EU Pesticide Policies: The Trade Perspective

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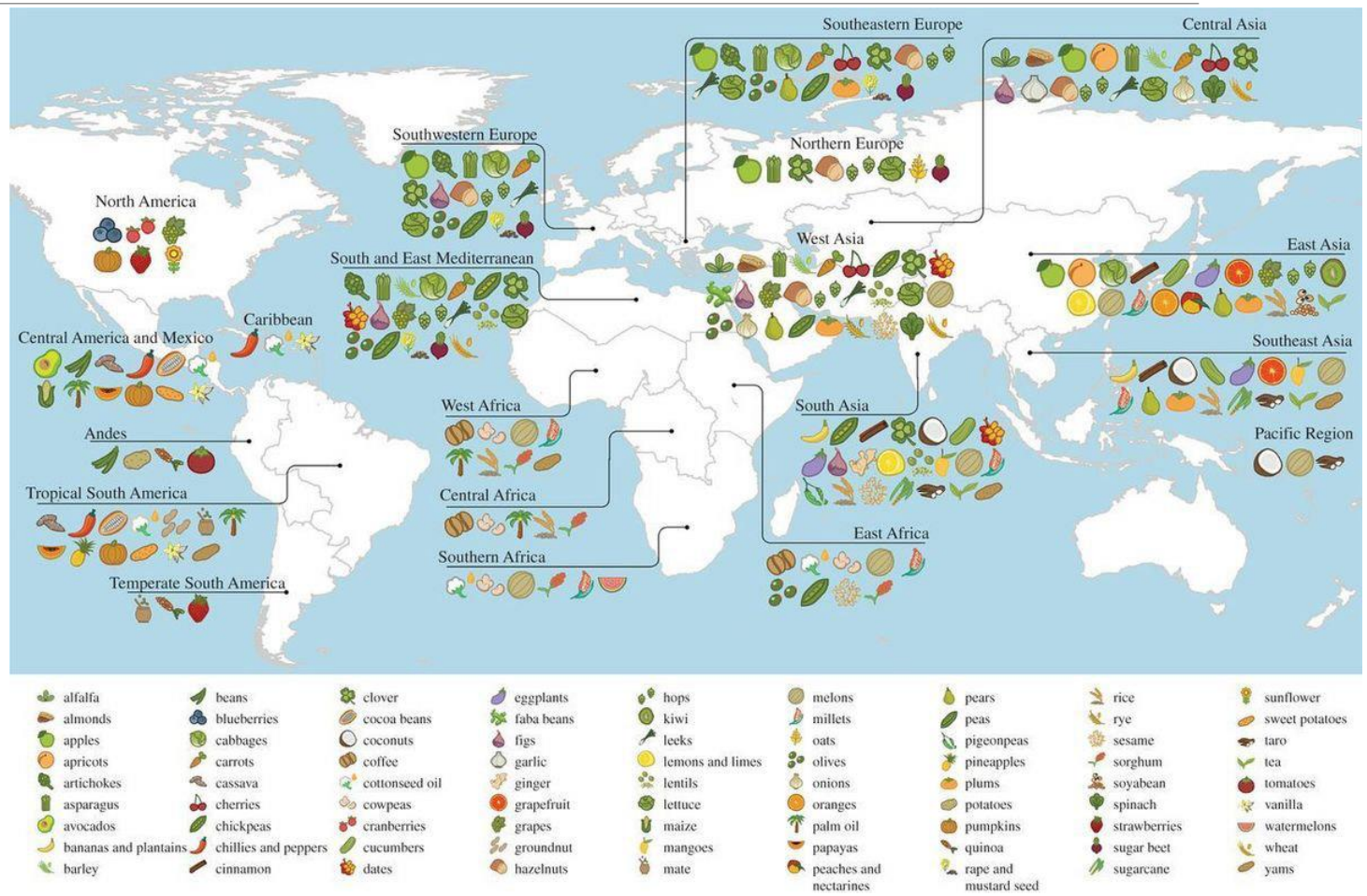
Outline of this presentation

- WTO SPS Agreement Primer
- Key concerns raised on EU policies
- Other relevant Committee activities
- Work ahead in 2019



