ONE World
ONE DOSSIER
ONE Review

IDRG

Imme Gerke – Global Regulatory Strategist

2017

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overview

- the problem
- the solution
- the engagement

IDRG

problems
farmers

registrants
products

crop x p ntry

authorities
regulations

IDRG

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

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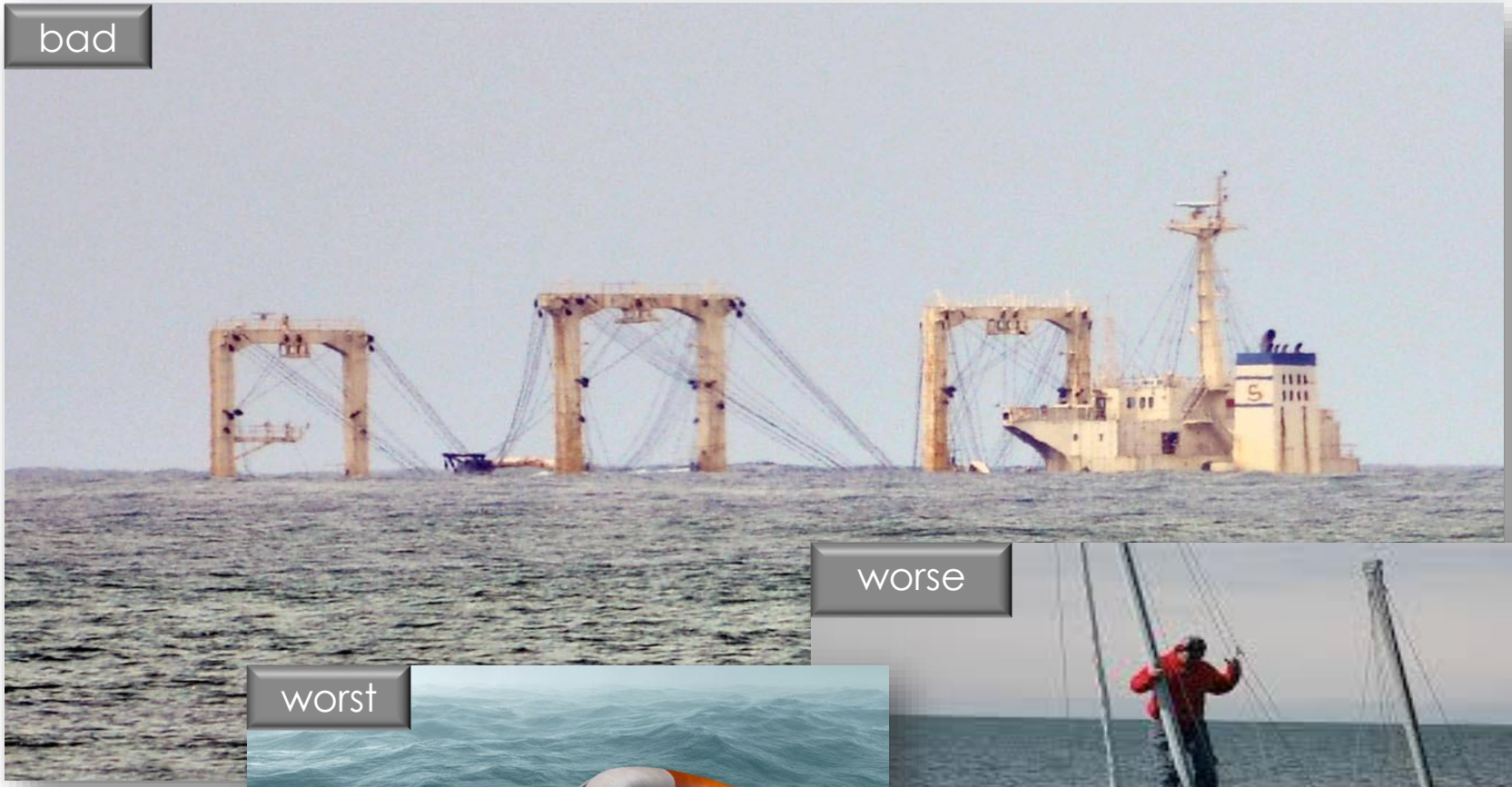

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INTERNATIONAL MARITIME ORGANIZATION

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

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

Worldwide, we grow over ...	10,000 crop species
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Countries require national authorizations ...	x 200 countries
That means worldwide ...	= 60,000,000 approvals

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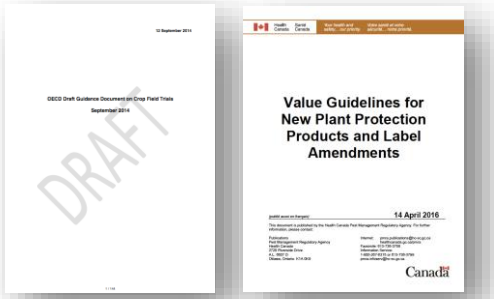
problem

