



San Francisco, California



MRL Situation in Central America

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www.croplifela.org





1. Introduction to CropLife Latin America



2. Overview Central America



3. MRL situation



4. Discussion





¿Who we are?

We are a nonprofit trade association that represents the Plant Science Industry.

Our members are nine R&D oriented companies and a network based in eighteen Latin American countries.





The Plant Science Industry

Improves the efficiency in production to feed the world.

Researches, develops, manufactures and markets technological solutions that help farmers protect their crops against pests, yield abundant harvests and improve the quality of food in a sustainable way.

The industry invests 6.3 billion dollars per year to develop new agrochemical, biotechnology and seed products, which are innovate for agriculture to meet global food demand.



The Plant Science Industry

Works to improve the efficiency in production to feed the world.



Dow AgroSciences



Bayer CropScience



Arysta LifeScience





Our network

MEXICO:	AMIFAC AMOCALI
GUATEMALA:	AGREQUIMA
EL SALVADOR:	APA
HONDURAS:	CropLife Honduras
NICARAGUA:	ANIFODA
COSTA RICA:	Cámara de Insumos Agropecuarios Fund. Limpiemos Nuestros Campos
R. DOMINICANA:	AFIPA
PANAMÁ:	ANDIA
COLOMBIA:	Cámara Procultivos – ANDI Corporación CampoLimpio
VENEZUELA:	AFAQUIMA
ECUADOR:	CropLife Ecuador
PERÚ:	CropLife Perú
BRASIL:	ANDEF e InpEV
BOLIVIA:	APIA
PARAGUAY:	CAFYF
URUGUAY:	CAMAGRO
CHILE:	AFIPA
ARGENTINA:	CASAFE

