

ONE World ONE DOSSIER ONE Review



IDRG

Imme Gerke – Global Regulatory Strategist

2017






IDRG







- the problem
- the solution
- the engagement



problems
farmers



registrants
products

crop x p

country

authorities
regulations



Worldwide, we grow over ... 10,000 crop species
These crops can be damaged by ... x 10 pest problems
IPM and trade require products with at least ... x 3 modes of action
Countries require national authorizations ... x 200 countries
That means worldwide we need ... = 60,000,000 approvals

impossible



bad



worse



worst





- ✓ 15 nautical miles for foods that sink
- ✓ 25 nautical miles for foods that float





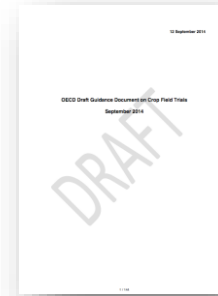
<http://www.iff.fraunhofer.de/de/geschaeftsbereiche/biosystems-engineering/forschung.html#tabpanel-25>



Worldwide, we grow over ...	10,000 crop species
These crops can be damaged by ...	x 10 problems
IPM and trade require at least ...	x 3 products
Countries require national authorizations ...	<u>x 200 countries</u>
That means worldwide ...	= 60,000,000 approvals



- CODEX
- EU
- US
- CAN
- AUS
- JPN
- ...



100

groups

Worldwide, we grow over ...

~~10,000~~ crop species

These crops can be damaged by ...

x 10 problems

IPM and trade require at least ...

x 3 products

200 countries require authorizations ...

x 200 countries

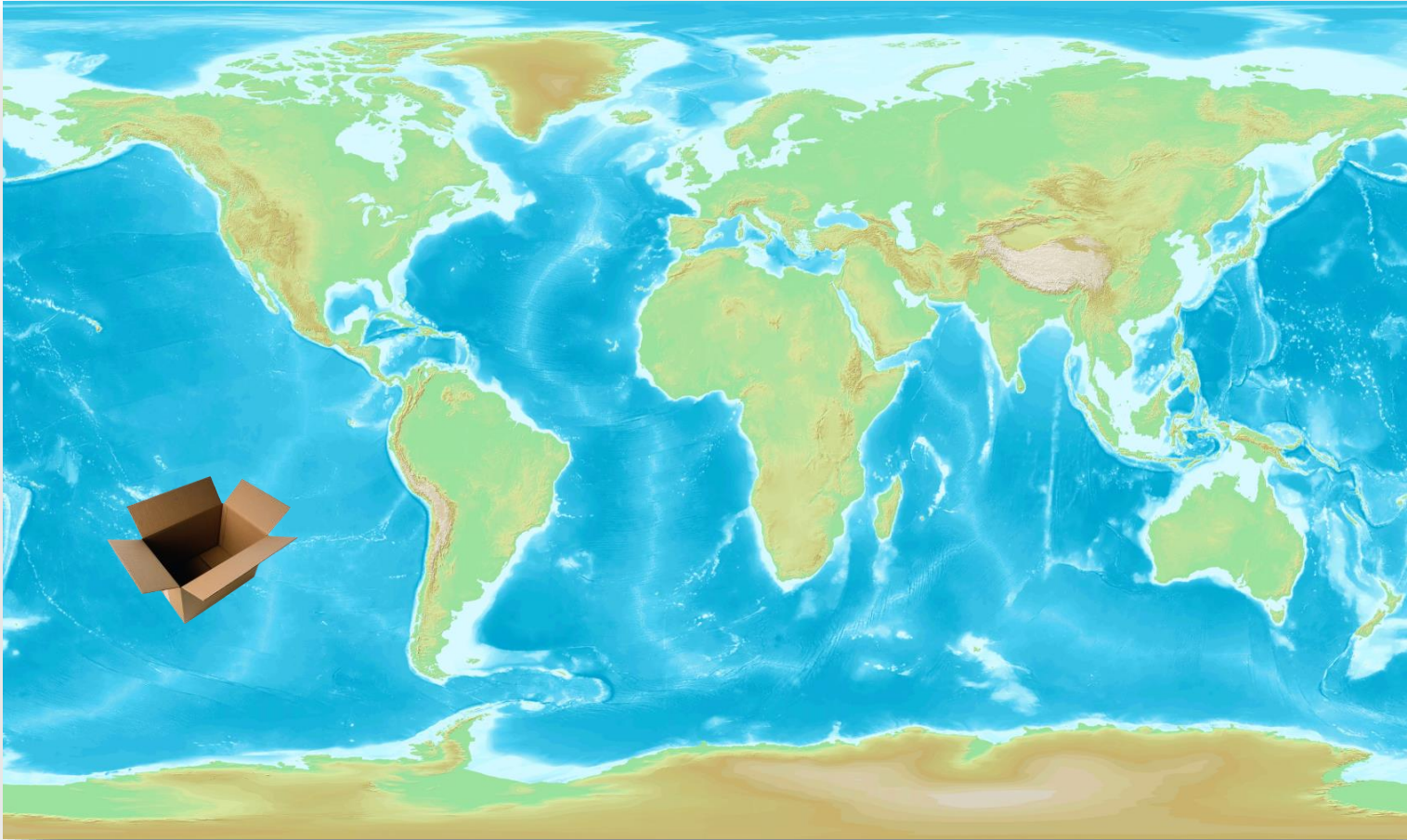
That leads us to ...

= ~~60,000,000~~ approvals

600,000





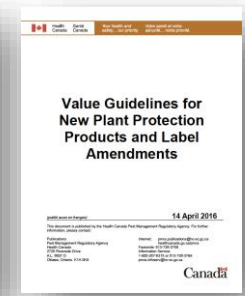
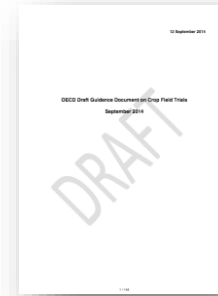


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problem

- CODEX
- EU
- US
- CAN
- AUS
- JPN
- ...



100

groups

Worldwide, we grow over ...

~~10,000~~ crop species

These crops can be damaged by ...

x 10 problems

IPM and trade require at least ...

