



A decade of Global MRL harmonization: industry highlights/lowlights

California Specialty Crops Council
MRL Workshop, June 2016
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Rise of the MRL



- 2005: MRLs received little attention in day to day business



- 2016: R/D companies have dedicated staff managing MRLs!

Reasons behind shift

- **Proliferation of MRL regulation**
- **Increase in international exports**
- **Food safety awareness**
- **Increase in residue monitoring**
- **MRL exceedances → commodities rejected**
- **Potential liability for growers/exporters**
- **Potential liability for registrants**
- **Change in growers' MRL expectations**

EU – landmark MRL regulation



2005: EU MRL legislation enacted

- Regulation (EC) No 396/2005

16.3.2005

EN

Official Journal of the European Union

L 70/1

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(Acts whose publication is obligatory)

REGULATION (EC) NO 396/2005 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 23 February 2005

**on maximum residue levels of pesticides in or on food and feed of plant and animal origin and
amending Council Directive 91/414/EEC**

EU Harmonized MRLs take effect



COMMISSION REGULATION (EC) No 149/2008

of 29 January 2008

amending Regulation (EC) No 396/2005 of the European Parliament and of the Council by establishing Annexes II, III and IV setting maximum residue levels for products covered by Annex I thereto

Harmonizes MRLs in 28 EU member countries;
creates problems for EU's trading partners

MRL evolution

Download MRLs data

Sustainable use of pesticides

Approval of active substances

Authorisation of Plant Protection Products

Maximum Residue levels

Showing 1 to 50 of 378 entries

50

records per page

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1

2

3

4







5

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8

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Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg. (EU) No 520/2011	Reg. (EC) No 459/2010	Reg. (EC) No 839/2008	Reg. (EC) No 149/2008
0100000	 FRUITS, FRESH or FROZEN; TREE NUTS				
0110000	 Citrus fruits	2.0	2.0	2.0	2.0
0110010	 Grapefruits	2.0	2.0	2.0	2.0
0110020	 Oranges	2.0	2.0	2.0	2.0
0110030	 Lemons	2.0	2.0	2.0	2.0
0110040	 Limes	2.0	2.0	2.0	2.0

<<

ALL TOPICS

0/22/16

2009 EU legislation on pesticide authorization

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

Cut-off criteria!

Having regard to the proposal from the Commission,

technical developments, that Directive should be replaced.

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having regard to the opinion of the Committee of the Regions ⁽²⁾,

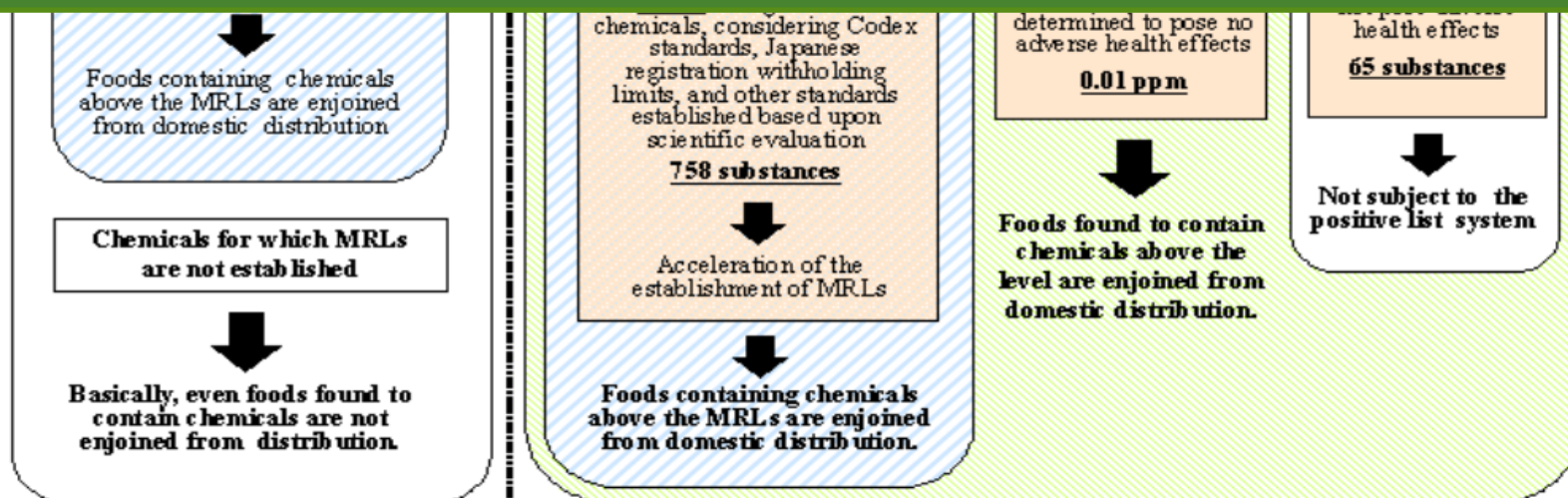
- (4) By way of simplification, the new act should also repeal Council Directive 79/117/EEC of 21 December 1978 prohibiting the placing on the market and use of plant protection products containing certain active substances ⁽⁶⁾.