All SPS documents cited are publicly available at www.wto.org

WTO Agreement on Sanitary and Phytosanitary Measures

The right to protect human, animal, or plant life or health

Avoiding unnecessary barriers to trade

WTO SPS Committee

- Regular forum for consultation and to carry out functions related to implementation of the SPS Agreement
  - ➢ Non-discrimination
  - ➢ Scientific justification
    - Harmonization to international standards
    - Risk assessment
    - Consistency
    - Least trade restrictiveness
  - ➢ Transparency

WTO SPS Committee: Role on Specific Trade Concerns (STCs)

- Forum for consultations with countries to resolve trade concerns with specific SPS measures
- Raise trade concerns, singly and in coalitions, on the “floor” of the Committee
- Provides regular access to SPS and trade officials for “bilateral” meetings on the margins

WTO SPS Committee: Role on International Standards

- Encourage and **monitor** the use of international standards
- Sponsor technical consultation and study
  - *"with objective of **increasing coordination and integration between international and national systems** and approaches for […] establishing tolerances for contaminants in food…"*
- Maintain close contact with Codex
  - *"with objective of securing the **best available scientific and technical advice**…"*

EU Pesticide Policies

Regulation 1107/2009

- Authorization and renewals
- Hazard-based cut off values
  - CMR substances, POPs
  - Endocrine Disruptors

Regulation 396/2005

- Maximum residue levels
- Import tolerances
- Risk-based

EU Endocrine Disrupters and 1107/2009
STC 382*

Concerns raised since 2014

- Hazard vs. Risk
- Sufficiency of scientific evidence
- Risk assessment
- Import tolerances
- Exemptions
- Notification practices
- Transition policies
- Level of protection sought
- Trade impact

Over 40 Members Raising Concerns

Australia; Benin; Brazil; Burkina Faso; Burundi; Canada; Central African Republic; Chile; Colombia; Costa Rica; Dominican Republic; Ecuador; Egypt; El Salvador; The Gambia; Ghana; Guatemala; Guinea; Honduras; Indonesia; Jamaica; Kenya; Korea, Republic of; Madagascar; Malaysia; Mexico; New Zealand; Nigeria; Pakistan; Panama; Paraguay; Peru; Philippines; Senegal; Sierra Leone; South Africa; Chinese Taipei; Thailand; Togo; Uruguay; Viet Nam; Zambia

**See G/SPS/GEN/204/REV.19; G/SPS/R/74 through G/SPS/R/93*

Hazard vs. Risk

Four Steps of Risk Assessment*

- Hazard Identification
- Hazard Characterization
- Exposure Assessment
- Risk characterization