1

x 3 products

200 countries require authorizations ...

x 200 countries

That leads us to ...

= ~~60,000,000~~ approvals



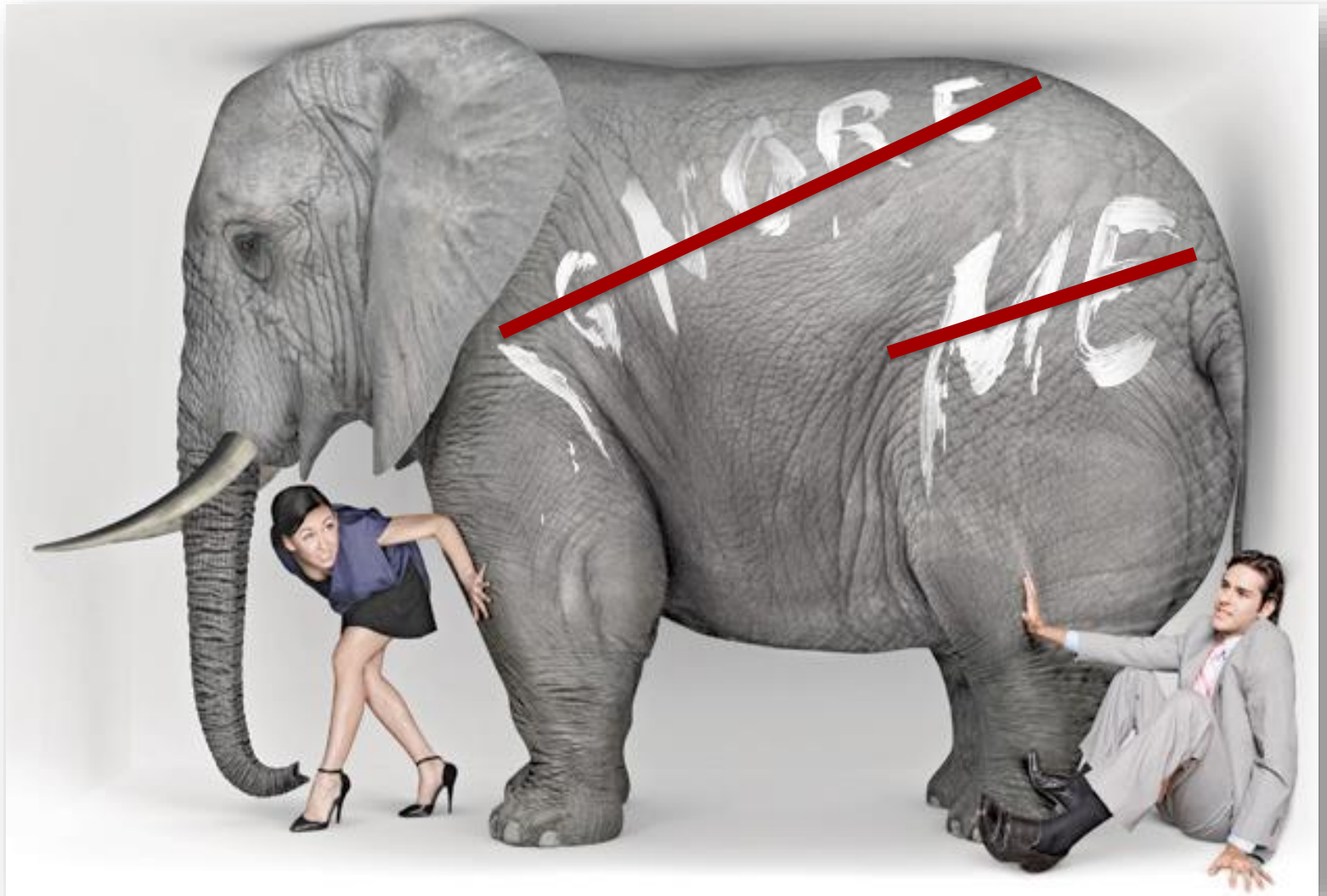
600,000



- the problem
- the solution
- the engagement



problem



 IDRG



Global Cooperation across Political Borders

among and between growers, industry and governments



1. OECD dossier
2. OECD monograph
3. communication



pest problems
farmers



options



registrants
products

HOMOLOGA New Updates last week Registrations (BELARUS, BELGIUM, ESTONIA) MrIs (CANADA, EU-MRLS-HARMONIZED, ISRAEL)
- for more informations please click [HERE](#) !

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Homologa™
The Global Crop Protection Database about
Plant Protection Products and their
Maximum Residue Limits (MRLs)

Detailed Information about:

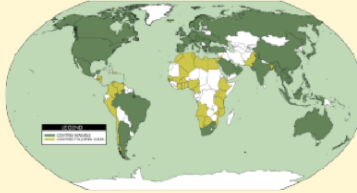
- Approved plant protection products
National product name, registration number, company name, active ingredients, concentration, formulation, product group, crop name, crop group, pest name, method of application, time of application, pest/problem, minimum dose rate, maximum dose rate, amount of water, maximum number of treatments, pre-harvest-interval and for some countries: risk phrases, symbols and environmental phrases.
- Registration-Status of active ingredients on EU-level
- Actual status of registration (new, expired and /or last use date)
- Approved parallel imports
- Maximum Residue Levels (MrIs) in foodstuffs
- New or modified MrIs
- Export-/import statistics of food and ornamentals

Country coverage:

Countries Product Registration



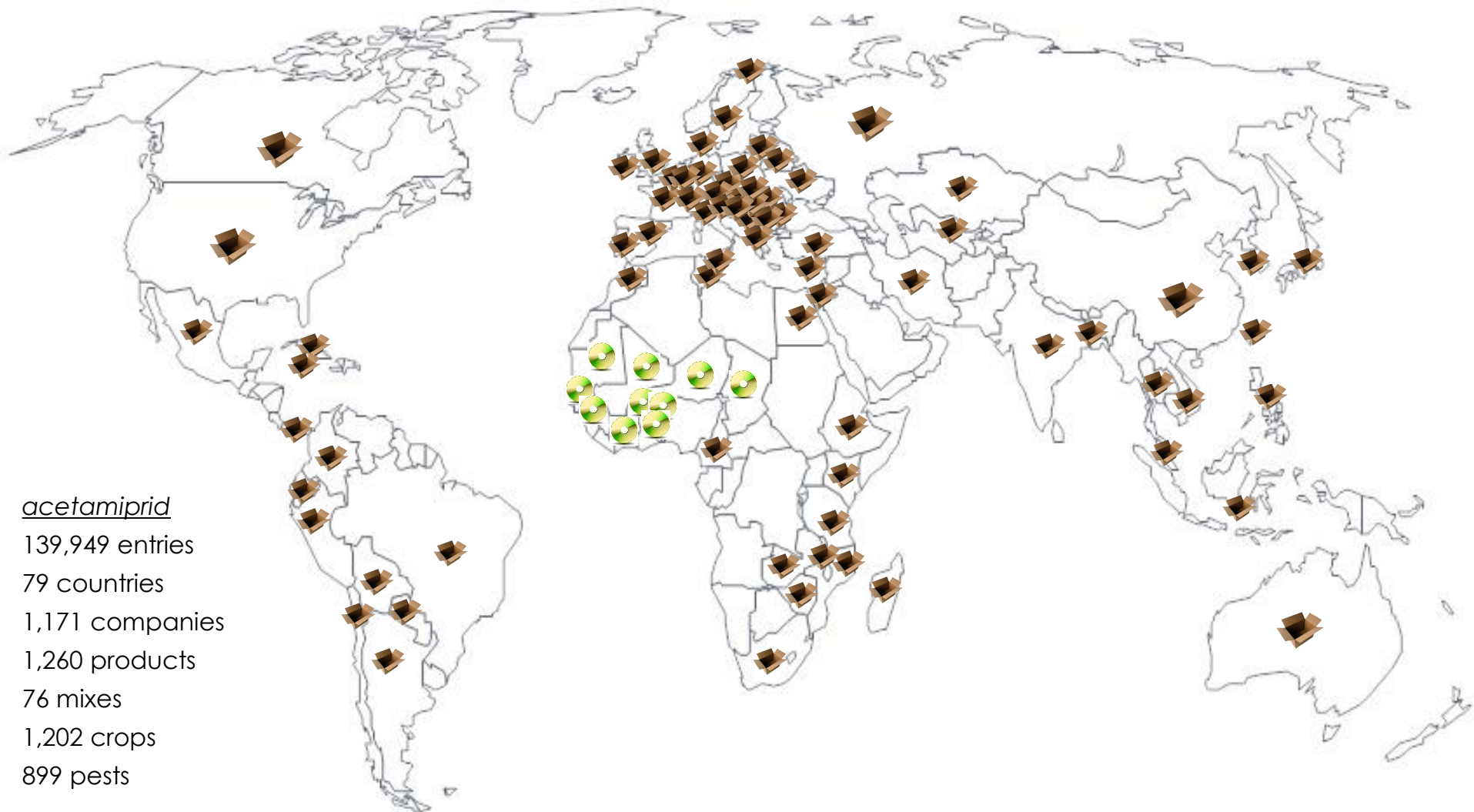
Countries MRLs

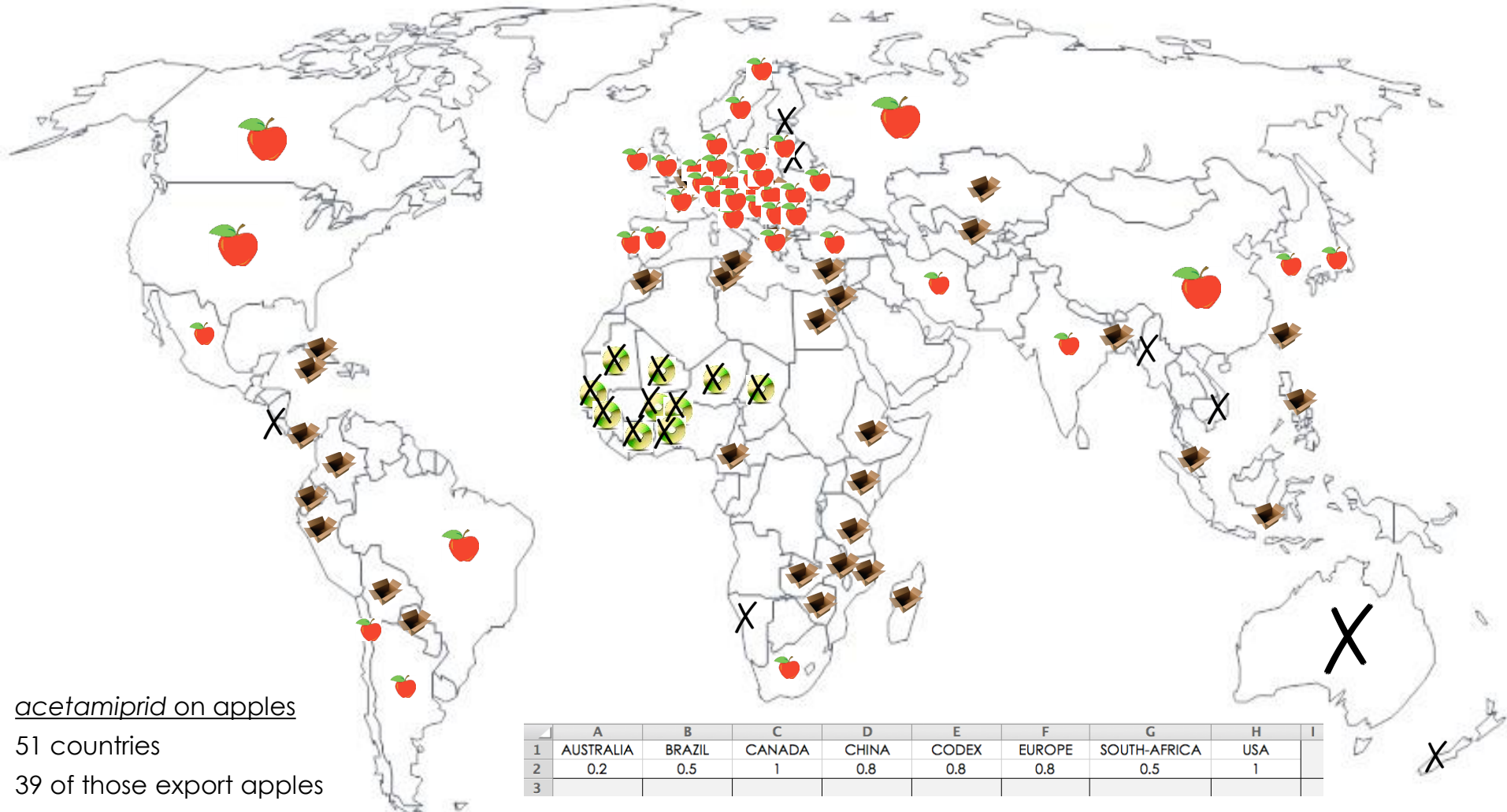


- trade
- MRLs
- registrations



solution





acetamiprid on apples

51 countries

39 of those export apples

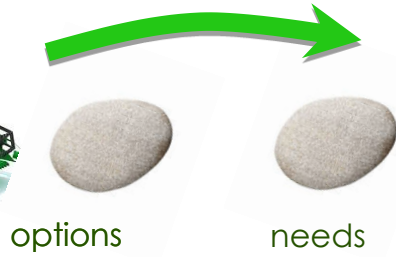
20 export but no acetamiprid on apples

5 export and have acetamiprid but not on apples

- first approval on apples in 1985
- since 1997 new approvals on apples every year



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products

20 export but no acetamiprid on apples
5 export and have acetamiprid ~~apples~~

	A	B	C	D	E	F	G	H	I
1	AUSTRALIA	BRAZIL	CANADA	CHINA	CODEX	EUROPE	SOUTH-AFRICA	USA	
2	0.2	0.5	1	0.8	0.8	0.8	0.5	1	
3									



EUMUDA Data Base

Minor Uses Table of Needs

Case id	Crop code	Crop	Pest code	Pest	Frequency	Minor/major crop	Minor/major pest	Year	Area of use	Function	Member State	Latest status	Comments
19	VACMY	Bilberry	ACRES	Blackberry mite	2			2014	Greenhouse application	acaricide	Austria	source : C-PM	
20	VACMY	Bilberry	ACRES	Blackberry mite	2			2014	Outdoor field use	acaricide	Austria	source : C-PM	
153	PRNAV	Sweet cherry	ABOPEP	Cherry moth	Fruit	1		2014	Outdoor field use	insecticide	Austria	source : C-PM	
269	BRAND	Beetroot	CERCBE	Leaf beet	of	2		2014	Outdoor field use	fungicide	Austria	source : C-PM	
305	CRICA	Common ranuncy	CRAS	Creeching thistle	1			2014	Outdoor field use	herbicide	Austria	source : C-PM	
309	ALLSA	Garlic	CLAGAC	Green leaf spot	1			2014	Outdoor field use	fungicide	Austria	source : C-PM	
318	SILMA	Holy thistle	COVAR	Field bindweed	1			2014	Outdoor field use	herbicide	Austria	source : C-PM	

Showing 1 to 100 of 1,319 entries



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- IR4 (USA)
- PMC (CAN)
- EMUCF (EU)
- ... (AUS)
- ... (...)

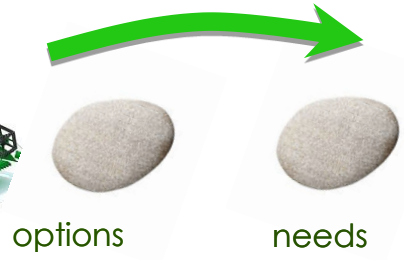
GMUPSM

