

## 53rd Session of the Codex Committee on Pesticide Residues

### Virtual meeting, 04 July - 13 July 2022

European Union Comments on

**Agenda Items 5(b) and 6:**

**Draft and Proposed Draft Maximum Residue Limits for Pesticides in Foods and Feeds at Steps 7 and 4**

**Comments at Steps 6 and 3**

#### **General comments for discussion in CWP**

##### **General comments**

It is an EU policy to align EU MRLs with Codex MRLs (CXLs) provided that:

- the EU sets MRLs for the commodity under consideration;
- the current EU MRL is lower than the CXL;
- toxicological data are available at EU level and the proposed CXL is safe for European consumers
- the CXL is acceptable to the EU with respect to areas such as consumer protection, supporting data and extrapolations, as well as environmental issues of global nature (such as the decline of pollinators or the accumulation of persistent bioaccumulative and toxic substances in the environment) in conformity with WTO rules and as announced in the Farm to Fork Strategy and the EU Green Deal.

In case the CXLs are not acceptable to the EU with regard to those criteria, the EU will make reservations to the advancement of the Codex MRLs during the discussions on the specific substances.

An assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for the 7 triazole substances for discussion at this meeting. Since several triazole substances are currently under periodic re-evaluation in the EU, the EU positions presented here might be revised in future.

##### **Terbufos (167)**

The JMPR toxicological assessment for terbufos has not been updated since 2003 and more critical reference values were proposed in the current Draft Decision Guidance Document of the Chemical Review Committee (CRC) of the Rotterdam Convention. The EU invites JMPR to update the toxicological assessment of terbufos, as outlined in the concern form submitted by the EU.

##### **Items 5(b)**

##### **Propiconazole (160) T**

Following a recent EU evaluation, the active substance was not approved in the EU. In that framework, the consumer risk assessment could not be finalised due to data gaps, and no conclusion could be drawn on the genotoxicity and the general toxicity of several metabolites. Specifically on peaches, an acute consumer risk has been identified for European consumers. The EU expresses the same concerns as submitted in the concern form in March 2020.

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for propiconazole.

## Items 6

### Ethion (034) R

### Imazalil (110) R

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

- Citrus fruits, Group of

### Metalaxyl (138) T/R

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

- Brussels sprouts
- Carrot
- Spinach
- Sunflower seed
- Ginseng
- Flowered brassicas, Subgroup of
- Grapes
- Lettuce, leaf
- Melons, except Watermelon
- Onion, Bulb
- Oranges, Sweet, Sour, Subgroup of
- Pepper, black, white, pink, green
- Potato
- Tomatoes, Subgroup of

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

- Apple
- Pear
- Cabbages, head

The EU notes that, for apple and pears, the residue trials are not representative of the presented GAP and not adequate to demonstrate a no-residue situation.

For cabbages, head, the calculation performed using the OECD MRL calculator suggests a lower MRL of 0.06 mg/kg. Therefore, the EU invites JMPR to review the Codex MRL proposal.

### Methoprene (147) R

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

**- Soya bean (dry)**

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 soya bean do not impact on the dietary burden of farm animals.

**Clofentezine (156) R**

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

**- Hops, dry**

**Tebuconazole (189) R**

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

**-Coffee beans**

The EU notes that the existing CXL of 0.1 mg/kg is not recommended for withdrawal in the summarized results.

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for tebuconazole.

**Fenpyroximate (193) T/R**

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

- **Mandarins (including Mandarin-like hybrids), Subgroup of**
- **Oranges, sweet, sour (including orange-like hybrids), Subgroup of**
- **Cane berries, Subgroup of**
- **Cucumbers and Summer squashes, Subgroup of**
- **Bush berries, Subgroup of**
- **Stems and petioles, Subgroup of**

JMPR concluded that the estimated acute dietary exposure to residues of fenpyroximate for the consumption of mandarins, oranges, raspberries, blackberries, blueberries, currants, gooseberries, cucumbers, courgette, cardoons, fennel, celery, and rhubarb may present a public health concern.

In addition, for mandarins, oranges, currants (juice), celeries, rhubarb, fennel, and cardoon acute consumer risk has been also identified by EFSA for European consumers.

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

- **Plums (including fresh Prunes), Subgroup of**
- **Succulent beans without pods, Subgroup of**
- **Milks**
- **Meat (from mammals other than marine mammals)**

- **Mammalian fats (except milk fats)**
- **Edible offal (mammalian)**

The EU also notes that, for mammalian fats, EFSA noted that a slightly lower MRL of 0.15 mg/kg might be sufficient.