- 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 ... x 3 products

200 countries require authorizations ... x 200 countries

That leads us to ... = ~~60,000,000~~ approvals

600,000

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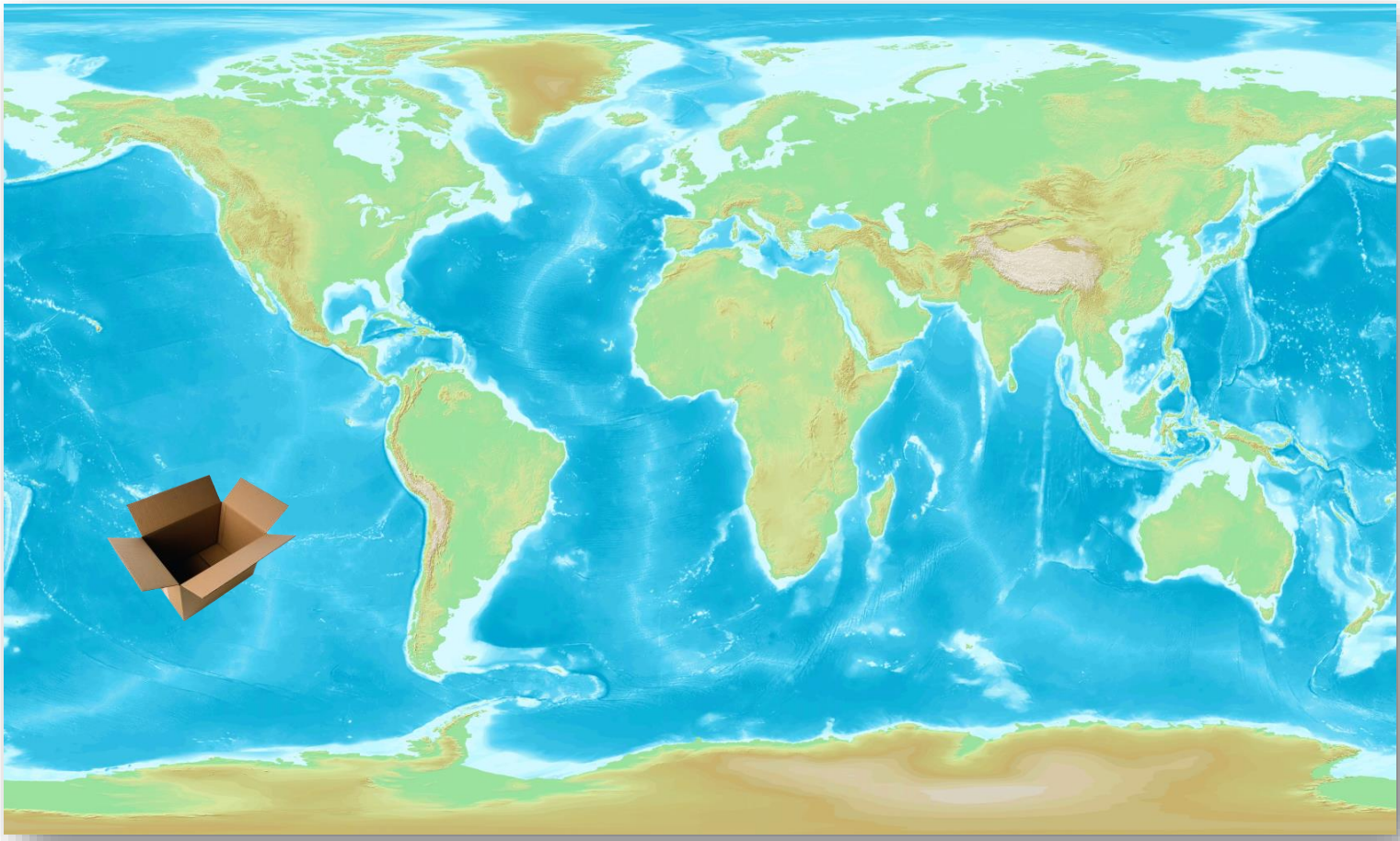

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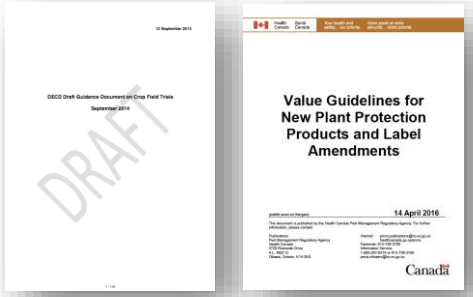
problem