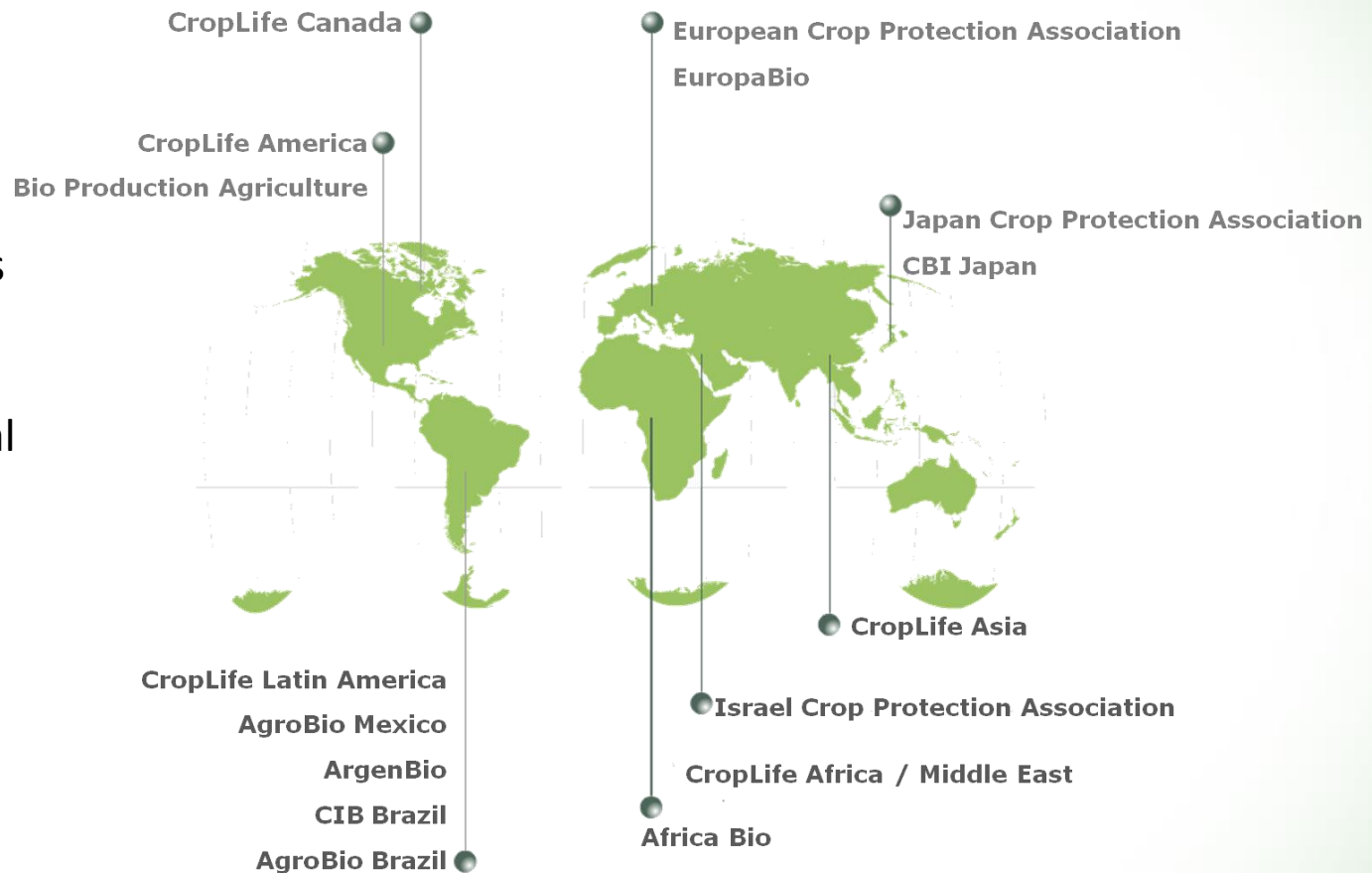


9 companies and 22 associations in the region



We are part of a global network

CropLife Latin America is part of 16 regional associations that make the CropLife International network, the Global Federation of the industry.





1. **Introduction to CropLife Latin America**



2. **Overview Central America**



3. **MRL situation**



4. **Discussion**



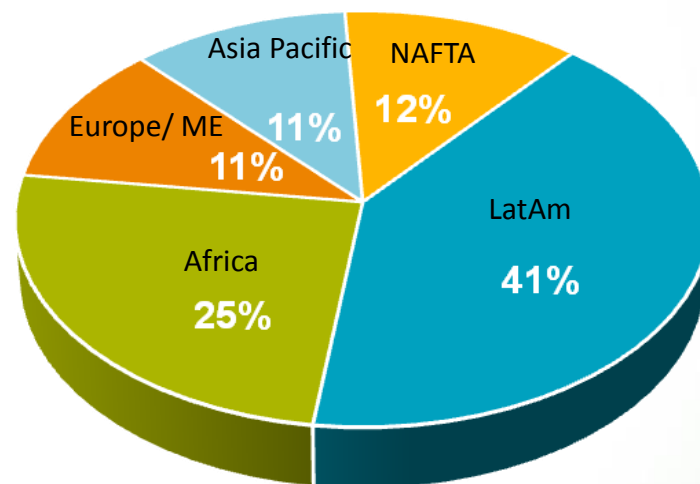
Overview Latin America: Increasing population vs. available arable land

Latin America has 41% of world's available land for agricultural expansion; thus potential to enhance agricultural exports globally

Available arable land or agricultural expansion



Source: FAO



Overview CAFTA: Annual U.S. trade balance

- As a region, DR-CAFTA countries combined are the 12th largest trading partner of the US with \$38.8 billion in total (two way) goods trade during 2009*
- Exports totaled \$20.0 billion
- Imports totaled \$18.8 billion
- DR-CAFTA provided better overview
 - USITC consolidated figures
 - Before CBI & MFN
 - Factor in different entry into force times



Source: www.ustr.gov*

Overview CAFTA: Annual U.S. trade balance

Imports from DR-CAFTA

- U.S. imports of agricultural products from DR-CAFTA countries totaled **\$3.6 billion** in 2009
 - Edible Fruit and Nuts (bananas and plantains) accounted for **\$1.5 billion** in 2009
- Leading categories include:
 - bananas and plantains (\$831 million)
 - coffee (unroasted) (\$762 million)
 - other fresh fruit (\$630 million)
 - raw beet and cane sugar (\$231 million)
 - processed fruit and vegetables (\$183 million)
 - fresh vegetables (\$180 million)



Overview CAFTA: Annual U.S. trade balance

Exports to DR-CAFTA

- U.S. goods exports to DR-CAFTA countries in 2009 were \$20.0 billion
 - Down 21.3% (\$5.4 billion) from 2008
 - Up 145% from 1994 (year before Uruguay Round)
- DR-CAFTA countries combined would have been the United States' 14th largest goods export market in 2009. Markets:
 - Dominican Republic (\$5.3 billion)
 - Costa Rica (\$4.7 billion)
 - Guatemala (\$3.9 billion)
 - Honduras (\$3.4 billion)
 - El Salvador (\$2.0 billion)
 - Nicaragua (\$715 million)
- Balance

