

# *Tracking EU MRLs: The EU Early Alert System*

*2020 MRL Harmonization Workshop*

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**BRYANT CHRISTIE INC.**

# EU Early Alert System

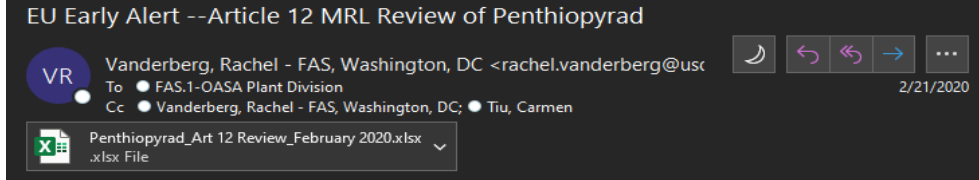
## I. Art. 12 MRL Reviews (EU risk based system)

- a) Ongoing notifications
- b) Registrant's contact information
- c) Attached list of established U.S., EU, and Codex MRLs
- d) Opportunity for industry to submit "MRL support letters"

## II. Pesticide Reviews (EU hazard based system)

- a) Updated quarterly
- b) Advance information on non renewals of approvals, restricted renewals, and substances that will expire for use within the EU

# I. Art. 12 MRL Review:



Dear Stakeholders:

On February 18th, the European Food Safety Authority (EFSA) announced the start of the review process for existing Maximum Residue Levels (MRLs) for the active substance **penthiopyrad**, as required under Article 12 of Regulation (EC) No 396/2005. Unlike the EU's pesticide review process, under the EU MRL review process substances are subject to a risk analysis that considers not only potential hazard, but its associated exposures and risks as well. This announcement at the start of the review process is an opportunity for stakeholders to liaise with the registrant if they wish to support the EU MRL review of this substance.

Attached you will find a list of established penthiopyrad EU MRLs with corresponding U.S. and Codex MRLs. You may search for your commodity from the drop down button in the [Search Commodity Here] column. This will tell you the current U.S., Codex, and EU MRLs.


To support the EU MRL review for your commodity, please contact Carmen Tiu ([carmen.tiu@corteva.com](mailto:carmen.tiu@corteva.com)) at Corteva, with a copy to me ([Rachel.Vanderberg@usda.gov](mailto:Rachel.Vanderberg@usda.gov)) and [PlantDivision@usda.gov](mailto:PlantDivision@usda.gov) by **March 9<sup>th</sup>**.

Please let us know if there are any questions or concerns.

Best regards,

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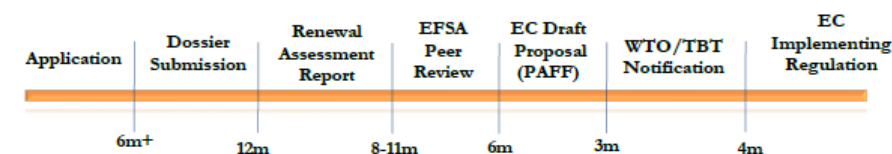
				
Market	Published Commodity	Search Commodity Here	MRL (ppm)	Commodity Notes
European Union	Plums	Sloe	1.5	Fresh or frozen fruit. MRL applies to whole product after removal of stems.
United States	Fruit, stone, group 12-12	Sloe	4	
Codex	Sorghum (GC 0651)	Sorghum, grain	0.8	
European Union	Sorghum	Sorghum, grain	0.8	MRL applies to kernels. Kernels are defined as whole grains including the bran.
United States	Sorghum, grain, grain	Sorghum, grain	0.8	Sorghum, US Definition: Sorghum spp. [sorghum, grain, sudangrass (seed crop),
Codex	Soya bean (dry) (VD 0541)	Soybean	0.3	
European Union	Soyabeans	Soybean	0.3	MRL applies to whole product after removal of capsules, shells and husk
United States	Soybean, seed	Soybean	0.4	
European Union	Beans (with pods)	Soybean (immature seed)	3	Fresh or frozen vegetables. MRL applies to whole product. Other products to which
European Union	Beans (without pods)	Soybean (immature seed)	0.4	Fresh or frozen vegetables. MRL applies to whole product. Other products to which
United States	Vegetable, legume, edible podded, subgroup 6A	Soybean (immature seed)	4	
Codex	Group of Leafy vegetables (includes all commodities in this group) (VL 0053)	Spinach	30	Except brassica leafy vegetables.
European Union	Spinaches	Spinach	30	Fresh or frozen vegetables. MRL applies to whole product after removal of roots,
United States	Leafy greens, subgroup 4-16A	Spinach		

## II. Pesticide Review:

- Quarterly
- Can be accessed [here](#)
- Look at active ingredients undergoing review in the EU
- Include only substances with corresponding U.S. MRLs
- **Application for renewal – expected to expire:** list active ingredients that were not supported by registrant. Will expire
- **Application for renewal – expired:** list active ingredients that were not supported by registrant. Expired.