- CODEX
- EU
- US
- CAN
- AUS
- JPN
- …



100 groups

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1

600,000

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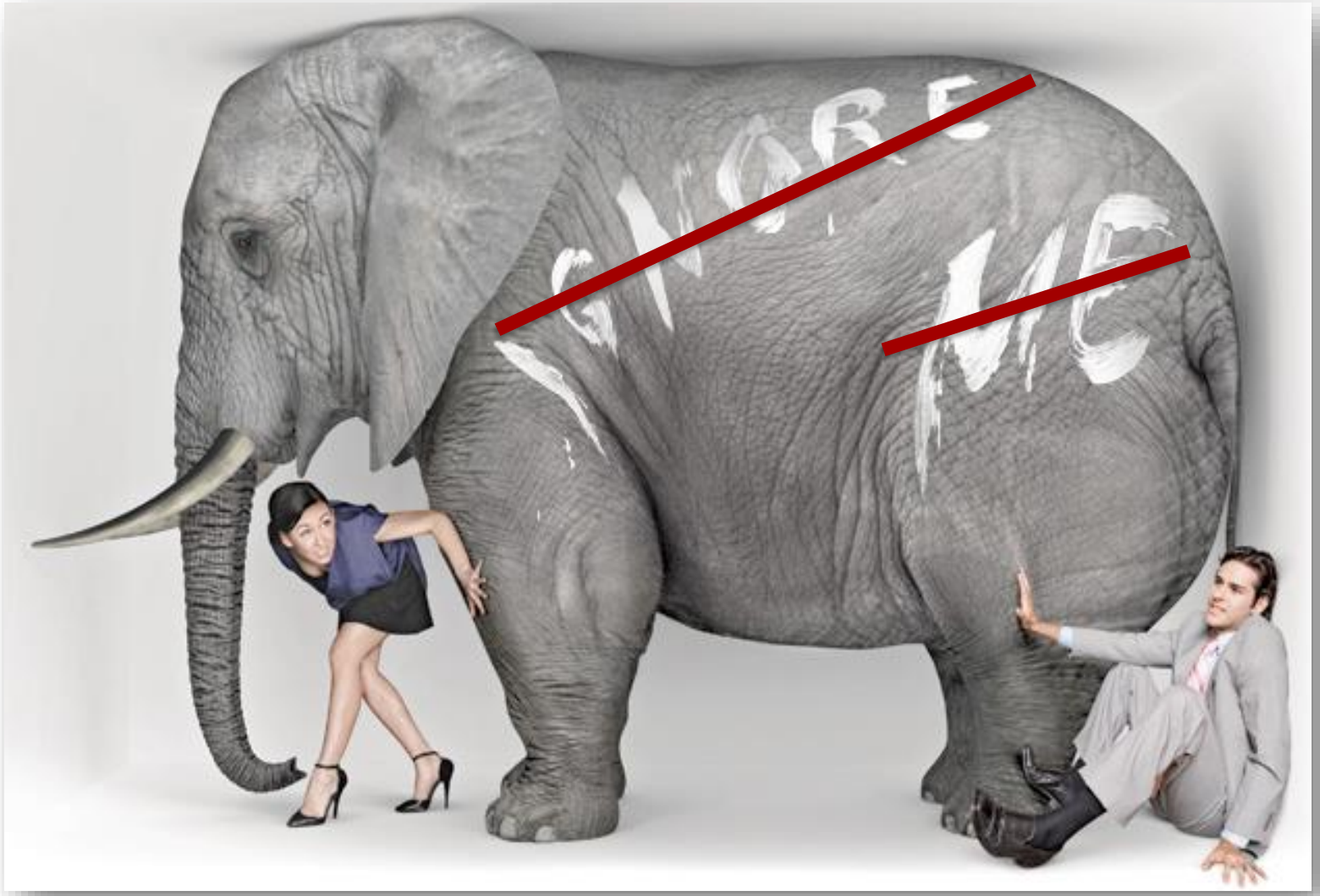

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Global Cooperation across Political Borders

among and between growers, industry and governments

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1. OECD dossier
2. OECD monograph
3. communication

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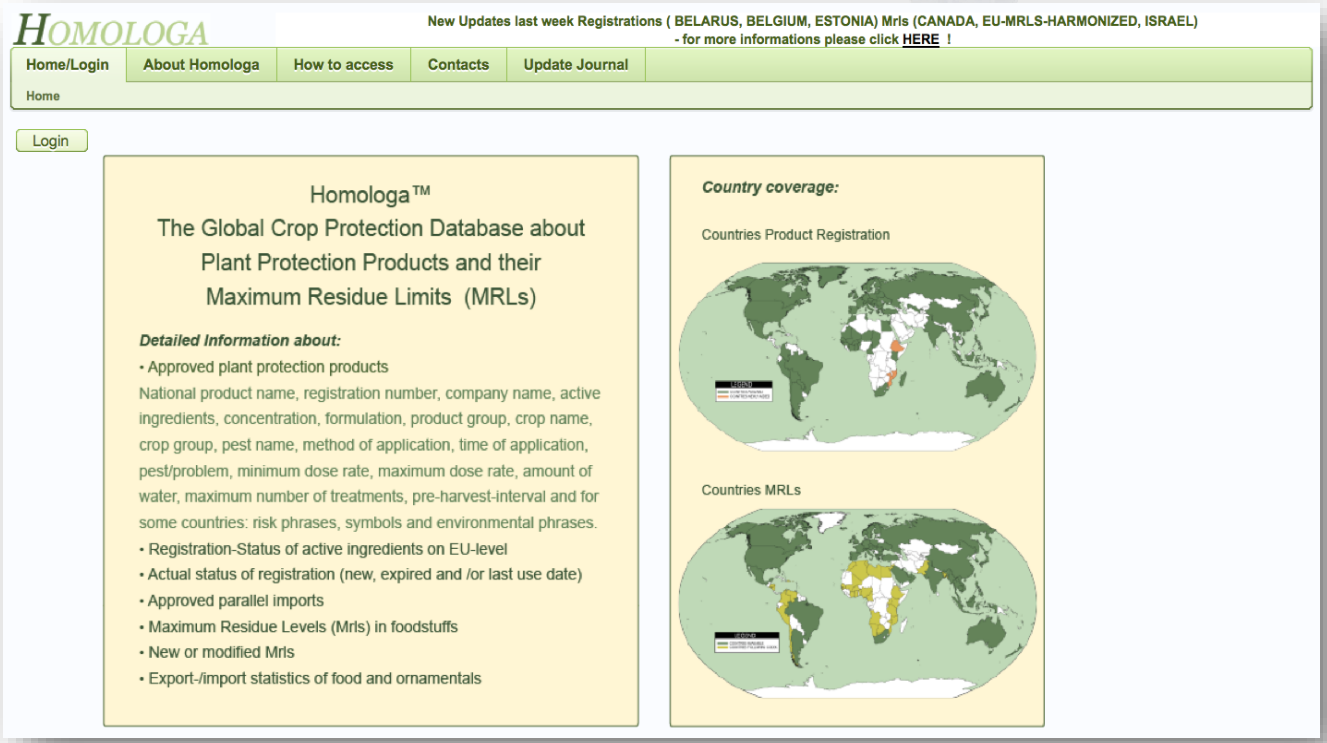
pest problems
farmers

registrants
products

- trade
- MRLs
- registrations



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exports (59 countries)