The U.S. goods trade surplus with DR-CAFTA was \$1.2 billion in 2009



Overview CAFTA: Trade agenda



- EU FTA
- CR looking into Asia through TPP
- CR application to OECD accession by 2015
- Interest in exploiting energy sources will shape trade relationships
 - President Obama visit to promote trade in gas
 - Chinese President visit for funding refinery
 - Nicaragua exploring opportunities to open its own canal
- Weakened dollar changes trade dynamics
 - Planting migrating to NIC, HON
 - Push to “added value” industries (computer processors, medical devices, call centers)
- Textile industries under pressure by SE Asia



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CA: CLLA MRL Regulation Survey

COUNTRY	REGULATION	Acceptance of MRLs				Acceptance of residues studies from other countries for same crop under similar climatic conditions.	Requires Local residue studies	Guidelines In case of local residue studies
		CODEX	EU	USA	Manufacturer proposed MRL			
Costa Rica	RTCR 424-2008	YES	YES	YES	YES	YES	Not compulsory, only if no EPA, EU or CODEX MRL or residue trial in not available under GLP	Not established
Central America Countries (other)		YES	YES	YES	YES	YES	NO	Not established

- No indication of domestic MRL requirements
- Limited capacity to perform dietary risk assessment





Regulatory challenges that impact MRLs & trade



Complexity



Trade barriers



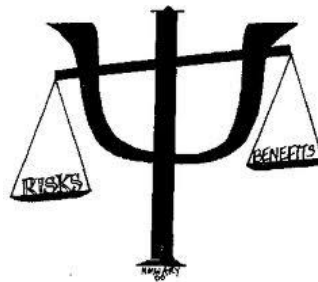
Predictability



Harmonization



R&D costs



Risk/benefit
analysis



Investment



Crop Protection product policies & regulations should...

- Provide clear protection goals
- Offer transparency
- Be science-based
- Allow access to technology
- Be integrated to a country's agricultural policy



CA Regulatory Issues: Framework

- Authority turnover in all CA countries except GT
 - New regulators face steep learning curve
 - Difficulties to entertain science-based discussions
 - Political appointees?
 - Risk of double standards, red tape & radical decisions
- MOA, MOH & ENV involved in ag chem evaluation in CR
 - Backlog; 2 a.i.s registered in 6 yrs.!!!!
 - ENV uses cut-offs for evaluation
 - No registrations affects GAP certification & impacts exports



CA Regulatory Issues: Regulatory Requirements

- No harmonization
 - CACU draft harmonized pesticide regulation stalled
 - SIECA is weak
 - CA: 5 countries = 5 authorities = 5 regulations!!
 - Impacts food chain & retailers → labelling
- For crop protection products → checklist evaluation for formulated products in HON, SAL & NIC
- Tiered evaluation (ai + formulation) based on comprehensive requirements in CR & GT



Harmonization

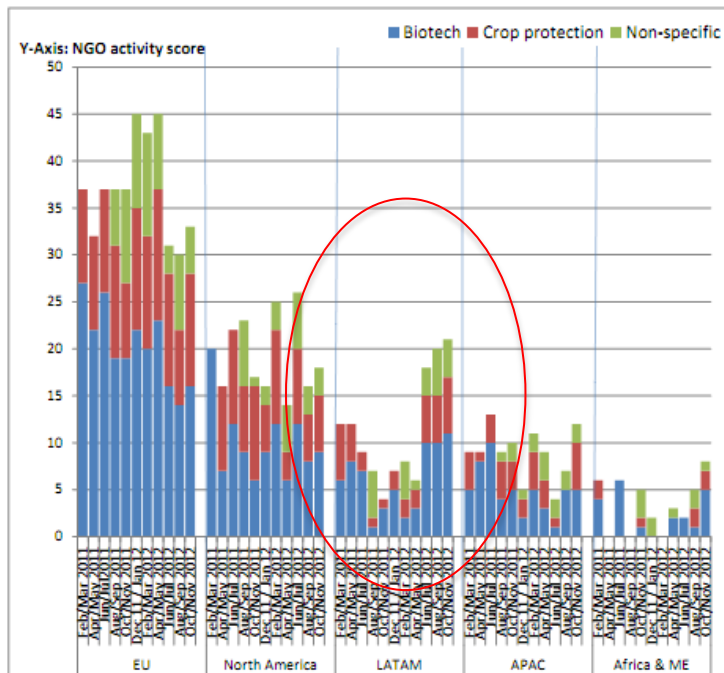
CA Regulatory Issues: External influence

