

Canadian MRL update

2016 MRL Harmonization Workshop

Pierre Petelle
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Dow AgroSciences



Representing the Canadian developers, manufacturers and distributors of pest control products and products of modern plant breeding.

Our priorities

- Communications – increase awareness of the benefits of our technologies
- Advocacy – work for legislative & regulatory environment that supports and protects innovation
- Stewardship – world-leaders in responsible product management
- Partnerships – work with others for the benefit of our members



Canada is one of the top 5 food exporters, sending food to 150 countries

Canadian Ag Exports - \$55B

Canadian Top 5 Agri-Food Exports (CDN\$ million)

	2013	2014	2015
Domestic Agri-Food Exports:	46,012.396	51,541.026	55,450.303
Non-durum wheat, other than seed for sowing	5,103.189	5,771.165	5,874.401
Canola seed, low erucic acid	4,306.481	5,149.679	4,952.713
Lentils, dried, shelled	1,175.333	1,461.978	2,495.699
Soybeans, other than seed for sowing	2,005.070	1,904.695	2,237.898
Durum wheat, other than seed for sowing	1,574.626	2,179.708	2,037.773

Source: Statistics Canada

Background and Updates

- PMRA employs approx. 390 staff
- Leadership role, along with US, on joint reviews
- Heavily invested in international work – OECD, Codex, etc.
- Ag Canada's PMC – well established minor use program, works closely with IR-4

Updates

- Canadian MRLs: 17,915 (March 2016) – doubled since 2010
- 8 Global Joint Reviews completed between 2012-15 yielded 100% alignment of US and Canadian MRLs
- New PMRA cost recovery regime expected to be in place by April 2017
 - Aims to recover 30% of review costs
 - Import tolerance goes from \$8500 for unlimited pests to approx 16K per pest for previously assessed chem and \$125K for new a.i. or first food use

Updates

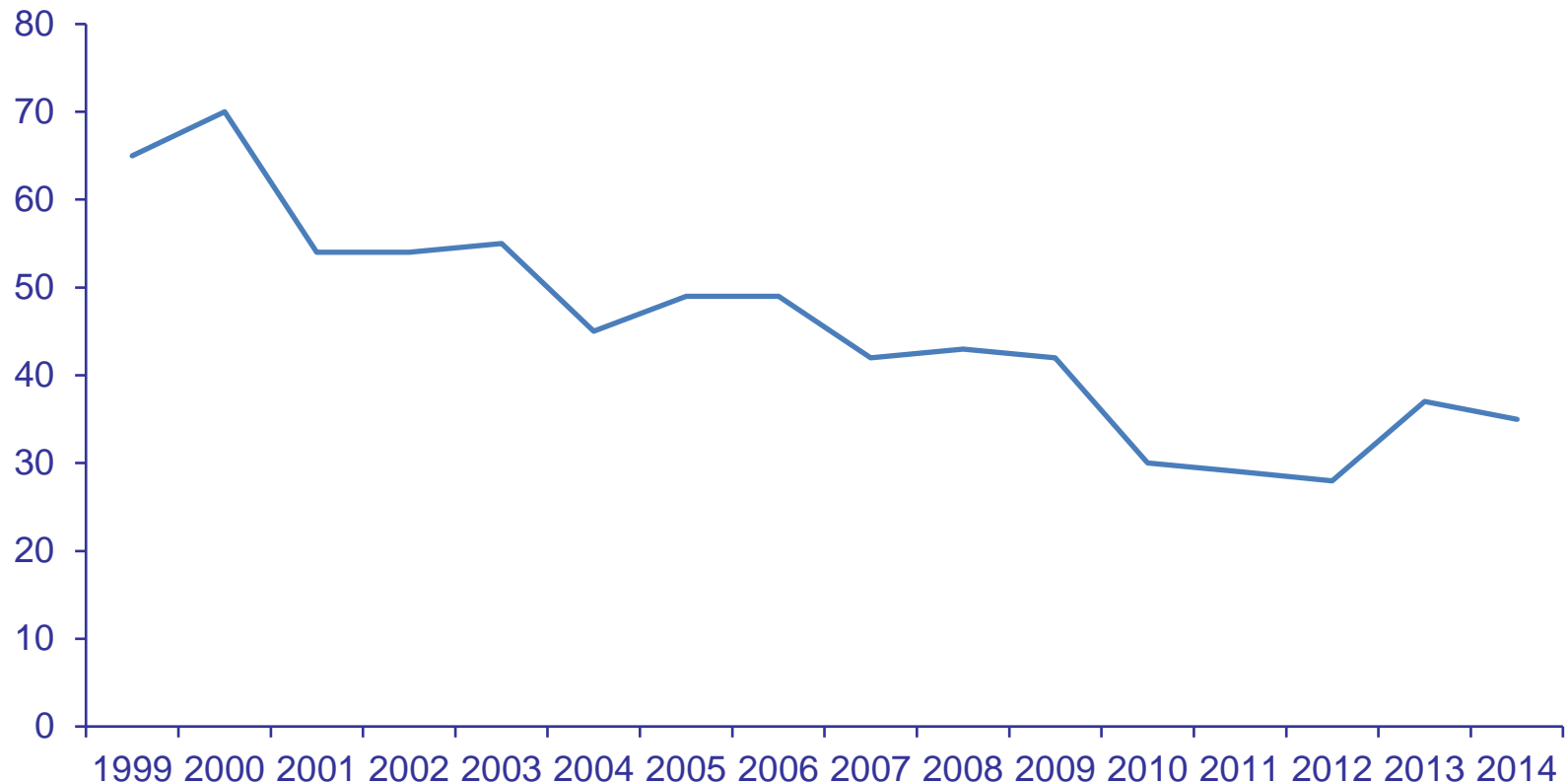
- CropLife Canada is concerned about eco-activism being viewed as public sentiment
 - Provincial regulatory actions, food industry (hormones, additives, GMOs, etc.)



