

Commenting on EU MRL Changes: Challenges and Opportunities

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CALIFORNIA SPECIALTY CROP MRL CONFERENCE

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I. For Starters - An Example:

- US and European Hop industries work cooperatively on MRLs
- Together 93% of world hops
- US exports 70% of crop
- 2017 US hop exports to Europe: \$110 million



I. The Development

Spinosad (Entrust) Hops

- 2014:
 - US MRL 22 ppm;
 - EU MRL 22 ppm
- July 4, 2014, EU WTO Announcement: G/SPS/N/EU/86
- EU Hop MRL to be lowered to 0.1 ppm (LOQ)
- If implemented: No more use of this insecticide



WORLD TRADE
ORGANIZATION

G/SPS/N/EU/86

4 July 2014

(14-3851)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	Notifying Member: EUROPEAN UNION If applicable, name of local government involved:
2.	Agency responsible: European Commission, Health and Consumers Directorate-General
3.	Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Certain selected commodities of plant and animal origin
4.	Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5.	Title of the notified document: Annexes to "Draft Commission Regulation amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for 2-naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad in or on certain products (Text with EEA relevance)" Language(s): English Number of pages: 27 http://members.wto.org/crnattachments/2014/sps/EEC/14_2978_00_e.pdf
6.	Description of content: These notified annexes to the draft Regulation set proposed maximum residue levels for 2-naphthyloxyacetic acid, acetochlor, chloropicrin, diflufenican, flurprimidol, flutolanil and spinosad in Annexes II, III and V to Regulation (EC) No 396/2005. MRLs for these substances in certain commodities are changed: either increased or lowered. Higher MRLs are set to accommodate new uses in the European Union and in third countries which export those commodities to the European Union. Lower MRLs are set after updating the limit of determination and/or deleting old uses which are not authorized any more in the European Union or for which there is not enough data for an MRL to be set.

I. The Reaction:

- Comments due Sept. 2, 2014
- Comments submitted Aug. 22, 2014
- No EU response
- EFSA proposal first published in March 2012!
- WTO comments solicited at end of multi-year process review
- No chance to change MRL
- WTO comments not useful



US Hop Industry Plant Protection Committee

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*A subcommittee of:
Washington Hop Commission • Oregon Hop Commission
Idaho Hop Commission • Hop Growers of America*

August 22, 2014

European Commission
DG Health and Consumers, Unit G6-Multilateral International Relations
Rue Froissart 101
B-1049 Brussels
Tel: +(32 2) 29 54263
E-mail: sps@ec.europa.eu

RE: Spinosad Hop MRL proposed by European Union
in World Trade Organization notification G/SPS/N/EU/86

Dear Sir or Madam:

I am writing on behalf of United States hop growers regarding the European Union's (EU) draft pesticide maximum residue level (MRL) proposal announced in World Trade Organization (WTO) notification G/SPS/N/EU/86.

The U.S. Hop Industry Plant Protection Committee (USHIPPC) works on behalf of the U.S. hop industry to seek the registration of crop protection products in the U.S. and to harmonize hop MRLs around the world. Over 70% of the U.S. hop crop is exported, so international MRL harmonization is a high priority for U.S. hop growers, hop merchants, and brewery customers.

We take great pride in providing high-quality U.S. hops to brewers around the world, and always strive to meet the foreign regulatory requirements of the markets to which we export.

The U.S. hop industry exported \$68.2 million of hops (including cones, pellets, and extract) to the EU in 2013. The EU is the number one export market for U.S. hops, accounting for approximately 35 percent of total U.S. hop exports each year.

We would like to continue to ensure that there are no barriers to trade in this important market. Reviewing the WTO notification EU/86, we note that the EU is proposing to lower its current 22 mg/kg MRL for spinosad on hops (dried) to the limit of determination of 0.1 mg/kg.

The U.S. MRL for spinosad on hops is 22 mg/kg. Lowering the spinosad MRL in the EU would mean that this crop protection material could not be used on U.S. product exported to the EU.