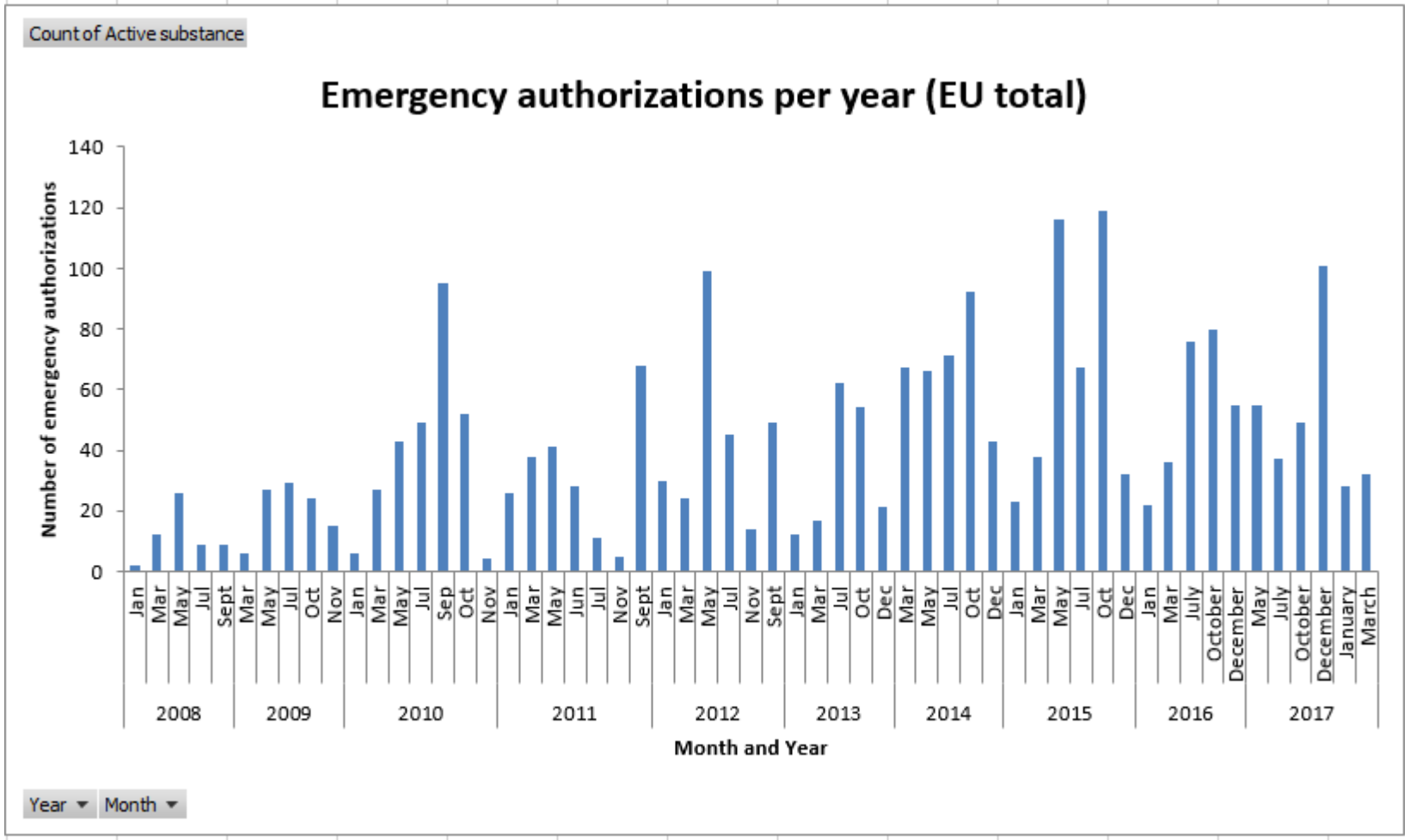
*See Codex Alimentarius Commission Procedural Manual

Derogations for EU Producers

Necessary Exemption (1107/2009 Article 4.7): ‘where on the basis of documented evidence included in the application an active substance is necessary to control a serious danger to plant health which cannot be contained by other available means including non-chemical methods, such active substance may be approved for a limited period necessary to control that serious danger … For such substances maximum residue levels shall be set in accordance with Regulation (EC) No 396/2005.’

Emergency Exemption (1107/2009 Article 53): 'in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products for limited and controlled use, where such a measure appears necessary because of a danger which cannot be controlled by any other reasonable means.’

Member State Reporting of Emergency Authorizations



Import Tolerances:

"Handling of import tolerances for active substances falling under hazard-based criteria of Regulation (EC) No 1107/2009 (18 May 2018)"*

- *"IT requests submitted for imports from 3rd countries will undergo systematically the procedures laid down in Regulation (EC) No 396/2005, including a risk assessment by a rapporteur Member State and a peer-review and opinion by EFSA.*

- *Consequently, the granting of the IT will be considered on **a case-by-case basis** following a risk assessment, **taking into account** the EFSA opinion and also, where appropriate, **other legitimate factors** as well as **the precautionary principle**."*

* "*This note has not been endorsed by the European Commission [….] and may not in any circumstances be regarded as stating an official position of the Commission.*"

Regulatory Procedures for MRLs (EC) No. 396/2005: Example: Clothianidin for Potatoes

Applicant submitted a request to the competent national authority in Germany to modify the existing MRL for the active substance clothianidin to accommodate the use on potatoes imported from Canada

