

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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

Agenda Item 6

CRD07
ORIGINAL LANGUAGE

JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON PESTICIDE RESIDUES 50th Session

Haikou, P. R. China, 9-14 April 2018

**COMMENTS at Steps 3 and 6 on draft and proposed draft maximum residue limits for pesticides
in foods and feeds at Steps 4 and 7,
submitted by Kenya and European Union and United States**

General comments

China

China thanks the JMPR and appreciates the hard work for establishment of Codex MRL. China supports the advancement of the MRL proposals as recommended by JMPR to the 5/8 steps besides some MRL proposals for the public health concern raised in JMPR report.

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 2017 report. We further proposes that these draft MRLs be advanced to the next codex step.

Captan (007)

European Union

The EU would like to **comment** that besides the analytical issues identified by JMPR, metabolism studies for root crops would be required to set an MRL on ginseng.

Chlormequat (015)

European Union

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

- Barley
- Oats
- Triticale
- Wheat
- Rye
- Grapes
- Milks
- Poultry meat
- Poultry fats
- Meat (from mammals other than marine mammals)
- Mammalian fats (except milk fats)
- Edible offal (mammalian)
- Poultry, edible offal of
- Eggs

The EU would like to **comment** that in the EU, residues are expressed differently and different definitions of certain commodities of animal origin (muscle/fat vs meat) are applied. The MRL values to be set in EU legislation may therefore differ numerically from those proposed by JMPR.

2,4-D (020)**European Union**

The EU **supports** the conclusion of JMPR: the questionable storage stability of both 2,4-D and 2,4-DCP in cotton seed trials prevents the evaluation of the trial data.

Given that 2,4-DCP concentration is two times higher than the concentration of 2,4-D in treated cotton seeds, the EU would like to **comment** that 2,4-DCP toxicity should be evaluated

United States

Submitted by: United States			
Date: 29 March 2018			
Pesticide/Pesticide Code Number	Commodity/Commodity Code Number	MRL (mg/kg)	Present Step
2,4-D / 020	cottonseed	Not proposed	
Is this a request for clarification? Yes			
Request for clarification (Specific statement of clarification requested)			
<p>The 2017 JMPR report states:</p> <p>“The present (or previous) Meetings agreed that ARfDs for ... 2,4-D... were unnecessary. For these compounds a short-term dietary exposure assessment was not undertaken.” and “The long-term dietary risk assessment was not conducted for ...2,4-D... as no new recommendations for maximum residue levels were made.”</p> <p>These statements are the only mention of 2,4-D in the 2017 JMPR report. In the available report, there is no reason listed why a cottonseed MRL for 2,4-D was not proposed. Dow AgroSciences (DAS) is seeking clarification on both why no MRL was proposed and why no mention of an MRL was made. The JMPR review is quite thorough and makes no mention of specific deficiencies, but does not in the end recommend a 2,4-D cottonseed MRL.</p>			
In this a Concern? Yes			
In this a Continuing Concern? Yes			
Concern (Specific statement of reason for concern to the advancement of the proposed MRL)			
<p>No recommendation for an MRL for 2,4-D on cottonseed was made and no reason (such as a study deficiency) for not recommending a cottonseed MRL for 2,4-D was listed in the JMPR report. We would like this to be reconsidered by JMPR without requiring an additional priority slot.</p>			
Do you wish this Concern to be Noted in the CCPR Report? Yes			
Data/Information (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR Meeting)			
<p>The additional soybean storage stability study mentioned in the request for clarification section was provided to the reviewer as supplemental data in response to questions about storage stability. The citation for this study follows.</p> <p>Li, Q., Wendelburg, B.M., 2013. Frozen Storage Stability of 2,4-D and 2,4-DCP in Soybean. Study ID 101561 Dow AgroSciences. Indianapolis, IN.</p>			

Thiophanate-methyl (077)**European Union**

The EU **reserves its position**, pending the outcome of the ongoing periodic re-evaluation in the EU.

