- Turnip
- Wheat, subgroup of (includes all commodities in this subgroup)

The EU **notes** that lower MRLs may be sufficient for several commodities of animal origin.

The EU **requests** that the MRL for pome fruits is not withdrawn as proposed, but maintained under the 4-year rule. The applicant is encouraged to provide the EU GAP and corresponding residue data to JMPR for evaluation.

Pyriproxyfen (200)

European Union

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

- Cucumbers
- Eggplant
- Gherkins
- Melons, except Watermelon
- Papaya
- Peppers
- Pineapple
- Summer squash
- Tomato

Cyprodinil (207)

European Union

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

- Pomegranate

Kenya

Kenya supports the recommendation of the JMPR 2018 for the proposed maximum residue levels for the Subgroup

Pyraclostrobin (210)

European Union

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

- Asparagus
- Avocado
- Beans with pods, subgroup of, except common beans (poroto)
- Broad beans without pods (succulent seeds)
- Cacao beans
- Celery
- Common bean (poroto)
- Common beans (succulent seeds)
- Dry peas (includes all commodities in this subgroup)
- Mango
- Olives for oil production
- Peas with pods
- Passion fruit
- Pineapple
- Rice, Husked
- Succulent peas without pods (includes all commodities of this subgroup)
- Sugar cane
- Table olives
- Tuberous and corm vegetables, commodities in this subgroup)
- Witloof chicory (leaves/sprouts)

The EU notes that for **cacao beans**, residues were below 0.01 mg/kg in the trials conducted in Brazil. The proposed CXL should be labelled with an asterisk to indicate that the value is set at the limit of quantification.

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

-Lettuce, head

An acute consumer risk has been identified for European consumers.

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

Considering the significant dietary burden, a feeding study would be required.

-Pome fruits

An acute consumer risk has been identified for European consumers.

-Root vegetables

Trials were performed on carrot and radish only. In accordance with the 2017 CCPR Report (see Appendix VIII), trials should be carried out also on sugar beet or beetroot.

-Spinach

The proposed CXL is based on EU uses. However, the proposed value does not match the GAPs currently authorised in the EU. In particular, the EU believes that the HR of 0.91 mg/kg was reported by mistake in the JMPR evaluation.

-Tea, Green, Black (black, fermented and dried)

The number of residue trials are insufficient and not fully reflecting the GAP.

Fludioxonil (211)**European Union**

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

- Avocado
- Bulb onions, Subgroup of (includes all commodities in this subgroup)
- Carrot
- Chick-pea (dry)
- Currants, Black, Red, White
- Edible offal (mammalian)
- Eggs
- Guava
- Lentils
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Poultry fats
- Poultry meat
- Poultry, edible offal of
- Soya bean (dry)

The EU introduces a reservation to the advancement of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing periodic re-evaluation in the EU that may lead to revised toxicological reference values:

- Celery
- Green onion, Subgroup of (includes all commodities in this subgroup) VA 2032
- Leaves of Brassicaceae, subgroup of (includes all commodities in this subgroup) Subgroup 013B, Brassica leafy vegetable
- Pineapple

For pineapple, the number of trials is insufficient according to the JMPR crop classification.

- Pomegranate

Madipropamid (231)**European Union**

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

- Beans with pods, subgroup of (includes all commodities in this subgroup)**
- Cacao bean
- Edible offal (mammalian)
- Eggs
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Potato
- Poultry edible offal
- Poultry fats
- Poultry meat

Spinetoram (233)**Kenya**

Kenya supports the extrapolation of the maximum residue levels.

Fluopyram (243)**European Union**

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

- Tomatoes, subgroup of (includes all commodities in this subgroup)

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing MRL review in the EU. Moreover, the number of processing studies is insufficient:

- Rice, husked

Kenya

Kenya supports the recommendations made by the 2018 JMPR. Kenya supports the extrapolation of the maximum residue levels.