EFSA concluded that the short-term and long-term intake of residues resulting from the use of clothianidin according to the notified agricultural practice in Canada is unlikely to present a risk to consumer health

European Commission submits draft Commission regulation amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for clothianidin, […], and prohexadione in or on certain products (D059754/02 – 2019/2520(RPS)

European Parliament (EP) opposes adoption of the draft Commission regulation and considers that the Commission exceeds the implementing powers provided for in (EC) No. 396/2005

EP Scrutiny of Draft Commission MRL Regulation* Example: Clothianidin for Potatoes

- "(D) whereas clothianidin is one of the three neonicotinoids that are **banned in the Union**;"
- "(F) whereas Article 191(2) of the Treaty on the Functioning of the **European Union (TFEU) sets out the precautionary principle** as one of the fundamental principles of the Union;"
- "(J) whereas the Commission's proposal to increase the MRLs for clothianidin **raised doubts, on the basis of the precautionary principle, given the data gaps and persistent uncertainty** as to the effects of clothianidin on public health, young mammals and the environment;"
- "(M) whereas the conclusions drawn by EFSA in its opinion of 30 August 2018 justify the clothianidin MRL increase only on the basis of the need to comply with Canadian normative values, **and totally omit to analyse the cumulative environmental impact of neonicotinoids and their use;**"
- "(8) Recalls that the use of **clothianidin as a pesticide affects pollinators on a global scale**;"
- "(9) Considers that **EFSA's opinion did not take into account the cumulative risk to human health and bees**;"

*P8_TA-PROV(2019)0195

EU Chief Scientific Advisors: Scientific Opinion 5/2018

1107/2009 intended to ensure that: PPPs do not have any harmful effect on human or animal health or any unacceptable effects on the environment; the precautionary principle should be applied; the competitiveness of Community agriculture is safeguarded; and, agricultural production is improved.

- "the objectives [of the PPP Regulation] may result in **unachievable goals in practice**"
- "a literal interpretation of the objectives of the PPP Regulation with respect to protection of human health **would thus not permit any PPP authorisation in the EU**"
- "the order of **priority of these different, sometimes conflicting, objectives, is not specified**"
- "the 'precautionary principle' **suffers from a degree of 'vagueness'**"

EU Notification Practices

EU notifies non-renewal of substance to WTO via the TBT Committee

EU notifies withdrawal of MRL to WTO via the SPS Committee

Substance	TBT Non-Renewal Notification	Date of TBT Notification	SPS MRL Notification	Date of SPS Notification	Date of MRL Regulation
Diquat	**G/TBT/N/EU/397**	**25/07/2016**			
Linuron	**G/TBT/N/EU/409**	**05/10/2016**	**G/SPS/N/EU/262**	**13/07/2018**	**04/08/2019**
Iprodione	**G/TBT/N/EU/495**	**25/07/2017**	**G/SPS/N/EU/263**	**17/07/2018**	**31/07/2019**
Pymetrozine	**G/TBT/N/EU/554**	**13/03/2018**			
Propiconazole	**G/TBT/N/EU/578**	**13/06/2018**			
Diphenylamine	G/TBT/N/EEC/289	06/08/2009	G/SPS/N/EU/247	28/03/2018	01/05/2019
Fenbutatin oxide	G/TBT/N/EU/173	16/12/2013	G/SPS/N/EU/260	20/06/2018	13/08/2019
3-decen-2-one	G/TBT/N/EU/316	18/09/2015	G/SPS/N/EU/158	28/10/2016	10/05/2017
Tricyclazole	G/TBT/N/EU/319	16/10/2015	G/SPS/N/EU/173	16/11/2016	30/06/2017
Triasulfuron	G/TBT/N/EU/354	15/02/2016	G/SPS/N/EU/313	20/03/2019	
Buprofezin	G/TBT/N/EU/418	28/10/2016	G/SPS/N/EU/264	19/07/2018	13/08/2019
Orthosulfamuron	G/TBT/N/EU/434	22/12/2016	G/SPS/N/EU/313	20/03/2019	
Picoxystrobin	G/TBT/N/EU/437	06/01/2017	G/SPS/N/EU/264	19/07/2018	13/08/2019
Diflubenzuron	G/TBT/N/EU/447	20/01/2017	G/SPS/N/EU/264	19/07/2018	13/08/2019
Malathion	G/TBT/N/EU/535	18/01/2018			
Thiram	G/TBT/N/EU/552	01/03/2018			
Fenamidone	G/TBT/N/EU/561	20/03/2018			
Chlorpropham	G/TBT/N/EU/565	29/03/2018			
Dithianon	G/TBT/N/EU/566	11/04/2018			

