

EU EARLY ALERT SYSTEM

*2019 MRL Harmonization Workshop
San Francisco, CA*

Matt Lantz

May 29, 2019



BRYANT CHRISTIE INC.

EU EARLY ALERT SYSTEM



MRL REVIEWS:
Art. 12 (EC) 396/2005



PESTICIDE REGULATORY
REVIEWS: (EC) 1107/2009

I. EU Early Alert System – Ongoing Art. 12 MRL Reviews

- Ongoing notifications
- Includes the registrant's contact information
- Includes list of established US, EU, and Codex MRLs
- Opportunity for industry to submit “MRL support letters”

Ziram	BE (IT)	New	to be defined	to be defined
Zoxamide	LV	New	to be defined	to be defined
Buprofezin	UK (IT)	New	to be defined	to be defined
Chlorates (incl. Mg, Na, K chlorates)	FR	New	to be defined	to be defined
Napropamide	DK (SI)	New	16/06/2017	11/07/2018
Bupirimate	NL	New	17/07/2017	20/06/2019
Acequinocyl	DE	New	14/08/2018	26/11/2019
Cyproconazole	IE	New	to be defined	to be defined
Ametoctradin	NL (DE)	New	15/05/2018	14/10/2019
Dithianon	EL	New	to be defined	to be defined
Chlorsulfuron	EL (PL)	New	13/07/2018	17/09/2019
Chromafenozide	HU	New	16/04/2018	02/12/2018
Flufenoxuron	FR	New	12/04/2019	
Fluometuron	EL	New	15/09/2017	12/12/2018
Fluquinconazole	IE (CZ)	New	16/08/2017	17/08/2018
Cycloxydim	AT (NL)	New	15/05/2018	14/08/2019
Isoxaben	SE	New	to be defined	to be defined
Oxyfluorfen	ES	New	15/08/2019	
Quinmerac	UK (EE)	New	15/06/2019	
Sintofen (aka Cintofen)	FR (CZ)	New	16/08/2017	13/08/2018
tau-Fluvalinate	DK	New	17/07/2017	22/10/2018
Terbuthylazine	UK (ES)	New	16/11/2017	01/08/2019
Aluminium sulphate	NL	New	to be defined	to be defined
Azadirachtin	DE	New	to be defined	to be defined
Clofentezine	ES	New	to be defined	to be defined
Dicamba	DK	New	to be defined	to be defined
Difenoconazole	ES	New	to be defined	to be defined
Diffubenzuron	EL	New	to be defined	to be defined
Fenoxaprop-P	AT	New	to be defined	to be defined
Imazaquin	BE	New	to be defined	to be defined
Lenacil	BE	New	to be defined	to be defined
Oxadiazon	IT	New	to be defined	to be defined
Picloram	PL	New	to be defined	to be defined
Pyriproxyfen	NL	New	to be defined	to be defined
Epoxiconazole	DE (UK)	New	to be defined	to be defined
2,5-Dichlorobenzoic acid methylester	DE (FR)	New	16/05/2017	08/06/2018
Aluminium ammonium sulfate	PT (IE)	New	to be defined	to be defined
Aluminium silicate (aka kaolin)	HU (EL)	New	to be defined	to be defined

EU Early Alert – Art. 12 MRL Reviews

AO

Thu 5/2/2019 2:25 PM

Alinne Oliveira

EU Early Alert - MRL Review of Acequinocyl

To

Alinne Oliveira

Acequinocyl (MRL ART_12) 8.27.18_public mode.xlsx

46 KB

Dear Stakeholders:

On August 14th, the European Food Safety Authority (EFSA) has announced the start of the review process for existing Maximum Residue Levels (MRLs) for the active substance **acequinocyl**, as required under Article 12 of Regulation (EC) No 396/2005. This announcement is a new process being implemented by the EU in an effort to increase transparency in its MRL reviews. At the start of the review process, stakeholders may liaise with the registrant, Arysta Lifesciences, if they wish to support the EU MRL review of this substance. Please note that this review is not intended to collect additional GAPs and residue trials that have not been submitted previously.



Acequinocyl is currently authorized for use in the EU with expiration of approval in August 2024. Attached you will find a list of established acequinocyl EU MRLs with corresponding U.S. MRLs. There are no established Codex MRLs for this active ingredient. 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. MRL and the current EU MRL.