Campaigns to reduce pesticide inventory

- (Deliberate?) misinterpretation of Intl Conventions → PICs
 - Despite GT, HON intervention in PIC COP 6 re. SHPF listing
- Local/Intl anti-pesticide NGO pressure
- HHP initiatives (FAO - CoC revision)

SIGWATCH | NGO TRACKING
& ISSUES ANALYSIS

Chart 2: NGO activity by region, Feb 2011 – Nov 2012



Latin America still surfs crest of supercycle wave in 2012

Latin America continued to ride the commodities wave in 2012, carrying on from where it had left off in recent years. The industry started the year reporting a 30% rise in sales across South and Central America for 2011, and took advantage of the further opportunities presented by poor harvests from extreme weather in the US.

The key concern in 2012 for Brazil was also unchanged: the lack of new active ingredient approvals. Industry blamed the split in competencies among three regulatory bodies. The main target of industry complaints was the toxicology authority, the Anvisa. It proposed changes to registrations, requiring companies to bring toxicological evaluations "up to date", such as listing any

The agrochemical market for South and Central America rose in 2011 to over \$10,800 million on preliminary figures, and separate national surveys later suggesting an even greater rise.

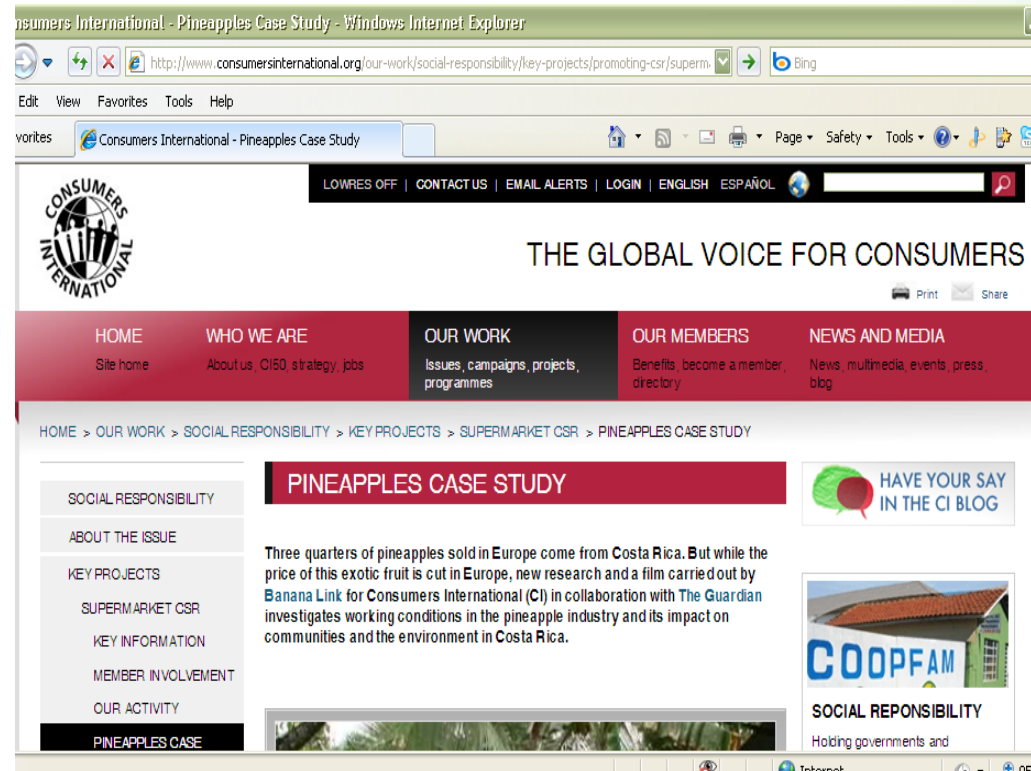
The dominant market, Brazil, accounting for well over half of sales, hit a record of well over \$8,000 million, with expectations that 2012 would be yet higher. Roaring