- MRL issue – all commodity sectors acutely aware

Agrochemical Active Ingredients in Development

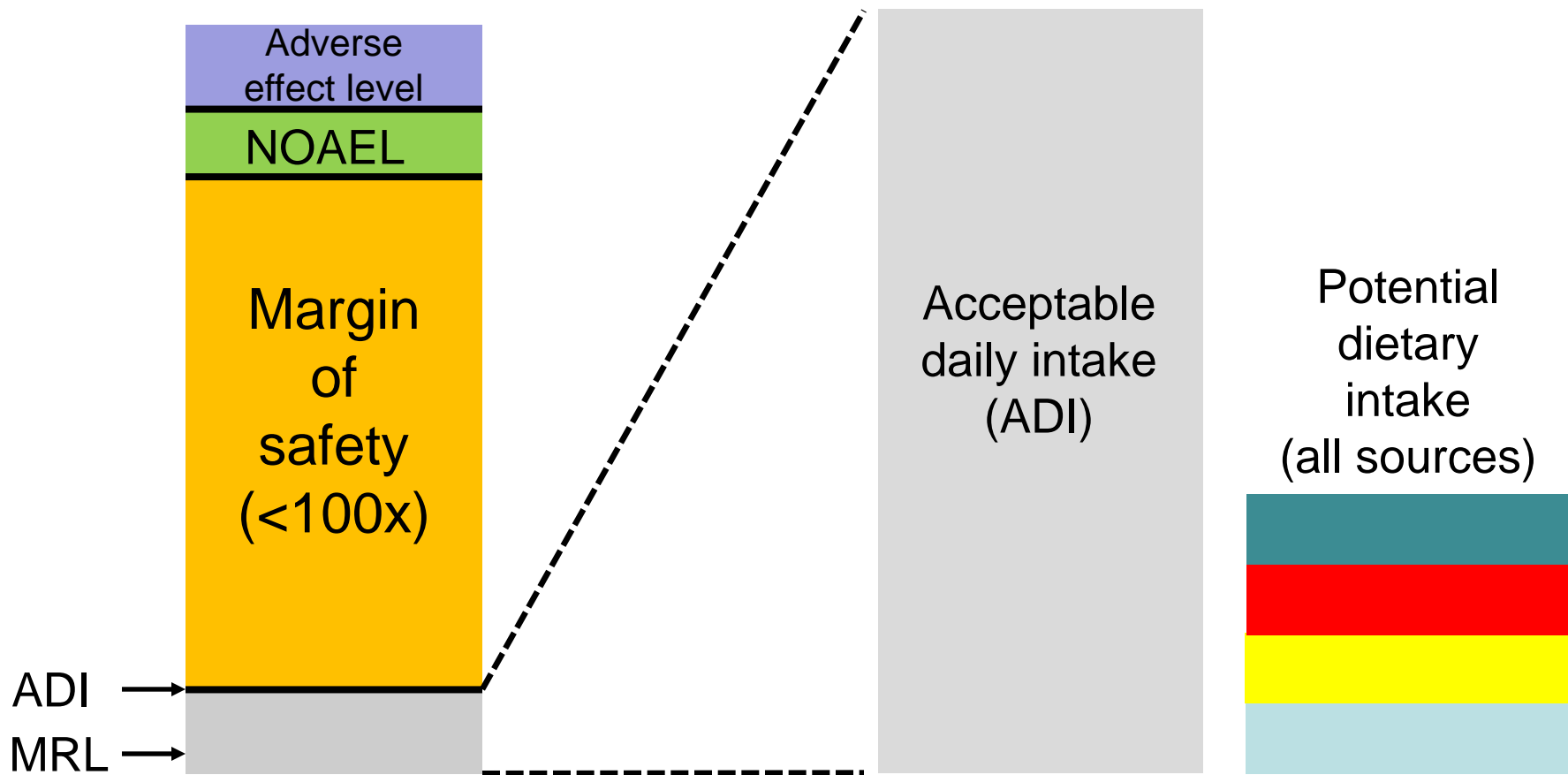
a.i.s in development



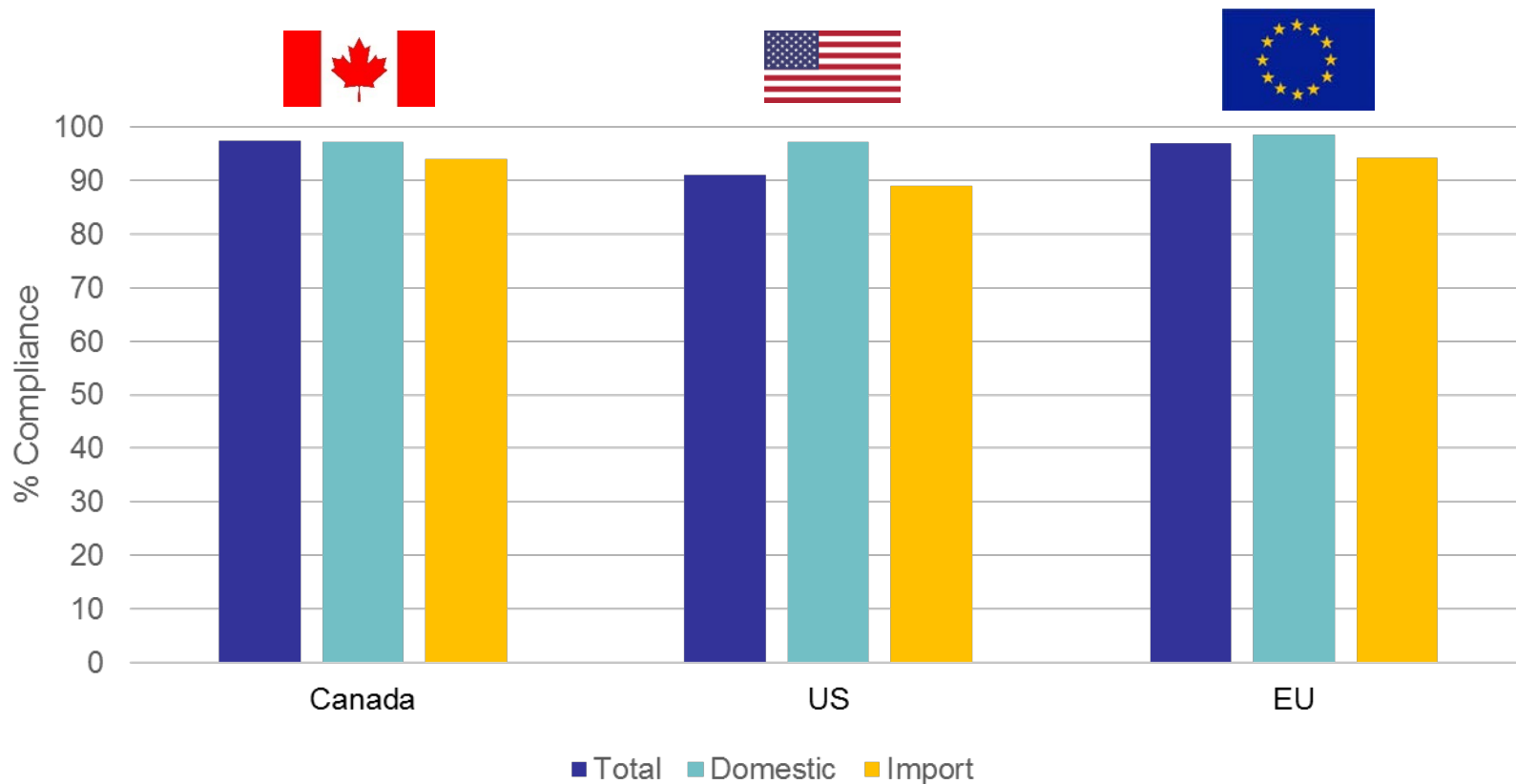
MRLs as safety levels

- Are MRLs a safety level or a trading standard?
- *“Health Canada sets science-based MRLs to ensure the food Canadians eat is safe. The MRLs set for each pesticide-crop combination are set at levels well below the amount that could pose a health concern.” [PMRA website]*

Dietary Risk Assessment



MRL Compliance Rates 2012-13



Agricultural Trade Dependency

Total U.S.-Canada Agriculture and Agri-Food Trade (2014) = \$50B

Total U.S. Agriculture and Agri-Food Exports to Canada: \$26.2B

- Fruits and Nuts \$3.7B
- Vegetables \$2.7B



Total U.S. Agriculture and Agri-Food Imports from Canada: \$23.7B

- Cereal Grains \$2.1B



MRL case study

- Canada's **0.1ppm** default MRL is 10x higher than many other jurisdictions
- Over 700 commodity/chemical combinations entering Canada from the US rely on the 0.1 ppm default
