



Agriculture Division of DowDuPont™

The Future of MRL Harmonization

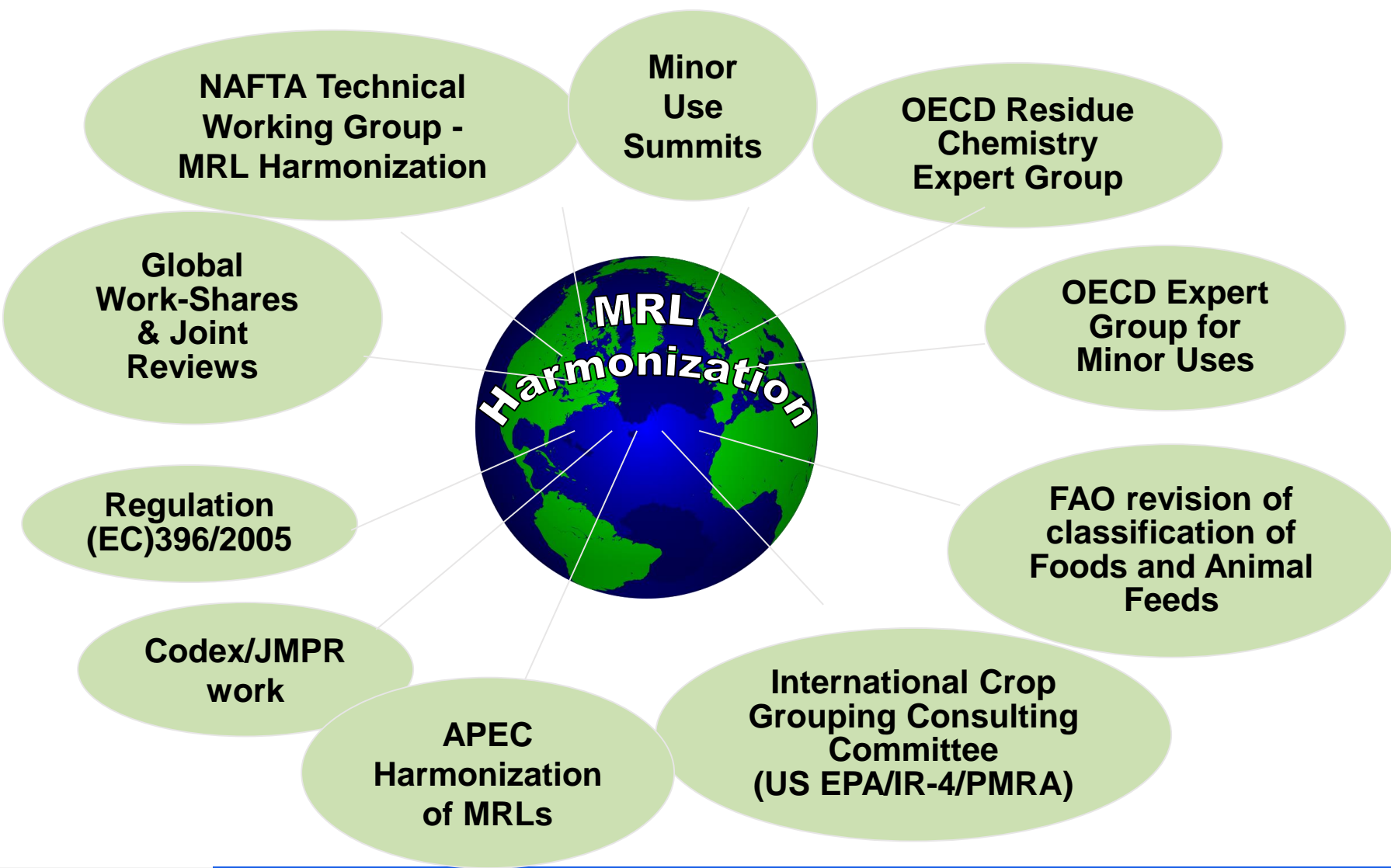
2019 MRL HARMONIZATION Workshop, San Francisco, May 29-30

CARMEN TIU - GLOBAL MRL & IT LEADER

Presentation Outline

1. Current Status of MRL Harmonization
2. Ongoing Initiatives & Pilots
3. Solutions for Missing MRL
4. The ONE MRL concept
5. Food for Thought