I. The Result:

- EU Spinosad MRL fell from 22 ppm to 0.1 ppm on November 5, 2015
- Handler letters prohibit Entrust usage
- Loss of US-approved crop protection product for growers
- Situation is repeating and growing



Do Not Use the Following Pesticides for all Hops		
EU		
Pesticide Type	Trade Name	Common Name
Do not use at any time during the growing season		
Fungicide	Accrue	Spiroxamine
Fungicide	Tanos	Famoxadone
Fungicide	Presidio	Fluopicolide
Fungicide	Miltrex/Torino	Cyflufenamid
Insecticide	Dibrom	Naled
Insecticide	Delegate WG	Spinetoram
Insecticide	Entrust 80W	Spinosad



APOLLO, BRAVO, CALYPSO, CASCADE, CENTENNIAL, COLUMBUS/TOMAHAWK, CRYSTAL, DENALI, EUREKA!, GALENA, LEMONDROP, NUGGET, SUMMIT, SORACHI ACE, SUPER GALENA, WILLAMETTE, and ZEUS

Pesticide Type	Trade Name	Common Name	Comments
Fungicide	Accrue	Spiroxamine	Do Not Use
Fungicide	Tanos	Famoxadone	Do Not Use
Fungicide	Topguard	flutriafol	Do Not Use
Fungicide	Presidio	Fluopicolide	Do Not Use new
Fungicide	Torino	Cyflufenamid	Do Not Use new
Insecticide	Magister	Fenazaquin	Do Not Use
Insecticide	Dibrom	Naled	Do Not Use
Insecticide	Fyfanon	Malathion	Do Not Use
Insecticide	Coragen	Chlorantraniliprole	Do Not Use
Insecticide	Delegate	Spinetoram	Do Not Use
Insecticide	Entrust	Spinosad	Do Not Use
Insecticide	Mocap	Ethoprop	Do Not Use
Herbicide	Alion	Indaziflam	Do Not Use new



Table 1: Pesticide use restrictions

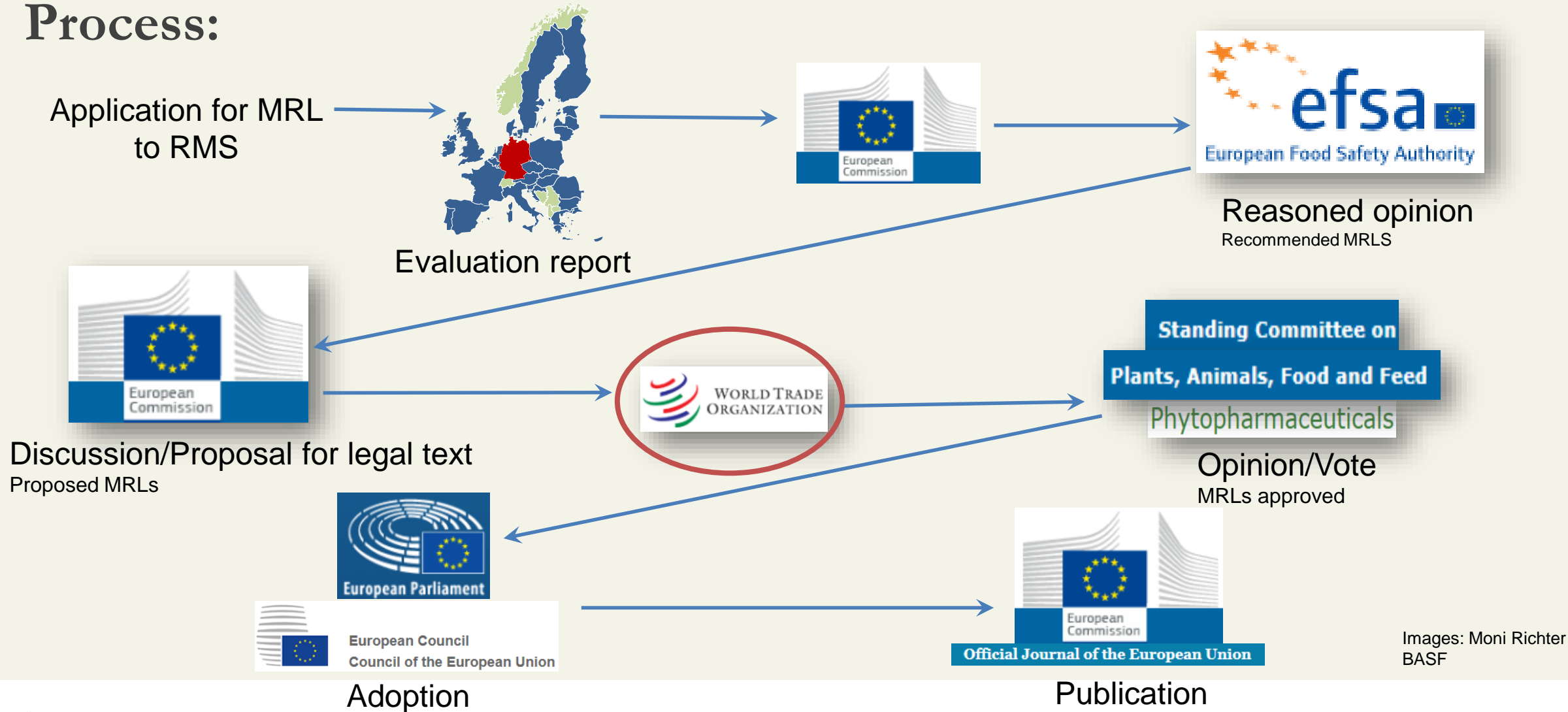
Pesticide Type	Pesticide Trade Name	Chemical Name
DO NOT USE		
Fungicide	Accrue	Spiroxamine
Fungicide	Miltrex, Torino	Cyflufenamid
Fungicide	Presidio	Fluopicolide
Fungicide	Tanos	Famoxadone
Fungicide	Topguard/Fortix/Rhyme	Flutriafol
Herbicide	Alion	Indaziflam
Insecticide	Delegate WG	Spinetoram
Insecticide	Dibrom	Naled
Insecticide	Entrust 80W	Spinosad
Insecticide	Fyfanon	Malathion