MRL Transition Policies

Transition Times – Active Substance Approval

In case of approval or renewal of approval

- No particular measures – in case of renewal, authorisation holders must apply within 3 months and Member States must decide on all existing authorisations within one year.

In case of non-renewal of approval

- Member States must withdraw product authorisations at the latest 6 months after entry into force of the non-renewal
- Grace periods for distribution, storage, use, disposal must end at the latest 12 months after entry into force of the non-renewal
- Where there are clear risks identified, the periods can be set shorter

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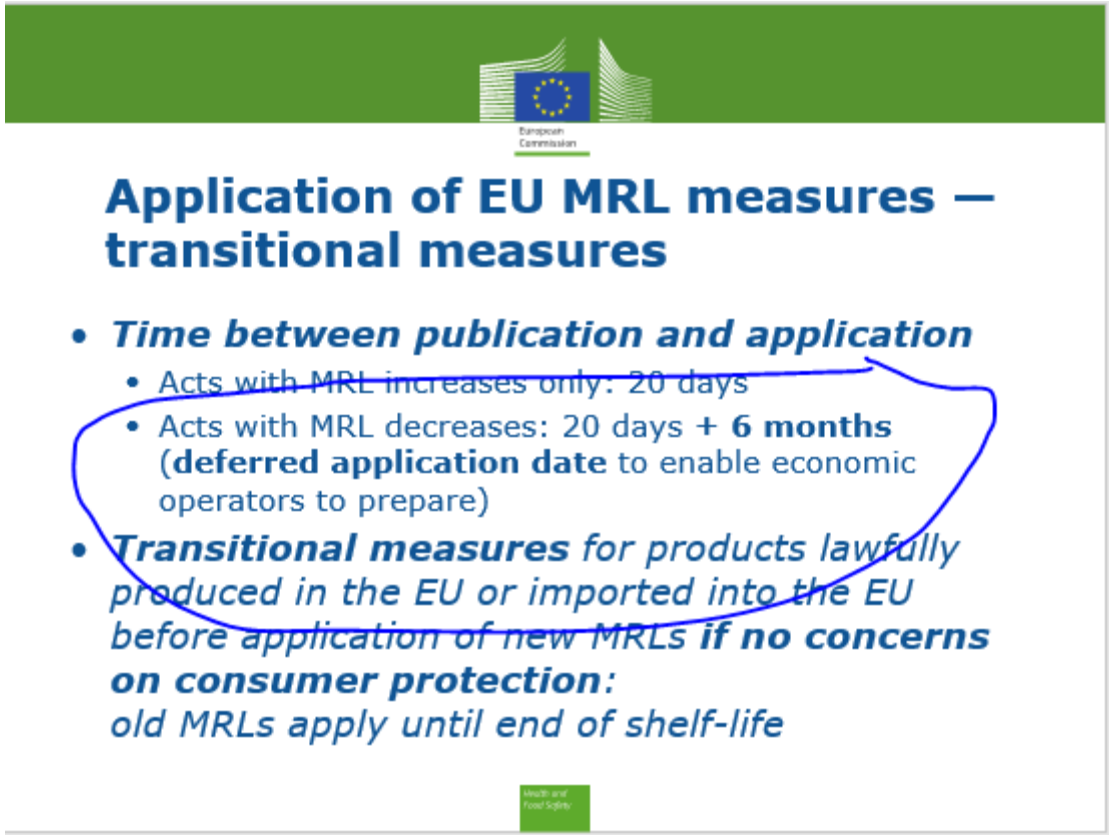