 - Many of these are crop groupings
 - Mostly specialty crops
- Canadian exporters to US face a **zero** tolerance
- Consumption patterns very similar
- Case in 2015 on wheat destined for US – grower advisories
- Opportunity for Canada – US leadership on MRL deferral?

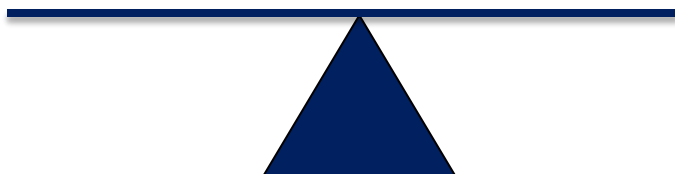
MRL Balancing Act

Trade Risk

- MRLs not established in key export markets (which and how many?)
- Likelihood of residues?
 - Chem properties
 - Application timing
- Codex deferral?
- Other deferral pathways?

Innovation

- Grower demand for new solutions
- Relentless pest pressures and invasives
- R&D and registration investment
- Return on investment, data protection timeline
- Regulatory cooperation to enhance trust & knowledge



Consequences



Lack of MRL harmonization coupled with unfortunate link to food safety:

- Negatively impacts innovation in new pest control tools for growers globally
- Deters the use of the latest crop protection solutions by farmers
- Adds unnecessary costs to global crop trade
- Adversely affects food security for vulnerable populations



OECD Vision 2008

- *The Organization for Economic Co-operation and Development (OECD) vision is that, by the end of 2014, data submissions (dossiers) for chemical agricultural pesticides will be prepared globally whenever possible, and dossiers in the OECD format will be accepted in all member countries...*

Joint Reviews

- When fully functional Joint Reviews to lead to:
 - Enhanced registration submission and approval timing for market entry,
 - Highest quality reviews,
 - Predictability, transparency in timelines and of aligned key end points (especially MRLs),
 - Faster reviews than stand-alone domestic reviews, and
 - Regulator and Company efficiencies.
- Global Joint Reviews – a proven path to MRL harmonization
- Most new active ingredients registered in Canada are being done through some sort of joint review or workshare
- Others?

Questions?

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