Export Country	Value in 000 euros	PCT value	Profile
ARGENTINA	120,736.35	01.30 %	IMPORT COUNTRY
AUSTRALIA	15,865.15	00.20 %	IMPORT COUNTRY
AUSTRIA	169,619.46	01.80 %	IMPORT COUNTRY
AZERBAIJAN	14,529.76	00.20 %	IMPORT COUNTRY
BELARUS	108,242.98	01.20 %	IMPORT COUNTRY
BELGIUM	193,772.99	02.10 %	IMPORT COUNTRY
BOSNIA-HERZEGOVENA	7,502.65	00.10 %	IMPORT COUNTRY
BRAZIL	62,163.99	00.70 %	IMPORT COUNTRY
BULGARIA	11,101.17	00.10 %	IMPORT COUNTRY
CANADA	74,509.79	00.80 %	IMPORT COUNTRY
CHILE	635,883.68	06.80 %	IMPORT COUNTRY
CHINA	1,443,562.89	15.40 %	IMPORT COUNTRY
CROATIA	14,615.97	00.20 %	IMPORT COUNTRY
CZECH REP.	32,494.12	00.30 %	IMPORT COUNTRY
DENMARK	51,416.42	00.50 %	IMPORT COUNTRY
EL SALVADOR	10,399.90	00.10 %	IMPORT COUNTRY
ESTONIA	11,545.39	00.10 %	IMPORT COUNTRY
FINLAND	12,829.73	00.10 %	IMPORT COUNTRY
FOR J REP MAC	17,487.84	00.20 %	IMPORT COUNTRY
FRANCE	618,969.53	06.60 %	IMPORT COUNTRY
GERMANY	309,791.05	03.30 %	IMPORT COUNTRY
GREECE	40,242.84	00.40 %	IMPORT COUNTRY
GUATEMALA	8,343.25	00.10 %	IMPORT COUNTRY
HONDURAS	14,201.24	00.20 %	IMPORT COUNTRY
HONGKONG	50,594.84	00.50 %	IMPORT COUNTRY
HUNGARY	74,395.07	00.80 %	IMPORT COUNTRY
INDIA	6,363.11	00.10 %	IMPORT COUNTRY
IRAN	123,722.00	01.30 %	IMPORT COUNTRY
IRELAND	69,854.52	00.70 %	IMPORT COUNTRY
ITALY	1,004,921.92	10.70 %	IMPORT COUNTRY
JAPAN	208,865.36	02.20 %	IMPORT COUNTRY
KOREA-SOUTH	130,436.69	01.40 %	IMPORT COUNTRY
LATVIA	7,033.77	00.10 %	IMPORT COUNTRY
LEBANON	11,064.29	00.10 %	IMPORT COUNTRY
LITHUANIA	123,344.44	01.30 %	IMPORT COUNTRY
MALAYSIA	5,325.11	00.10 %	IMPORT COUNTRY
MEXICO	6,266.13	00.10 %	IMPORT COUNTRY
MOLDOVA	48,069.23	00.50 %	IMPORT COUNTRY
NAMIBIA	25,247.42	00.30 %	IMPORT COUNTRY
NETHERLANDS	276,750.52	02.90 %	IMPORT COUNTRY
NEW ZEALAND	392,953.49	04.20 %	IMPORT COUNTRY
POLAND	557,710.96	05.90 %	IMPORT COUNTRY
PORTUGAL	30,005.18	00.30 %	IMPORT COUNTRY
ROMANIA	8,463.30	00.10 %	IMPORT COUNTRY
RUSSIAN FED.	13,469.03	00.10 %	IMPORT COUNTRY
SERBIA REP.	106,387.35	01.10 %	IMPORT COUNTRY
SINGAPORE	13,004.95	00.10 %	IMPORT COUNTRY
SLOVAKIA	16,304.96	00.20 %	IMPORT COUNTRY
SLOVENIA	22,713.35	00.20 %	IMPORT COUNTRY
SOUTH-AFRICA	366,898.30	03.90 %	IMPORT COUNTRY
SPAIN	127,851.74	01.40 %	IMPORT COUNTRY
SWEDEN	159,656.33	01.70 %	IMPORT COUNTRY
SWITZERLAND	5,367.60	00.10 %	IMPORT COUNTRY
THAILAND	33,567.89	00.40 %	IMPORT COUNTRY
TURKEY	110,465.46	01.20 %	IMPORT COUNTRY
U.KINGDOM	97,080.82	01.00 %	IMPORT COUNTRY
UKRAINE	97,898.45	01.00 %	IMPORT COUNTRY
USA	1,052,897.47	11.20 %	IMPORT COUNTRY
VIETNAM	9,211.81	00.10 %	IMPORT COUNTRY

imports (108 countries)

Registrations
61,624 entries
69 countries
28,638 products
14,743 mixes
4,835 companies
1,430 active substances
MRL differences up to 3 fold
122 do not require an MRL

Biopesticides
3,535 entries
61 countries
1,473 products
325 mixes
606 companies

Microbial Insecticides
1,168 entries
52 countries
429 products
60 mixes
308 companies

