



# Endocrine Disruption and Hazard Criteria in the EU:

## *Managing the Trade Challenges*

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# Content...



 **About ECPA**

 **Hazard criteria and Endocrine Disruption**

 **EU Policy on Import Tolerances**

 **Trade implications**

 **Conclusions**



# About ECPA...



- ...represents the **R&D-driven crop protection industry** in Europe
  - 22 multinational companies; 32 national associations; 26,000 people
- ...advocates **policies & legislation that foster innovation**
  - giving Europe's farmers the tools they need
- ...promotes **good agricultural practices** projects to
  - Protect health
  - Ensure safe & affordable food
  - Safeguard water;
  - Enhance biodiversity;



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# And 32 national associations...



- Austria
- Belgium
- Bulgaria
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Finland
- France
- Germany
- Greece
- Hungary
- Ireland
- Italy
- Kazakhstan
- Latvia
- Lithuania
- Netherlands
- Norway
- Serbia
- Slovakia
- Slovenia
- Spain
- Sweden
- Switzerland
- Poland
- Portugal
- Romania
- Russia
- Turkey
- UK
- Ukraine



# Content...



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■ **Hazard criteria and Endocrine Disruption**

■ EU Policy on Import Tolerances

■ Trade implications

■ Conclusions



# EU Pesticides legislation



## ■ Regulation 1107/2009

- Replaced Directive 91/414 (risk based legislation)
- **Hazard-based approach added**
  - Inc. POPs, CMR & endocrine disruptors

## ■ Regulation 396/2005

- Maximum residue levels (MRLs) and import tolerances
- Risk based (no mention of hazard criteria)





# Endocrine Disruption

## *in EU pesticides legislation*

### ■ Introduced in Regulation 1107/2009

- Endocrine disruption: a hazard based cut off criteria

### ■ Detail criteria: Annex II, Regulation 1107/2009

*An active substance ... only be approved if ... it is not considered to have **endocrine disrupting properties** that may cause adverse effects...*

*By [13 December 2013], the Commission shall **present** ... specific **scientific criteria** for the determination of **endocrine disrupting properties**...*



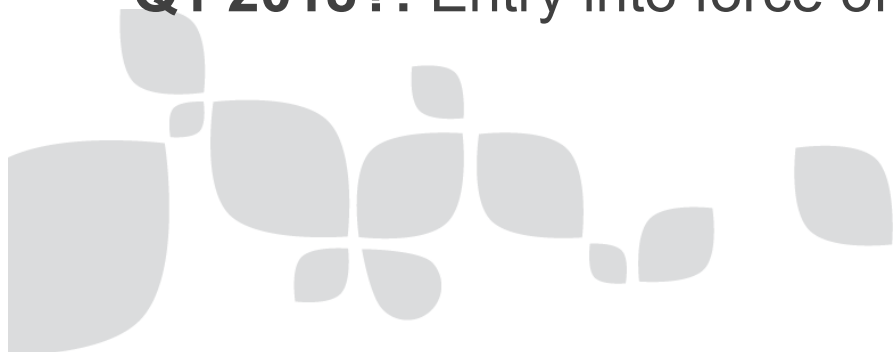
# Steps towards adoption of criteria



- **June 2016** – Proposal for criteria (with impact assessment)
- **July 2016 - Present:** Discussions between Commission and committee of Member States (SCoPAFF)
- **17 May 2017:** Draft proposal presented for discussion
- **30 May 2017:** Vote postponed, until...?

## Next steps

- *Will depend on when they vote – and how they vote...*
  - **Q4 2017?:** Formal adoption of criteria
  - **Q1 2018?:** Entry into force of final ED criteria



# EU Impact Assessment

## 26 PPP substances identified as being 'impacted'

- Final result could be greater (with conservative evaluations)
- Knock on effect
- Esp. on trade



# Content...



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■ **EU Policy on Import Tolerances**