CA Regulatory Issues: Media/NGO Activities

Costa Rica: Drinking water pineapple growing area

- Official monitoring identified pesticide residues in ground water
- Consumer International lobbies and launches media campaign in UK to taint pineapple production in Costa Rica
- CR MOH threatens to ban certain pesticides as a political reaction



CA Regulatory Issues: External Influence

- Crop Protection & MRL regulations harmonized & applicable to all 27 member States, but
 - ✓ ...if no EU A.I. registration, need to apply for import tolerance pursuant to Regulation EC 396/2005
 - ✓ ... if there is no import tolerance, a default value of 0,01 mg/kg (detection) is considered
 - ✓ ... if an A.I. is not candidate for Annex I inclusion, import tolerance could be permitted
- Cut-off criteria & hazard-based approach hinder MRL establishment
 - 1107/2009
 - EDs
 - Pollinators



CA Regulatory Issues: External Influence

Food chain « no risk » or « clean food agenda » though secondary standards

- Increasing restrictions from German Supermarkets (ALDI, LIDL), Tesco lists, Morrison, Sainsbury, Waitrose, et. al.



- Residue value reduction requires more complex data
 - (50% MRL, 25% MRL and then...?)
 - 3-5 metabolites in the residue and then...?
 - Formulations with 2 or more actives become problematic
 - Who bears the cost?
 - Pressure for cheap pesticides in all LATAM

CA Regulatory Issues: External Influence



The Fairtrade is influential in key Latin American agricultural products (e.g. coffee, cocoa, banana, etc). Not only imposes, ethical and social standards, but also regulations for pesticide use:

- **Prohibits substances**
- Promotes pesticide use reduction
- Integrated Pest Management (IPM)



Sustainable Agriculture Network (SAN) -

Rainforest Alliance is a coalition of NGOs that promote social and environmental sustainability of agriculture through standard establishment:

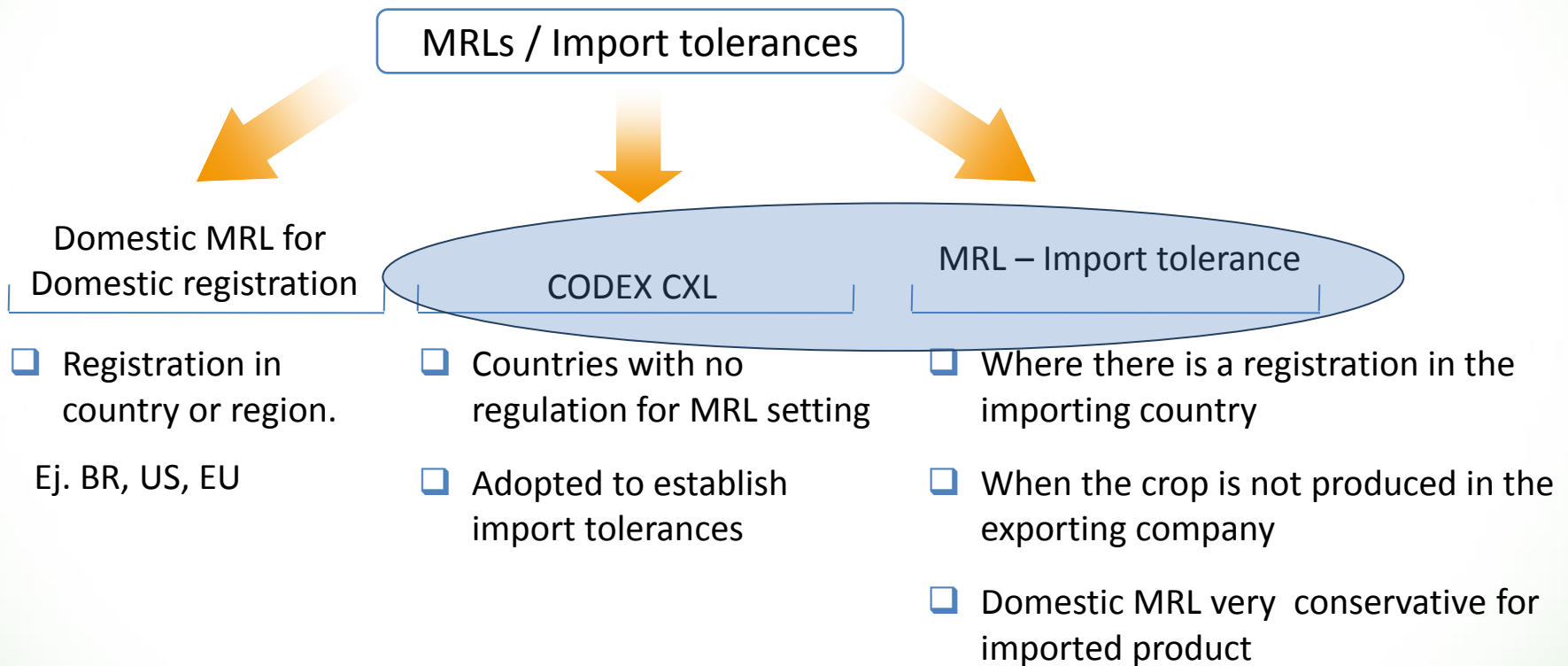
- **Prohibited substances**
- Sustainable agriculture standard