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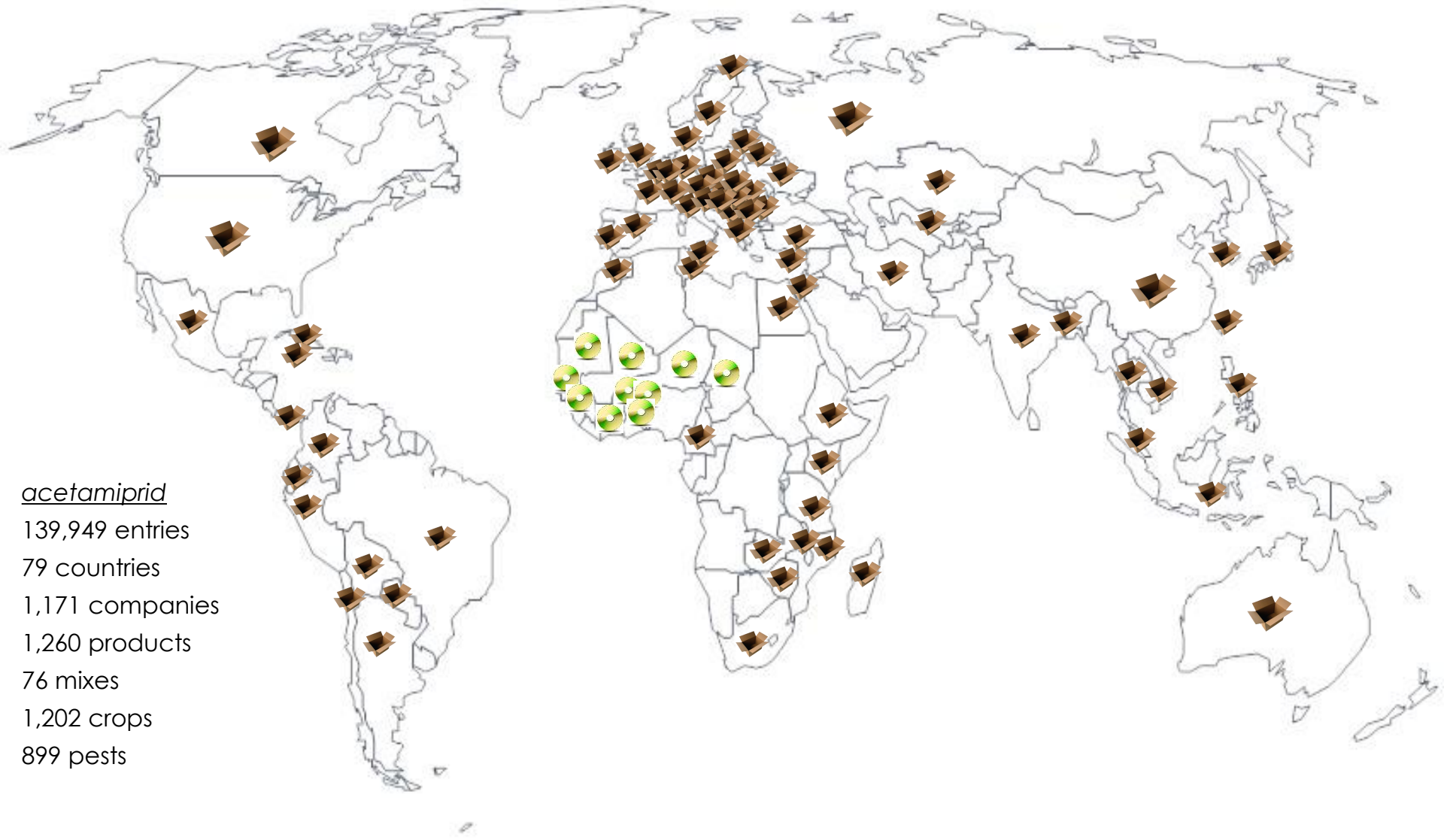
solution