■ Trade implications

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# Setting Import Tolerances

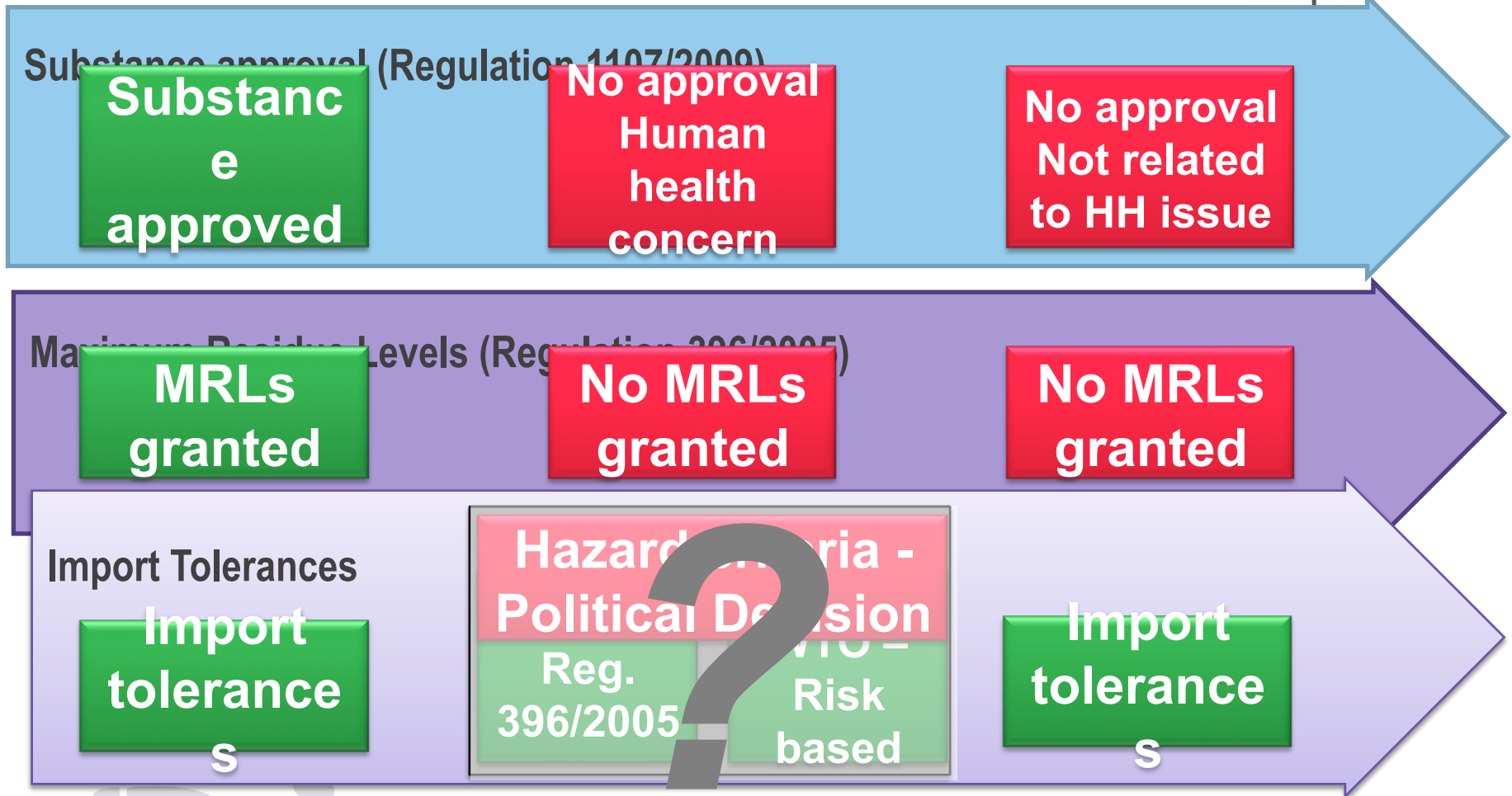


- The policy on endocrine disruption will impact on the availability of products in the EU
- Any impact on trade will be due to restrictions in the setting of import tolerances
- Question to be answered: *If a substance is not approved in EU due to human health issues, will import tolerances still be set for 3<sup>rd</sup> country trade?*