The EU would like to **comment** that in the most recent EU assessment of thiophanate-methyl, no toxicological reference values were derived. EU risk assessors considered thiophanate-methyl a clastogenic substance for which no threshold is assumed and could not rule out a potential for aneugenicity.

Oxamyl (126)

European Union

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

- Brussels sprouts
- Carrot
- Cherry tomato
- Edible offal (mammalian)
- Eggplant (includes all commodities in this subgroup)
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Melons, except Watermelon
- Milks
- Parsnip
- Peppers, chili (dried)
- Potato
- Subgroup of eggplants (includes all commodities in this subgroup)
- Subgroup of peppers (except martynia, okra and roselle)
- Sugar beet
- Tomato
- Watermelon

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

- Cucumber
- Squash, summer

The proposed draft MRLs cannot be taken over in EU legislation because **acute health risks** were identified for a group of EU consumers.

The EU would like also to **comment** that two draft MRL were proposed for **eggplants**, one for the individual crop (crop code **VO0440**) and a second one for the **subgroup of eggplants** (crop code **VO2016**). To avoid confusions, the MRL for the individual crop (crop code **VO0440**) could be deleted.

Propiconazole (160)

European Union

The EU introduces a **reservation to the advancement** of the proposed draft MRLs the following commodities, pending the outcome of an ongoing review. For this review EFSA could not finalise consumer assessment due to data gaps and no conclusion could be drawn on the genotoxicity and the general toxicity of several metabolites:

- Subgroup of oranges, sweet, sour (including orange-like hybrids)
- Subgroup of mandarins (including mandarin-like hybrids)
- Subgroup of lemons and limes (including citron)
- Subgroup of pummelo and grapefruits (including shaddock-like hybrids)
- peach
- subgroup of cherries (includes all commodities in this subgroup)
- Subgroup of plum including prunes) (includes all commodities in this subgroup)
- Pinapple

The EU would like to **comment** that for post-harvest uses, the MRLs should be calculated as mean + 4SD, considering that for post-harvest uses a more homogeneous residue distribution is expected. Thus, the MRL proposals derived by JMPR seem to be too high.

Furthermore, a metabolism study for post-harvest uses is required.

Fenpropimorph (188)

European Union

The EU would like to **comment** that different residue definitions appear in Annex 1 of JMPR summary report and on page 161 of JMPR report. The EU would like, to have the confirmation that the residue definitions reported in on page 161 of JMPR report are the correct ones.

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

- Rye

It is not appropriate to extrapolate the draft MRL for rye from the draft MRL for wheat as the GAPs for wheat and rye are different.

- Bananas

An acute consumer risk has been identified for European consumers.

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

- Barley

- Oats

- Rye

- Triticale

- Wheat

- Sugar beet

- Wheat

Tebuconazole (189)

European Union

The EU **reserves its position**, pending the outcome of the ongoing periodic re-evaluation in the EU.

- Subgroup of Beans with pods (includes all commodities in this subgroup)

Fenpyroximate (193)

China

China noted the public concerns raised by fenpyroximate on cherry (110% for children from Netherland and Denmark), peach (130% for children from Japan and Canada), watermelon (190% for children from Canada), dried tomato (310% the for general population from Australia), and dried plums (270% for children from Australia). Considering the health risks to Chinese children and general population, China maintains reservation on these MRL proposals.

European Union

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

- Apple

- Avocado

- Apricot

- Grapes

- Strawberries

- Raspberry

- Squash, summer

- Subgroup of Eggplants (includes all commodities in this subgroup)

- Subgroup of Beans with pods (includes all commodities in this subgroup)

- Potato

- Maize

- Tree nut

- Hops, dry

- Tea, green, black, dried

- Milks

The EU **reserves its position** on the proposed draft MRLs for the following commodities:

- Pear
- Cucumbers
- Melons, except watermelon

Pending the outcome of an ongoing review of the substance in the EU. Using the lower ARfD of JMPR, an intake concern was identified for the EU.