I. The Upshot:

- Unless major trade ramifications meriting political intervention, commenting on proposed EU MRL changes through the WTO announcement process is highly unlikely to yield MRLs changes in the EU.
- Heaven forbid if you miss commenting. ☹️
- EU recognizes this is a challenge and working to improve situation.
- With Cut Off Criteria, situation likely to repeat...often.



II. The EU Pesticide Approval Process:



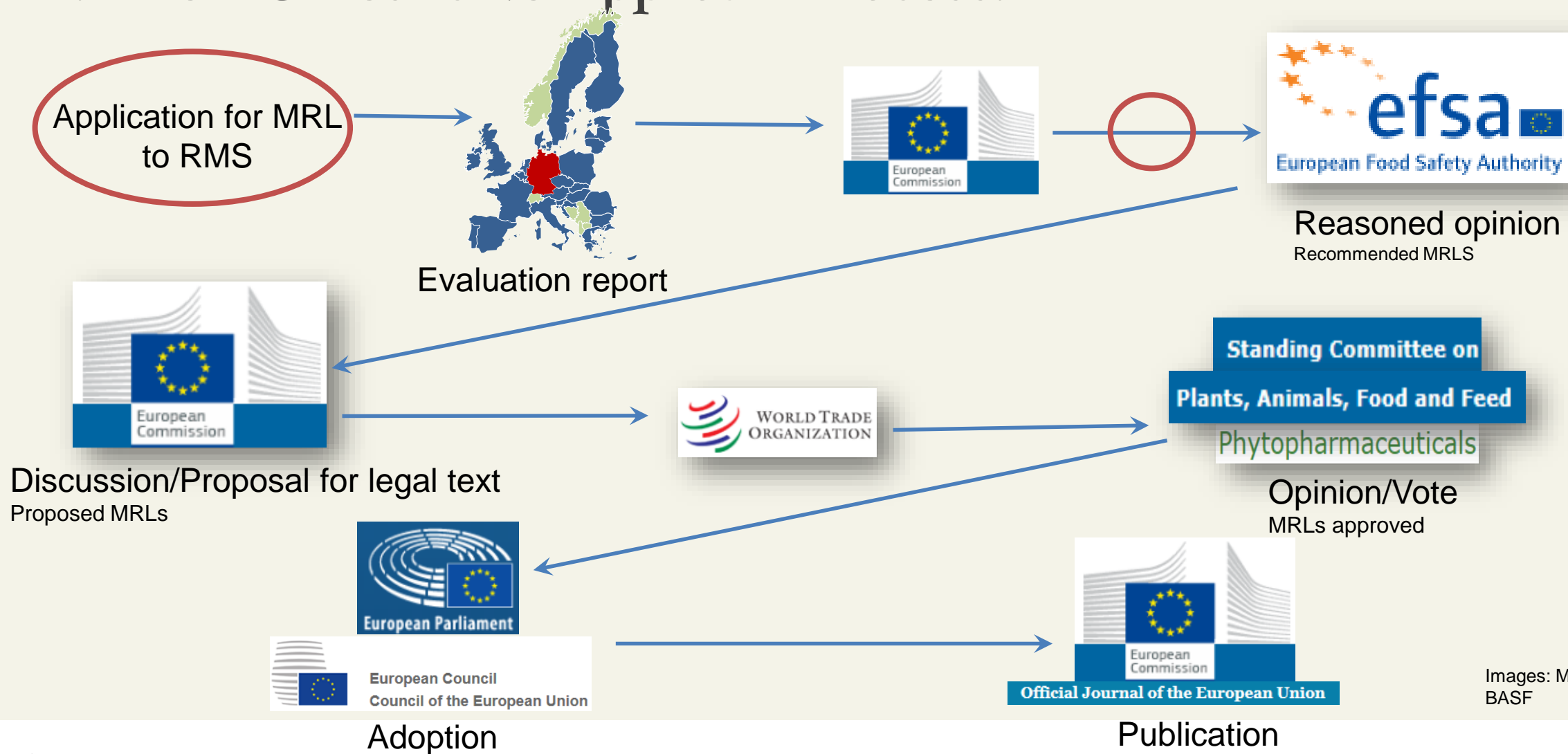
Images: Moni Richter
BASF

II. Review of All Existing EU MRLs

- Article 12 of Regulation EC 396/2005 says all existing EU MRLs must be reviewed
- Has been ongoing since 2008
- List of reviews published
<http://www.efsa.europa.eu/en/events/event/140619>
- European Commission recommendation: Comment at start of reevaluation through registrant

Active Substance	RMS (new RMS where applicable)	Process	Start of data collection* (expected date)	RMS/EFSA preparing dRO**	MS consultation	Finalisation of RO	Adoption of the RO (expected date)
Chlorpyrifos	ES	Interim	26/11/2015				13/02/2017