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

- **Lemons and Limes (including Citron), Subgroup of**
- **Pummelo and Grapefruits (including Shaddock-like hybrids), Subgroup of**

An acute consumer risk has been identified for European consumers.

In addition, the EU notes that after JMPR established, in 2021, lower ADI and ARfD for this substance, and re-evaluated the existing CXLs and Codex MRL proposals at step 4 accordingly, acute consumer health risks were identified for several commodities. The EU recommends CCPR to revoke the existing CXLs for apples, pears, cherries, melons, watermelons, tomatoes, eggplants, beans with pods, and edible offal (mammalian), and to withdraw the CXLs for apricots, peaches, and nectarines, currently at step 4.

### **Fenbuconazole (197) R**

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

- **Tea, green, black (black, fermented and dried)**

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for fenbuconazole.

### **Fipronil (202) T/R**

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

- **Banana**
- **Barley, similar grains, and pseudocereals with husks (Subgroup of)**
- **Basil, leaves**
- **Dry beans, Subgroup of (except soya beans)**
- **Cottonseed**
- **Eggs**
- **Leafy vegetables, Group of**
- **Beans with pods, Subgroup of**
- **Maize cereals, Subgroup of**
- **Onion, bulb**
- **Potato**
- **Poultry fat**
- **Poultry meat**
- **Poultry edible offal**
- **Rice, husked**
- **Root and tuber vegetables**
- **Soya bean (dry)**
- **Sugar beets**
- **Sugar cane**
- **Sunflower seeds, Subgroup of**
- **Tomato**
- **Wheat, similar grains, and pseudocereals with husks, Subgroup of**
- **Edible offal (Mammalian)**

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

On the basis of the information provided to the JMPR, it was concluded that the estimated **long-term dietary exposure to residues of fipronil may present a public health concern**.

### **Cyprodinil (207) R**

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

- Ginseng, dried including red ginseng
- Peas with pods, Subgroup of
- Dry beans, Subgroup of (except soya beans)
- Dry peas, Subgroup of

### **Methoxyfenozide (209) R**

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

- Basil, leaves
- Sugar cane
- Coffee bean

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

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

The proposed Codex MRL is not acceptable because it is based on a GAP in Japan that is no longer in place (MRL in Japan is 40 mg/kg, not 80 mg/kg). The EU would like to ask Japan for clarifications.

The EU notes that, since risks for honey bees cannot be excluded, in the EU the authorised uses of methoxyfenozide are restricted to greenhouses uses only.

### **Metalaxyl-M (212) T/R**

The EU **supports the proposed withdrawal** of Codex MRLs for the following commodities:

- Apple
- Cocoa beans
- Grapes
- Lettuce, head
- Onion, Bulb
- Peppers, sweet (including pimento or pimienta)
- Potato
- Spinach
- Sunflower seed
- Tomatoes

### **Trifloxystrobin (213) R**

The EU **supports the proposed withdrawal** of Codex MRLs for the following commodities:

- Citrus fruits

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

commodities:

- Beans with pods, Subgroup of
- Bilberry
- Bilberry, red
- Blueberry
- Cane berries, Subgroup of
- Coffee beans
- Currant, black, red, white
- Corn salad
- Edible offal (mammalian) including liver of cattle, goats, pigs and sheep and kidney of cattle, goats, pigs and sheep
- Eggs
- Gooseberry
- Lettuce, leaf
- Linseed
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Peas with pods, subgroup of (includes all commodities in this subgroup)
- Poultry fats
- Poultry meat
- Poultry, edible offal of
- Rose hip

Following a recent EU evaluation, no conclusion could be drawn on the general toxicity of several metabolites.

### **Fenhexamid (215) R**

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

- Asparagus
- Pears
- Bulb onions, Subgroup Of

For asparagus, the EU recommends that as the residues were below the LOQ in all trials, the Codex MRL should be labelled with an asterisk to indicate that the MRL is at the LOQ.

### **Quinoxifen (222) R**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the ongoing review of MRLs in the EU for certain non approved substances due to environmental issues of global nature, such as the accumulation of persistent, bio-accumulative and toxic substances in the environment:

- Cherries, Subgroup of (except Choke cherries)

### **Difenoconazole (224) R**

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

- Guava
- Cranberry
- Cotton seed
- Tea, green, black (black, fermented and dried)

A chronic consumer risk has been identified for European consumers

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for difenoconazole.