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

- **Subgroup of Peppers (except Martynia, Okra and Roselle)**

The residue trials used to derive the MRL proposal were analysed only for the parent compound. Thus, the HR and STMR values are likely to underestimate the total residues (sum of fenpyroximate and M-1).

- **Group of Citrus fruit (includes all commodities in this group)**

According to the current EU guidelines the proposed extrapolation is not supported. Moreover, the peeling factor used in the risk assessment could not be verified, without which it was not possible to exclude an acute risk to consumers.

- **Coffee beans**

The residue trials used to derive the MRL proposal were analysed only for the parent compound. Thus, the HR and STMR values are likely to underestimate the total residues (sum of fenpyroximate and M-1).

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

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

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

- **Subgroup of Cherries (includes all commodities in this subgroup)**
- Peach
- **Subgroup of Plums (including fresh prunes) (includes all commodities in this subgroup)**
- Watermelon
- Tomato

An acute consumer risk has been identified by JMPR.

Imidacloprid (206)

European Union

The EU **supports** the conclusion of JMPR: the supplied data do not match the GAP for **pistachio nuts** and do not allow any MRL proposal.

Cyprodinil (207)

European Union

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

- **Artichoke, globe**
- **Carrot**
- **Celery**
- **Guava**
- **Subgroup of Beans with pods (includes all commodities in this subgroup)**
- **Potato**
- **Tree nuts (except almond and pistachio)**

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

- **Pomegranate**

As metabolism studies in fruit crops are available only for foliar uses, it is unclear whether the fate of residues following post-harvest use is comparable with foliar use. As the GAP is a post-harvest treatment, the MRL should be calculated as "mean + 4 SD" and an MRL proposal of 5 mg/kg would be sufficient.

Trifloxystrobin (213)**European Union**

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

- Cotton seed
- Ginseng
- Spinach

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

- Cabbages, Head

The EU has a different policy to apply the same commodity definition, i.e. whole plant after removal of roots and decayed leaves, to derive both the MRL and the STMR and HR.

Difenoconazole (224)**European Union**

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

- Pome fruits

A chronic and an acute risk for European consumers are identified.

- Rice

EU MRLs for rice are set for husked rice and no processing factor is available to derive such MRL.

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

- Blueberries
- Strawberries
- Pitaya (dragon fruit)
- Watermelon
- Peppers, chili
- Peppers, chili, dried

The EU would like to **comment** that the trial results for peppers, chili and the processing factor of 4.5 lead to a MRL of 4 mg/kg for **peppers, chili, dried**. The CXL of 5mg/kg for peppers, chili, dried should therefore be replaced by 4 mg/kg

- Sweet corn (corn on the cob) (kernels plus cob with husk removed)
- Subgroup of dry beans (except soya bean)
- Subgroup of dry peas (includes all commodities in this subgroup)
- Ginseng, dried
- Globe artichoke
- Coffee beans

Azoxystrobin (229)**European Union**

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

- Pitaya (dragon fruit)
- Sugar cane
- Rape seed

Prothioconazole (232)

European Union

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

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

Spinetoram (233)

European Union

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

- Subgroup of mandarin
- Subgroup of cherries
- Apricot
- Currant, Black, Red, White
- Strawberry
- Table olives
- Litchi
- Mango
- Passionfruit
- Leek
- Subgroup of Fruiting vegetables, Cucurbits - Cucumbers and Summer squashes (includes all commodities in this subgroup)
- Melons, except watermelon
- Subgroup of Peppers (except Martynia, Okra and Roselle)
- Soya bean (dry)
- Potato
- Husked rice
- Maize
- Sweet corn (Corn on the cob) (kernels plus cob with husk removed)
- Cotton seed
- Poultry meat
- Poultry, edible offal
- Poultry fats
- Eggs

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

- Subgroup of plums

The proposed draft MRL based on combining 10 trials approximating the GAP and 11 trials with a higher number of applications is unnecessarily high (0.09 mg/kg). Ten trials approximating the GAP are considered sufficient to derive an MRL (0.015 mg/kg).