Application of EU MRL measures — transitional measures

- ***Time between publication and application***
  - Acts with MRL increases only: 20 days
  - Acts with MRL decreases: 20 days **+ 6 months** (**deferred application date** to enable economic operators to prepare)
- ***Transitional measures*** *for products lawfully produced in the EU or imported into the EU before application of new MRLs* ***if no concerns on consumer protection:***
  old MRLs apply until end of shelf-life

Example: Buprofezin

August 7, 2015	EFSA publishes Peer Review and recommends restricting use to non-edible crops only
October 28, 2016	EU notifies proposed decision to restrict use to the WTO Committee on Technical Barriers to Trade (TBT), G/TBT/N/EU/418
February 28, 2017	Commission Implementing Regulation (EU) 2017/360 amends conditions of approval to remove uses on edible crops, but grants Member States a **grace period** through June 21, 2018.
July 19, 2018	Following the end of the EU grace period, EU notifies proposed decision to lower MRLs to the WTO Committee on Sanitary and Phytosanitary (SPS) Measures, G/SPS/N/EU/264
January 24, 2019	Commission Implementing Regulation (EU) 2019/91 publishes in the Official Journal, amending the MRLs for various substances. No **transition measure** is provided for buprofezin.
February 13, 2019	Commission Implementing Regulation (EU) 2019/91 enters in to force but allows for a 6 month **deferred application date**.
August 13, 2019	MRLs are implemented following the 6 month deferred application date.

Example: Buprofezin

24.1.2019 EN Official Journal of the European Union L 22/75

Date of publication

COMMISSION REGULATION (EU) 2019/91

of 18 January 2019

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 buprofezin, diflubenzuron, ethoxysulfuron, ioxynil, molinate, picoxystrobin and tepraloxydim in or on certain products

Article 1

Annexes II, III and V to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

Transitional measures only provided for the four substances listed, not buprofezin.

Article 2

As regards the active substances ethoxysulfuron, ioxynil, molinate and tepraloxydim in and on all products, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 13 August 2019.

Under transitional measures for other substances, only EU products benefit from old MRLs.

Imports must comply at the time they reach the border, regardless of when they were produced.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Regulation entered in to force on February 13, 2019 (20 days after publication).

It shall apply from 13 August 2019.

MRLs are implemented (i.e., go in to effect) on August 13, 2019. This is the **deferred application date** (6 months after entry in to force).

Example: Buprofezin

"Produced"

Article 2

As regards the active substances ethoxysulfuron, ioxynil, molinate and tepraloxydim in and on all products, Regulation (EC) No 396/2005 as it stood before being amended by this Regulation shall continue to apply to products which were produced in the Union or imported into the Union before 13 August 2019.

To enforce "produced," the EU is linking the requirement to comply with MRLs to the moment of "placing on the market."

For products "produced in the Union," the Commission considers "date of harvest" as "placing on the market."

For products "imported into the Union," the Commission considers "arrival at the border" with "placing on the market."

Example: Buprofezin

Hypothetical Impact when Transition Measures are Granted

Scenario:

- Substance restricted in EU as of February 2017.
- MS grace period in place through June 2018.
- Transitional measures are granted since there is no human health concern.
- New MRLs effective August 13, 2018.

	EU	United States
March 1, 2018	Chemical X restricted in EU but is applied during MS grace period. EU MRLs exist that cover the use.	Chemical X legal to apply in United States. EU MRLs exist that cover use.
August 10, 2018	Commodity harvested and placed into MS warehouse.	Commodity harvested and placed into California warehouse.
December 25, 2018	Commodity containing residues above 0.01 mg/kg but compliant with old MRL is distributed to EU retail market and sold.	Commodity containing residues above 0.01 mg/kg but compliant with old MRL is rejected at the EU border.

Identical product, different treatment?

EU MRLs
Acrinathin, metalaxal and thiabendazole
STC 428

July 2017, November 2017 and March 2018, March 2019 - Peru raises concern about the lowering of MRLs to 0.01 mg/kg

Bolivia, Brazil, Colombia, Costa Rica, Dominican Republic, Ecuador, Guatemala, Nigeria, United States support.