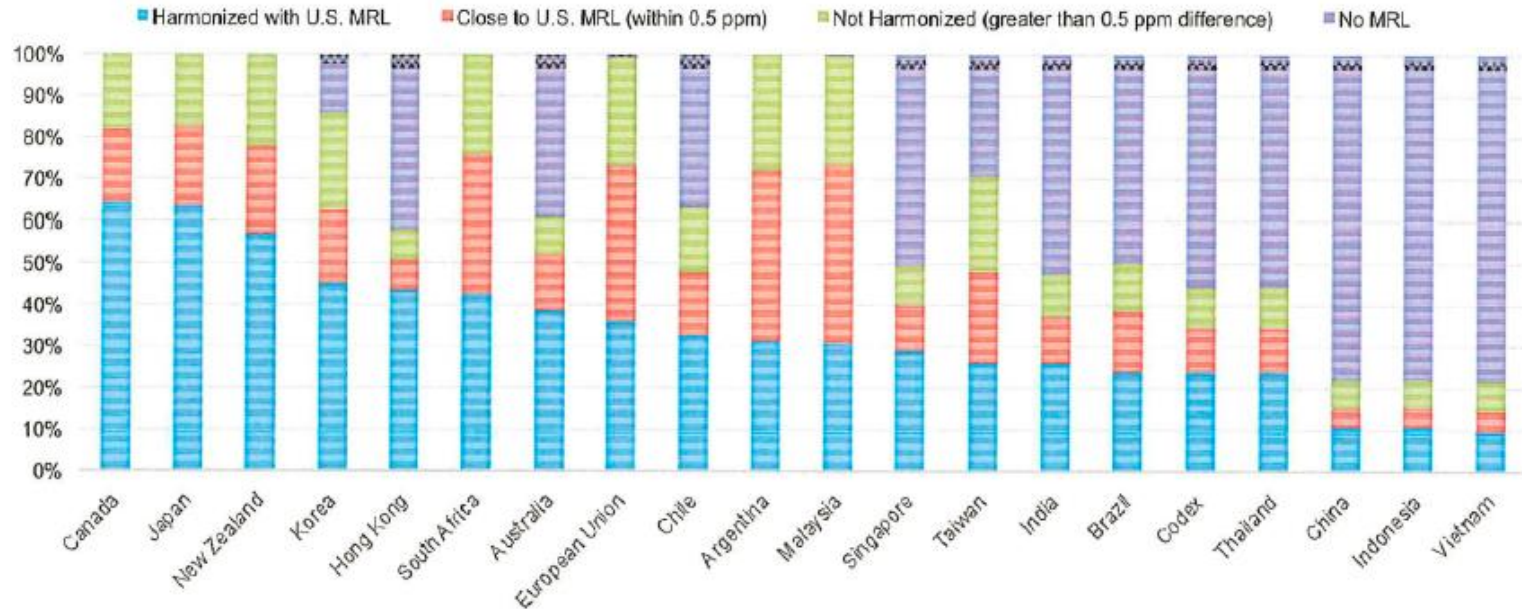
1. International Harmonization Attempts



Example of MRL (dis) Harmonization



INTERNATIONAL MRLS COMPARED TO U.S. MRLS FOR SELECTED COMMODITIES (BY MARKET)



Based on 389 AIs and 779 commodities

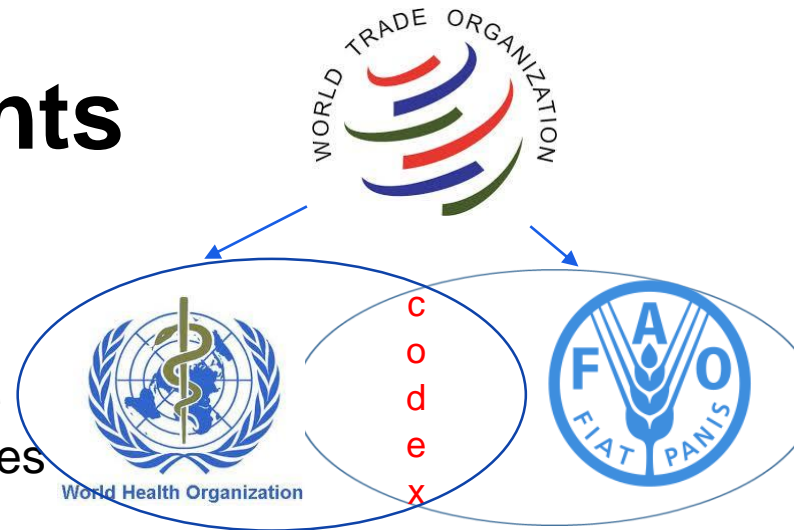
2. Initiatives & Pilots

- A. Codex Enhancement
- B. EU REFIT
- C. APEC IT Guideline
- D. Missing MRL Workshops

2-A. Codex Enhancements

UPDATES – AFTER 55 YEARS!