Chlorpyrifos-methyl	ES	Interim	26/11/2015				13/02/2017
Cinidon-ethyl	UK	Interim	23/12/2014				22/06/2015
Deltamethrin	SE	Interim	22/12/2014				06/11/2015
Imazalil	NL	Interim	10/03/2016				09/08/2017
Triclopyr	IE	Interim	26/11/2015				13/02/2017
Triflumizole	NL	Interim	29/08/2016				09/03/2017
Bromuconazole	BE	Interim	08/08/2016				31/08/2017
Bitertanol	UK	Interim	14/07/2015				21/01/2016
Clethodim	NL	Interim	10/08/2017				11/06/2018
Carboxin	UK	Interim	31/10/2016				26/09/2017
Dazomet	BE	Interim	10/04/2017				31/07/2018
Fenbuconazole	UK (SI)	Interim	11/10/2016				05/06/2018
Fenbutatin oxide	BE	Interim	28/07/2017				27/11/2017
Fenoxycarb	NL	Interim	11/04/2017				21/12/2017
Fluazifop-P	FR	Interim	21/01/2015				04/09/2015
Flurochloridone	ES	Interim	20/06/2017				15/12/2017
Hexythiazox	FI	Interim	21/12/2016				06/07/2018
Myclobutanil	BE (AT)	Interim	23/06/2017				05/06/2018
Pencycuron	NL	Interim	21/11/2016				15/05/2018
Paclobutrazol	UK (AT)	Interim	16/12/2016				03/08/2017
Prochloraz	IE	Interim	23/05/2016				15/05/2018
Pyridaben	NL	Interim	03/10/2016				20/10/2017