Sulfoxaflor (252)

European Union

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

- Edible offal (Mammalian)
- Maize
- Mammalian fats
- Meat (mammalian except marine mammals)
- Milks
- Poultry meat
- Poultry edible offal
- Poultry fats
- Eggs
- Rice, husked
- Sorghum
- Sweet corn (corn-on-the-cob) kernels plus cobs with husks removed)
- Tree nuts

Chlorfenapyr (254)

European Union

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, in view of the approach to taken by JMPR to derive input values for risk assessment using conversion factors derived from metabolism studies, which is not line with the EU policy on setting MRLs:

- Edible offal (Mammalian)
- Eggs
- Garlic
- Lemons and Limes, subgroup pf (includes all commodities in this subgroup)
- Mammalian fats
- Meat (from mammals other than marine mammals)
- Melons, except Watermelon
- Milks
- Onion, bulb
- Oranges, Sweet, Sour (includes all commodities in this subgroup)
- Papaya
- Peppers
- Poultry, edible offal of
- Poultry, fats
- Poultry, meat
- Potato
- Soya bean (dry)
- Tomatoes
- Tea, Green, Black (black, fermented and dried)

For tea, an acute consumer risk has been identified for European consumers.

The EU would like to **comment** that the Brazilian GAPs for garlic, melons, onions, papaya, potato, soya bean and tomatoes do not specify the number of applications and/or the water amount per ha.

Fluxapyroxad (256)**European Union**

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

- Coffee beans
- Cotton seed
- Mango
- Papaya
- Potato
- Tuberous and corm vegetables, except potato (includes all commodities in this subgroup)

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

- Citrus fruit (includes all commodities in this group)

According to the current EU and FAO guidelines the proposed extrapolation is not supported, as the data sets for oranges, lemons and grapefruit are significantly different (Kruskal Wallis H-test) and only one trial was submitted for mandarin.

Picoxystrobin (258)**Kenya**

Kenya supports the conclusion from the JMPR 2018

Benzovindiflupyr (261)**European Union**

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

- Dry beans, subgroup of, except soya bean, dry
- Dry peas, subgroup of (includes all commodities in this subgroup)

The EU **noted** a typo in the 2018 publications (both Summary report & Report): the STMR for peas (dry) has been reported as "0.014 mg/kg" instead of "0.011 mg/kg" (please refer to 2016 Summary report & Report, where the residue data were assessed).

Kenya

Kenya supports the outcome of the review done by the JMPR, and seeks clarification on the basis of the expansion of the maximum residue level recommendation to the whole subgroup 15A, Dry Beans (VD 2065)

Cyantraniliprole (263)**European Union**

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

- Cranberries
- Fruiting vegetables, Cucurbits, Group of (includes all commodities in this group)
- Mango
- Rice, husked
- Strawberry
- Wine grapes

Cyazofamid (281)**European Union**

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

- Bulb onions, Subgroup of (includes all commodities in this subgroup)

The EU notes that the MRL proposal was reported for code (VA0035) which refers to the group of bulb vegetables. The correct code for the subgroup of bulb onions is VA2031.

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities. JMPR extrapolation policy would support an MRL of 6 mg/kg for chives only, and of 2 mg/kg for the subgroup of green onions except chives:

- Green onions, Subgroup of (includes all commodities in this subgroup)

Lufenuron (286)

European Union

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

- Coffee beans
- Edible offal (Mammalian)
- Lime
- Mammalian fats
- Meat (mammalian except marine mammals)
- Maize
- Milks
- Oranges sweet, sour (includes all commodities in this subgroup)
- Pome fruits (includes all commodities in this group)

The EU **notes** that:

- for **maize**, residues were below 0.01 mg/kg in the trials conducted in Brazil. The proposed CXL should be labelled with an asterisk to indicate that the value is set at the limit of quantification;
- for **meat** a different definition applies in the EU considering muscle only. The MRL value to be set in EU legislation may therefore differ numerically from the one proposed by JMPR.

Quinclorac (287)

European Union

The EU would like to thank JMPR for the response. The EU maintains the position taken at CCPR 50.