Japan – landmark MRL regulation



2006: MRL Positive List System enacted

Provisional MRLs a good approach



S. Korea - landmark MRL regulation



2014: MRL Positive List System – advance notice

Improves food safety in Korea regarding pesticide residues; Codex deferral tree disappears

❖ Need MRLs?
➡ Import tolerance

and NO provisional MRL
* uniform level(0.01ppm)

❖ Need MRLs?
➡ Import tolerance

Taiwan – revised IT application



2014: Taiwan introduces detailed IT application

Data intensive compared to previous application; bio-efficiency data requirement

2.1.2 Pesticide name, active ingr...	for import tolerance:
2.1.3 Commercial name (AI%, lis...	
2.1.4 Pests controlled :	
2.1.5 Mode of action :	⊕
2.1.6 Application treatment and...	Applicant:
2.1.7 Application equipment :	Contact Name:
2.1.8 Application rate : (Pages : ...	Telephone:
2.1.9 Number times of applicati...	Application Date
2.1.10 Preharvest Interval (days)...	(M/D/Y):
2.1.11 Table of Pesticide use lab...	
2.2 Pesticide product use label s...	
3 Residue trial data	
3.1 Residue trial abstract (1)	
3.1.1 Report title : (File name : ...	
3.1.2 Tested crop commodities :	