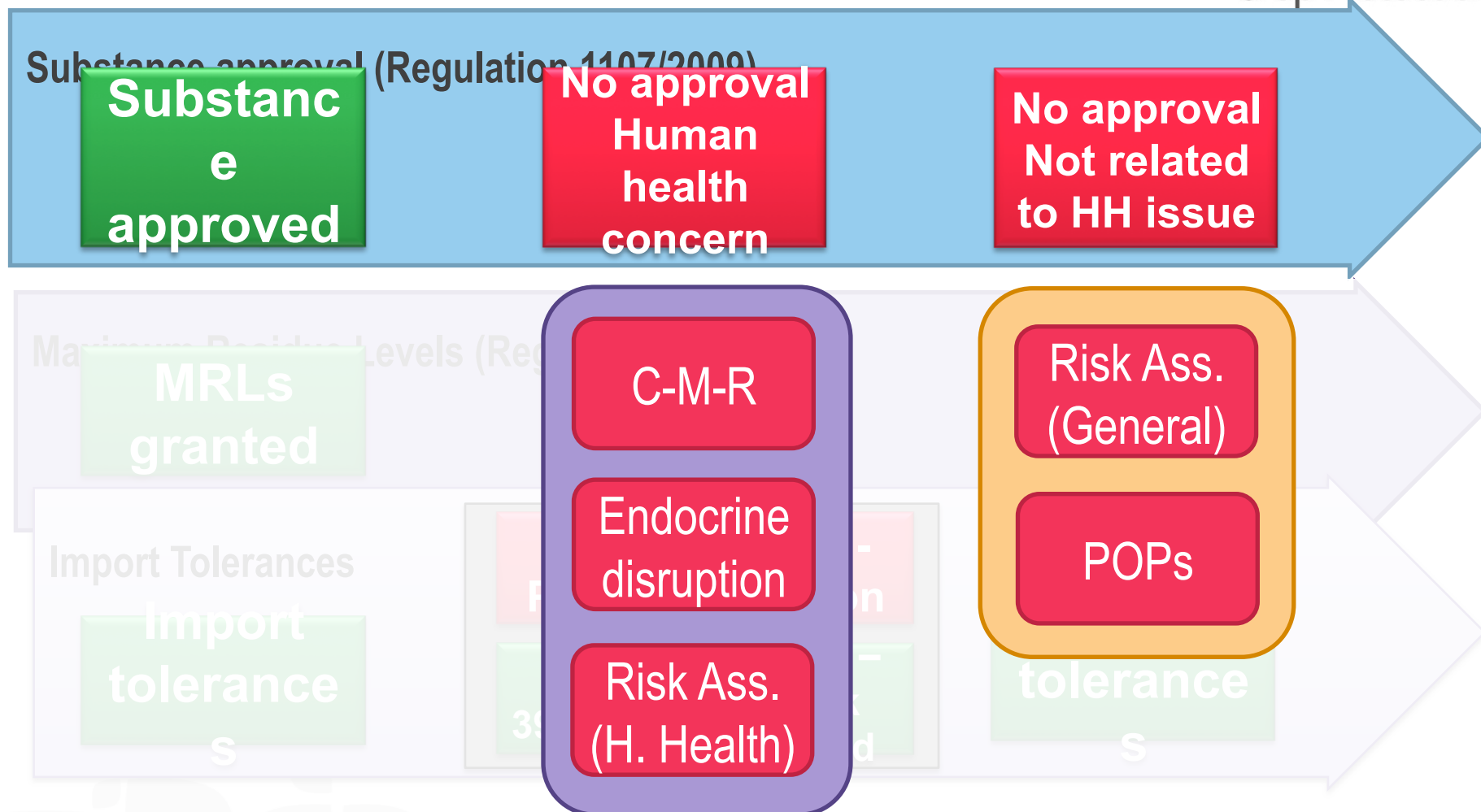
# Setting import tolerances

*Politics vs science and law*



# Setting import tolerances

## *Politics vs science and law*



# Policy on import tolerances



## Key points for policy discussion:

- Regulation 1107/2009 introduces hazard based criteria
- Hazard based restrictions on import tolerances would be
  - Contrary to the EU's MRL legislation (Reg.396/2005)
  - Contrary to WTO SPS agreement
    - *With substantial impact on international trade!*
- WTO requires that decisions are based on risk assessment
  - the EU must continue to comply with SPS principles
    - *Third country voices needed (political and trade)!*





