

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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Agenda Item 5b,6

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Comments on Agenda Item 5b: Report on 2016 JMPR responses to specific concerns, and Agenda Item 6: Draft and proposed draft maximum residue limits for pesticides in foods and feeds at Steps 7 and 4, submitted by Australia, European Union, Ghana, Kenya, Thailand and African Union

Chlorothalonil (81)

European Union

The EU **shares the view of JMPR** that no MRL can be proposed for cranberries due to uncertainties regarding the storage stability of chlorothalonil and metabolite SDS-3701.

Chlorpyrifos-Methyl (90)

Australia

Concerning Chlorpyrifos-Methyl in Cereal Commodities

Introduction

1. Chlorpyrifos-methyl (90) was subject to a periodic re-evaluation by the 2009 JMPR. At 42CCPR in 2010, draft MRLs for various cereal commodities were advanced to Step 5 pending the JMPR's consideration of alternative GAP in 2012. The 2012 JMPR was not able to recommend any new MRLs. Subsequent JMPR evaluations of an Australian label in 2013 and 2014 ultimately resulted in no new recommendations for MRLs in cereal commodities.
2. At Australia's request, the 47CCPR (2015) retained all draft MRLs and CXLs for various cereal commodities under the 4 year rule (REP 15/PR, para 46). Australia committed to supply new GAP information and residue data for evaluation by the JMPR in 2019.
3. Australia wishes to inform the Committee that it is no longer in a position to provide the information required for a new JMPR evaluation.

Key issues

4. None of the information on GAP submitted to the JMPR since the periodic re-evaluation in 2009 was suitable to enable the JMPR to make any changes to the recommendations for MRLs on cereal grains or cereal commodities.
5. Accordingly, Australia requests that CCPR act on the recommendations of the 2009 JMPR.
6. The many draft MRLs and CXLs currently listed for chlorpyrifos-methyl in various cereal commodities are potentially confusing (see CX/PR 17/49/05).
7. Australia has considered the status of all the listed MRLs and CXLs and provides the following analysis in case it may assist the Committee to finalise CXLs for the listed cereal commodities.

Draft MRLs and CXLs for chlorpyrifos-methyl in cereal commodities as shown in CX/PR 17/49/05

8. The draft MRLs and CXLs may be placed into three groups:
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Group 1: Draft MRLs and CXLs that were in place before the periodic re-evaluation in 2009

barley	10 mg/kg	Step 7
oats	10 mg/kg	Step 7
rice	0.1 mg/kg	CXL
rice	10 mg/kg	Step 7
sorghum	10 mg/kg	CXL
wheat	10 mg/kg	CXL
wheat bran, unprocessed	20 mg/kg	CXL

Group 2: MRLs recommended by the 2009 JMPR

barley	3 mg/kg	Step 7
wheat	3 mg/kg	Step 7
wheat bran, unprocessed	6 mg/kg	Step 7
wheat germ	5 mg/kg	Step 7

9. The 2009 JMPR evaluated trial data for wheat and barley based on Spanish GAP for post-harvest treatment. The above MRLs plus a MRL at 3 mg/kg for maize were recommended, however the 42CCPR (2010) withdrew the recommendation for maize because it was informed that the GAP for maize was no longer supported (Alinorm 10/33/24, para. 38).

10. The 2009 JMPR reported long-term dietary intake concerns for chlorpyrifos-methyl, but the CCPR's deletion of the draft MRL for maize effectively overcame the concerns. The 2012 JMPR reviewed a new Spanish label to confirm that use on maize was not supported. Accordingly, the JMPR withdrew its earlier recommendation for maize, which justified the action taken by the 42CCPR. The 2012 JMPR also reported that, with maize omitted from dietary estimates, the IEDI ranged from 3-60% of the ADI for the 13 GEMS/Food diets in place at the time.

Group 3: Draft MRLs recommended by the 2013 JMPR

cereal grains, except maize & rice	5 mg/kg	Step 4
rice, husked	1.5 mg/kg	Step 4
rice, polished	0.2 mg/kg	Step 4

11. The 2014 JMPR advised CCPR that the recommendations from their 2013 meeting were based on trial data that did not match critical GAP on the Australian label. Accordingly the 2014 JMPR withdrew the recommendations from the 2013 JMPR. The CCPR should delete these draft MRLs because they are no longer recommended by the JMPR.

12. Noting that the recommendations from the 2013 JMPR were withdrawn, effectively nothing has changed since the periodic re-evaluation in 2009, except for deletion of the draft MRL for maize.

Consideration of the recommendations from the periodic re-evaluation conducted by the JMPR in 2009

13. For a periodic re-evaluation;

- existing CXLs for commodities that are supported are either confirmed or recommended for withdrawal and replaced by a new recommendation (JMPR)
- existing CXLs for commodities that are not supported are recommended for withdrawal (JMPR)
- existing draft MRLs for commodities that are supported are replaced by new recommendations from the JMPR (CCPR)
- existing draft MRLs for commodities that are not supported are deleted (CCPR)

14. Since the periodic re-evaluation in 2009, the CCPR has maintained all draft MRLs and CXLs for cereal commodities, except for the draft MRL for maize, awaiting outcomes from the JMPR's evaluations of alternative GAP.

15. Because alternative GAP is no longer under consideration, the CCPR may now review the draft MRLs and CXLs listed in Group 1 and Group 2 according to normal practice for a periodic re-evaluation.

16. Noting that the 2012 JMPR reported no intake concerns, the normal action would be;

- delete the draft MRL for barley at 10 mg/kg and advance the new recommendation at 3 mg/kg to Step 8
- revoke the CXL for wheat at 10 mg/kg and advance the new recommendation at 3 mg/kg to Step 8
- revoke the CXL for wheat bran, unprocessed at 20 mg/kg and advance the new recommendation at 6 mg/kg to Step 8
- advance the new recommendation for wheat germ at 5 mg/kg to Step 8
- delete the draft MRL for oats at 10 mg/kg
- revoke the CXL for rice at 0.1 mg/kg
- delete the draft MRL for rice at 10 mg/kg
- revoke the CXL for sorghum at 10 mg/kg

Recommendations

17. Australia recommends that the Committee;

- advances the draft MRLs for wheat, barley, wheat bran (unprocessed) and wheat germ, recommended by the 2009 JMPR and currently at Step 7, to Step 8,
- deletes all other draft MRLs for cereal grains and cereal commodities, and
- revokes all existing CXLs for cereal commodities.