### **Mandipropamid (231) R**

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

- Edible offal (mammalian)
- Lemons and Limes, Subgroup of
- Mammalian fats (except milk fats)
- Mandarins, Subgroup of
- Oranges, Sweet, Sour (including Orange- like hybrids), Subgroup of
- Pummelo and Grapefruits (including Shaddock- like hybrids, among other Grapefruit), Subgroup of

### **Prothioconazole (232) R**

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

- Edible offal (Mammalian), including liver and kidney of cattle, pigs, goat and sheep
- Eggs
- Linseed
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Poultry, Edible offal of
- Poultry, fats
- Poultry meat
- Rape seed
- Rape seed oil, Edible
- Sunflower seeds, Subgroup of

The EU recommends that as the residues for meat and mammalian fats were below the LOQ in all trials, the Codex MRL should be labelled with an asterisk to indicate that the MRL is at the LOQ.

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for prothioconazole.

### **Spinetoram (233) R**

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

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

The data set supporting the MRL proposal for teas is not sufficient since the concentration of metabolites was not measured, but only estimated from metabolism studies in apples. In addition, an acute intake concern was identified for tea with exceedance of EU ARfD (181%).

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

- Pitaya

### **Clothianidin (238) R**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the ongoing review of MRLs in the EU for certain non approved substances due to the contribution of these substances to the worldwide decline of pollinators:

- Barley
- Eggs
- Liver of cattle, goats, pigs & sheep
- Milks
- Oats
- Poultry, edible offal of
- Poultry fats
- Poultry meat
- Rice, husked
- Sorghum grain
- Sorgo or Sorghum, Sweet
- Sweet Corns, Subgroup of
- Triticale
- Wheat

### **Fluopyram (243) R**

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

- Coffee beans

### **Thiamethoxam (245) R**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities pending the ongoing review of MRLs in the EU for certain non approved substances due to the contribution of these substances to the worldwide decline of pollinators:

- Barley
- Edible offal (mammalian)
- Eggs
- Japanese persimmon
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Oats
- Poultry, edible offal of
- Poultry fats
- Poultry meat
- Rice, husked
- Sorghum grain
- Sorgo or Sorghum, Sweet
- Sweet Corns, Subgroup of
- Triticale
- Wheat

### **Acetamiprid (246) R**

The EU introduces a **reservation to the advancement** of the proposed draft MRLs for the following commodities, pending the outcome of an ongoing evaluation concerning toxicological reference values and residue definitions in the EU:



- Tree nuts, Group of, except Pistachio nut
- Pistachio nut

### **Sulfoxaflor (252) R**

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

- Asparagus
- Avocado
- Bush berries, Subgroup of
- Cane berries, Subgroup of
- Coffee beans
- Mango

The EU notes for coffee beans the crop analysed in the residue trials do not fully comply with the crop description on the Codex classification.

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

- Elderberry

An extrapolation from blueberries to elderberries is not foreseen in the Codex extrapolation rules. The EU understands that JMPR derived the proposed draft CXL for elderberries based on the scope of the underlying authorisation.

The EU notes that, since risk for honey bees can not be excluded, the authorised uses of sulfoxaflor are restricted to greenhouses uses only.

### **Bixafen (262) R**

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

- Barley
- Cotton seeds
- Maize
- Peanut
- Pulses (except Soya bean (dry))
- Root and tuber vegetables
- Sorghum
- Soya bean (dry)
- Sunflower seed
- Sweet corn (corn on the cob) (kernels plus cob with husk removed)
- Wheat

For peanuts, the EU recommends that as the residues were below the LOQ in all trials, the Codex MRL should be labelled with an asterisk to indicate that the MRL is at the LOQ.

The EU notes that, in the dietary burden calculation the input value of 0.08 mg/kg was used instead of 0.33 mg/kg for barley. While it is not expected that the corrected dietary burden calculation would change the conclusion, the EU recommends JMPR to correct the value as to avoid the perpetration of the error.

### **Fluensulfone (265) R**

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

- Pome fruits

The previous reservations of the EU are not addressed. 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

### **Isoxaflutole (268) R**

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

- **Soya beans**

The EU notes that the EU residue definition for risk assessment also includes the metabolite RPA 203328.