# Content...



■ About ECPA

■ Hazard criteria and Endocrine Disruption

■ EU Policy on Import Tolerances

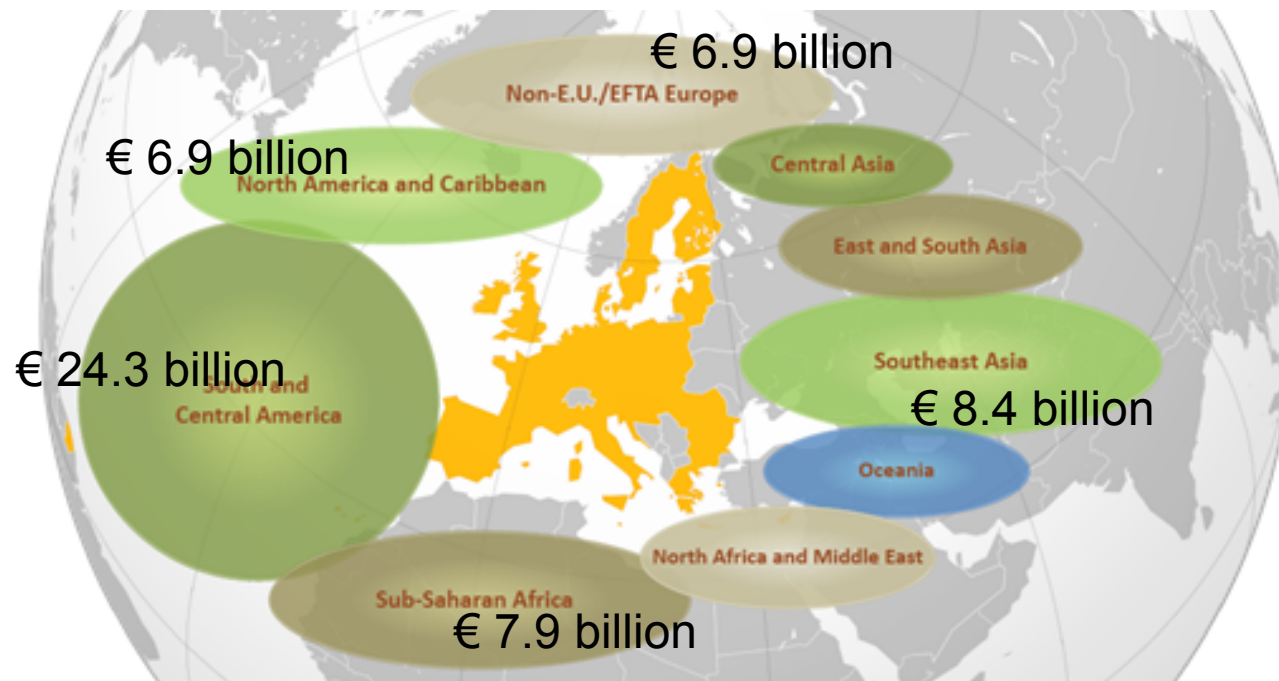
■ **Trade implications**

■ Conclusions



# ED criteria – Trade Impact

€65 billion of EU imports potentially affected



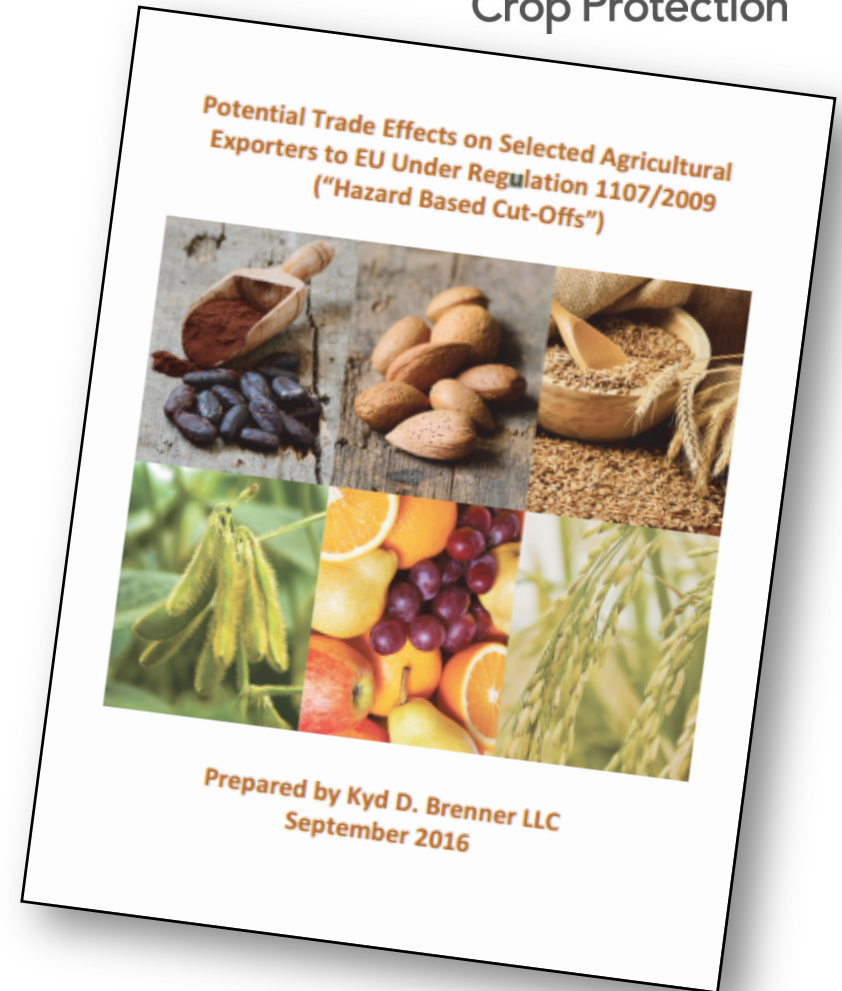
**Potential Trade Effects on World Agricultural Exporters of European Union Regulations on Endocrine Disruptors** Kyd D. Brenner, February 2014

Category	€m (2012)
Fruit & Nuts	€ 13,795
Animal Feed Ingredients	€ 9,780
Oilseeds & Groundnuts	€ 9,574
Coffee, Tea & Spices	€ 9,470
Vegetable Oil	€ 8,222
Cereals	€ 4,613
Cocoa	€ 4,336
Vegetables	€ 3,525
Sugar	€ 2,046
<b>Total</b>	<b>€ 65,362</b>

# Updated study on potential impact



- Targeted review of crop & country combinations
- Based *only* on ASs identified as ***probable Endocrine Disruptors*** (in EU impact assessment)



# Report: potential impact – exports to EU

*Based on list of ASs identified in EU Commission impact*



Commodity	Country	Affected MRLs	Million € (ave. 3 yrs)
Almonds	United States	14	1,282
Peanuts	United States	11	178
Soybeans	United States	13	1,555
Apples/Pears	New Zealand	18	170
Apples/Pears	South Africa	27	245
Banana/Plantain	Colombia	10	786
Citrus Fruits	Argentina	14	199
Citrus Fruits	South Africa	13	485
Cocoa	Ivory Coast	8	1,267
Coffee	Brazil	15	2,221
Coffee	Mexico	4	85
Table Grapes	Chile	19	294
Palm/Palm Kernel Oil	Malaysia	9	1,494
Peanuts	Argentina	13	351
Rapeseed (Canola)	Australia	7	666
Rice	India	12	318
Soybeans	Brazil	21	2,182
Wheat	Canada	6	601
<b>TOTAL TRADE:</b>			<b>€ 14,386</b>