Deltamethrin (135)

European Union

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

-rape seed

Kenya

Issue: Deltamethrin is a non-systemic synthetic pyrethroid insecticide, and was scheduled by the 47th Session of the CCPR for the evaluation of additional uses by the 2016 JMPR, new GAP information and residue data on rape seed (canola) were submitted to the JMPR for evaluation.

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the commodity (Rape seed).

Rationale: The IEDIs of deltamethrin for the 17 GEMS/Food cluster diets, based on estimated STMRs were 0–50% of the maximum ADI of 0.01 mg/kg bw. Similarly the IESTI varied from 0–0% of the ARfD (0.05 mg/kg bw). The low percentage of long and short term dietary exposures to residues of deltamethrin does not present any public health concern and therefore is unlikely to impede trade in the above commodity.

Methoprene (147)

European Union

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.

African Union

Issue: Methoprene is an insect growth regulator and was scheduled at the 47th Session of the CCPR (2015) for the evaluation of additional MRLs in 2016 JMPR. Data from supervised trial on sunflower seeds were submitted by the manufacturer for additional MRLs for oilseeds.

Position: AU supports the proposed draft MRLs and their advancement to the next step of the Codex stepwise process for the oilseed except peanut.

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 10–60% of the maximum ADI for S-methoprene (0.05 mg/kg bw). The 2001 JMPR decided that an ARfD is unnecessary. Long and short term dietary exposures to residues of S- methoprene is therefore unlikely to present a public health concern.

Bentazone (172)

European Union

The EU **supports** the introduction of an ARfD of 0.5 mg/kg bw for this substance.

African Union

Issue: Bentazone is a post emergence herbicide and was evaluated by JMPR in 2012, as part of the periodic review programme of the CCPR. The 2012 Meeting established an acceptable daily intake (ADI) and also reaffirmed its conclusion that no acute reference dose (ARfD) was necessary. During the 48th Session of the CCPR, the WHO representative informed CCPR that the new studies on acute toxicity of bentazone identified by the experts working on WHO Guidelines for drinking water quality had not yet submitted to the JMPR for re-evaluation specifically to determine whether there is a need to establish an ARfD.

Position: AU supports the conclusion of the JMPR 2016 to establish an ARfD of 0.5mg/kg for bentazone.

Rationale: Short-term exposure to residues of bentazone represent 0-1% of the ARfD for the general population and 0-3% of the ARfD for children; thus when used in the way that is prescribed, bentazone is unlikely to present a risk to public health.

Buprofezin (173)

European Union

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

Kenya

Position: We support the propose draft MRLs and the advancement to the next Codex step process for the following commodities (Avocado, Basil and Soya bean, dry)

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 40% of the maximum ADI of 0.009 mg/kg bw. Similarly the IESTI represented maximum of 0.2% of the ARfD. The low percentage of long and short term dietary exposure to residues of buprofezin does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

Thailand

Thailand would like to strongly support the draft MRLs of Buprofezin and Fipronil on basil for adoption at step 5/8.

African Union

Issue: Buprofezin is an insecticide and was scheduled by the 47th Session of the CCPR for the evaluation of additional uses by the 2016 JMPR meeting, new use supervised field residue trial data were provided for the following crops; basil, mango, papaya and soya bean.

Position: AU supports the propose draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Avocado, Basil and Soya bean, dry)

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 40% of the maximum ADI of 0.009 mg/kg bw. Similarly the IESTI represented maximum of 0.2% of the ARfD. The low percentage of long and short term dietary exposure to residues of buprofezin is unlikely to present any public health concern and therefore not likely to impede trade in the above-mentioned commodities.

Penconazole (182)**European Union**

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.

Kenya

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Apple, Artichoke, globe, Blackcurrant, Cucumber, Dried grape (currants, raisins and sultanas), Eggplant, Gherkin, Grapes, Melons, except watermelon, Peaches, Pear, Pepper, Sweet, Squash, summer, Strawberry and Tomato).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 0–3% of the maximum ADI of 0–0.03 mg/kg bw. Similarly the calculated IESTIs represented 0–6% of the ARfD (0.8 mg/kg bw) for the general population and 0–10% of the ARfD for children. The low percentage of long and short term dietary exposures to penconazole residues is unlikely to present a public health concern and therefore is improbable to impede trade in the above commodities.

African Union

Issue: Penconazole is a systemic triazole fungicide and was scheduled at the 47th Session of the CCPR (2015) for periodic re-evaluation of residues by the 2016 JMPR. Supervised residue trial data for pome fruits (apple, pear), stone fruits (peach, cherry), berries and other small fruits (blackcurrant, grape, strawberry), fruiting vegetables (melon, cucumber, tomato, sweet pepper) and globe artichoke were submitted and evaluated.

Position: AU supports the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Apple, Artichoke, globe, Blackcurrant, Cucumber, Dried grape (currants, raisins and sultanas), Eggplant, Gherkin, Grapes, Melons, except watermelon, Peaches, Pear, Pepper, Sweet, Squash, summer, Strawberry and Tomato).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 0–3% of the maximum ADI of 0–0.03 mg/kg bw. Similarly the calculated IESTIs represented 0–6% of the ARfD (0.8 mg/kg bw) for the general population and 0–10% of the ARfD for children. These risk characterization outcomes are unlikely to present intake concerns.

Fenpropimorph (188)**European Union**

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.