To support the EU MRL review for your commodity, please contact Tim Wilson (tim.wilson@arysta.com) and Christine Villegas (christine.villegas@arysta.com) at Arysta Lifesciences by September 15th.

Please let us know if you have any questions.

Best regards,

Alinne B. Oliveira | Trade Policy Specialist


BRYANT CHRISTIE INC. |  **BCGLOBAL**
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1418 Third Avenue, Suite 300, Seattle, WA 98101

t: 206-292-6340 | www.bryantchristie.com

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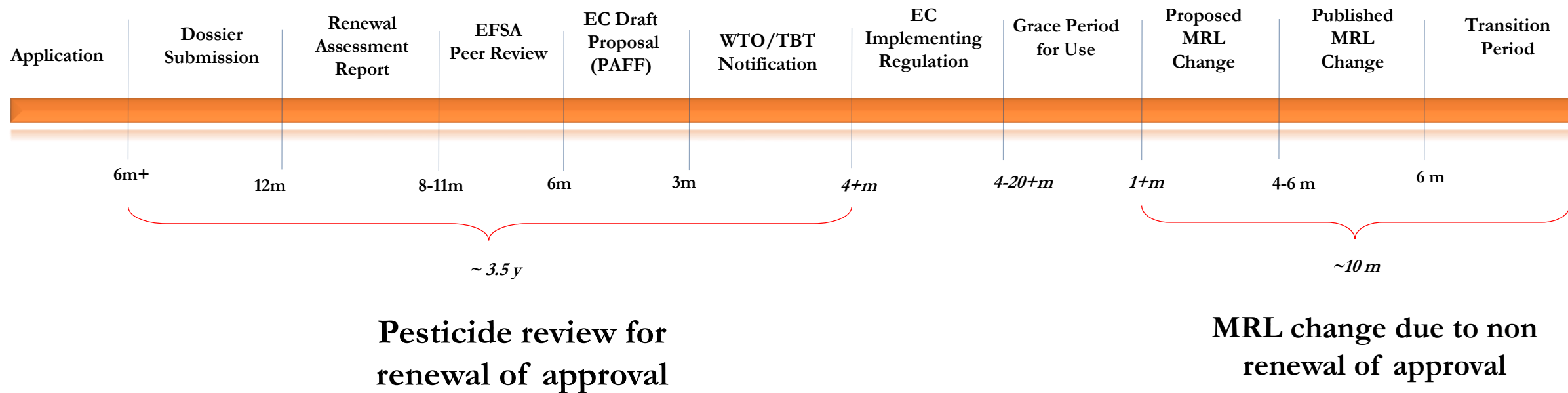
GLOBAL MRL DATABASE™ A service of BRYANT CHRISTIE INC.				
Market	Search Commodity Here	Published Commodity	MRL (ppm)	Commodity Notes
European Union	Cranberries	Lingonberry	0.01	Fresh or frozen fruit. MRL applies to whole product after removal of caps,
United States	Berry, low growing, subgroup 13-07G	Lingonberry	0.5	
European Union	Dewberries	Loganberry	0.01	Fresh or frozen fruit. MRL applies to whole product after removal of caps,
United States	Caneberry, subgroup 13-07A	Loganberry	4	
European Union	Litchis/lychees	Longan	0.01	Fresh or frozen fruit. MRL applies to whole product after removal of stems.
United States	Tropical and Subtropical, small fruit, inedible peel, subgroup 24A	Longan	2	
European Union	Courgettes	Loofah, angled	0.01	Fresh or frozen vegetables. MRL applies to whole product after removal of stems.
United States	Vegetable, cucurbit, group 9	Loofah, angled	0.3	
European Union	Cucurbits with edible peel; Others	Loofah, smooth	0.01	Fresh or frozen vegetables. MRL applies to whole product after removal of stems.
United States	Vegetable, cucurbit, group 9	Loofah, smooth	0.3	
European Union	Loquats/Japanese medlars	Loquat	0.1	Fresh or frozen fruit. MRL applies to whole product after removal of stems.
United States	Fruit, pome, group 11-10	Loquat	0.4	
European Union	Lentils	Lupin	0.01	Fresh or frozen vegetables. MRL applies to whole product. Other products to which
European Union	Pulses; Lupins/lupini beans	Lupin	0.01	MRL applies to dry seeds.
United States	Bean, dry, seed	Lupin	0.15	