## Almonds from the United States

Active substance	US	EU	Codex*	Functional Use	CMR Based on EFSA/ECHA	Option 2 - ED
2,4-D	0.2	0.2	0.2	Herbicide		YES
8-Hydroxyquinoline incl. oxyquinoline		0.01		Fungicide	R1B	YES
Amitrole		0.02		Herbicide		YES
Boscalid	0.7	1	0.05	Fungicide		YES
Brodifacoum**				Rodenticide	R1A	
Bromadiolone				Rodenticide	R1B	
Carbendazim**		0.1	0.1	Fungicide	M1B & R1B	
Carbetamide		0.05		Herbicide	C2 + R1B	
Chlorophacinone**				Rodenticide	R1B	
Cypermethrin		0.05	0.05	Insecticide		YES
Cyproconazole		0.05		Fungicide	R1B	YES
Desmedipham		0.01		Herbicide		YES
Difencoum				Rodenticide	R1A	
Difethialon**				Rodenticide	R1B	
Epoxiconazole		0.05		Fungicide	C2 + R1B	YES
Fenamidone		0.02		Fungicide		YES
Flocoumafen**				Rodenticide	R1B	
Flubendiamide	0.06	0.1	0.1	Insecticide		YES
Flumioxazin	0.02	0.05	0.02	Herbicide	R1B	
Flupyriflufen-methyl		0.02		Herbicide	Interim(R2+C2)	
Flurochloridone		0.1		Herbicide		YES
Flusilazole**				Fungicide	R1B	
Folpet		0.02		Fungicide	C2 + R1B	
Glufosinate	0.1	0.1	0.1	Herbicide	R1B	
Iprodione	0.3	0.2	0.2	Fungicide		YES
Isoxafflutole		0.02		Herbicide	Interim(R2+C2)	
Lenacil		0.1		Herbicide		YES
Linuron		0.05		Herbicide	C2 + R1B	YES
Malathion	8	0.02		Insecticide		YES
Mancozeb	0.1	0.05	0.1	Fungicide		YES
Maneb		0.05	0.1	Fungicide		YES
Metiram		0.05	0.1	Fungicide		YES
Myclobutanil	0.1	0.05		Fungicide		YES
Oxadiazon		0.05		Herbicide		YES
Pendimethalin	0.1	0.05		Herbicide		YES
Propyzamide		0.02		Herbicide		YES

Active substance	US	EU	Codex*	Functional Use	CMR Based on EFSA/ECHA	Option 2 - ED
Pymetrozine		0.02		Insecticide	Interim(R2+C2)	
Spirodiclofen	0.1	0.1	0.05	Insecticide		YES
Tebuconazole	0.05	0.05	0.05	Fungicide		YES
Tepraloxymid		0.1		Herbicide		YES
Tetraconazole		0.02		Fungicide		YES
Thioproprid		0.02	0.02	Insecticide	R1B	
Thiophanate-methyl	0.1	0.2	0.1	Fungicide		YES
Thiram		0.1	0.1	Fungicide		YES
Tralkoxydim		0.02		Herbicide		YES
Triflumizole		0.1		Fungicide	R1B	YES
Triflurosulfuron		0.02		Herbicide		YES
Warfarin**		0.01		Rodenticide	R1B	
Ziram	0.1	0.1	0.1	Fungicide		YES

\*Does not adopt Codex MRLs, \*\* No longer approved in EU

EU IMPORTS - ALMONDS FROM US - ANNUAL AVERAGE 2013 - 2015					
Product	HS Code	Unit	All EU Imports	From US	% of Imports From US
Almonds In Shell	80211	Metric Tons	3,382	2,855	84.4%
Almonds Shelled	80212	Metric Tons	226,399	202,792	89.6%
Almonds In Shell	80211	Euros	€ 14,500,066	€ 12,609,969	87.0%
Almonds Shelled	80212	Euros	€ 1,417,811,102	€ 1,269,431,655	89.5%
All Almonds		Metric Tons	229,781	205,67	89.4%
		Euros	€ 1,432,311,168	€ 1,282,041,624	89.5%

# Example:

## *Almonds from the United States*

Active substance	US	EU	Codex*	Functional Use	CMR Based on EFSA/ ECHA	Option 2 ED
<b>2,4-D</b>	0.2	0.2	0.2	Herbicide		<b>YES</b>
<b>Boscalid</b>	0.7	1	0.05	Fungicide		<b>YES</b>
<b>Flubendiamide</b>	0.06	0.1	0.1	Insecticide		<b>YES</b>
<b>Flumioxazin</b>	0.02	0.05	0.02	Herbicide	R1B	
<b>Glufosinate</b>	0.1	0.1	0.1	Herbicide	R1B	
<b>Iprodione</b>	0.3	0.2	0.2	Fungicide		<b>YES</b>
<b>Malathion</b>	8	0.02		Insecticide		<b>YES</b>
<b>Mancozeb</b>	0.1	0.05	0.1	Fungicide		<b>YES</b>
<b>Myclobutanil</b>	0.1	0.05		Fungicide		<b>YES</b>
<b>Pendimethalin</b>	0.1	0.05		Herbicide		<b>YES</b>
<b>Spirodiclofen</b>	0.1	0.1	0.05	Insecticide		<b>YES</b>
<b>Tebuconazole</b>	0.05	0.05	0.05	Fungicide		<b>YES</b>
<b>Thiophanate-methyl</b>	0.1	0.2	0.1	Fungicide		<b>YES</b>
<b>Ziram</b>	0.1	0.1	0.1	Fungicide		<b>YES</b>