Teflubenzuron (190)**European Union**

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
- 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

Kenya

Position: Kenya supports the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Apple, Cauliflower, Coffee beans, Cucumber, Gherkin, Grapes, Lemons and limes (includes all commodities in this subgroup), Maize, Maize oil, edible, Melons, except watermelon, Orange oil, Oranges, Sweet and Sour (includes all commodities in this subgroup), Papaya, Soya bean (dry), Soya bean hulls, Sugar cane, Sunflower seed and Tomato).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 1–30% of the maximum ADI of 0–0.005 mg/kg. The 2016 JMPR decided that ARfD for teflubenzuron was unnecessary. The long and short term dietary exposures to residues of teflubenzuron are unlikely to present a public health concern.

African Union

Issue: Teflubenzuron is a benzoylurea insecticide and was scheduled at the 47th Session of the CCPR for periodic re-evaluation for residues and toxicology by the 2016 JMPR. Supervised residue trial data were received and evaluated for the following crops; citrus fruits, apples, grapes, mangoes, papaya, pineapples, broccoli, cauliflower, melons, cucumbers, gherkins, tomatoes, sweet peppers, pulse, maize and coffee.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Apple, Cauliflower, Coffee beans, Cucumber, Gherkin, Grapes, Lemons and limes (includes all commodities in this subgroup), Maize, Maize oil, edible, Melons, except watermelon, Orange oil, Oranges, Sweet and Sour (includes all commodities in this subgroup), Papaya, Soya bean (dry), Soya bean hulls, Sugar cane, Sunflower seed and Tomato).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 1–30% of the maximum ADI of 0–0.005 mg/kg. The 2016 JMPR decided that ARfD for teflubenzuron was unnecessary. The long and short term dietary exposures to residues of teflubenzuron are unlikely to present a public health concerns.

Fipronil (202)

European Union

The EU introduces a **reservation to the advancement** 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.

Ghana

Ghana has the following pesticides registered for use in the country and supports the MRLs set for them as fair and achievable:

2. 5.9-Fipronil

Thailand

Thailand would like to strongly support the draft MRLs of Buprofezin and Fipronil on basil for adoption at step 5/8.

African Union

Issue: At the 47th Session of the CCPR (2015), fipronil was scheduled for the evaluation of additional MRLs in 2016 JMPR. Supervised residue trials data on basil was submitted.

Position: AU supports the proposed draft MRLs and its advancement to the next step of the Codex stepwise process for basil.

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 20–90% of the maximum ADI. Similarly the IESTI represented 10% of the ARfD for the general population and 20% of the ARfD for children. The low percentage of long and short term dietary exposures to residues of fipronil does not present any public health concern and therefore is unlikely to impede trade in the above commodity.

Dimethomorph (225)

European Union

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

-lettuce, leaf

Ghana

Ghana has the following pesticides registered for use in the country and supports the MRLs set for them as fair and achievable:

1. 5.7-Dimethomorph

Kenya

Position: We support the proposed draft MRL and the advancement to the next Codex step process for the commodity (Leaf Lettuce).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0–2% of the maximum ADI (0–0.2 mg/kg bw). Similarly the IESTI represented 0 – 20% of the ARfD (0.6 mg/kg bw for the general population and for children 0-60% of the ARfD). The low percentage of long and short term dietary exposures to residues of dimethomorph does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

African Union

At 47th session of the CCPR (2015), dimethomorph was scheduled for evaluation of an alternative GAP and of additional MRLs by 2016 JMPR. They re-evaluated supervised field residue trial data for Lettuce, head, Leaf lettuce and Corn salad (Lambs lettuce).

Position: AU supports the proposed draft MRL and its advancement to the next step of the Codex stepwise process for the commodity (Leaf Lettuce).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0–2% of the maximum ADI (0–0.2 mg/kg bw). Similarly the IESTI represented 0 – 20% of the ARfD (0.6 mg/kg bw for the general population and for children 0-60% of the ARfD).

The low percentage of long and short term dietary exposures to residues of dimethomorph does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

Chlorantraniliprole (230)

European Union

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

- 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:

- eggs
- peanut
- poultry fat
- poultry, edible offal of

Kenya

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the commodity (Peanut).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet of the estimated STMRs were 0-1% the maximum (ADI 2 mg/kg bw). The 2008 JMPR decided that an ARfD for Chlorantraniliprole was unnecessary, therefore, both the long and short term dietary exposure to residues of chlorantraniliprole does not present any public health concern.

African Union

Issue: At the 47th Session of the CCPR (2015), chlorantraniliprole was listed for consideration of further additional maximum residue levels by the 2016 JMPR. Supervised residue trials data on Bulb vegetables-green onion, cereals (barley, sorghum, wheat) and peanuts were provided to JMPR for additional MRLs.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for Peanut.

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet of the estimated STMRs were 0-1% the maximum (ADI 2 mg/kg bw). The 2008 JMPR decided that an ARfD for Chlorantraniliprole was unnecessary, therefore, both the long and short term dietary exposure to residues of chlorantraniliprole does not present any public health concern.

Saflufenacil (251)

European Union

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.

Kenya

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Alfalfa fodder, Barley, Barley bran (unprocessed), Barley straw and fodder, dry, Hay or fodder (dry) of grasses, Peanut, Pomegranate, Sugar cane, Sugar cane molasses, Sunflower seed, Triticale, Triticale straw and fodder, dry, Wheat and Wheat straw and fodder, dry).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 2–20% of the maximum ADI (0.05 mg/kg bw). The 2011 JMPR determined that establishment of ARfD is not necessary. Long and short term dietary exposures to residues of saflufenacil does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

African Union

Issue: Saflufenacil is a herbicide and was listed by the 47th Session of the CCPR for the evaluation of additional MRLs. The 2016 JMPR received supervised residue data on pomegranate, barley, wheat, peanut, sunflower, olive, sugarcane, alfalfa, and perennial grasses.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Alfalfa fodder, Barley, Barley bran (unprocessed), Barley straw and fodder, dry, Hay or fodder (dry) of grasses, Peanut, Pomegranate, Sugar cane, Sugar cane molasses, Sunflower seed, Triticale, Triticale straw and fodder, dry, Wheat and Wheat straw and fodder, dry).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 2–20% of the maximum ADI (0.05 mg/kg bw). The 2011 JMPR determined that establishment of ARfD is not necessary. Long and short term dietary exposures to residues of saflufenacil does not present intake concerns and therefore is unlikely to impede trade in the above commodities.