- Avocado

Only in two trials the treatment regime did not differ significantly from the cGAP. From the information presented in the JMPR evaluation and the JMPR report, it is not clear how the scaling factors were calculated.

- Persimmons

The critical GAP for persimmons differs from the cGAP for pome fruit. Therefore it is not appropriate to extrapolate the MRL from pome fruit to persimmon.

- Milks

- Meat (from mammals other than marine mammals)

- Edible offal (mammalian)

- Mammalian fats (except milk fats)

Since cabbage/kale was not included in the dietary burden calculation, the proposed MRL for animal products should be reconsidered.

Fluopyram (243)

European Union

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

- Artichoke, globe
- Barley
- Basil
- Cotton seed
- Dill seed
- Edible offal (mammalian)
- Eggs
- Hops (dry)
- Mammalian fat
- Mango
- Meat (from mammals other than marine mammals)
- Oats
- Onion, Welsh
- Peanut
- Potato
- Poultry fat
- Poultry meat
- Poultry, Edible offal of
- Pummelo and Grapefruits (including Shaddock-like hybrids, among others Grapefruit)
- Rye
- Soya bean (dry)
- Spring onion
- Subgroup of Bush berries (includes all commodities in this subgroup)
- Subgroup of Cane berries (includes all commodities in this subgroup)
- Subgroup of Cherries (includes all commodities in this subgroup)

The EU would like to comment that despite the limited number of residue trials available for evaluation, the proposed draft MRL is acceptable, taking into account the similarity to the existing EU-MRL.

- Subgroup of Dry Beans (except Soya bean (dry))
- Subgroup of Eggplants (includes all commodities in this subgroup)
- Subgroup of Lemons and Limes (includes all commodities in this subgroup)
- Subgroup of Maize Cereals (includes all commodities in this subgroup)
- Subgroup of Mandarins (includes all commodities in this subgroup)
- Subgroup of Oranges, Sweet, Sour (includes all commodities in this subgroup)
- Subgroup of Peppers (except Martynia, Okra, Roselle)
- Sunflower seed
- Sweet corn (Corn on the cob) (kernels plus cob with husk removed)
- Tomato
- Triticale
- Wheat
- Witloof chicory (sprouts)

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

- Milks

A long-term consumer health risk was identified. The overall chronic exposure accounted for 205% of the ADI. The food item with the largest contribution to the most critical diet and for which a CXL has been proposed was milk representing the 158% of the ADI.

- Rice

In the EU, a different commodity definition is applied, and processing data allowing a recalculation of the MRL value are not available.

- Subgroup of Dry Peas (includes all commodities in this subgroup)

The number of residue trials was insufficient to be in accordance with the FAO Manual.

Acetamiprid (246)

European Union

The EU **supports** the conclusion of JMPR: the supplied data do not match the GAP for pistachio nuts and do not allow any MRL proposal.

Isopyrazam (249)

European Union

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

- Group of Pome fruits(includes all commodities in this group)

- Cucumbers

- Melon, except watermelon

- Peppers, Sweet (including pimento or pimiento)

- Tomato

- Subgroup of Eggplants (includes all commodities in this group)

- Carrot

- Barley

- Wheat

- Rye

- Triticale

- Rape seed

- Peanut

- Mammalian fats (except milk fats)

- Meat (from mammals other than marine mammals)

- Edible offal (mammalian)

- Milks

Propylene oxide (250)

European Union

The EU **supports** the conclusion of JMPR: the supplied residue data do not allow any MRL proposal.

Saflufenacil (251)

European Union

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

- Mustard seed

- Linseed

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.