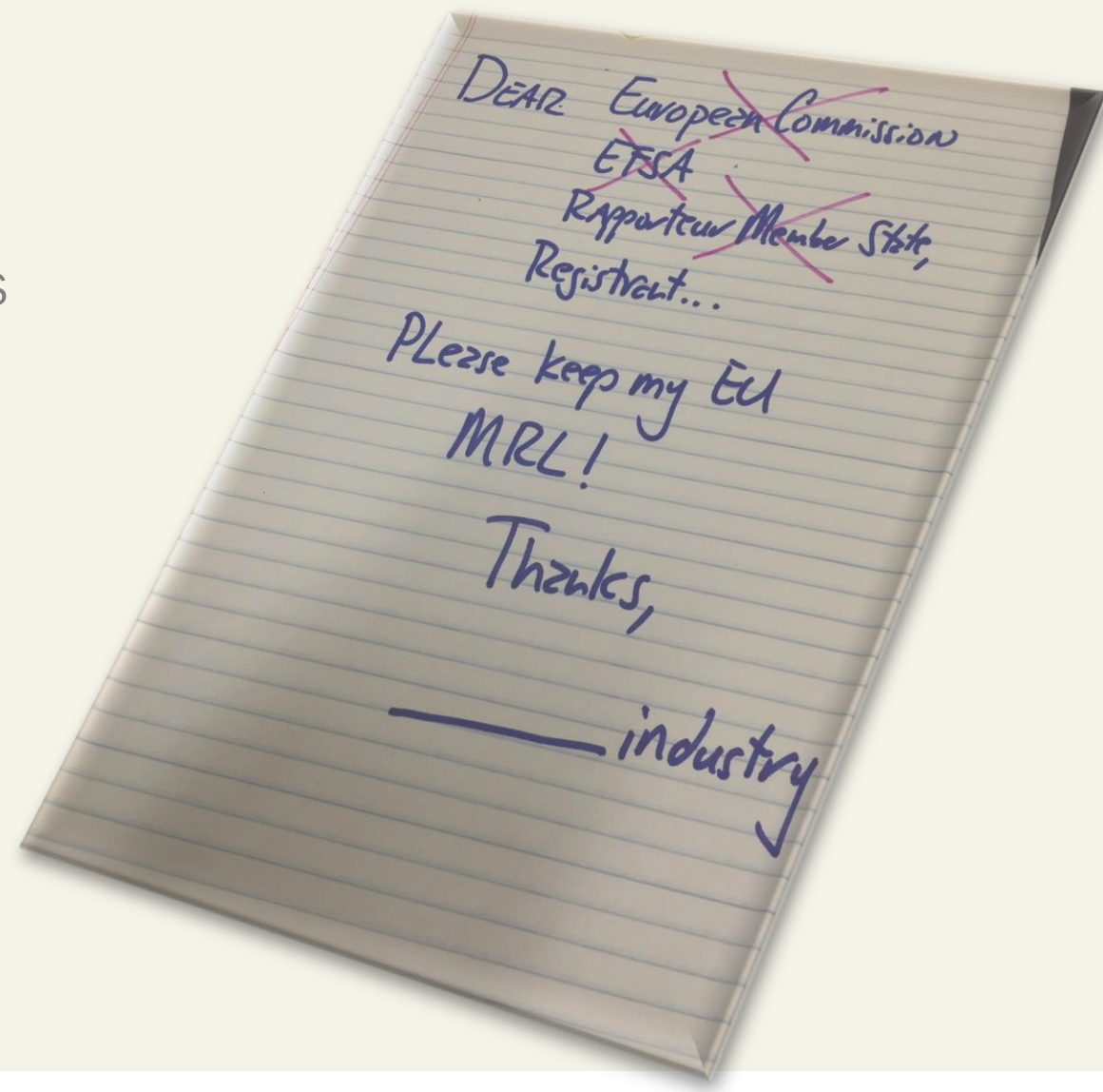
II. The EU Pesticide Approval Process:



Images: Moni Richter
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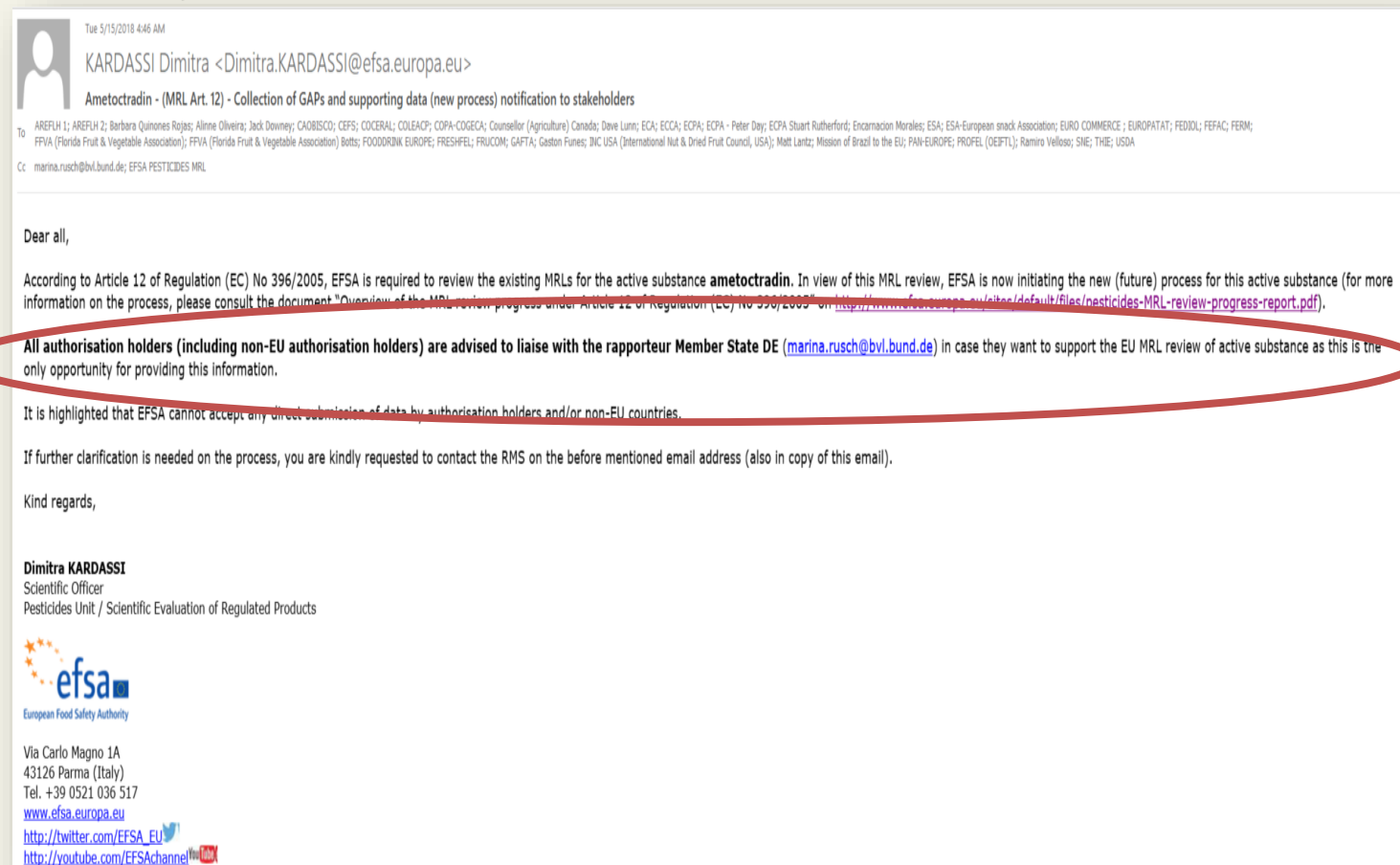
III. Commenting Early:

- Pros:
 - Ability to indicate importance of MRL as reviews start
 - Address concerns as review is ongoing
- Challenges:
 - Knowing when to comment (short window)
 - Who to comment to
 - Differing registrants
 - Differing requirements




IV. BCI TASC Grant: EU Early Notification

- Goal is to let stakeholders know when evaluations are open for comment, who could be affected, and to whom comments should be directed.