Sulfoxaflor (252)

European Union

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.

-Tree nuts

African Union

Issue: Sulfoxaflor, a sulfoximine insecticide was also evaluated by JMPR in 2014 where the previously reviewed residue trial data on citrus fruits, pome fruits, stone fruits and tree nuts were reassessed against the registered USA GAP. The proposed MRL for tree nuts was held at Step 4 pending additional crop field trials. The 2016 JMPR received additional supervised residue trials for almonds and pecans as well as new GAP information and supervised residue trials on assorted tropical and subtropical fruits, sweet corn, cereal grains and seed for beverages and sweets. Supervised residue trials data were provided for cocoa beans, avocados, rice and sorghum.

Position: No MRLs were recommended.

Rationale: Supervised trials for cocoa beans, avocados, rice and sorghum did not match the critical GAPs provided and proportionality could not be applied due the different number of applications and PHIs. Also, no GAPs were provided to the 2016 JMPR for almonds, pecans, assorted tropical and subtropical fruits, sweet corn, cereal grains, seed for beverages and sweets pineapples, sweet corn, maize and tree nuts, hence maximum residue levels could not be recommended.

Penthiopyrad (253)

European Union

PenthiopyradThe EU would like re-confirm its **reservation to the advancement** of proposed draft MRLs for the following commodities:

-edible offal (mammalian)

-mammalian fats (except milk fats)

-meat (from mammals other than marine mammals)

-milks

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

-mustard greens

An acute consumer risk has been identified for a European consumer group. As no information on an alternative GAPs was provided, the proposed MRL should be withdrawn.

Picoxystrobin (258)

European Union

The EU **supports** the conclusion of JMPR.

African Union

Issue: Picoxystrobin was evaluated as a new compound by the 2012 JMPR for toxicology and residues. The 2012 JMPR established an ADI of 0-0.09 mg/kg bw for picoxystrobin and an ARfD of 0.09 mg/kg bw. The 2012 JMPR proposed a residue definition for enforcement of picoxystrobin and estimated a number of maximum residue levels. However for two metabolites IN-H8612 and 2-(2-formylphenyl)-oxoacetic acid compounds with potential for genotoxicity above TTC, it was not possible to propose a residue definition for dietary risk assessment or calculate dietary intakes, and therefore maximum residue levels were not recommended.

Position: AU notes the conclusion of JMPR that further information is required on the interconversion of IN-H8612 and 2-(2-formylphenyl)-oxoacetic acid compounds

Rationale: For a comprehensive risk assessment to be conducted, all the information on the parent compound and its metabolites is required in order to ensure public health protection.

Benzovindiflupyr (261)

European Union

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

African Union

Issue: Benzovindiflupyr is a broad spectrum fungicide, new use supervised field residue trial data and additional analytical methods were provided for the following crops; wheat, barley, grapes, apples, pears, pulses (beans and peas), soya beans, tomato, cucumber, summer squash, melon (cantaloupe), sweet corn, maize, cotton, peanuts, potatoes, sugar cane, rape seeds and coffee.

Position: AU supports the advancement of the proposed draft MRLs to the next Codex step process for the following commodities (Fruiting vegetables, Cucurbits, Barley, Barley straw and fodder, dry, Beans (dry), Coffee beans, Dried grapes (currants, raisins and sultanas), Fruiting vegetables other than Cucurbits, Grapes, Oat straw and fodder, dry, Oats, Pea hay or fodder, dry, Peanut, Peanut fodder, Peas (dry), Peppers Chili, dried, Pome fruits, Potato, Rape seed, Rye, Rye straw and fodder, dry, Soya bean (dry), Sugar cane, Sweet corn (corn-on-the-cob), Triticale, Triticale straw and fodder, dry, Wheat and Wheat straw and fodder, dry).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0-2% of the maximum ADI of 0-0.5 mg/kg bw. Similarly the IESTI represented 0 – 70% of the ARfD (0.1 mg/kg bw for the general population and for children 0-60% of the ARfD).

The low percentage of long and short term dietary exposure to residues of benzovindiflupyr does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

Bixafen (262)

European Union

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**

African Union

Issue: Bixafen is a pyrazole-carboxamide fungicide, new use supervised field residue trial data and additional analytical methods and storage stability data for the metabolites were provided for the following crops; rape seeds, barley, rye, triticale, oats and wheat.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Barley, Barley, straw and fodder, dry, Oats, Oats, straw and fodder, dry, Rape seed, Rape seed oil, refined, Rye, Rye, straw and fodder, dry, Triticale, Triticale, straw and fodder, dry, Wheat, Wheat, bran and Wheat, straw and fodder, dry)

Rationale: The IEDI of the 17 GEMS/Food cluster diets, based on the estimated STMRs represented 1-9% of the maximum ADI of 0.02 mg/kg bw. Similarly, IESTI represented 0–20% of the ARfD (0.2 mg/kg bw) for the general population and 0–20% of the ARfD for children.