Picoxystrobin (258)

European Union

The EU introduces a **reservation to the advancement** of the proposed draft MRLs the following commodities due to several health concerns identified in the EFSA peer review, including possible genotoxicity of picoxystrobin and its main plant metabolites:

- Barley
- Edible offal (mammalian)
- Eggs
- Maize
- Maize oil, edible
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals) (fat)
- Milks
- Oats
- Oat straw and fodder, dry
- Pea hay or pea fodder (dry)
- Popcorn
- Poultry, edible offal of
- Poultry fats
- Poultry meat
- Rye
- Soya bean oil, refined
- Subgroup of dry beans (includes all commodities in this subgroup)
- Subgroup of dry peas (includes all commodities in this subgroup)
- Sweet corn (corn-on-the-cob) (kernels plus cob with husk removed)
- Triticale
- Wheat

United States

Submitted by: United States			
Date: 29 March 2018			
Pesticide/Pesticide Code Number	Commodity/Commodity Code Number	MRL (mg/kg)	Present Step
Picoxystrobin/258	Oilseed rape, seed	Not proposed	To be confirmed at CCPR 50
Is this a request for clarification? Yes			
Request for clarification (Specific statement of clarification requested)			
<p>The 2017 JMPR report states:</p> <p style="padding-left: 40px;">“The GAP for oilseed rape in the USA and Canada is 2 × 0.22 kg ai/ha applications with a 28-day PHI. Trials were conducted in oilseed rape in the USA and Canada, and were evaluated against the Canadian GAP. Residues in seed from trials (n=3) at the Canadian GAP were < 0.01, 0.012, and 0.031 mg/kg. The Meeting concluded that there were insufficient trials at GAP to estimate a maximum residue level for oilseed rape.”</p> <p>However, eighteen residue trials were conducted and summarized in the 2012 JMPR Evaluation document with the correct application use pattern (2 applications at 0.22 kg ai/ha, 7-day retreatment interval). In two MOR trials, the seeds were collected at the labelled 28-day PHI while in 14 MOR trials the seeds were collected at a 21-day PHI instead of the labelled 28-day PHI (25% variation). In the two residue decline trials, mature seed was collected at both 21- and 28-day PHI. In these decline trials, residues in the 21-day PHI mature seed samples (<0.01 mg/kg, 0.013 mg/kg) were the same as residues in the 28-day PHI mature seed samples (<0.01 mg/kg, 0.012 mg/kg) confirming that residues in the 21-day PHI mature seed samples from the MOR trials can be used to estimate a maximum residue level and STMR for canola and canola products.</p>			

<p>These residue data are summarized in Table 29 of the JMPR report. These data are not described in the JMPR report as unacceptable and it is unclear why the JMPR review indicated that there were insufficient trials at the GAP to estimate a maximum residue level for oilseed rape</p> <p>For clarification, since the residue data review and summary is already complete, can JMPR-2018 revisit the oilseed rape crop to propose MRLs?</p>
In this a Concern? Yes
In this a Continuing Concern? Yes
<p>Concern (Specific statement of reason for concern to the advancement of the proposed MRL)</p> <p>We would like the conclusion that there were an insufficient number of MOR field trials to be re-reviewed or clarified by JMPR 2018 as it appears to us that there were a sufficient number of field trials at or sufficiently close to the GAP to allow the recommendation for an MRL for oilseed rape.</p>
Do you wish this Concern to Noted in the CCPR Report? Yes
<p>Data/Information (Description of each separate piece of data/information which is attached or will be provided to the appropriate JMPR secretary within one month of the CCPR Meeting)</p> <p>No additional information is needed. All residue data are summarized in the 2012 JMPR Evaluation and the labelled use pattern is summarized in the 2017 JMPR Report.</p>

Imazapyr (267)

European Union

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

- Barley

The number of available residue trials is lower than required by EU policy, in combination with an inhomogeneous distribution of trial results.

Imazamox (276)

European Union

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

- Barley

Imazamox is under review in the EU and EFSA advises an enforcement residue definition that is not compatible with the one decided by JMPR, as it includes the metabolite CL 263284 for plant products.

Flonicamid (282)

European Union

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

- Subgroup of beans with pods(except soya bean (succulent seeds in pods))**
- Subgroup of peas with pods**
- Subgroup of succulent beans without pods (except soya bean (succulent seeds))**
- Subgroup of succulent peas without pods**
- Subgroup of dry beans (except soya bean (dry))**
- Subgroup of dry peas**

The proposed draft MRLs for commodities of plant origin cannot be taken over in EU legislation because they are derived from a different residue definition for enforcement.