Kenya

Kenya agrees with the earlier decision that the residue definition estimating the dietary intake for the crops evaluated should be, quinclorac plus quinclorac conjugates plus quinclorac methyl ester expressed as quinclorac as per the 2015 JMPR. We note that the parent compound was the main residue in crops examined and metabolite quinclorac methyl ester was a significant residue in rape seeds but a minor residue in other primary crops and also in rotational crops. The outcome of this evaluation reaffirms that there is no risk to the consumers due to exposure to these parent compound and its metabolites.

Isfetamid (290)

European Union

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

- Beans with pods (includes all commodities in this subgroup)
- Cane berries (includes all commodities in this subgroup)
- Cherries (includes all commodities in this subgroup)
- Dry beans (except soya bean (dry))
- Dry peas (includes all commodities in this subgroup)
- Peaches (including Nectarine and Apricots) (includes all commodities in this subgroup)
- Peas with pods (includes all commodities in this subgroup)
- Plums (including fresh Prunes) (includes all commodities in this subgroup)
- Pome fruits (includes all commodities in this group)

The EU **notes** that for **dry beans** and **dry peas**, the CXL should be proposed at 0.09 mg/kg, as suggested by the OECD calculator. Moreover, the proposed CXL should cover the HR of 0.08 mg/kg.

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

- Bush berries (includes all commodities in this subgroup)

According to the OECD calculator, the appropriate CXL proposal is 4 mg/kg.

Oxathiapiprolin (291)

European Union

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

- Basil (fresh) 1
- Cane berries, Subgroup of (includes all commodities in this subgroup) 1
- Citrus fruit, Group of (includes all commodities in this group) 1,2
- Edible offal (mammalian) 2
- Eggs 2
- Leaves of Brassicaceae, Subgroup of (includes all commodities in this subgroup) 1,2
- Maize 1,2
- Mammalian fats (except milk fats) 2
- Meat (from mammals other than marine mammals) 2
- Milks 2
- Poppy seed1
- Poultry edible offal 2
- Poultry fats 2
- Poultry meats 2
- Soya bean (dry)1,2
- Sunflower seed 1,2
- Tuberos and corm vegetables, Subgroup of (includes all commodities in this subgroup) 1,2
- Young shoots, Subgroup of (includes all commodities in this subgroup) 1

Justification 1:

Pending the outcome of the ongoing evaluation of toxicological properties of metabolite IN-WR791 in the EU.

Justification 2:

The dietary burden calculation do not cover feed items other than soybean meal and soybean seed residues.

The EU **notes** that regarding the update of STMR values based on residues observed in rotational crops, it is unclear for several commodities why residues in rotational stem vegetables were considered instead of residues in rotational leafy vegetables.

Phosphonic Acid (301) / Fosetyl-Aluminium (302)

Kenya

Kenya supports the conclusion from the JMPR 2018

Ethiprole (304)

European Union

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing evaluation of toxicological properties of ethiprole and metabolites RPA112916 and RPA097973 in the EU:

- Coffee beans
- Edible offal (mammalian)
- Eggs
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Poultry meat
- Poultry edible offal of
- Poultry fats
- Rice, husked

The EU would like to **comment** that the dietary burden calculation was not reported in Annex 6 of the JMPR Report.

Fenpicoxamid (305)

European Union

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

- Banana

Norflurazon (308)**European Union**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, due to the overall poor quality of the toxicological studies, the lack of data on the genotoxic potential of metabolite (NOA-452075) and the lack of a reliable calculation of the livestock dietary burden:

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

Pydiflumetofen (309)**European Union**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing evaluation in the EU:

- **Small fruit vine climbing, Subgroup of (includes all commodities in this subgroup)**

Pyrifenone (310)**European Union**

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

- Cane berries (includes all commodities in this subgroup)
- Bush berries (includes all commodities in this subgroup)
- Fruiting vegetables, Cucurbits
- Low growing berries (includes all commodities in this subgroup)
- Small fruit vine climbing (includes all commodities in this subgroup)

Tioxazafen (311)**European Union**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of the ongoing evaluation in the EU:

- Cottonseed
- Edible offal (mammalian)
- Eggs
- Maize
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Poultry edible offal
- Poultry fats
- Poultry meats
- Soya bean (dry)

The EU **notes** that lower MRLs may be sufficient for several commodities of animal origin.