EU MRLS

BUPROFEZIN, DIFLUBENZURON, ETHOXYSULFURON, GLUFOSINATE, IMAZALIL, IOXYNIL, IPRODIONE, MOLINATE, PICOXYSTROBIN AND TEPRALOXYDIM

STC 448

November 2018, March 2019 – Colombia, India, Costa Rica, United States raise concern about lowering of MRLs to 0.01 mg/kg

Argentina; Brazil; Canada; Chile; Costa Rica; Ecuador; Guatemala; Honduras; Japan, Nicaragua; Panama; Paraguay; Peru; Turkey; Uruguay support

EU MRLs
Chlorothanonil

November 2019 – Colombia raises concern regarding the impending withdrawal of the MRL for chlorothanonil.

Bolivia, Brazil, Chile, Costa Rica, Ecuador, Guatemala, Honduras, Panama, Paraguay, Turkey and the United States support

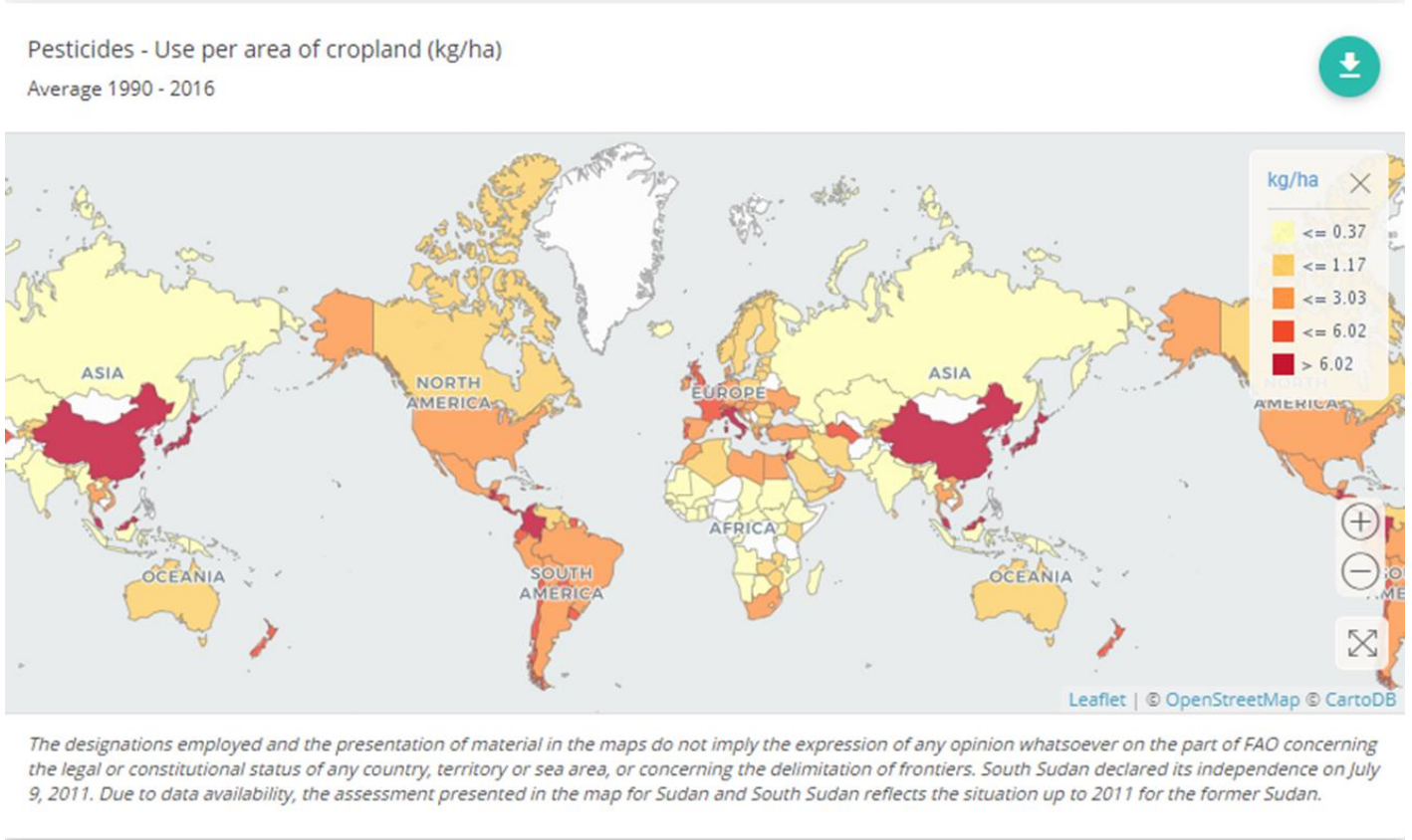
Global Context

Trade and production disruptions from EU MRL withdrawals expected to accelerate

Rural livelihoods in developing countries (e.g., bananas) particularly impacted

800 million food insecure people in world and food insecurity is expected to increase in many countries in near term

Impact on long term agricultural innovation and sustainability



The designations employed and the presentation of material in the maps do not imply the expression of any opinion whatsoever on the part of FAO concerning the legal or constitutional status of any country, territory or sea area, or concerning the delimitation of frontiers. South Sudan declared its independence on July 9, 2011. Due to data availability, the assessment presented in the map for Sudan and South Sudan reflects the situation up to 2011 for the former Sudan.

Source: FAOSTAT

Joint Statement at MC11 Signed by 17 Minsters

WORLD TRADE ORGANIZATION

WT/MIN(17)/52

12 December 2017

(17-6846)

Page: 1/3

Ministerial Conference
Eleventh Session
Buenos Aires, 10-13 December 2017

Original: English

TRADE IN FOOD AND AGRICULTURAL PRODUCTS

JOINT STATEMENT OF UNDERSIGNED MINISTERS

BUENOS AIRES, ARGENTINA

11 DECEMBER 2017

The following joint statement, dated 11 December 2017, is being circulated at the request of the delegations of Kenya, Uganda and the United States.

In order to face the challenge of producing more food in a safer and sustainable way, farmers must be able to access the full range of tools and technologies available for agricultural production. Yet, our farmers' choice of safe tools is increasingly undermined by regulatory barriers that lack a sufficient scientific justification, and this is having substantial negative impact on the production of, and trade in, safe food and