Flupyradifurone (285)

European Union

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

- Subgroup of Cherries (includes all commodities in this subgroup)**
- Subgroup of Peaches (including Nectarine and Apricots) (includes all commodities in this subgroup)**
- Subgroup of Plums (including fresh Prunes) (includes all commodities in this subgroup)**

The proposed draft MRLs cannot be taken over in EU legislation because they are derived for a different enforcement residue definition.

Quinlorac (287)

European Union

The EU would like to thank JMPR for their reply to the concern form.

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

- Rape seed

In view of the high toxicity of quinlorac methyl ester (10 times more toxic than the parent) and its high occurrence in rape seed (up to 400% of the parent compound), the EU considers it appropriate to include quinlorac methyl ester in the enforcement residue definition, at least for rape seed. The 2017 JMPR noted in its report that quinlorac methyl ester is included in the enforcement residue definition for rape seed in the countries where the critical GAP is authorised on which JMPR based its MRL proposal.

- Rice, husked

The samples of the supervised field trials were not analysed for the full residue definition for risk assessment. The use of an indicative conversion factor from metabolism studies to estimate the residues of the more toxic metabolite is leading to a high uncertainty. Considering that the dietary exposure to residues via rice is close to the ARfD, this high level of uncertainty is not acceptable. Moreover, the definition of commodity is different in the EU and insufficient data is available to derive a robust processing factor.

- Edible offal (mammalian)

- Eggs

- Mammalian fats (except milk fats)

- Meat (from mammals other than marine mammals)

- Milks

- Poultry, Edible offal of

- Poultry fats

- Poultry meat

The calculation of the livestock dietary burden included feed items derived from rape seed and rice. The reservation to the advancement of the proposed draft MRLs for animal commodities is a consequence of the reservations for rape seed and rice.

The EU would like to **comment** that it needs to be verified whether routine enforcement methods are also covering quinlorac conjugates.

Bicyclopyrone (295)

European Union

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

- Sweet corn (Corn on the cob) (kernels plus cob with husk removed)

- Barley

- Maize

- Wheat

- Sugar cane

- Milk of cattle, goats and sheep

- Mammalian fats (except milk fats)

- Meat (from mammals other than marine mammals)

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

- Edible offal (mammalian)

Using the ARfD of JMPR, an intake concern was identified for the EU.

Cyclaniliprole (296)

European Union

In its peer review in 2016, EFSA could not finalise the consumer risk assessment because of the data gaps relating to the toxicological assessment, including genotoxic potential of metabolites NK-1375, YT-1327, BCPBA and BPQO. The EU introduces therefore a **reservation to the advancement** of the proposed draft MRLs for the following commodities:

- **Subgroup of Cherries(includes all commodities in this subgroup)**
- **Cherry Tomato**
- **Subgroup of Cucumbers and**
- **Summer Squashes(includes all commodities in this subgroup)**
- **Subgroup of Eggplants (includes all commodities in this subgroup)**
- **Subgroup of Flowerhead Brassicas(includes all commodities in this subgroup)**
- **Subgroup of Head Brassicas (includes all commodities in this subgroup)**
- **Subgroup of Leaves of Brassicaceae Brassica spp. (includes all commodities in this subgroup)**
- **Subgroup of melons, pumpkins and Winter squashes (includes all commodities in this group)**
- **Subgroup of Peaches (including Apricots and Nectarines) (includes all commodities in this subgroup)**
- **Subgroup of Peppers (except Martynia, Okra and Roselle)**
- **Group of Pome fruits (includes all commodities in this group)**
- **Subgroup of Plums (includes all commodities in this subgroup)**
- **Grapes**
- **Tomato**

JMPR used a new tool that was developed to model the residue behaviour and would predict residue concentrations for a given GAP from residue trials that differ in terms of application rates, treatment intervals, PHI.