The mission of the Forest Stewardship Council is to support environmentally appropriate, socially beneficial, and economically viable management of the world's forests. FSC develops, supports and promotes international, national and provincial standards in line with its mission; evaluates, accredits and monitors certification bodies which verify the use of FSC standards; provides training and information; and promotes the use of products that carry the FSC logo.

- FSC certified paper and wood
- **List of prohibited pesticides**

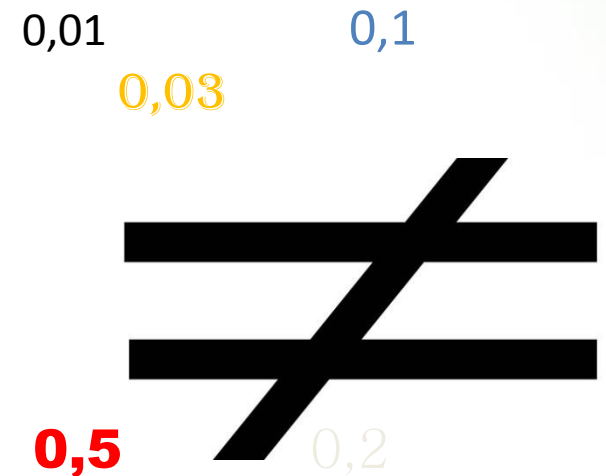
CA Regulatory Issues: MRL compliance/harmonization



CA Regulatory Issues: MRL compliance/harmonization

Differences in MRLs at a global level

- ☐ Different GAPs between countries or regions
- ☐ Different definitions of residue (a.i. vs a.i. + metabolite)
- ☐ Different tox end-points
- ☐ Different ways to perform dietary risk assessment
- ☐ Different procedures to calculate MRLs





Summary

- MRL acceptance is not an issue in CA
- Other factors impact trade
 - Deficient or no regulatory harmonization in CA
 - Domestic regulatory red tape (crop protection, food chain, retail)
 - Global MRL harmonization for compliance
 - Pressure to reduce crop protection product availability & use
 - EU
 - NGO campaigns
 - Intl Conventions
 - Secondary standards



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BACKUP SLIDES

Food chain & MRLs

- Farming and food trade went global
- Agricultural products may contain pesticide residues subject to regulations: MRLs, tolerances, et.al.
- MRLs are trading, not safety standards
 - Used to establish monitoring programs



MRLs in trade

- MRL exceedances are legal violations that lead to:
 - products not allowed to be marketed
 - rejections
 - breach of contracts
 - administrative sanctions
 - bad reputation
- ... however, exceedances are not a safety issue:
 - very high residue concentration is required to jeopardize ADI





MRL setting

- Definition based on critical GAP
 - Maximum recommended dosis
 - Time of application
 - Number of applications
 - Minimum interval between applications
- PHIs





MRL setting

Must undergo dietary risk assessment

Toxicology



Residues



Consumption



$$\text{RISK} = \text{TOXICOLOGY} \times \text{EXPOSURE}$$



MRL setting

Exposition



EXPOSURE

Where: R = Residue concentration in food (mg/kg);
C = Food consumption (kg/day)

BW = Body weight(kg)

$$\text{Daily intake: } \frac{\sum (R_i \times C_i)}{bw}$$



MRL setting



Acceptable
Daily Intake

Exposition

How much can be eaten?

How much is actually eaten?



Risk assessment

Exposition < ADI



MRL is acceptable

Exposition ≥ ADI



Refinement or change of GAP