CCPR schedule, nomination, label is now online
- Procedures, funding, harmonization, efficiencies



Six e-Working Groups(eWG) going on at CCPR:

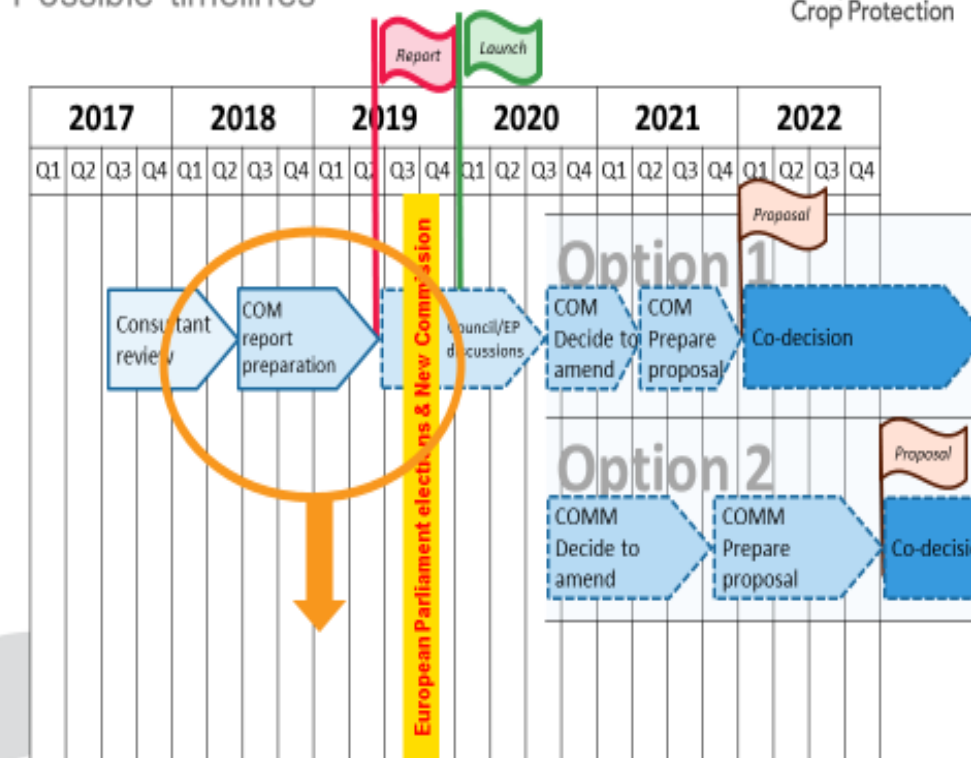
1. New Compound Reviews: Canada & Costa Rica lead Joint National Reviews + JMPR/CCPR
2. New Use Reviews: US/IR-4/CLI proposing APEC-like procedure
3. Periodic Reviews: Chile/Kenya/C.Rica to prevent cancel Codex-MRL if any active use
4. National Registration database at Codex: to prioritize periodic reviews and when to cancel (no active registration)
5. Analytical method for enforcement review to include MS/MS-characterization
6. Guideline for Biopesticides and low-toxicity compounds (Chile/India) has proposed process for tolerance exemption

2-B. EU Regulatory Updates MRL/IT

EU REFIT (Reg.1107+396) Timelines (3 review processes)

Issue	Report conclusions
Reg 396/2005	+ Efficient except art 12
Reg 1107/2009 Recommendations	+/- Harmonising, with deficiencies - To solve complexity & scarce resources: coordinate, harmonise, GDs, IT tools - Balance public concerns with agri competitiveness

Commission report
Possible timelines



MRL Needs

- MRL evaluation
- Fast-track MRLs (default MRLs, Minor Uses)
- Central evaluation system (on-line)

2-C. APEC Pilot for IT



21 economies from the Pacific may have an ideal system for The Global MRL

**APEC Food Safety Cooperation Forum
Sub-Committee on Standards and Conformance, July | 2016**

IMPORT MRL GUIDELINE FOR PESTICIDES

A guideline on possible approaches to achieve alignment of international MRLs

- Accepts MRL from export country (based on agency's review report, no data), if dietary risk is acceptable to import country
 - This implies significant save of time and resources, **plus SAME** MRL
 - Implemented in Australia, US, partially in Canada, Korea
 - Pending pilot across all countries (phase IV)

2-D. Missing MRL

EXPONENTIAL INCREASE IS NOT SUSTAINABLE!