However, there is no information available regarding the necessary validation of this tool.

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

Fenazaquin (297)

European Union

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

- **Subgroup of cherries**
- **Hops, dry**

In the EU, separate risk assessments are conducted for fenazaquin and the metabolite TBPE due to the different toxicological reference values (TBPE is of higher toxicity than fenazaquin). Since no residue data on TBPE were reported by JMPR, the EU could not ascertain the acceptability of the proposed draft MRLs and reserves its position.

Fenpyrazamine (298)

European Union

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

- **Subgroup of Cherries(includes all commodities in this subgroup)**
- **Subgroup of Plums(includes all 2 commodities in this subgroup)**
- **Subgroup of Peaches(includes all commodities in this subgroup)**

The EU would like to **comment** that for these 3 subgroups it calculated different MRLs using the same data but based on individual European geographical zones, while JMPR pooled all the available data of the different zones. The proposed draft MRLs should therefore be reconsidered as follows:

For the **subgroup of Cherries**, the results of the 8 trials in the north EU zone lead to a MRL of 4 mg/kg instead of 3 mg/kg.

For the **Subgroup of Plums**, the results of the 8 trials in the north EU zone lead to a MRL of 3 mg/kg instead of 2 mg/kg.

For the **Subgroup of Peaches**, the results of the 12 trials in the south EU zone lead to a MRL of 5 mg/kg instead of 4 mg/kg.

- **Subgroup of Cane berries (includes all commodities in this subgroup)**
- **Subgroup of Bush berries(includes all commodities in this subgroup)**
- **Grapes**

The EU would like to **comment** that the OECD calculator provides a MRL of 3 mg/kg and that the draft proposed MRL of 4 mg/kg should be corrected down to this value.

The EU would like also to **comment** that on the basis of a MRL of 3 mg/kg for grapes, the draft proposed MRL for dried grape should be set at 9 mg/kg.

- **Strawberry**
- **Cucumber**
- **Peppers, sweet (including pimento or pimiento)**
- **Tomato**
- **Cherry tomato**
- **Subgroup of eggplants(includes all commodities in this subgroup)**
- **Lettuce, Head**
- **Lettuce, Leaf**
- **Ginseng**
- **Almond**
- **Mammalian fats (except milk fats)**
- **Meat (from mammals other than marine mammals)**
- **Milks**
- **Edible offal (mammalian)**

Isoprothiolane (299)

European Union

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

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

Natamycin (300)

European Union

The EU is **opposed to the advancement** of the proposed draft MRLs for the following commodities:

- **Citrus fruit (includes all commodities in this group)**

The residue definition is not sufficiently supported by experimental data and no toxicological reference values are available to perform a dietary risk assessment.

The EU would like also to **comment** on the following deficiencies:

- lack of storage stability data;
- nature of residues in edible part of the crop expected to be different due to hydrolytic degradation under acidic conditions; and
- method to calculate the MRL for post-harvest uses is “mean + 4 SD” for Po, which leads to a MRL proposal of 4 mg/kg.

Phosphonic acid (301)

European Union

See fosetyl.

Fosetyl Aluminium (302)

European Union

The EU would like also to **comment** that the residues for enforcement are expressed as fosetyl in the EU, while they are expressed as phosphonic acid by JMPR. If adopted, the proposed draft MRLs will be recalculated to match with the EU residue definition.

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

- Avocado
- Cucumber
- Edible offal (mammalian)
- Grapes
- Group of pome fruits (includes all commodities in this group)
- Hops (dry)
- Lettuce, head
- Lettuce, leaf
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Melon (except water melon)
- Milks
- Peppers, sweet, (including pimento or pimiento)
- spinach
- Strawberries
- Summer squash
- Tomato
- Tree nuts (includes all 400 commodities in this group)

Concerning the proposed draft MRL for the group **tree nuts**, the EU would like to **comment** that it will not apply it to **coconut**, as different extrapolation rules apply in the EU.

Triflumezopyrim (303)

European Union

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

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