✓ 2015

✧ 2017



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cooperation



registrants
products

presubmission
consultation



PRESUBMISSION CONSULTATION REQUEST FORM

1. Applicant (company, name of contact and address)

2. Participants (list of individuals that regulator is encouraged to communicate with include titles and affiliations)

3. Product Information

4. Area of Expertise Requested (select all that apply for the specific questions or issues)

5. Administrative process, date requirements, submission format, deadlines

6. Ethical, Sustainability, Value

7. Environmental Fate and Toxicology

8. Food Residue, Metabolites

9. Occupational Exposure

10. Toxicology

11. Chemistry/Compliance

12. Other (e.g. Residues)

13. Is this being proposed as a reduced risk product (e.g. microbials, antimicrobials, conventional biocontrol or natural product or other "biopesticide")?

14. Is this being proposed as a new risk biotechnical or other non-conventional biopesticide?

15. Is a Joint Review or Work Share Review (with the EPA, Bf or other OECD country) being proposed?

PROPOSED USES

Product Name	Active Ingredient	Mode of Action	Target Pest	Target Plant	Target Tissue	Target Part	Target Stage	Target Location	Target Time	Target Frequency	Target Duration	Target Other
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												

Name and Date: _____ Signature: _____

PROPOSED USE PATTERNS

USE RANGE	1000	1000-10000	10000	100000	1000000	10000000	100000000	1000000000	10000000000	100000000000	1000000000000	10000000000000
1												
2												
3												
4												
5												
6												
7												
8												
9												
10												
11												
12												
13												
14												
15												
16												
17												
18												
19												
20												