### **Trinexapac-ethyl (271) R**

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

- **Rye**
- **Rice**

### **Pendimethalin (292) R**

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

- **Grapes**
- **Flowerhead Brassicas, Subgroup of**
- **Fruiting vegetables, other than Cucurbits, Group of**
- **Soya bean (dry)**
- **Wheat**
- **Rice**
- **Maize**
- **Sugar cane**
- **Sunflower Seed**
- **Parsley, leaves**

The EU notes that the proposed CXLs of 0.01\* for flowerhead brassicas and sugar cane are based on trials analysed with different methods reaching LOQ of 0.01 and 0.05, thus there is not complete evidence that residues would be < 0.01\*.

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

- **Leek**

The Hungarian GAP assessed by JMPR is not correct as pendimethalin is only authorized in preemergence (< BBCH09).According to the Hungarian GAP, residues are expected < 0.05\*.

### **Isoprothiolane (299) R/T**

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

- **Bananas**

The ongoing EU evaluation of the import tolerance application for bananas is pending of additional

toxicological data

### **Ethiprole (304) R**

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

**- Soya bean (dry)**

In a recent EU assessment, data gaps were identified concerning the clastogenic and aneugenic potential of RPA 112916. In addition, clarifications were requested on whether RPA097973 is covered by parent. These data gaps prevented setting EU toxicological reference values. In addition, a recent one generation developmental neurotoxicity study in mice might trigger lower reference values as the one proposed by JMPR. The EU invites JMPR to re-assess the established TRVs taking into consideration this new information.

### **Fenpicoxamid (305) R**

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

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

### **Pydiflumetofen (309) R**

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

- Beans with pods, Subgroup of
- Bulb onions, Subgroup of
- Bush berries, Subgroup of
- Cherries, Subgroup of
- Citrus Fruit, Group of
- Cottonseed
- Edible offal (mammalian)
- Eggs
- Elderberry
- Flower head Brassicas, Subgroup of
- Green onions, Subgroup of
- Head Brassicas, Subgroup of
- Low growing berries, Subgroup of (except cranberries)
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Peaches, Subgroup of
- Peas with pods, Subgroup of
- Plums, Subgroup of
- Pome fruit, Group of, except Persimmon, Japanese
- Poultry, Edible offal of
- Poultry fats
- Poultry meat
- Root vegetables, Subgroup of

- Sorghum Grain and Millet, Subgroup of, except grain sorghum
- Sorghum Grain
- Stem Brassicas,
- Subgroup of Succulent beans without pods, Subgroup of- Tree nuts, Group of
- Sunflower seeds, Subgroup of
- Underground immature beans and peas, Subgroup of

The approach taken to derive the MRLs for the following commodities :

- Bulb onions, Subgroup of
- Subgroup of Green onions,
- Subgroup of Head Brassicas,
- Root vegetables, Subgroup of
- Subgroup of Succulent beans without pods, Subgroup of
- Succulent peas without pods, Subgroup of
- Sunflower seeds, Subgroup of

is not fully in line with the OECD methodology for rotational crop studies.

The EU notes that an extrapolation from blueberries to elderberries is not foreseen in the Codex extrapolation rules. The EU understands that JMPR derived the proposed draft CXL for elderberries based on the scope of the underlying authorisation.

### **Metconazole (313) R**

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

- Wheat
- Triticale

The EU notes that an assessment strategy for triazole derivatives metabolites (TDMs) is applicable in the EU. Residue definitions for risk assessment and toxicological reference values have been revised. The EU notes that an assessment for TDMs has not been carried out for metconazole.

### **Flutianil (319) T/R**

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

- Apple
- Cherries, Subgroup of
- Small fruit vine climbing, Subgroup of

### **Mefentrifluconazole (320) T**

### **Pyrasulfotole (321) T/R**

The EU **introduces a reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level:

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

- Poultry meat
- Poultry, Edible offal of
- Poultry fats
- Rye
- Sorghum Grain
- Triticale
- Wheat

### **Pyraziflumid (322) T/R**

The EU **introduces a reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level:

- Apple
- Grapes
- Pear
- Persimmon, Japanese

### **Spiropidion (323) T/R**

The EU **introduces a reservation to the advancement** of the proposed draft MRLs for the following commodities based on the lack of available toxicological data at EU level:

- Cucumber
- Melons (except watermelon)
- Pumpkins
- Watermelon
- Winter squash
- Tomato
- Peppers, Subgroup of (except martynia, okra, roselle)
- Soya bean (dry)
- Potato
- Edible offal (mammalian)
- Mammalian fats (except milk fats)
- Meat (from mammals other than marine mammals)
- Milks
- Eggs
- Poultry meat
- Poultry, edible offal of
- Poultry fat

### **Tetraniliprole (324) T**