acetamiprid

139,949 entries

79 countries

1,171 companies

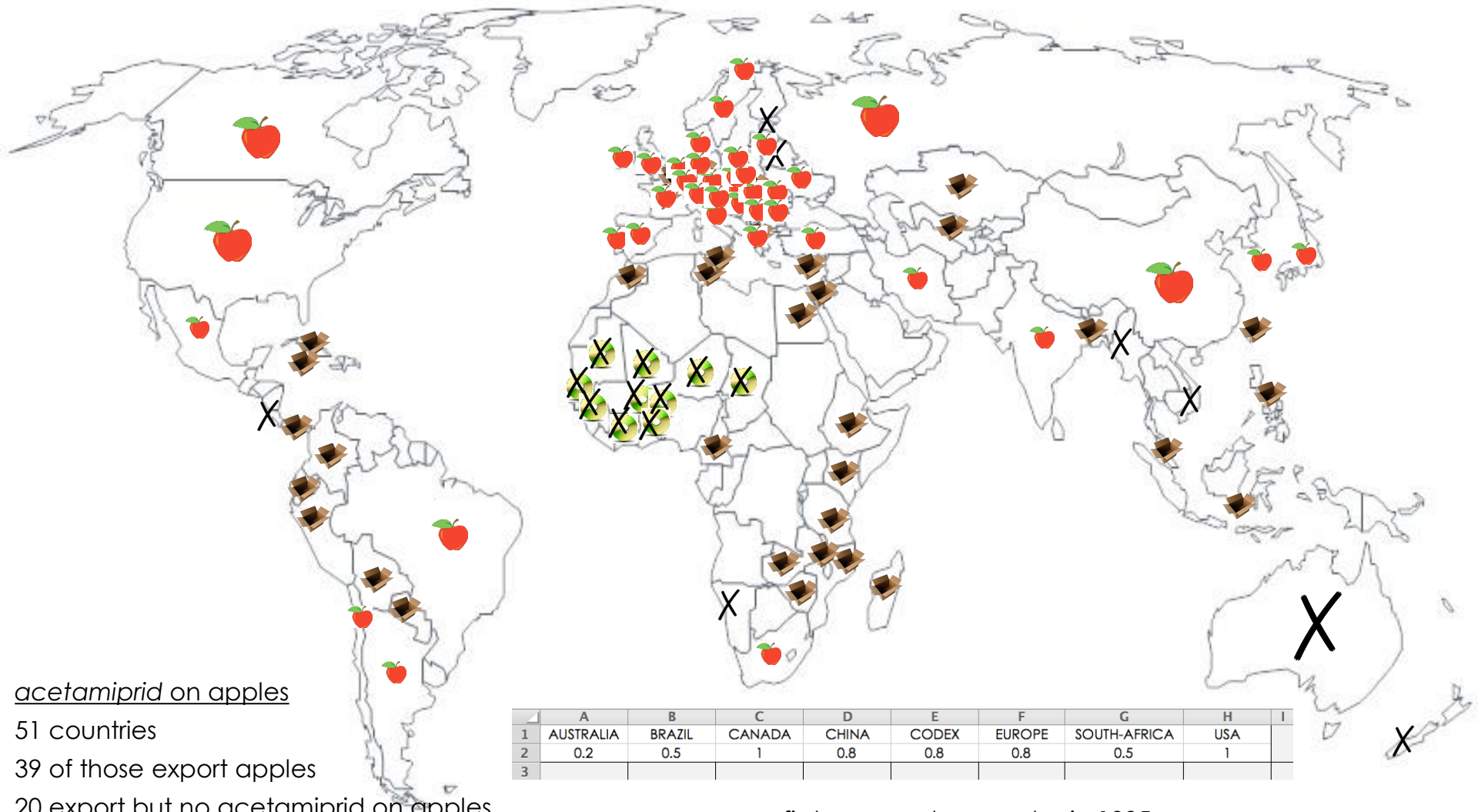
1,260 products

76 mixes

1,202 crops

899 pests

solution



	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									

<u>*acetamiprid* on apples</u>

51 countries

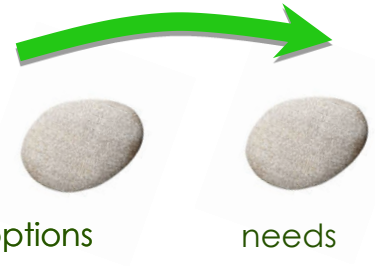
39 of those export apples

20 export but no acetamiprid on apples

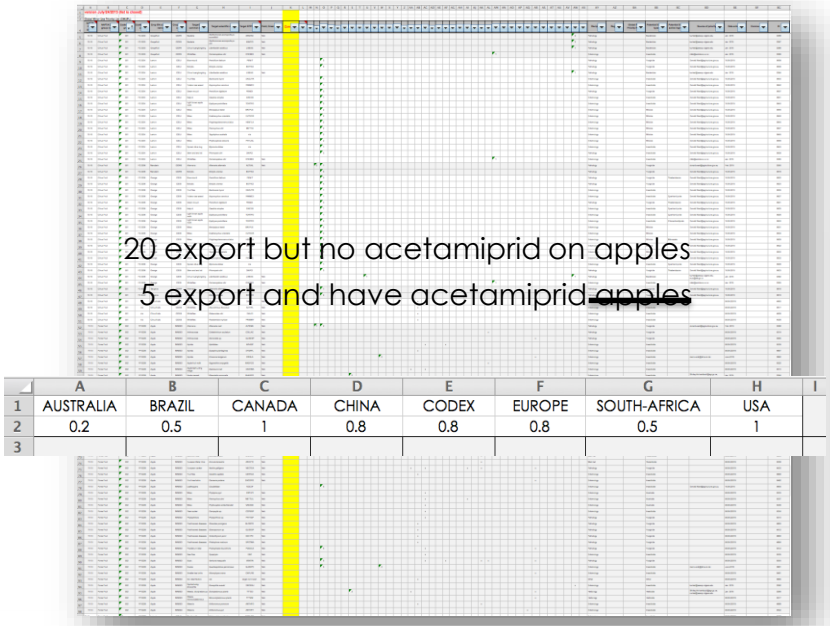
5 export and have acetamiprid but not on apples