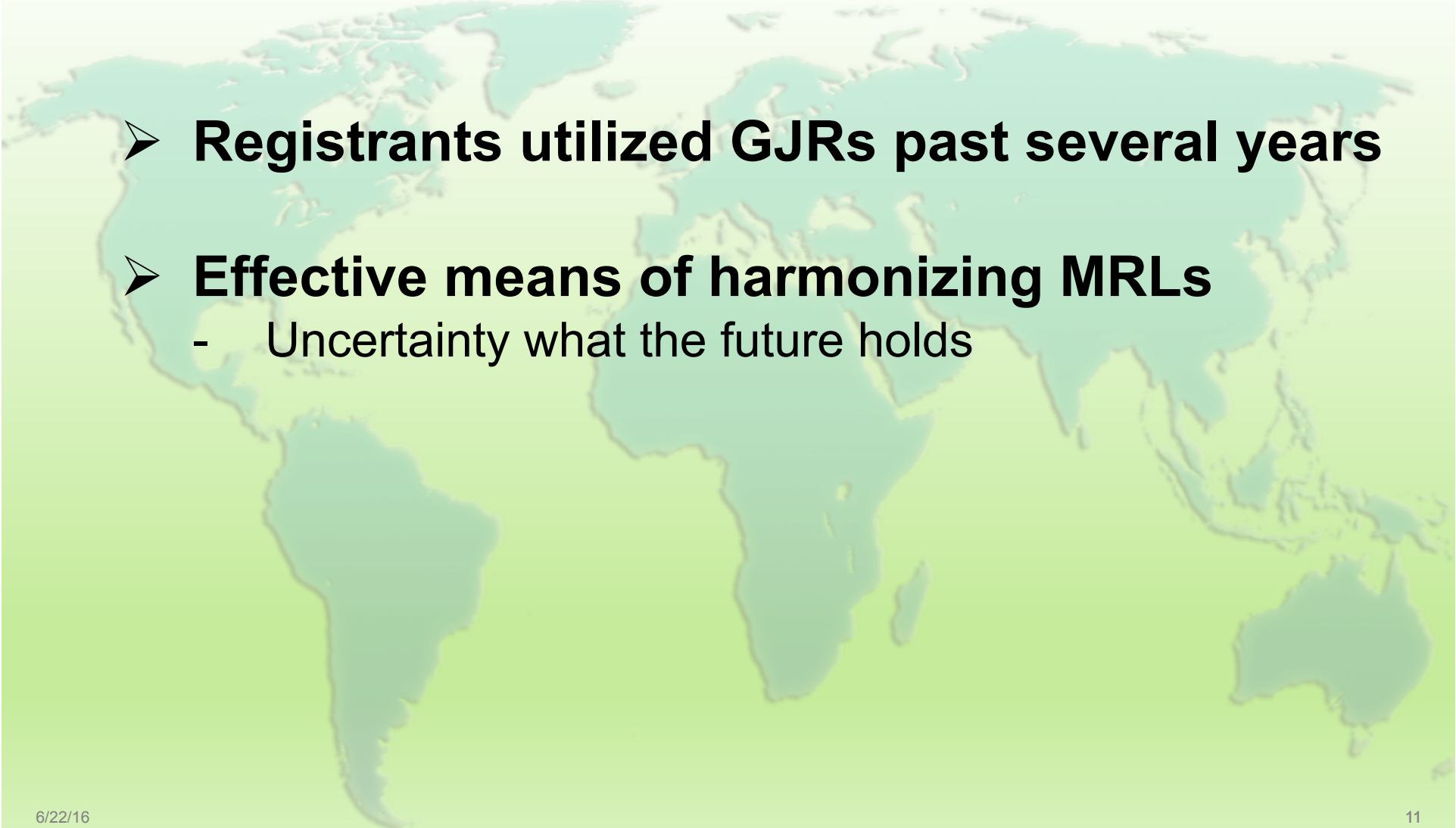
Codex today



- **Increase in Grower/Exporter awareness and expectations**
- **Registrants' activity (and frustrations) increased**

5/8 Step allows for faster CXLs to be established;
fundamental problems within JMPR to be resolved

Global Joint Reviews

- 
- **Registrants utilized GJRs past several years**
 - **Effective means of harmonizing MRLs**
 - Uncertainty what the future holds

Hong Kong & China



HK introduced IT application process Aug 2014

- made application Dec 2104, no fee but still waiting to hear outcome



China converts CXLs into national MRLs

- considering IT process for future with fee
- 3-5 years timeline

APEC Guideline (draft)



IMPORT MRL GUIDELINE FOR PESTICIDES

*A guideline on possible approaches to achieve alignment of international
MRLs*

[Month/Year of Publication]

(Draft version: 15 March 2016)

APEC Food Safety Cooperation Forum
Sub-Committee on Standards and Conformance
APEC Project: SCSC 01 2015S

- GL drafted to facilitate MRL alignment among APEC countries
- supported by CropLife International

MRLs strategic today for R/D companies

**This way to
global MRL
planning
meeting**



- 
- Registrations
 - Major, minor crops
 - IR-4/Canada PMC
 - Codex
 - Foreign MRLs
 - Trade Flow
 - GAP harmonization
 - Residue trial program
 - Biology data
 - Expected residues
 - Residue definition
 - Dietary RA/risk cup

Thank You



Questions



We create chemistry