IV. BCI TASC Grant: EU Early Notification

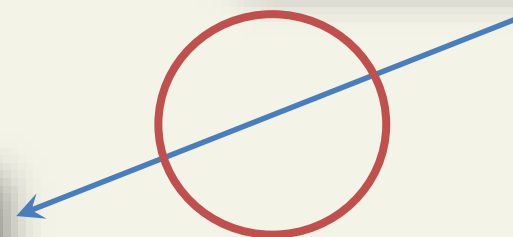
- Added value; Provide clear information on:
 - Commodities affected
 - US vs EU MRL
 - Deadline for comment
 - Registrant and contact
- Working with USDA on content and distribution

<div> <div>Quinoxifen</div> <div>  GLOBAL MRL DATABASE™ A service of BRYANT CHRISTIE INC. </div> </div>				
Market	Search Commodity Here	Published Commodity	MRL (ppm)	Commodity Notes
European Union	Amur river grape	Wine grapes	1	
United States	Amur river grape	Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F	2	
European Union	Apricot	Apricots	0.05	Fresh or frozen fruit. MRL applies to whole product after removal of stems. Other
United States	Apricot	Fruit, stone, group 12	0.7	
European Union	Artichoke, globe	Globe artichokes	0.3	Fresh or frozen vegetables. MRL applies to whole flower head including receptacle.
United States	Artichoke, globe	Artichoke, globe	1.4	
European Union	Bearberry	Blueberries	2	Fresh or frozen fruit. MRL applies to whole product after removal of caps, crown and
United States	Bearberry	Berry, low growing, subgroup 13-07G	1	
European Union	Bilberry	Blueberries	2	Fresh or frozen fruit. MRL applies to whole product after removal of caps, crown and
United States	Bilberry	Berry, low growing, subgroup 13-07G	1	
European Union	Blueberry, lowbush	Blueberries	2	Fresh or frozen fruit. MRL applies to whole product after removal of caps, crown and
United States	Blueberry, lowbush	Berry, low growing, subgroup 13-07G	1	
European Union	Cantaloupe	Melons	0.05	Fresh or frozen vegetables. MRL applies to whole product after removal of stems.
United States	Cantaloupe	Melon, subgroup 9A	0.08	
European Union	Cherry, sweet	Cherries (sweet)	0.3	Fresh or frozen fruit. MRL applies to whole product after removal of stems. Other
United States	Cherry, sweet	Fruit, stone, group 12	0.7	
European Union	Cherry, tart	Cherries (sweet)	0.3	Fresh or frozen fruit. MRL applies to whole product after removal of stems. Other

IV. BCI TASC Grant: EU Early Notification

Possible Addition:

- Notify when EFSA has advanced active ingredient to European Commission with recommended MRLs
- (But no comment opportunity)



V. Conclusions and Challenges Ahead

- Current WTO commenting not effective
- EU and stakeholders seeking way to make commenting more useful through early commenting
- Gathering storm as Cut Off Criteria/Endocrine Disruptor reg enacted
- TASC Grant seeking to inform stakeholders of earlier opportunities to comment and possible advancement of proposed MRLs

Thank You!