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Missing MRLs occurs when:

- MRL has not been established for the crop or crop-grouping, that may be different crop groupings in the importing countries or;
- MRL has not been established for the crop or crop-grouping/pesticide combination and instead a default MRL (typically 0.01 mg/kg is applied).
- Import market does not have a formal regulatory framework to establish MRLs or to recognize exporting country's MRL;

3. Initiatives for Missing MRLs

1st INTERNATIONAL WORKSHOP ON MISSING MRLs

February 26, 2018 World Trade Organization (Geneva)

– 15 countries & industry

- WTO SPS Ministerial Agreements
- WTO paper on MRLs – to help address missing MRLs



2nd INTERNATIONAL DISCUSSION ON MISSING MRLs

– May 31, 2019, San Francisco, CA, USA.

Follow-up from the 1st Workshop

Updates from Minor Use Initiatives, WTO SPS, Codex, Industry



3. Solutions for Missing MRL

Existing Precedents – all countries accept traces in trade if lower than analytical LOQ (0.01 ppm) → risk is negligible

Agency	Pros	Cons
Codex	- MRL adopted by 70 countries, possibly all 189	Shortest list of MRL (<5,000)
EU	- EU harmonized MRL - Default MRL	88% default MRL Trigger illegal uses
Japan	2006 PSL (highest existing MRL)	Heavy workload periodic reviews
APEC	22 countries mutually accepting MRL, if risk OK	Implementation still in progress
Australia	- MRL for “all other foods, except animal commodities” - Monitoring accepted <0.1 ppm	Contribution to risk < 20%
China	Applied Codex, MRL export country, or LOQ	IT regulation is pending