The low percentage of long and short term dietary exposure to residues of bixafen does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

Fluensulfone (265)

European Union

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

African Union

Issue: Fluensulfone, a nematicide was reviewed by the 2016 JMPR meeting at the request of CCPR, as an additional study on one metabolite and information on the mode of action for lung tumours induced by fluensulfone had been made available. Supervised trials data for the following crops; head lettuce, leaf lettuce, carrots, strawberries, Brassica vegetables, Fruiting vegetables, Cucurbits, spinach, komatsuna, mizuna, mustard greens, potatoes, radish, Japanese radish or turnips and celery

Position: AU supports the proposed draft MRLs for which the requirement for data submission have been met and the advancement to the next step of the Codex stepwise process for the following commodities (Beetroot, Brassica (cole or cabbage) vegetables, Head cabbage, Flowerhead brassicas, Carrot, Celery, Celery, Chervil, Turnip-rooted, Cucumber, Fruiting vegetables, other than Cucurbits, except sweetcorn and mushroom, Horseradish, Komatsuna, Leafy vegetables (not specified elsewhere), Legume vegetables, Lettuce, Head, Low-growing berries, Melons, except watermelon, Mustard greens, Parsnip, Peppers, chilli, dried, Potato, Potato, dried, Radish, Radish Japanese, Radish leaves, Root and tuber vegetables (not specified elsewhere), Spinach, Squash, summer, Swede, Sweet potato, Tomato, dried, Tomato paste, Turnip, Garden, Turnip greens and Watermelon)

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 1–3% of the maximum ADI of 0–0.01 mg/kg bw. Similarly the IESTI represented 9% of the ARfD (0.3 mg/kg bw) for children and 5% for the general population, hence the chemical is unlikely to present long and short term intake concerns.

Tolfenpyrad (269)**European Union**

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

-pecan

-potato

African Union

Issue: Tolfenpyrad is a broad spectrum insecticide and a miticide and was listed by the 47th Session of the CCPR for the evaluation of additional uses. The 2016 JMPR received information on the latest use patterns and supervised residue trials on potato and tree nuts (almonds and pecans).

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Pecan and Potato).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0–8% of the maximum ADI (0.006 mg/kg bw). Similarly the IESTI represented 0% of the ARfD (0.01 mg/kg bw) for children and 0% for the general population, hence long and short term dietary exposures to residues of tolfenpyrad are unlikely to present intake concerns.

Metrafenone (278)**European Union**

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.

African Union

Issue: Metrafenone, a benzophenone fungicide was scheduled by the 47th Session of the CCPR for the evaluation of additional uses by the 2016 JMPR and the Meeting received new GAP and residue information on pome fruit, grapes, fruiting vegetables, stone fruit and hops from the manufacturer.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Cherries, Eggplant, Fruiting vegetables, Cucurbits, Hops, dry, Peaches, Peppers Chili, dried, Peppers, Chili, Peppers, Sweet (including Pimento or pimiento), Pome fruits and Tomato).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 0–1% of the maximum ADI of 0.3 mg/kg bw. The 2014 JMPR decided that an ARfD was unnecessary. Metrafenone residues are therefore unlikely to present intake concerns.

Flonicamid (282)**European Union**

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

- almonds
- brassica vegetables, head cabbage, flowerhead brassica
- brassica leafy vegetables
- pome fruit
- potatoes
- rape seed
- wheat

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.

The EU **supports** the conclusion of JMPR that the MRL for cucurbits should be based on the Australian GAP. The number of trials submitted by the USA is insufficient to consider the more critical GAP.

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

- meat (from mammals other than marine mammals)
- mammalian fats
- edible offal (mammalian)
- milks
- poultry meat
- poultry fats
- poultry, Edible offal of
- eggs

Fluazifop-p-butyl (283)**European Union**

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).

Ghana

Ghana has the following pesticides registered for use in the country and supports the MRLs set for them as fair and achievable:

3. 5.10-Flazipop-p-butyl

Kenya

Issue: Fluazifop-P-butyl was scheduled for residue evaluation as a new compound by the 2015 JMPR at the 46th Session of the CCPR (2014). Because the dossier was considered incomplete at the start of the 2015 JMPR, the evaluation was postponed until the 2016 JMPR. Supervised residue trials data on grapefruits, lemons, apples, cherries, plums, peaches, apricots, nectarines, bananas, olives, almonds, macadamia nuts, pecans, walnuts, hazelnuts, coffee beans, blackberry, bilberry, blueberry, currants, gooseberry, strawberry, bulb onion (dry harvested), raspberry, head cabbages, tomatoes, leaf lettuce, beans (green pods and immature seeds), peas, pods and succulent immature peas (Pisum spp, Vigna spp), peas, shelled (succulent seeds) (Pisum spp, Vigna spp), beans (dry, Phaseolus spp), peas (dry, Pisum spp), soya beans (dry, Glycine spp), carrots, celeriac, potato, sugar beets, turnips and swedes, sweet potato, Bean fodder (dry weight), Soya bean hay and straw (dry weight), sugar cane, cotton seed, sunflower seed, pears and oranges were submitted

Position: We express our reservation on the advancement of the proposed draft MRLs for commodities whose percentage long-term dietary exposure is above 100%, but support the proposed MRLs and the advancement to the next Codex step process for the following commodities (Almonds, Banana, Bean fodder, Beans (dry), Beans, except broad bean and soya bean, Cabbages, Head, Caneberries, Carrot, Celeriac, Citrus fruits, Citrus pulp, dry, Coffee beans, Cotton seed, Currants, black, red, white, Eggplant, Field pea (dry), Fodder beet, Garlic 0.3, Gooseberries, Grapes, Lettuce, Leaf, Macadamia nuts, Olives for oil production, Onion, Bulb, Orange oil, Peas (pods and succulent, immature seeds), Peas, shelled (succulent seeds), Pecan, Pome fruits, Potato, Shallots, Soya bean (dry), Soya bean fodder, Stone fruits, Strawberries, Sugar beet, Sugar beet molasses, Sugar beet pulp, dry, Sugar cane, Sunflower seed, Swede, Sweet potato, Table Olives, Tomato, Turnip, Garden and Walnuts).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 40–160% of the maximum ADI of 0.004 mg/kg bw, expressed as fluazifop acid. Long-term dietary exposure to residues of fluazifop-P-butyl from uses considered by the Meeting may present a public health concern because an exceedance was found for GEMS/Food cluster diet G16 (160%). The IESTI represented 40% of the ARfD (0.4 mg/kg bw, expressed as fluazifop acid), therefore short-term dietary exposure to residues of fluazifop-P-butyl is unlikely to present a public health concern. The high percentage of long-term dietary exposure to residues of fluazifop-P-butyl is unsafe and is likely to impede trade. However, the low percentage of short-term dietary exposure to residues of this parent compound does not present public health concern.