Matthew Lantz

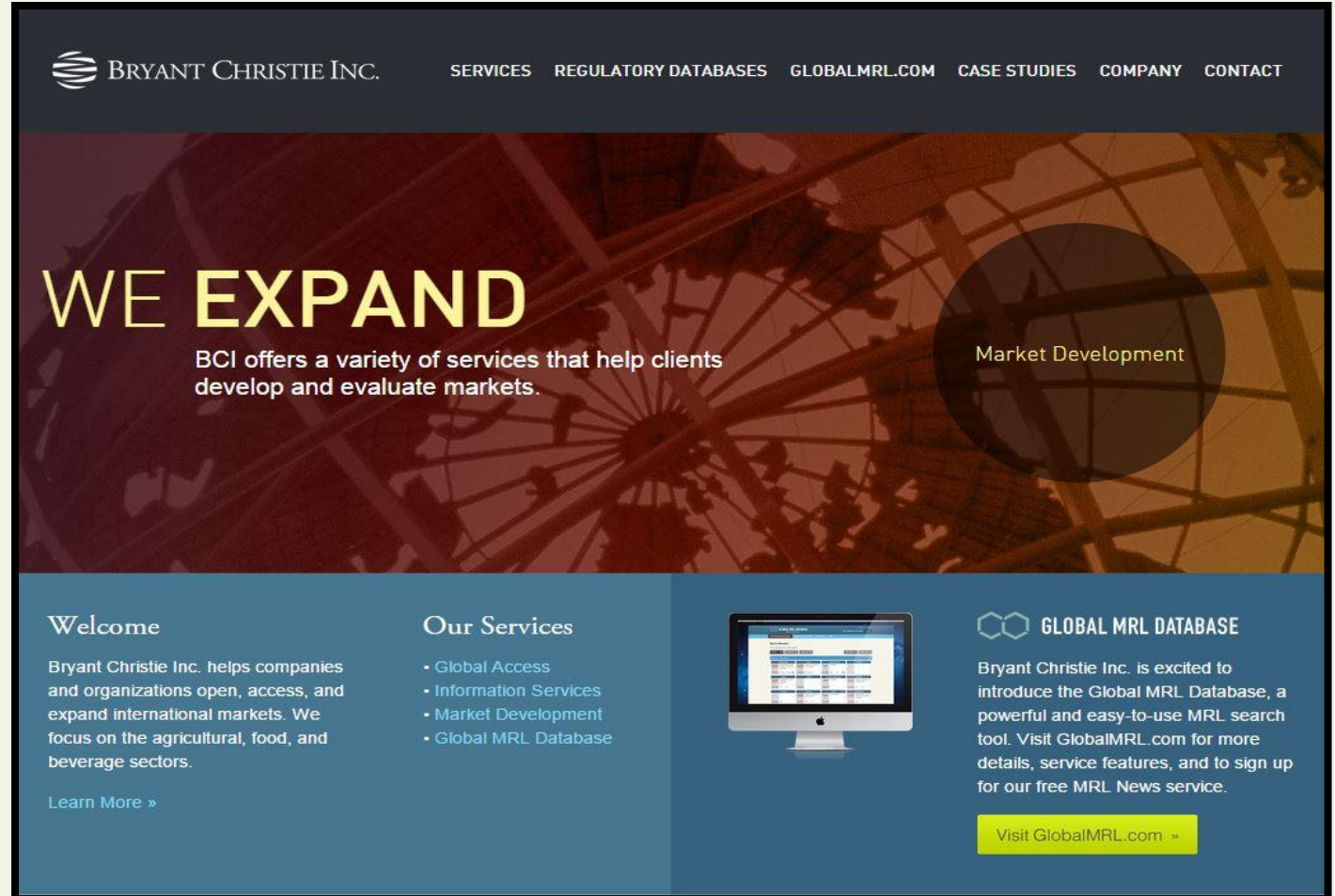
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The screenshot shows the Bryant Christie Inc. website. The header features the company logo and a navigation menu with links to SERVICES, REGULATORY DATABASES, GLOBALMRL.COM, CASE STUDIES, COMPANY, and CONTACT. The main banner has a background image of a Ferris wheel and the text "WE EXPAND" in large yellow letters, followed by "BCI offers a variety of services that help clients develop and evaluate markets." A circular graphic on the right says "Market Development". The footer is divided into three columns: "Welcome" with a brief description and a "Learn More »" link; "Our Services" with a bulleted list including Global Access, Information Services, Market Development, and Global MRL Database; and "GLOBAL MRL DATABASE" with a description of the tool, a computer monitor icon, and a yellow button that says "Visit GlobalMRL.com »".

BRYANT CHRISTIE INC. SERVICES REGULATORY DATABASES GLOBALMRL.COM CASE STUDIES COMPANY CONTACT

WE EXPAND

BCI offers a variety of services that help clients develop and evaluate markets.

Market Development

Welcome

Bryant Christie Inc. helps companies and organizations open, access, and expand international markets. We focus on the agricultural, food, and beverage sectors.

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Our Services

- Global Access
- Information Services
- Market Development
- Global MRL Database

GLOBAL MRL DATABASE

Bryant Christie Inc. is excited to introduce the Global MRL Database, a powerful and easy-to-use MRL search tool. Visit GlobalMRL.com for more details, service features, and to sign up for our free MRL News service.

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