# Potentially impacted substances by 'wrong' policy on import tolerances

## Indicative list of substances that:

- Trigger CMR criteria
- Potentially trigger ED (based on 2 published evaluations)

Active substance	CMR Based on EFSA/ECHA	Option 2 - Identified substances		Comments
		Taken from Commission IA	Contractors report	
2,4-D		YES		
8-Hydroxyquinoline incl. oxyquinoline		YES		
Amitrole		YES	YES	EU non-approval (phase-out)
Boscalid		YES		
Brodifacoum	R1A			No longer approved in EU
Bromadiolone	R1B			
Carbendazim	M1B & R1B			No longer approved in EU
Carbetamide	C2 + R1B			
Chlorophacinone	R1B			No longer approved in EU
Cypermethrin		YES	YES	
Cyproconazole	R1B	YES	YES	
Desmedipham		YES	YES	
Difenacoum	R1A			
Difethialon	R1B			No longer approved in EU
Epoxiconazole	C2 + R1B	YES	YES	
Fenamidone		YES	YES	
Flocoumafen	R1B			No longer approved in EU
Flubendiamide		YES	YES	
Flumioxazin	R1B			
Flupyrsulfuron-methyl	Interim (R2 + C2)			
Flurochloridone	R1B	YES	YES	
Flusilazole	R1B			No longer approved in EU
Folpet	C2 + R1B)			
Glufosinate	R1B			
Iprodione		YES	YES	
Isoxaflutole	Interim (R2 + C2)			
Lenacil		YES	YES	
Linuron	C2 + R1B	YES	YES	
Malathion		YES		
Mancozeb		YES	YES	
Maneb		YES	YES	Expiry 30 June 2017
Metiram		YES	YES	
Myclobutanil		YES	YES	
Oxadiazon		YES		
Pendimethalin		YES	YES	
Propyzamide		YES	YES	
Pymetrozine	Interim (R2 + C2)			
Spirodiclofen		YES	YES	
Tebuconazole		YES	YES	
Tepraloxydim		YES		
Tetraconazole		YES		
Thiacloprid	R1B			
Thiophanate-methyl		YES	YES	
Thiram		YES		
Tralkoxydim		YES		
Triflumizole	R1B	YES		
Triflurosulfuron		YES	YES	
Warfarin	R1B			No longer approved in EU
Ziram		YES		
Pyriproxyfen			YES	
2-Phenylphenol (incl. sodium salt ortho-hydroxyphenol)			YES	

# Content...



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# Conclusion

## *Take home messages*

- **ED criteria will have a significant impact**
  - On product availability - in EU
  - On regulatory coherence - globally
- **Wrong EU policy on setting Import Tolerances**
  - Would be incompatible with EU law and WTO rules
  - With major impact on trade in agricultural products
- **Third country voices need to be heard**
  - Continued input at political and trade levels





# European Residues Conference 2017



**16th & 17th October 2017**

**Sheraton Airport Hotel, Brussels**

More details and registration to follow @

<https://ecpa.events.idloom.com/residues2017>



# Reference documents



01. ECPA paper – Setting import tolerances in the EU
02. Presentation initial trade impact study – 2014
03. 2016 study on trade impact of EU policy on endocrine disruption & ITs
04. Presentation of EU policy on ED in chemicals