agricultural products. We believe in both protecting human health and facilitating access to food – both goals of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Having in mind the importance of transparency and predictability to international trade, we call on all Members to strengthen the implementation of the WTO SPS Agreement by reinforcing the work of relevant international standards organizations and ensuring the scientific basis of SPS measures is sound. The development and application of sound SPS measures is needed to support farmers' choice in tools that can expand agricultural production and facilitate access to food and agricultural products, and also to safeguard human, animal and plant health.

In this regard, we recognize the work undertaken by the WTO SPS Committee to examine pesticide-related issues that have an adverse impact on international trade in food and agricultural products, and to achieve consensus on collaborative actions to reduce that impact on trade, particularly on the agricultural exports of developing countries. We affirm the central importance of risk analysis to assess, manage, and communicate risks of concern associated with pesticide use in order to protect public health while enabling the safe use of pesticides and facilitating trade in food and agricultural products. We support the voluntary actions by Members put forward by Kenya, Uganda and the United States (G/SPS/W/292/Rev.2) to increase the capacity and efficiency of Codex in setting international standards on pesticide maximum residue levels (MRLs); to improve

WTO activities on MRLs in 2019

- Members take forward MC11 Joint Statement recommendations to SPS Committee under 5th Review of the SPS Agreement
- Fall Armyworm Joint Submission to promote streamlined regulatory approaches to facilitate access to safe tools and technologies
- Coalition building on international standards/risk assessment/scientific principles in setting MRLs
- Greater engagement in WTO governing councils

Questions for You

- How do commodity and specialty crop groups liaise with partner groups in other countries/regions on concerns on loss of EU MRLs?
- How do plant protection companies liaise with Crop Life at the national, regional and international levels on concerns on loss of EU MRLs?
- How do crop groups and PP companies liaise with others in the cross-border food value chain on concerns regarding loss of EU MRLs?

Thanks to Julie Chao and Rachel Vanderberg at USDA