Name and Date: _____ Signature: _____

PRODUCT SPECIFICATION FORM

1. Applicant Information

2. Product Information

3. Environmental Fate and Toxicology

4. Occupational Exposure

5. Chemistry/Compliance

6. Other (e.g. Residues)



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MICROBIALS					
CODE	TITLE MPC/A	REQUIREMENT	TYPE	SOURCE	DATE
1 Identify of the Active Substance / Plant Protection Product					
1.1	Applicant (name, address, contact, telephone and telefax numbers)				
1.2	Producer (name, address, contact, telephone and telefax numbers)				
1.3.1	Scientific name of microorganism to species level or a level sufficient to show taxonomic relation to known microorganisms, especially pathogens; - accession no. of sample in a recognized culture collection; - test procedures and criteria, using best available technology, to characterize the strain or serotype; - for mutant or genetically-modified strains, indicate all known differences between the modified microorganism and the parent wild strain(s) - include any trade names, common names, developmental code names - indigenous or non-indigenous at the species level to the intended area of application (required in the EU)				
1.4 Composition of Technical Grade of MPC/A/Active Substance					
1.4.1	Concentration of microorganism (and metabolite, if appropriate) in terms of g/kg, or g/L, (for US and Canada also in % w/w) and cfu's/mL, or appropriate potency units; include acceptable range for each term. Potency should be expressed in recognized units of potency or an appropriate expression of biological activity per unit weight/volume				
1.4.2.1	Composition of microbial material used for manufacture of end use products in terms of g/kg or g/L, (for US and Canada also in % w/w) for each active ingredient including: - the MPC/A - additives (preservatives, stabilizers, diluents) - microbial impurities, classified/identified to a taxonomic level required by quality criteria to support the hygienic state of the production process - non-microbial impurities (eg. metabolic products, impurities in starting materials, fermentation residues, extraneous host residues). This information is not required if Technical Grade of MPC/A is a hypothetical stage in a continuous production process of an end-use product.				
1.4.2.2	Composition in terms of % g/kg or g/L, w/w for each ingredient: The identity and maximum content of all microbial impurities must be reported, if possible and appropriate, expressed in appropriate units, as outlined in point 1.3.1 (in terms of cfu's/mL or appropriate expression of biological activity / viability)				
1.4.3	Quality criteria for the production and storage of the MPC/A, including: criteria for consistency and integrity of the master and working seed stock, typically, measures of biological activity and phenotypic or genotypic properties; - acceptable range for content of MPC/A, in appropriate terms; - presence of human/mammalian pathogens; - presence or maximum accepted level of known mammalian toxins, if their presence is suspected at any stage in process, or if MPC/A is closely related to a toxigenic human pathogen - maximum accepted level for microbial impurities, using suitable indicators of an unhygienic process				
1.4.4	Quality control data (measures of quality criteria) from 3 - 5 production batches, including storage stability data, if the Technical Grade of MPC/A is a stage in a continuous production process of an end-use product, this information should be provided for the entire production process.				
1.4.5.1	A theoretical discussion regarding - formation and/or presence of unintentional ingredients, including impurities of toxicological concern, likely to occur in the Technical Grade of the MPC/A, - the impact of these ingredients on product quality, and - appropriate quality criteria				
1.4.5.2	Physical and chemical properties, if MPC/A is produced as a manufacturing product that is stored prior to formulation of end-use products; physical state; density; viscosity or surface tension; explosivity, combusive character, oxidizing properties; technical characteristics as appropriate.				
1.4.5.3	International regulatory status of microorganism				
1.4.5.4	Comprehensive Data Summary / Tier II summaries in OECD format; "Guidelines and Criteria for Industry for the Preparation and Presentation of Complete Dossiers and of Summary Dossiers for Plant Protection Products and their Microbial Active Substances in Support of Regulatory Decisions in OECD Countries, Appendix 7 and B / Tier II format required by Annex Ito of 91/414/EEC.				
1.4.5.5	Sample of MPC/A, analytical standard of metabolite (and reference substances for the relevant impurities - EU only); if requested				
1.5.3	Patent Status				
2 Properties of the Active Substance					



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OECD Guidelines for the Testing of Chemicals

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The OECD Guidelines for the Testing of Chemicals are a unique tool for assessing the potential effects of chemicals on human health and the environment. Accepted internationally as standard methods for safety testing, the Guidelines are used by professionals in industry, academia and government involved in the testing and assessment of chemicals (industrial chemicals, pesticides, personal care products, etc.). These Guidelines are regularly updated with the assistance of thousands of national experts from OECD member countries. OECD Test Guidelines are covered by the Mutual Acceptance of Data, implying that data generated in the testing of chemicals in an OECD member country, or a partner country having adhered to the Decision, in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), be accepted in other OECD countries and partner countries having adhered to the Decision, for the purposes of assessment and other uses relating to the protection of human health and the environment.

Also available in: French

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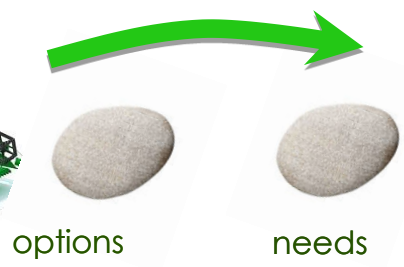
- OECD Guidelines for the Testing of Chemicals, Section 1
- OECD Guidelines for the Testing of Chemicals, Section 2
- OECD Guidelines for the Testing of Chemicals, Section 3
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Agricultural pesticides and biocides

Industry Data Submissions for Biological Pesticides

DOSSIER GUIDANCE (FOR INDUSTRY)

Microbial

OECD Guidance for Industry Data Submissions for Microbial Pest Control Products and their Microbial Pest Control Agents (Dossier Guidance for Microbials), Series on Pesticides No. 23
Microbials Dossier Main Document

- Appendix 1
- Appendix 2
- Appendix 3
- Appendix 4
- Appendix 5
- Appendix 6a Parts 1,2,3
- Appendix 6b Part 4
- Appendix 6c Part 5
- Appendix 7
- Appendix 8
- Appendix 9
- Appendix 10
- Appendix 11

Pheromones and Semiochemicals

OECD Guidance For Industry Data Submissions for Pheromones and Other Semiochemicals and their Active Substances (Dossier Guidance for Pheromones and Other Semiochemicals) Series on Pesticides No. 16 (2003)

Pheromone Dossier Main Document

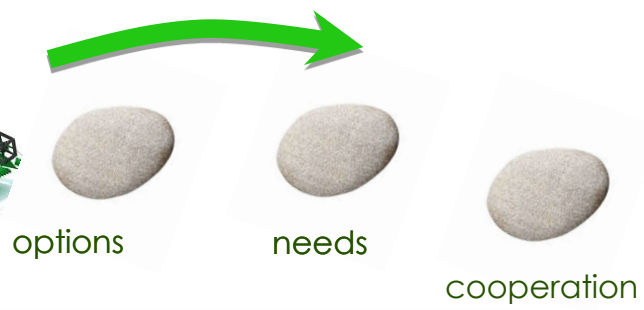
- Appendix 1
- Appendix 2
- Appendix 3
- Appendix 4
- Appendix 5
- Appendix 6 Parts 1,2,3
- Appendix 6 Part 4
- Appendix 6 Part 5
- Appendix 7
- Appendix 8
- Appendix 9
- Appendix 10
- Appendix 11 Part 1
- Appendix 11 Part 2
- Appendix 11 Part 3
- Appendix 11 Part 4
- Appendix 11 Part 5

Benefits for industry

Pesticide producers, who are responsible for testing any pesticide they want to register, usually have to present registration submissions in different formats for different OECD countries. The OECD common format should therefore reduce redundancies in the preparation of submissions by industry.