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

problems
farmers



registrants
products

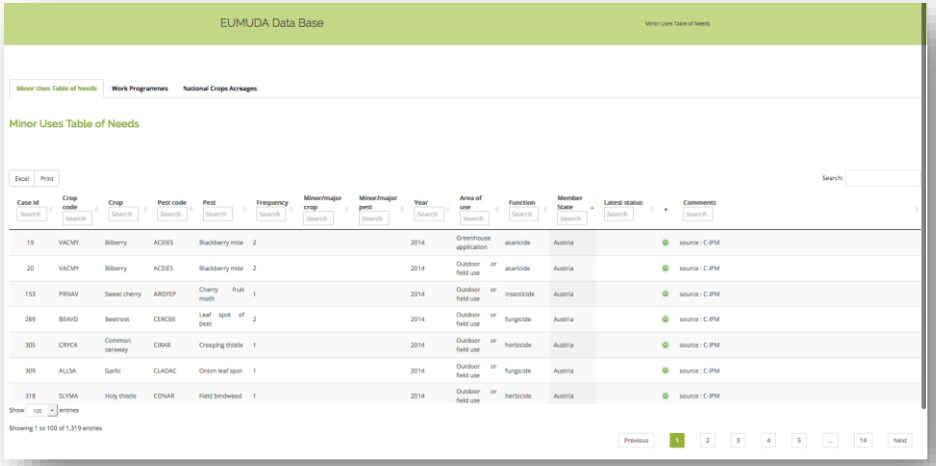


20 export but no acetamiprid on apples

5 export and have acetamiprid ~~apples~~

	A	B	C	D	E	F	G	H
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								

MinorUses



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

GMUPSM

- ✓ 2015
- ✧ 2017

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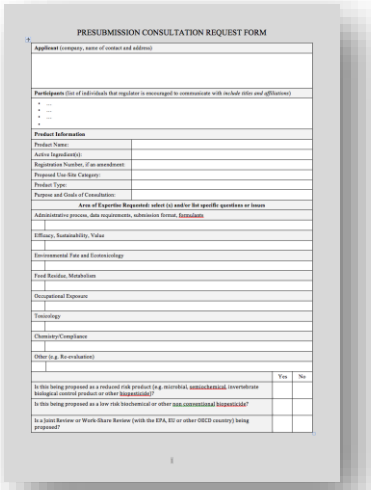
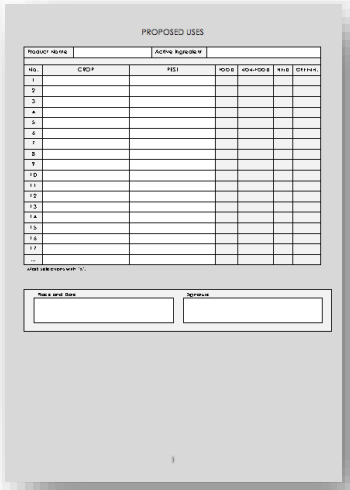
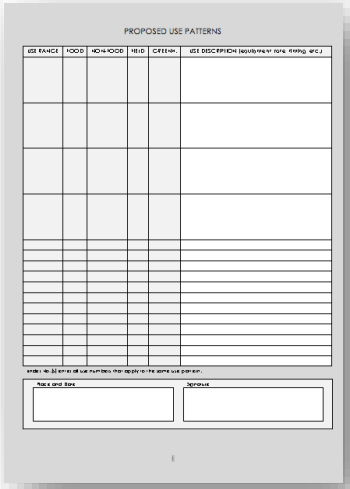
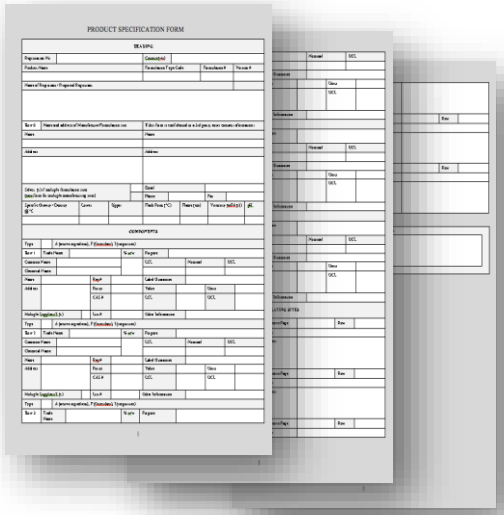

PRESUBMISSION CONSULTATION REQUEST FORM


PROPOSED USES


PROPOSED USE PATTERNS


PRODUCT SPECIFICATION FORM

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MICROBIALS							
CODE			TITLE MPCA	REQUIREMENT	TYPE	SOURCE	DATE
1	Identity 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 MPCA/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 MPCA · 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 MPCA 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 MPCA, 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 MPCA, 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 MPCA 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 MPCA is a stage in a continuous production process of an enduse 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 MPCA, · the impact of these ingredients on product quality, and · appropriate quality criteria.				
		1.4.5.2	Physical and chemical properties, if MPCA is produced as a manufacturing product that is stored prior to formulation of end-use products: physical state; density; viscosity or surface tension; explosivity, corrosive 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 8 / Tier II format required by Annex IIb of 91/414/EEC.				
		1.4.5.5	Sample of MPCA, 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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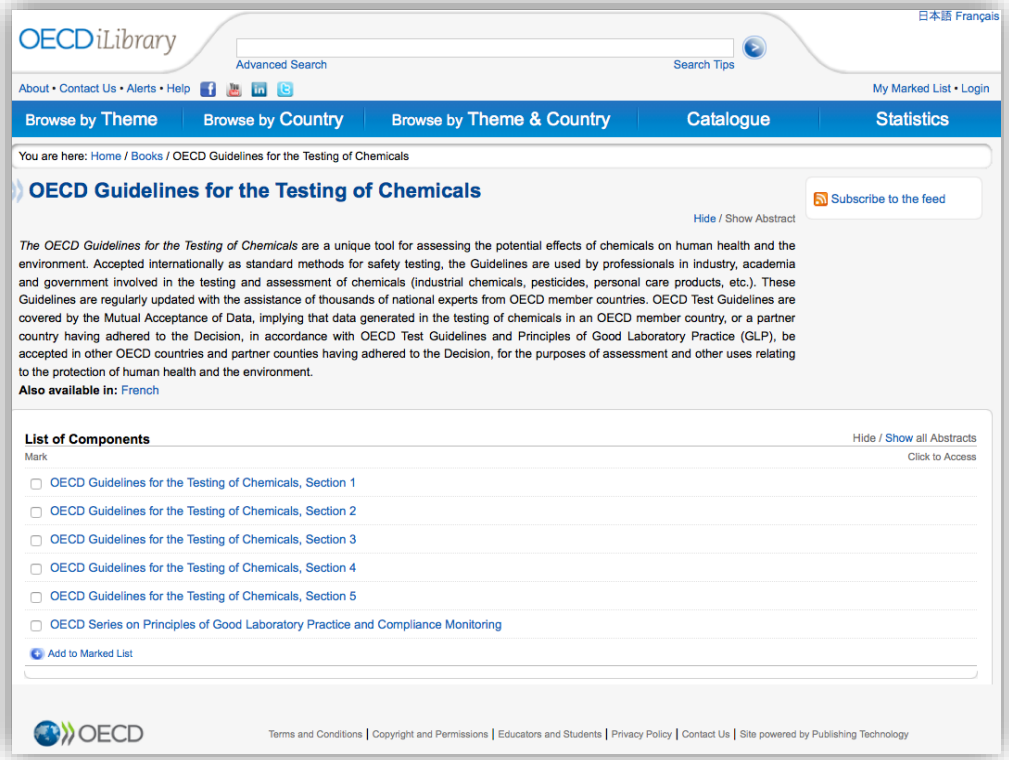