African Union

Issue: Fluazifop-P-butyl was scheduled for residue evaluation as a new compound by the 2015 JMPR at the 46th Session of the CCPR (2014). Because the dossier was considered incomplete at the start of the 2015 JMPR, the evaluation was postponed until the 2016 JMPR. Supervised residue trials data on grapefruits, lemons, apples, cherries, plums, peaches, apricots, nectarines, bananas, olives, almonds, macadamia nuts, pecans, walnuts, hazelnuts, coffee beans, blackberry, bilberry, blueberry, currants, gooseberry, strawberry, bulb onion (dry harvested), raspberry, head cabbages, tomatoes, leaf lettuce, beans (green pods and immature seeds), peas, pods and succulent immature peas (*Pisum* spp, *Vigna* spp), peas, shelled (succulent seeds) (*Pisum* spp, *Vigna* spp), beans (dry, *Phaseolus* spp), peas (dry, *Pisum* spp), soya beans (dry, *Glycine* spp), carrots, celeriac, potato, sugar beets, turnips and swedes, sweet potato, Bean fodder (dry weight), Soya bean hay and straw (dry weight), sugar cane, cotton seed, sunflower seed, pears and oranges were submitted

Position: AU expresses its reservation on the advancement of the proposed draft MRLs for commodities whose long-term dietary exposure is above the health-based value (ADI), but support the proposed MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Almonds, Banana, Bean fodder, Beans (dry), Beans, except broad bean and soya bean, Cabbages, Head, Caneberries, Carrot, Celeriac, Citrus fruits, Citrus pulp, dry, Coffee beans, Cotton seed, Currants, black, red, white, Eggplant, Field pea (dry), Fodder beet, Garlic 0.3, Gooseberries, Grapes, Lettuce, Leaf, Macadamia nuts, Olives for oil production, Onion, Bulb, Orange oil, Peas (pods and succulent, immature seeds), Peas, shelled (succulent seeds), Pecan, Pome fruits, Potato, Shallots, Soya bean (dry), Soya bean fodder, Stone fruits, Strawberries, Sugar beet, Sugar beet molasses, Sugar beet pulp, dry, Sugar cane, Sunflower seed, Swede, Sweet potato, Table Olives, Tomato, Turnip, Garden and Walnuts).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 40–160% of the maximum ADI of 0.004 mg/kg bw, expressed as fluazifop acid. Long-term dietary exposure to residues of fluazifop-P-butyl from uses considered by the Meeting may present a public health concern because an exceedance was found for GEMS/Food cluster diet G16 (160%). The IESTI represented 40% of the ARfD (0.4 mg/kg bw, expressed as fluazifop acid), therefore short-term dietary exposure to residues of fluazifop-P-butyl is unlikely to present a public health concern.

However, residues of fluazifop-P-butyl have long-term intake concerns which may affect consumers and is likely to impede trade. However, the low percentage of short-term dietary exposure to residues of this parent compound does not present public health concern.

Flupyradifurone (285)

European Union

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.

African Union

Issue: Flupyradifurone is an insecticide belonging to the chemical class of butenolides. It was scheduled for evaluation as a new compound by the 2015 JMPR at the 46th Session of the CCPR (2014). It was evaluated for toxicology in 2015 and residue in 2016. Supervised residue trials data on citrus fruits (grapefruit, lemons, mandarins and oranges), pome fruits (apples and pears), berries and other small fruits (blueberries, grapes and strawberries), assorted tropical and sub-tropical fruit—inedible peel (prickly pear), bulb vegetables (bulb onion and green onions), Brassica vegetables (broccoli, cabbage, and cauliflower), cucurbits (cucumber, melons and summer squash), fruiting vegetables other than cucurbits (tomatoes, chilli and sweet peppers and sweet corn), leafy vegetables (mustard greens, head and leafy lettuce and spinach), legume vegetables (common bean, snow peas, lima beans and garden peas), pulses (peas, beans and soya beans), root and tuber vegetables (carrots, radishes and potatoes), stalk and stem vegetables (celery), cereals (barley, wheat, sorghum and maize), tree nuts (almonds and pecans), oilseeds (cotton and peanuts), coffee and hops were submitted and evaluated.

Position: AU supports the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Alfalfa hay, Apples, dried, Beans, dry, Beans, shelled (succulent, immature seeds), Beans, except broad bean and soya bean (green pods and immature seeds), Bean hay, Bulb vegetables, except Fennel, Bulb, Bush berries, Cabbages, Head, Cauliflower, Cereal grains (except maize and rice), Cotton seed, Cucumber, Dried grapes, Grapes, Lemons and limes (including citron), Lettuce, Head, Mandarins, Maize, Maize bran, Melons, except watermelon, Oranges, Sweet, Sour, Peanut, Peanut hay, Peas (dry), Pea hay, Peas (pods and succulent, immature seeds), Peas, shelled (succulent seeds), Pecan, Peppers, Peppers Chili, dried, Pome fruits, Potato, Pummelo and Grapefruits, Root and tuber vegetables (except potato), Soya bean (dry), Soya bean hay, Straw and fodder, dry of cereal grains, Strawberry, Squash, Summer, Sweet corn (corn-on-the-cob), Sweet potato, Tomato, Wheat bran, unprocessed, Wheat germ and Wheat wholemeal).

However, AU expresses its reservation on the advancement of the proposed draft MRLs for celery, leaf lettuce, mustard greens and spinach due to intake concerns.