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Globally Harmonised Submission and Transport Standard

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[ENV GHSTS](#) · Introduction

Introduction

- > [What is the Globally Harmonised Submission and Transport Standard \(GHSTS\)?](#)
- > [Using the GHSTS](#)
- > [History of the development of the GHSTS](#)
- > [Benefits of the GHSTS](#)
- > [Next steps in the GHSTS project](#)

What is the Globally Harmonised Submission and Transport Standard (GHSTS)?

The Global Harmonised Submission Transport Standard (GHSTS) is a standardised set of technical specifications used to assemble electronic files for any pesticide package in a predefined manner. Microsoft Word and Excel, Adobe PDF, and XML data files are just some of the file types which can be transferred using the GHSTS according to business needs. Once the files are assembled according to the specifications, they can be transferred from one business entity to a regulatory authority with the receiving regulatory authority able to extract the files for use in a regulatory process. The GHSTS can potentially be used to create electronic packages for other regulatory purposes as well.

Limited metadata are included in the GHSTS. Only enough information is included to identify who the submitting entity is, the purpose of the files contained within the GHSTS, and how to handle the files once received. The GHSTS itself is not intended to use the content of the files. It is not a standard for the information itself. The GHSTS is not a tool or software application.

Information Technology (IT) systems can be constructed to utilise the Standard and by doing so, would be able to easily transfer data to each other.

For more information on the GHSTS, read the [Documentation and Training materials](#).



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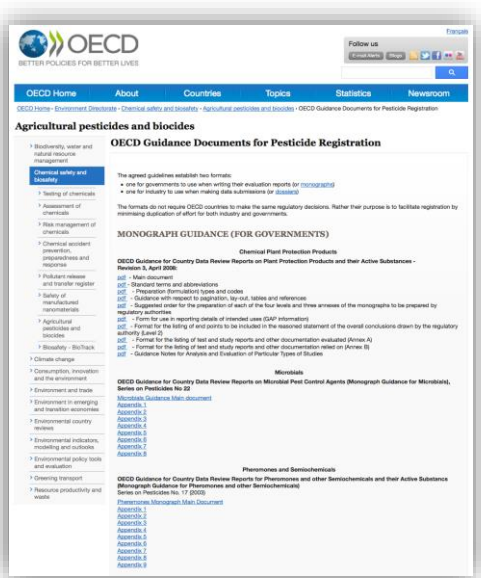
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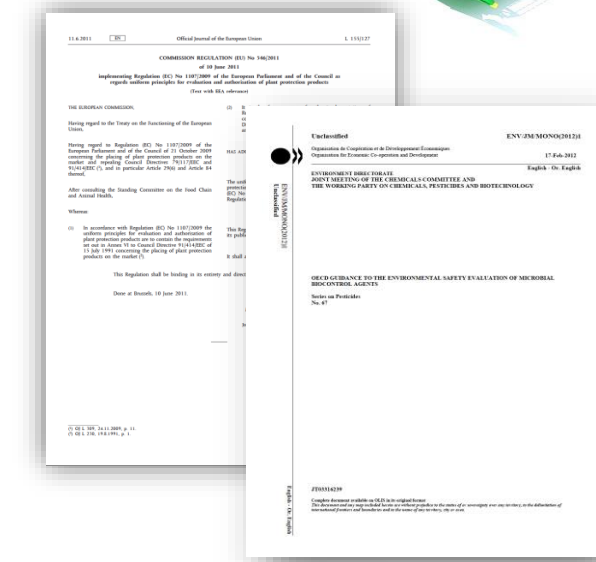
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risk
assessment



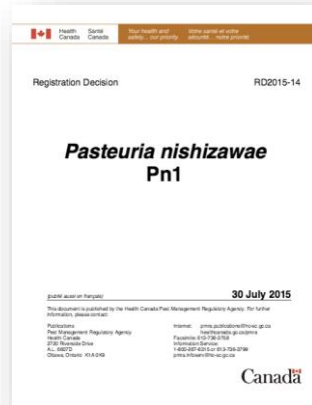
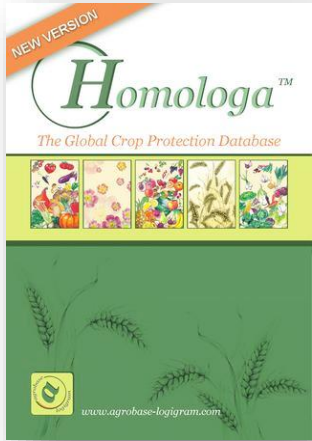
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needs

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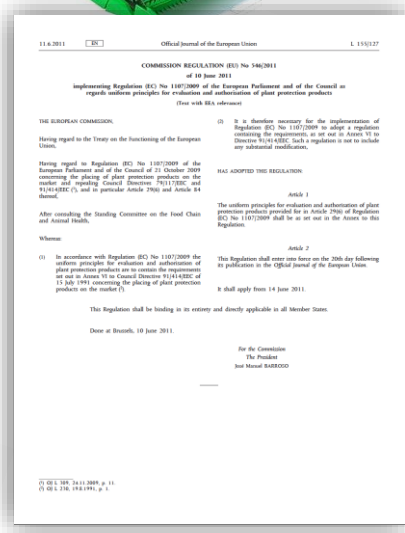
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national label
legalization