II. EU Early Alert System – Pesticide Regulatory Reviews:

- Updated quarterly
- Advance information on non renewals, restricted renewals, and substances that will expire
- Organized in sections corresponding to review process to facilitate understanding:
 - Application for renewal
 - Up Next for Review
 - PAFF discussion
 - WTO TBT notification
 - Commission Implementing regulation
 - MRL Changes (WTO SPS notification and Implementing regulation)



EU Pesticide Review Process Timeline:



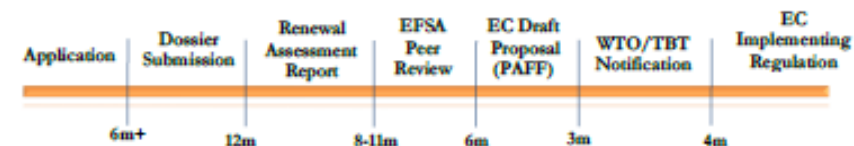
- Look at active ingredients undergoing review in the EU; Include only substances with corresponding U.S. MRLs
- **Application for renewal:** list active ingredients that were not supported by registrant. Will expire
- **Up next for review:** substances with application deadline coming up

EU EARLY ALERT - PESTICIDE REVIEW

December 14, 2018

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 may have restricted or non-renewal of approval. It analyzes all 2018 publications and will be updated quarterly. The arrows to the left of each section explain where a substance is in the EU review process as of December 7, 2018.

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 (Art. 12 Reviews). MRL-specific reviews are notified on a rolling basis.



Application for Renewal

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 and approval will expire. Corresponding MRLs may be restricted to the limit of determination* (LOD).

- Fenbuconazole: expires on April 30, 2021
- Diethofencarb: expires on May 31, 2021
- Etridiazole: expires on May 31, 2021
- Myclobutanil: expires on May 31, 2021
- Oryzalin: expires on May 31, 2021

UP NEXT for Review July-Dec 2018

Under the EU pesticide review program, the substances listed in this section have upcoming deadlines for the submission of the renewal application.

- 1-Naphthylacetamide (1-NAD)
- 1-Naphthylacetic acid (1-NAA)
- Azoxystrobin
- Bispyribac
- Fluzifop-P
- Fluroxypyr
- Imazalil (aka enilconazole)
- Kresoxim-methyl
- Oxyfluorfen
- Prohexadione
- Spiroxamine
- Tefluthrin
- Triazoxide

- **PAFF Meeting:** lists substances that the EC commission recommended for non-renewal or restricted renewal based on EFSA's Conclusions or Peer Review.
- **WTO Notification:** lists 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.

EU EARLY ALERT - PESTICIDE REVIEW

PAFF
Meeting

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). After the Committee's deliberation the Commission will notify the decision to the World Trade Organization (WTO).

- Propanil
- Desmedipham
- Phenmedipham
- Thiophanate-methyl
- Indoxacarb

WTO
Notification

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 ().

Chlorpropham: non-renewal based on potential endocrine disrupting properties. (March 29, 2018)

Dithianon: restriction for use on non-edible crops based on an inconclusive consumer exposure assessment. (April 11, 2018)

Etoxadazole: non-renewal based on persistent, bioaccumulative and toxic characteristics. (July 5, 2018)

Copper Compounds: 5-year renewal as a candidate for substitution¹ due to persistent, bioaccumulative and toxic properties. (August 31, 2018)

Methoxyfenozide: 7-year renewal as a candidate for substitution¹ and limiting the uses to fruiting vegetables of Solanaceae in greenhouses. (August 31, 2018)

Mepanipyrim: restricted use in greenhouses based on endocrine disrupting potential. (Sep 3, 2018)

Ethoprophos: non-renewal based on concerns that could not be finalized (high acute risk to birds, endocrine disrupting potential, secondary poisoning for birds and mammals, metabolite exposure to soil organisms). (November 1, 2018)

Chlorothalonil: non-renewal based on carcinogenic properties, genotoxicity concerns, high risk to amphibians and fish, in addition to lack of data to confirm several areas of the risk assessment as it regards consumer risk from dietary exposure and residue levels. (December 4, 2018)

- **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, grace period for usage of available stocks.