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 6–20% of the maximum ADI of 0.08 mg/kg bw. The IESTI for celery represented 120% of the ARfD for children, for leaf lettuce the IESTI represented 250% of the ARfD for children, for mustard greens the IESTI represented 250% of the ARfD for the general population and 610% for children and for spinach the IESTI represented 130% of the ARfD for the general population and 420% for children. The high percentage of short-term dietary exposure to flupyradifurone from the consumption of celery, leaf lettuce, mustard greens and spinach may present a public health concern and impede trade.

Estimates of intakes for the other commodities considered by the 2016 JMPR varied from 0–90% of the ARfD (0.2 mg/kg bw). Apart from celery, leaf lettuce, mustard greens and spinach, the short-term dietary exposure to residues of flupyradifurone, is unlikely to present a public health concern and therefore is unlikely to impede trade in the above commodities.

Acibenzolar-S-methyl (288)

European Union

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**

African Union

Issue: Acibenzolar-S-methyl is a new compound. Supervised residue field trial and toxicology data was submitted to the JMPR in 2016 for evaluation for the following crops; onion bulb, strawberry, pome fruits, stone fruits, citrus, leafy vegetables, cucurbits, potato, wheat, tomato, cabbage and banana.

Position: AU supports the proposed MRLs for the following commodities (Apple, Banana, Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas, Brassica leafy vegetables, Citrus fruits, Fruiting vegetables, Cucurbits, Garlic, Kiwifruit, Lettuce, Head, Lettuce, Leaf, Low growing berries (including strawberries), Onion, Bulb, Peaches (including nectarines and apricots), Shallot, Spinach and Tomato) and agree that these proposed draft MRLs should be advanced to the next Codex step.

Rationale: The IEDIs in the seventeen cluster diet based on the estimated STMRs were 0-1% maximum ADI (0.08 mg/kg bw). Similarly the IESTI represents 0 – 10% of the ARfD (0-9% general population, 0-10% children 8 months -6 years old) and therefore it is within the safety limits. With the low percentage of ADI and ARfD, the long and short term dietary exposure to residues of acibenzolar-S-methyl is unlikely to pose a public health concern and impede trade in the above commodities.

Imazethapyr (289)

European Union

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)

Ghana

Ghana has the following pesticides registered for use in the country and supports the MRLs set for them as fair and achievable:

4. 5.13-Imazetapyr

African Union

Issue: Imazethapyr is an imidazolinone herbicide and has not been evaluated previously by JMPR and was reviewed at the request of CCPR. Supervised field residue trial data were provided for the following crops; various beans and peas, soya beans, maize, rice, peanut, rape seed, sunflower, alfalfa and clover.

Position: AU supports the proposed draft MRLs and their advancement to the next step of the Codex stepwise process for the following commodities (Clover hay or fodder, Lentil (dry), Maize, Maize fodder, Peanut, Rape seed, Rice, Rice straw and fodder, dry and Soya bean (dry)).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented were 0.0–0.1% of the maximum ADI (0.6 mg/kg bw). The 2016 JMPR decided that an ARfD is unnecessary.

Both long-term and short-term dietary exposures do not exceed the ADI and ARfD respectively hence it is unlikely that residues of imazethapyr will present public health concern and therefore is unlikely to impede trade in the above commodities.

Isfetamid (290)

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**
- **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 isfetamid 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)**

African Union

Issue: Isfetamid is a systemic, broad-spectrum thiophene fungicide. At the 47th Session of the CCPR (2015), it was scheduled for evaluation as a new compound by the 2016 JMPR. Supervised field residue trial data were provided for the following crops; cherries, plum, apricot, peach, grapes, strawberry, lettuce, almonds and oilseed rape.

Position: AU supports the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Almonds, Almond hulls, Dried grapes (Currants, Raisins and Sultanas), Lettuce, Head, Lettuce, Leaf, Low growing berries (includes all commodities in this subgroup), Rape seed, Rape seed oil, edible, Small fruit vine climbing (includes all commodities in this subgroup).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 0–1% of the maximum ADI (0-0.05 mg/kg bw). The ARfD was 3 mg/kg bw and the calculated IESTI was a maximum of 3% of the ARfD for the general population and 10% of ARfD for children. These risk long and short term risk characterization outcomes for residues of isfetamid indicate the compound is unlikely to present a public health concern and therefore does not impede trade in the above commodities.

Oxathiaprolin (291)

European Union

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.

African Union

Issue: Oxathiapiprolin is a systemic piperidinyl thiazole isoxazoline fungicide and was scheduled by the 47th Session of the CCPR as a new compound for consideration by the 2016 JMPR. Data from supervised residue trials for the following crops; Broccoli, Cabbages, Head, Cauliflower, Dried grapes, Fruiting vegetables, Cucurbits, Fruiting vegetables, other than Cucurbits, Garlic, Garlic, Great-headed, Ginseng, dried including red ginseng, Grapes, Leek, Lettuce, Head, Lettuce, Leaf, Onion, Bulb, Onion, Welsh, Peas (pods and succulent, immature seeds), Peas, shelled, Peppers Chili, dried, Potato, Pulses, Shallots, Spring onion, Spinach, Sweet potato and Tomato, dried were submitted and evaluated.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Broccoli, Cabbages, Head, Cauliflower, Dried grapes, Fruiting vegetables, Cucurbits, Fruiting vegetables, other than Cucurbits (except sweetcorn and mushrooms), Garlic, Garlic, Great-headed, Ginseng, dried including red ginseng, Grapes, Leek, Lettuce, Head, Lettuce, Leaf, Onion, Bulb, Onion, Welsh, Peas (pods and succulent, immature seeds), Peas, shelled, Peppers Chili, dried, Potato, Pulses, Shallots, Spring onion, Spinach, Sweet potato and Tomato, dried).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0–0% of the maximum ADI of 4 mg/kg bw. The Meeting decided that an ARfD is unnecessary. Long and short term dietary exposures to oxathiapiprolin residues does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

Pendimethalin (292)

European Union

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)