The information presented in this document provides interested stakeholders with advance notice of active ingredients under review for renewal of approval in the EU and highlights which substances that have expired, are expected to expire, may have restricted renewal or non-renewal of approval. The green arrows reflect where a substance is in the EU review process as of February 29, 2020.

In the European Union active ingredients must be reviewed every 10-15 years. The review process takes about three years to complete. Registrants must submit an application for renewal no later than thirty-six months prior to the expiration date. The figure below highlights the general timeline between the main steps of the process. During these reviews, substances are checked against EU cut off criteria. Triggering the cut off criteria is likely to result in the removal of the pesticide from use in the EU. It can also result in the elimination of the associated MRLs. These reviews are separate and different from the ongoing MRL-specific reviews that are occurring simultaneously (Article 12 Reviews). MRL-specific reviews are notified on a rolling basis.



### APPLICATION FOR RENEWAL – EXPECTED TO EXPIRE

Chemical companies must support the review of their substance. If they do not, the active ingredient will automatically expire in the EU on a set date. For the substances below, registrants have not submitted the application for renewal of approval or have withdrawn the application and approval will expire. Corresponding MRLs may be affected. The substance's expiration date is outlined in parentheses ( ).

- Triflumizole (June 30, 2020)
- Spirodiclofen (July 31, 2020)
- Fenbuconazole (April 30, 2021)
- Carboxin (May 31, 2021)
- Etridiazole (May 31, 2021)
- Myclobutanil (May 31, 2021)
- Oryzalin (May 31, 2021)

### APPLICATION FOR RENEWAL - EXPIRED (February 2019 – February 2020)

Substances in this section have already expired due to non-submission of application for renewal or withdrawal of application for renewal. This list includes substances that have expired in the last year. Corresponding MRLs may be affected. Expiration date is outlined in parentheses ( ).

- Propanil (February 20, 2019)
- Ammonium acetate (August 31, 2019)
- Methomyl (August 31, 2019)
- Sodium hypochlorite (August 31, 2019)
- Triadimenol (August 31, 2019)
- Quinalofop-P (November 30, 2019)
- Chlorsulfuron (December 31, 2019)
- Cyromazine (December 31, 2019)

- **Up Next for Review:** substances that are schedule to begin review soon.
- **PAFF Meeting:** substances that the EC recommended for non-renewal or restricted renewal based on EFSA's Conclusions or Peer Review.
- **WTO Notification:** substances that have been notified to the WTO TBT Committee as proposed for non-renewal or restricted renewal. Substances may be notified prior to the PAFF's vote.

## UP NEXT FOR REVIEW (Up to December 2020)

Under the EU pesticide review program, the substances listed in this section are scheduled to go through the periodic review process. They have upcoming deadlines for the submission of the application for renewal.

- Benzovindiflupyr (March 2, 2020)
- Isopyrazam (March 31, 2020)
- Lambda-Cyhalothrin (March 31, 2020)
- Metsulfuron methyl (March 31, 2020)
- Phosphane (March 31, 2020)
- Cyflumetofen (May 31, 2020)
- Ametoctradin (July 20, 2020)
- Mandipropamid (July 20, 2020)
- Bixafen (September 30, 2020)
- Halosulfuron-methyl (September 30, 2020)
- Spiromesifen (September 30, 2020)

## STANDING COMMITTEE ON PLANTS, ANIMALS, FOOD AND FEED (PAFF)

Based on the European Food Safety Authority (EFSA) conclusions, the European Commission has proposed the substances in this section for **non-renewal** or **restricted renewal**. They are now **under consideration** by the Standing Committee on Plants, Animals, Food and Feed (PAFF). Some draft proposals are notified to the World Trade Organization (WTO) prior to the Committee's final vote. In these cases, substances are listed below and in the next section.

- Bifenazate
- Etoxazole
- Indoxacarb
- Mancozeb
- Metalaxyl-M
- Phenmedipham
- Thiophanate-methyl

## WTO NOTIFICATION (February 2019 – February 2020)

The substances in this section have been notified to the WTO as **proposed for non-renewal or restricted renewal**. After the comment period, the Commission will analyze the comments received and publish the Implementing Regulation. Notification date is outlined in parentheses (). Please refer to the draft Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

**Thiophanate-methyl:** proposed non-renewal based on potential reproductive toxicity. (March 1, 2019)

**Metalaxyl-M:** proposed renewal limits the use of treated seeds to greenhouses. (November 4, 2019)

**Beta-cyfluthrin:** proposed non-renewal based on unacceptable risk to workers, high risk to residents, non-target arthropods, and to aquatic organisms. (February 20, 2020)

- **Commission Implementing Regulation:** After the PAFF vote on the recommended action, the European Commission will publish the implementing regulation with information on the basis for non-renewal and grace period for usage of available stocks.