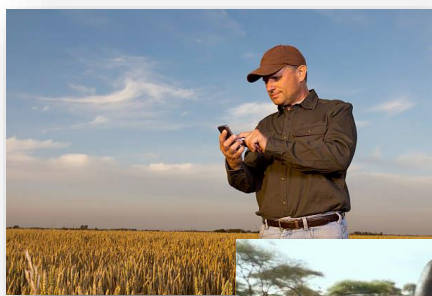
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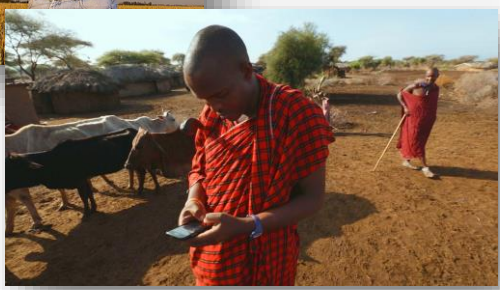
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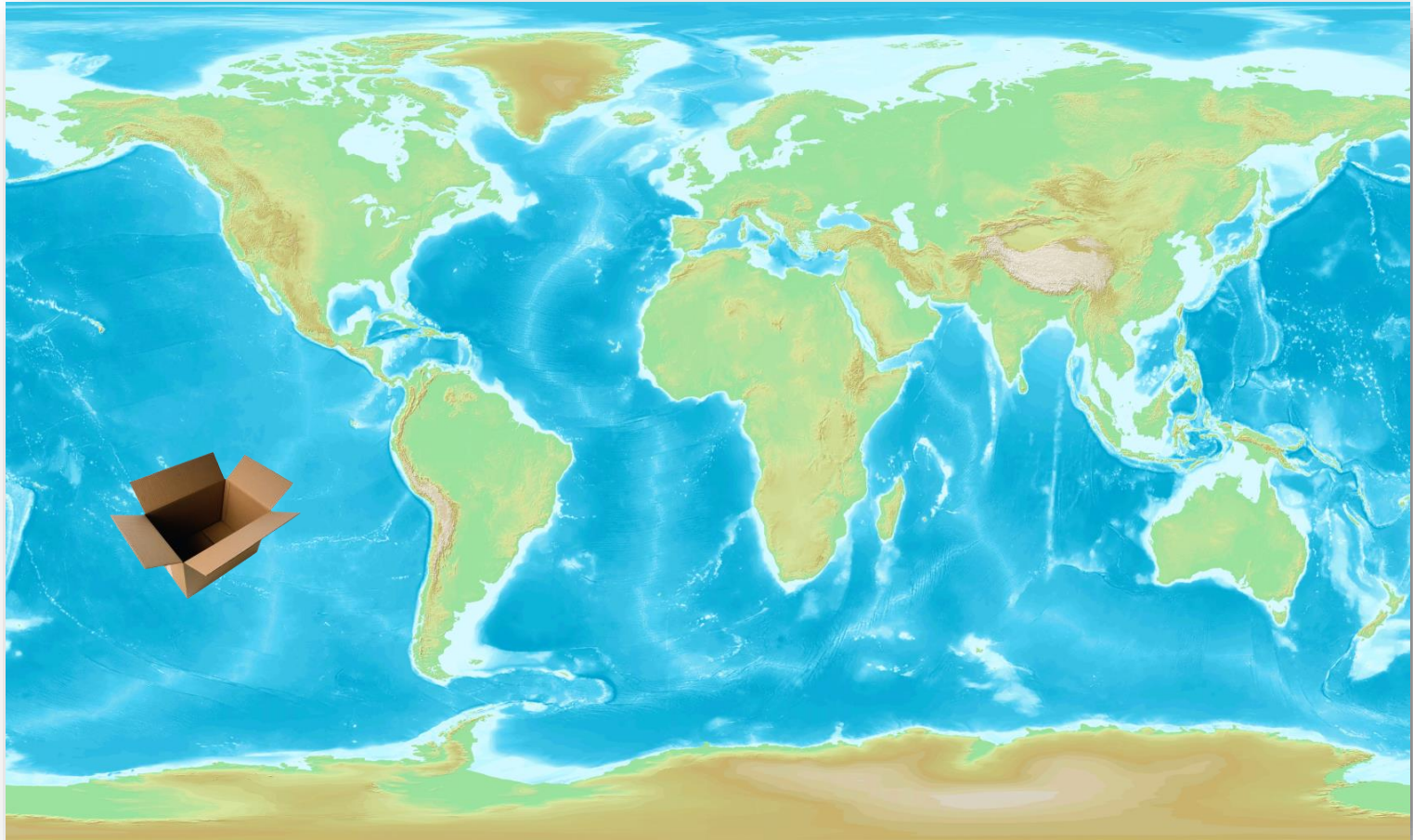
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- the problem
- the solution
- the engagement





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- I. **Growers/Processors/Traders:** establish a global map that shows which authorizations by crop/product/country need to be processed to achieve global harmonization



farmer / processor / trader

Code	Crop	Product	MRL	Frequency	Maximum MRL	Maximum MRL (EU)	No. of uses	Status	Country	MRL date	Comments
18	MAIZE	Allyl	40000	Intermediate	0	0	2014	Approved	Canada	2014-08-14	Approved CPE
19	MAIZE	Allyl	40000	Intermediate	0	0	2014	Approved	Canada	2014-08-14	Approved CPE
20	MAIZE	Allyl	40000	Intermediate	0	0	2014	Approved	Canada	2014-08-14	Approved CPE
21	MAIZE	Allyl	40000	Intermediate	0	0	2014	Approved	Canada	2014-08-14	Approved CPE
22	MAIZE	Allyl	40000	Intermediate	0	0	2014	Approved	Canada	2014-08-14	Approved CPE
23	MAIZE	Allyl	40000	Intermediate	0	0	2014	Approved	Canada	2014-08-14	Approved CPE

Third Global Minor Use Summit (GMUS-3)