Ghana

Ghana has the following pesticides registered for use in the country and supports the MRLs set for them as fair and achievable:

5. 5.19-Pendimethalin

Kenya

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Alfalfa fodder, Almond hulls, Asparagus, Bean fodder, Beans, dry, Beans, except broad bean and soya bean (green pods and immature seeds), Brassica leafy vegetables, except kale, Carrot, Celery, Citrus fruits, Fennel Bulb, Garlic, Hay or fodder (dry) of grasses, Hops, dry, Kale, Lettuce, Leaf, Onion, Bulb, Onion, Welsh, Peas (dry), Peas (pods and succulent, immature seeds), Peas, shelled (succulent seeds), Shallots, Spring onion and Tree nuts).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0.1% of the maximum ADI of 0.1 mg/kg bw. Similarly the IESTI represented 0–4% of the ARfD (1 mg/kg bw) for the general population and 0–10% of the ARfD for children. The low percentage of long and short term dietary exposures to residues of pendimethalin does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

African Union

Issue: Pendimethalin is a selective herbicide. At the 47th Session of the CCPR (2015) it was scheduled for the evaluation as a new compound for toxicology and residues by the 2016 JMPR. Toxicological data and supervised residue trial data for citrus fruit, bulb vegetables, leaf lettuce, brassica leafy vegetables, legume vegetables, carrots, celeriac, asparagus, celery and tree nuts were submitted and evaluated.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Alfalfa fodder, Almond hulls, Asparagus, Bean fodder, Beans, dry, Beans, except broad bean and soya bean (green pods and immature seeds), Brassica leafy vegetables, except kale, Carrot, Celery, Citrus fruits, Fennel Bulb, Garlic, Hay or fodder (dry) of grasses, Hops, dry, Kale, Lettuce, Leaf, Onion, Bulb, Onion, Welsh, Peas (dry), Peas (pods and succulent, immature seeds), Peas, shelled (succulent seeds), Shallots, Spring onion and Tree nuts).

Rationale: The IEDIs of the seventeen GEMS/Food cluster diet represented 0.1% of the maximum ADI of 0.1 mg/kg bw. Similarly the IESTI represented 0–4% of the ARfD (1 mg/kg bw) for the general population and 0–10% of the ARfD for children. These risk characterization outcomes are unlikely to present intake concerns.

Pinoxaden (293)**European Union**

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****Kenya**

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Barley, Barley straw and fodder, dry, Wheat and Wheat straw and fodder, dry).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 0–1% of the maximum ADI of 0–0.1 mg/kg bw. Similarly the IESTI represented 1% of the ARfD (0.3 mg/kg bw) for the general population including children. The low percentage of long and short term dietary exposures to residues of pinoxaden does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

African Union

Issue: Pinoxaden is a selective post-emergence herbicide and was evaluated for the first time by the 2016 JMPR for both toxicology and residues. Supervised field trials on wheat, cereal grains, barley, wheat and barley forage, hay and straw were provided and evaluated.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Barley, Barley straw and fodder, dry, Wheat and Wheat straw and fodder, dry).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 0–1% of the maximum ADI of 0–0.1 mg/kg bw. Similarly the IESTI represented 1% of the ARfD (0.3 mg/kg bw) for the general population including children. These risk characterization outcomes are unlikely to present intake concerns and therefore pinoxaden residues in the above-mentioned commodities are unlikely to impede trade.

Spiromesifen (294)

European Union

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.

Kenya

Position: We support the proposed draft MRLs and the advancement to the next Codex step process for the following commodities (Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead Brassicas, Brassica leafy vegetables, Cassava, Coffee beans, Common bean (pods and/or immature seeds), Cotton seed, Cucumbers, Eggplants, Fruiting vegetables, Cucurbits, except melon and cucumber, Leafy vegetables, Low-growing berries, Maize, Maize fodder, Melon, except watermelon, Okra, Pepino, Peppers, Peppers chili, dried, Popcorn, Potato, Sweet corn (corn-on-the-cob), Sweet potato, Tea, Green, Black (black, fermented and dried), Tomato, Tomato paste and Tomato, dried).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 2–20% of the maximum ADI (0.03 mg/kg bw). The 2016 JMPR determined that an ARfD is not necessary for spiromesifen. The long and short term dietary exposures to residues of spiromesifen does not present any public health concern and therefore is unlikely to impede trade in the above commodities.

African Union

Issue: Spiromesifen is a contact insecticide-acaricide. Toxicology and residue evaluation was scheduled for the 2016 JMPR by the 47th Session of the CCPR. Supervised residue trial data on the following crops; strawberry, papaya, broccoli, cabbage, cucumber, melon, summer squash, peppers, tomato, sweet corn, head and leaf lettuce, spinach, mustard greens, common bean (pods and/or immature seeds), dry bean, cassava, potato, maize, popcorn, cotton, coffee and tea were received and evaluated.

Position: AU supports the proposed draft MRLs and the advancement to the next step of the Codex stepwise process for the following commodities (Brassica (cole or cabbage) vegetables, Head cabbages, flowerhead Brassicas, Brassica leafy vegetables, Cassava, Coffee beans, Common bean (pods and/or immature seeds), Cotton seed, Cucumbers, Eggplants, Fruiting vegetables, Cucurbits, except melon and cucumber, Leafy vegetables, Low-growing berries, Maize, Maize fodder, Melon, except watermelon, Okra, Pepino, Peppers, Peppers chili, dried, Popcorn, Potato, Sweet corn (corn-on-the-cob), Sweet potato, Tea, Green, Black (black, fermented and dried), Tomato, Tomato paste and Tomato, dried).

Rationale: The calculated IEDIs of the seventeen GEMS/Food cluster diet represented 2–20% of the maximum ADI (0.03 mg/kg bw). The 2016 JMPR determined that an ARfD is not necessary for spiromesifen. The long and short term dietary exposures to residues of spiromesifen does not present any public health concern and therefore is unlikely to impede trade in the above commodities.