## COMMISSION IMPLEMENTING REGULATION (February 2019 – February 2020)

The Commission has published the final decision on non-renewal or restricted renewal in the EU for the substances in this section. EU MRLs may be subject to change as a result. Implementing regulation publication date is outlined in parentheses (.). Please refer to the published Commission Regulation for the full explanation of the justification for the restricted or non-renewal of approval.

**Methoxyfenozide:** restricted renewal as a candidate for substitution and limiting the uses to fruiting vegetables of Solanaceae in greenhouses. (February 1, 2019)

**Ethoprophos:** non-renewal based on health and environmental concerns that could not be finalized. (March 1, 2019)

**Chlorothalonil:** non-renewal based on concerns of groundwater pollution, persistent biotoxicity and carcinogenic properties. (April 30, 2019)

**Cyflumetofen:** restricted renewal for plant protection products containing cyflumetofen shall only be authorised for uses where the level of metabolite B3 in groundwater is expected to be below 0,1 µg/L. (April 30, 2019)

**Chlorpropham:** non-renewal based on concerns of endocrine disrupting properties and risk to non-target arthropods. (June 18, 2019)

**Dimethoate:** non-renewal based on concerns of genotoxic, reproductive, persistent bioaccumulative toxicity, high risk to mammals and non-target arthropods, and risk to honeybees. (June 27, 2019)

**Desmedipham:** non-renewal based on potential endocrine disrupting, carcinogenic, and mutagenic properties. (June 28, 2019)

**Methiocarb:** non-renewal based on unacceptable risk to workers and genotoxic potential of metabolite. (September 30, 2019)

**Alpha-cypermethrin:** restricted renewal as a candidate for substitution until October 31, 2026. (October 9, 2019)

**Chlorpyrifos:** non-renewal based on genotoxic potential, developmental neurotoxicity, and classification of the substance as toxic for reproduction, category 1B. (January 13, 2020)

**Chlorpyrifos-methyl:** non-renewal based on genotoxic potential, developmental neurotoxicity, and classification of the substance as toxic for reproduction, category 1B. (January 13, 2020)

**Thiacloprid:** non-renewal based on a critical concern in relation to the contamination of groundwater by metabolites containing carcinogenic properties. There is also an undetermined risk to aquatic organisms, bees, and non-target plants, as well as concerns on the impact on reproductive toxicity. (January 14, 2020)



## MRL CHANGES (February 2019 – February 2020)

As a result of non-renewal or expiration of approval, restrictive MRLs have either been proposed (WTO notification) or implemented (Commission Regulation) for the substances below.

- **MRL Changes:** As a result of non-renewal or expiration of approval, the EC restricts associated MRLs. This section includes proposed and implemented actions.

EFSA is not required to issue an opinion on MRL withdrawals in cases where substances are not renewed. (Art. 17 (EC) 396/2005)

WTO Notification:

- **Flufenoxuron:** WTO notification G/SPS/N/EU/371. February 28, 2020
- **Chlorpyrifos:** WTO notification G/SPS/N/EU/360. December 12, 2019
- **Chlorpyrifos-methyl:** WTO notification G/SPS/N/EU/360. December 12, 2019

Implementing Regulation:

- **Triasulfuron:** Commission Regulation 2019/1792 on October 17, 2019. *Effective date: May 18, 2020.*
- **Fipronil:** Commission Regulation 2019/1792 on October 17, 2019. *Effective date: May 18, 2020.*
- **Imazosulfuron:** Commission Regulation 2019/1792 on October 17, 2019. *Effective date: May 18, 2020.*
- **Orthosulfamuron:** Commission Regulation 2019/1792 on October 17, 2019. *Effective date: May 18, 2020.*

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## Examples of Timeline from Proposed Non-Renewal to MRL withdrawal:

Active Ingredient	WTO/TBT notification of proposed non-renewal	Non-renewal Implementing Regulation	Grace period for use within EU	WTO/SPS proposed MRL withdraw	Implemented withdraw	MRL withdraw (end of transition period)
Buprofezin	October 2016	Feb 2017 <i>16 m</i>	June 2017 (Max June 2018)	July 19, 2018	January 18, 2019	August 13, 2019
Iprodione	July 2017	Nov 2017 <i>7 m</i>	March 2018 (Max June 2018)	July 17, 2018	January 10, 2019	July 31, 2019
Diflubenzuron	January 2017	May 2017 <i>16 m</i>	September 2017 (Max Sept 2018)	July 19, 2018	January 18, 2019	August 13, 2019
Chlorpyrifos	October 2019	January 2020 <i>3 m</i>	February 2020 (Max April 2020)	December 12, 2019	<b>Date</b>	<b>Date + 3 months</b>