EU EARLY ALERT - PESTICIDE REVIEW

Commission
Implementing
Regulation

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 reevaluation and change as a result. Publication date is outlined in parentheses ().

Penflufen: approval restricted to use on seeds and other propagating materials. (February 7, 2018)

Bifenthrin: approval restricted to greenhouse use based on potential bioaccumulation and biomagnification in the aquatic environment. (February 26, 2018)

Fenazaquin: approval restricted to greenhouse and ornamental use only. (May 7, 2018)

Propyzamide: restricted renewal as a candidate for substitution[†] due to persistent and toxic properties for freshwater organisms with no observed long-term effect. (May 23, 2018)

Imidacloprid: approval restricted to permanent greenhouse use due to high risk to bees. (May 29, 2018)

Clothianidin: approval restricted to permanent greenhouse use due to risk to bees. (May 29, 2018)

Thiamethoxam: approval restricted to permanent greenhouse use due to high risk to bees. (May 29, 2018)

Fenamidone: non-renewal based on inconclusive risk assessments for genotoxic potential, aquatic organisms, and a toxic groundwater metabolite. (July 25, 2018)

Malathion: approval restricted to permanent greenhouses use based on high risk to birds. (October 9, 2018)

Pymetrozine: non-renewal based on endocrine disrupting properties, potential toxic groundwater exposure, and potential risk to aquatic organisms. (October 9, 2018)

Thiram: non-renewal based on high risk to consumers, birds, mammals, and endocrine disrupting potential. (October 10, 2018)

Diquat: non-renewal due to high risk to bystanders and birds. (October 12, 2018)

Propiconazole: non-renewal based on reproductive toxicity characteristics and endocrine disrupting potential. (November 28, 2018)

Quinoxifen: non-renewal based on persistent, bioaccumulative and toxic; very persistent and very bioaccumulative; and persistent organic pollutant properties. (December 7, 2018)

- **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)

EU EARLY ALERT - PESTICIDE REVIEW

MRL
Changes

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

- Linuron: WTO notification SPS 262 on July 13, 2018
- Iprodione: WTO notification SPS 263 on July 17, 2018
- Buprofezin: WTO notification SPS 264 on July 19, 2018
- Diflubenzuron: WTO notification SPS 264 on July 19, 2018
- Picoxystrobin: WTO notification SPS 264 on July 19, 2018
- Tepraloxydim: WTO notification SPS 264 on July 19, 2018
- Diphenylamine: Implementing Regulation 2018/1515 on October 10, 2018

*Level of determination (LOD) means the validated lowest residue concentration which can be quantified and reported by routine monitoring with validated control methods.

*Candidates for substitution (CS) are pesticides for which national authorities need to carry out an assessment to establish whether more favorable alternatives to using the plant protection product exist, including non-chemical methods. The aim is to encourage more sustainable crop protection.

The EU Early Alert project is comprised of two notification systems to U.S. stakeholders regarding 1) the EU pesticide review under EC 1107/2009 and 2) the MRL Review under Art. 12 of EC 395/2006 legislations. The project is funded by the Technical Assistance for Specialty Crops (TASC) Program of the U.S. Department of Agriculture and prepared by Bryant Christie Inc.

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

Active Ingredient	TBT notification of non-renewal	Non-Renewal Implementing Regulation	Grace period	Proposed MRL Withdraw	Implemented Withdraw	MRL Withdraw (end of transition period)
Linuron	October 2016	Feb 2017	June 2017 (Max June 2018)	July 2018	January 2019	August 4, 2019
Iprodione	July 2017	Nov 2017	March 2018 (Max June 2018)	July 2018	January 2019	July 31, 2019
Buprofezin	October 2016	Feb 2017	June 2017 (Max June 2018)	July 2018	January 2019	August 13, 2019
Diflubenzuron	January 2017	May 2017	September 2017 (Max Sept 2018)	July 2018*	January 2019	August 13, 2019
Picoxystrobin	January 2017	August 2017	Nov 2017 (Max Nov 2018)	July 2018*	January 2019	August 13, 2019

Thank you!