The ONE MRL Concept

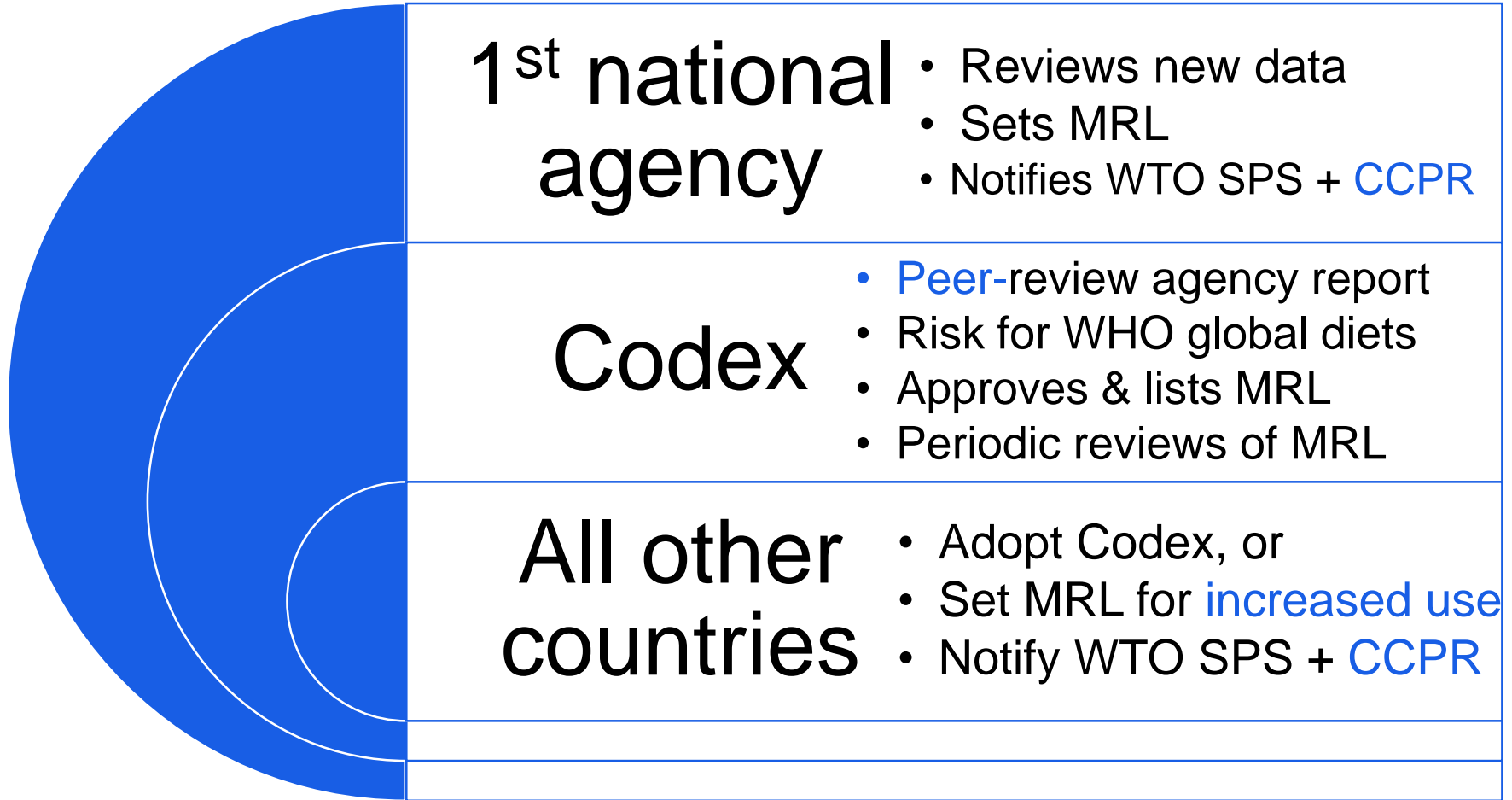
ONE GLOBAL MRL – THE IDEAL SYSTEM

- First country to approve a new use sets MRL
 - Notify WTO SPS & CCPR for JMPR peer-review, global risk & posting MRL
- All other countries (189) to adopt Codex MRL (same, lower GAP)
 - Submit for increased MRL, in case of increased GAP
- **Benefits**
 - Harmonized MRL (domino effect)
 - No IT needed (or very few)
 - Faster introduction of new uses
 - Cost optimization for avoiding re-work
 - Less, or no trade-irritants



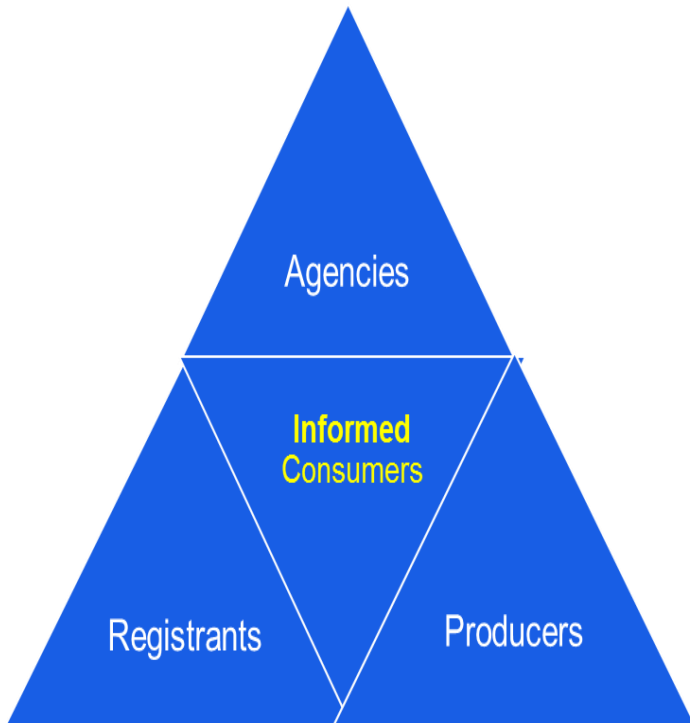
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The Future of MRL: ONE MRL



Food for Thought: 2 choices

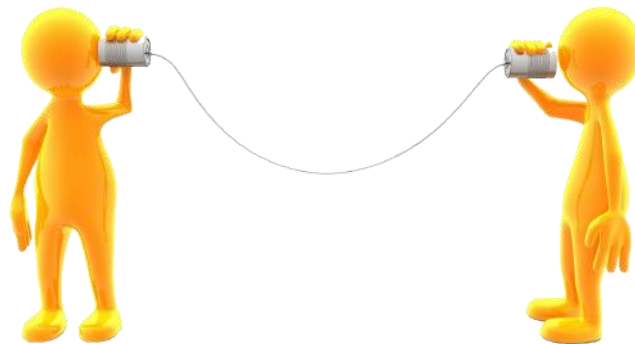
1. Support true harmonization (e.g ONE MRL)
2. KEEP RUNNING THE MRL MAZE!



Many Thanks!

More information:

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