# Questions?

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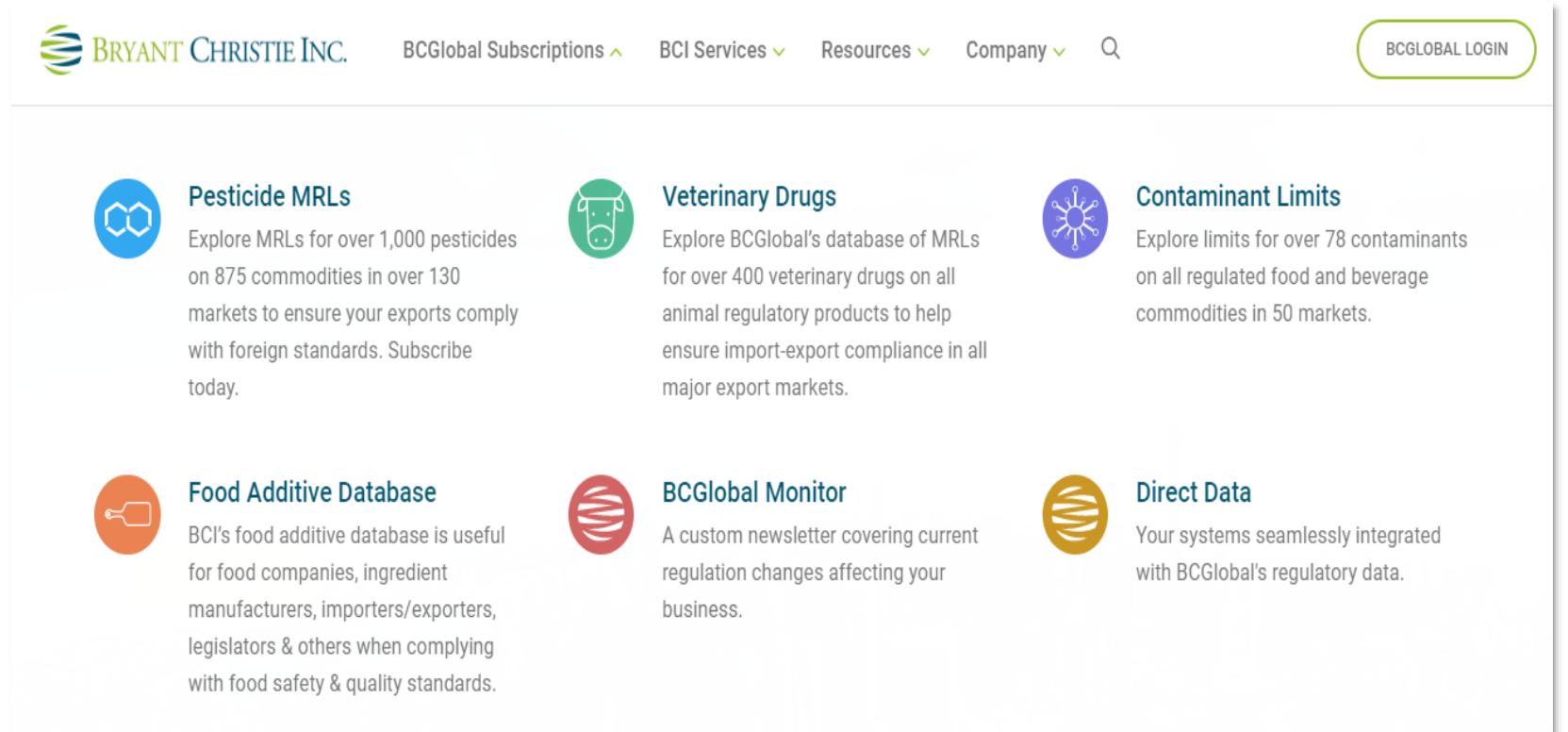
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Below the navigation bar are six service cards arranged in a 2x3 grid:

- Pesticide MRLs**: Explore MRLs for over 1,000 pesticides on 875 commodities in over 130 markets to ensure your exports comply with foreign standards. Subscribe today.
- Veterinary Drugs**: Explore BCGlobal's database of MRLs for over 400 veterinary drugs on all animal regulatory products to help ensure import-export compliance in all major export markets.
- Contaminant Limits**: Explore limits for over 78 contaminants on all regulated food and beverage commodities in 50 markets.
- Food Additive Database**: BCI's food additive database is useful for food companies, ingredient manufacturers, importers/exporters, legislators & others when complying with food safety & quality standards.
- BCGlobal Monitor**: A custom newsletter covering current regulation changes affecting your business.
- Direct Data**: Your systems seamlessly integrated with BCGlobal's regulatory data.