October 1-4, 2017

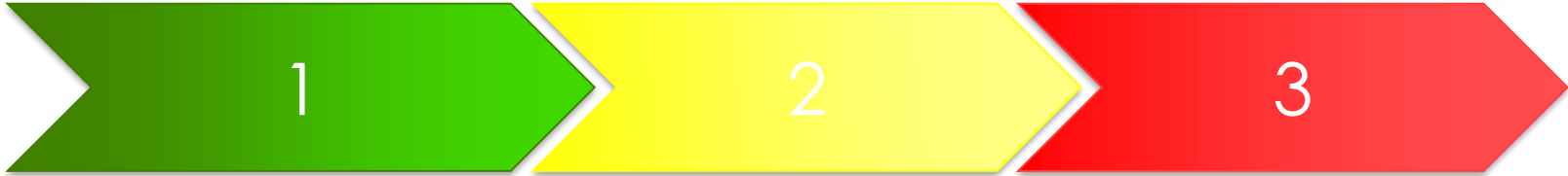
Fairmont The Queen Elizabeth
900 Rene Levesque Boulevard West
Montreal, Quebec, Canada H3B 4A5

REGISTRATION DEADLINE IS SEPTEMBER 4, 2017

A limited number of rooms have been secured at a special conference rate of \$249.00 CAD for single or double occupancy for a standard room, on a first-come, first-serve basis.

To reserve a room, please contact the Fairmont Queen Elizabeth directly: Toll Free: 1-800-441-1414 and mention the Block code: GMUS2017 or reserve online: <https://resweb.passkey.com/qa/gmusummitworkshop>. The guestroom cut-off date is August 31st, 2017.

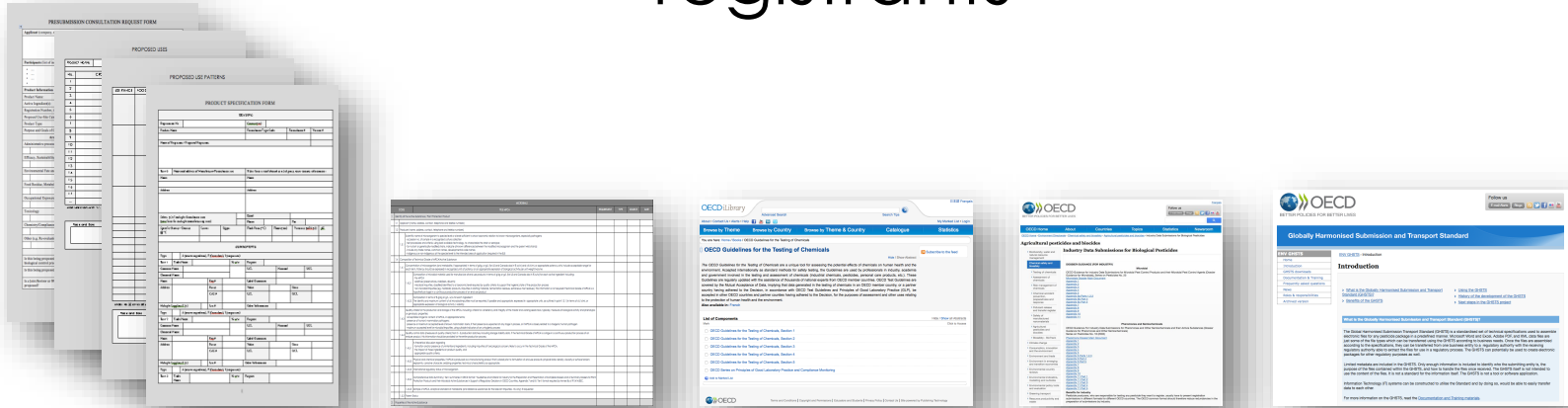
[Terms and conditions](#)



- I. **Growers/Processors/Traders:** establish a global map that shows which authorizations by crop/product/country need to be processed to achieve global harmonization
- II. **Registrants and Contract Research Organizations:** conduct a global presubmission consultation, build a global data package in cooperation with companies in other countries and allow regulators to communicate with each other



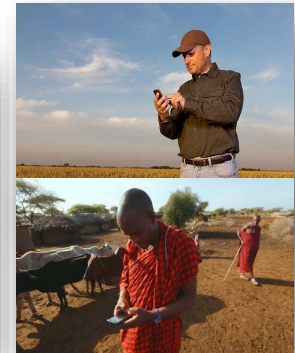
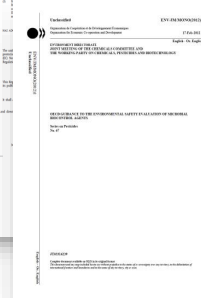
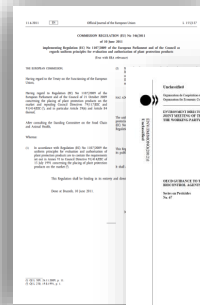
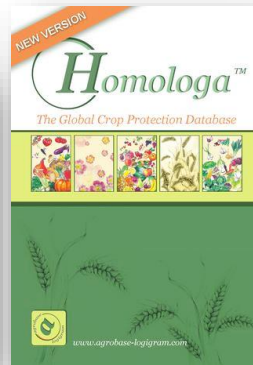
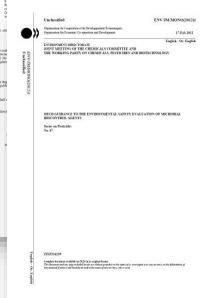
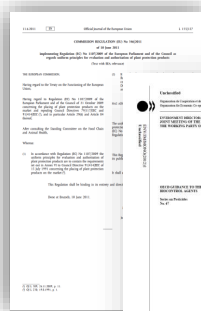
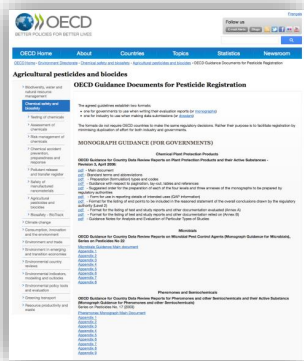
registrants



- I. **Growers/Processors/Traders:** establish a global map that shows which authorizations by crop/product/country need to be processed to achieve global harmonization
- II. **Registrants and Contract Research Organizations:** conduct a global presubmission consultation, build a global data package in cooperation with companies in other countries and allow regulators to communicate with each other
- III. **Regulators:** exchange review reports and communicate with each other to reach compatible decisions whenever identical decisions can not be reached



regulators






IDRG