Matt Lantz

Matthew.lantz@bryantchristie.com

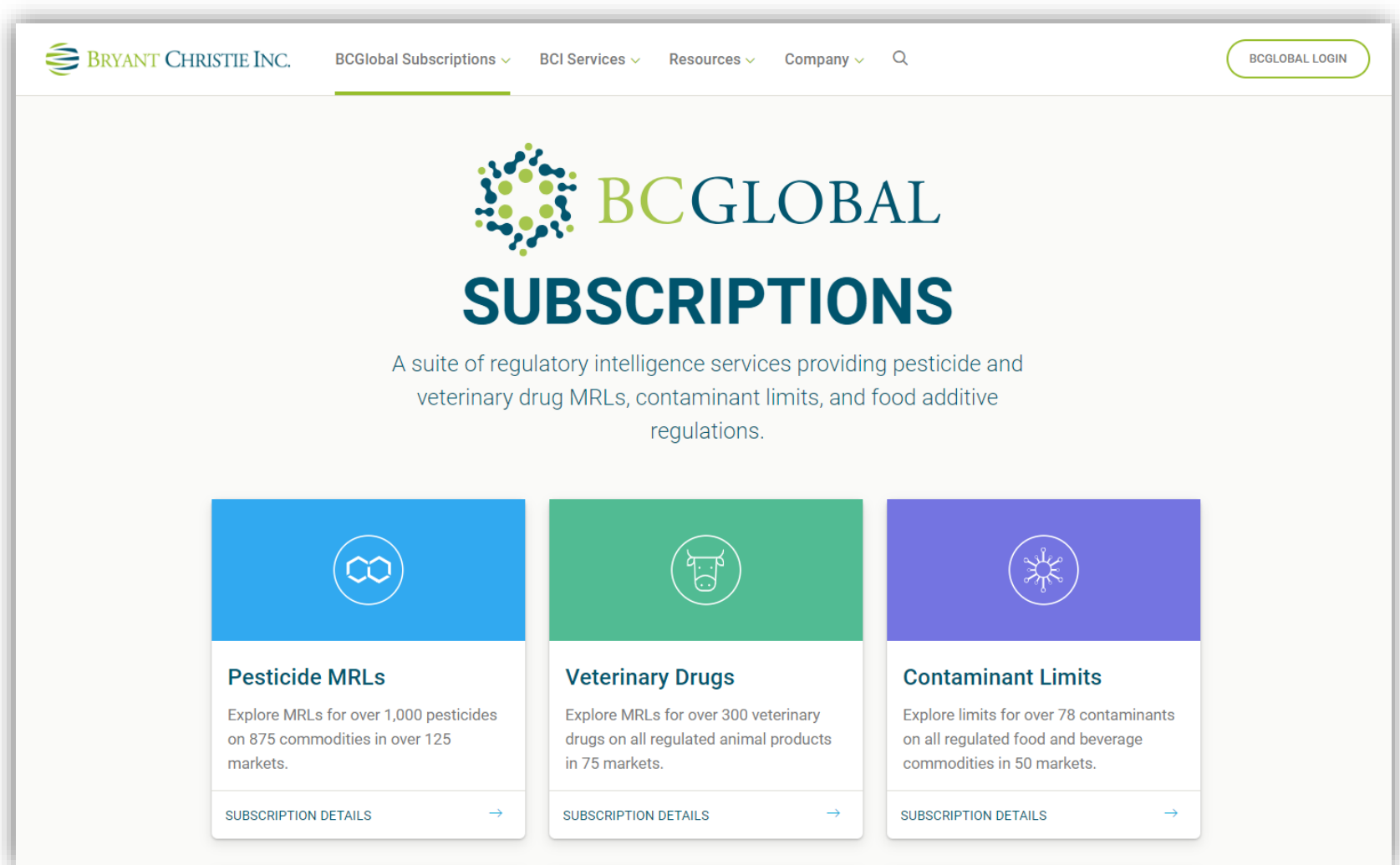
Tel: +1-206-292-6340

Bryant Christie Inc.

Seattle, WA

Sacramento, CA

www.bryantchristie.com




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