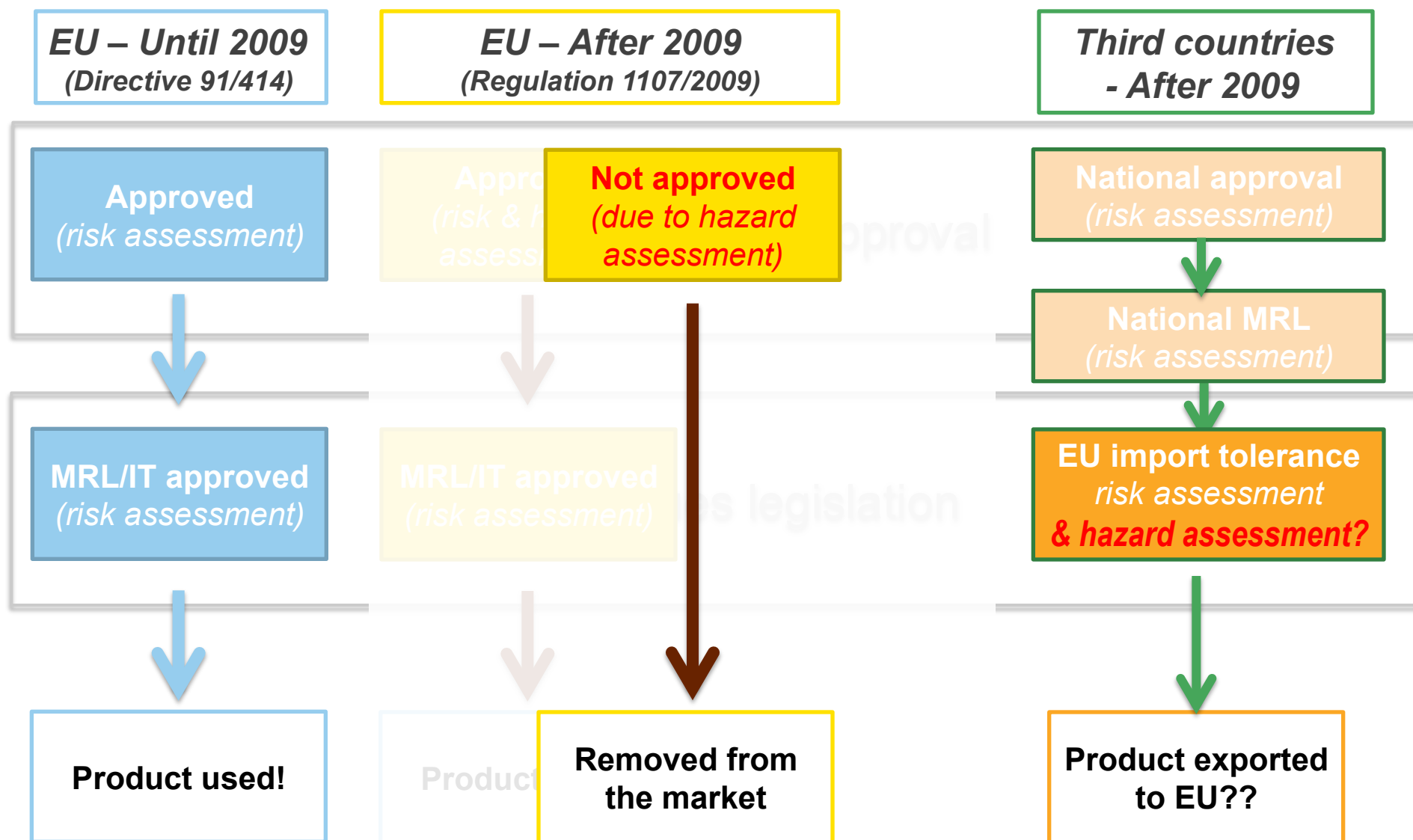
# Thank you for your attention!



# ADDITIONAL INFORMATION



# What it means for a particular substance?



# Almonds & Peanuts from the United States



EU IMPORTS - ALMONDS FROM US - ANNUAL AVERAGE 2013 - 2015				
Product	Unit	All EU Imports	From US	% Imports From US
All Almonds	Metric Tons	229,781	205,67	89.4%
	Euros	€ 1,432,311,168	€ 1,282,041,624	89.5%

EU IMPORTS - PEANUTS FROM THE US - ANNUAL AVERAGE 2013 - 2015				
Product	Unit	All EU Imports	From US	% of EU Imports
All Groundnuts (Peanuts), Roasted	Metric Tons	625,277	149,553	23.9%
	Euros	€ 768,248,483	€ 178,094,830	23.2%