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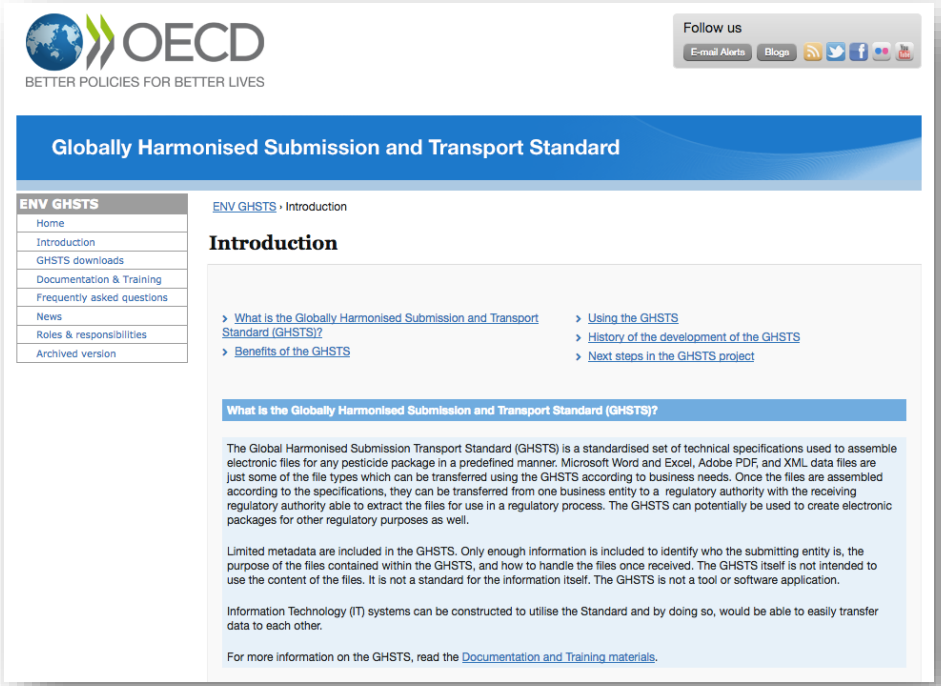

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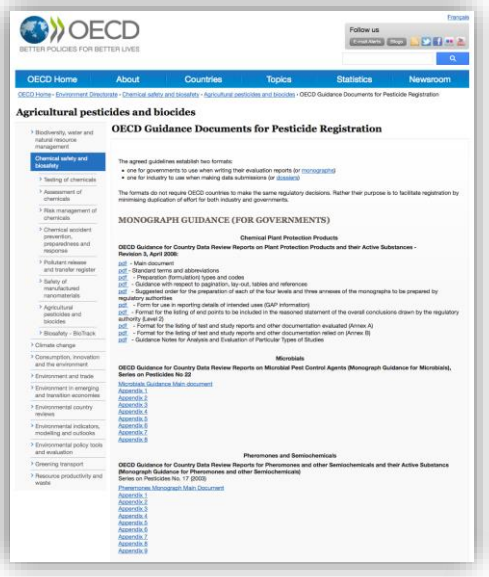

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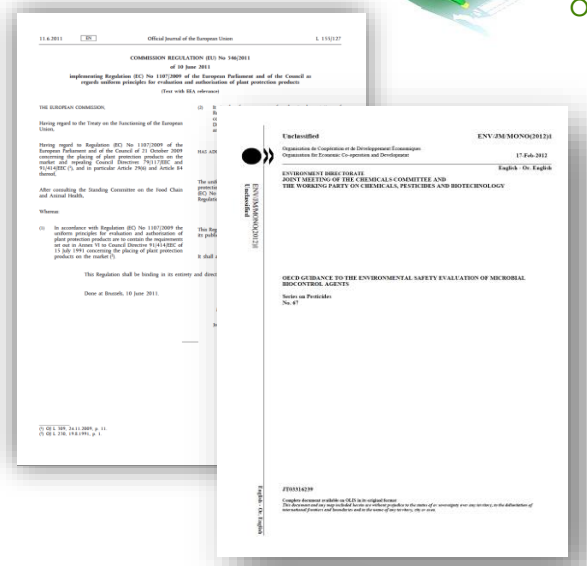

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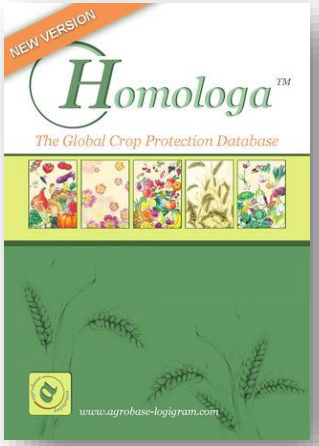

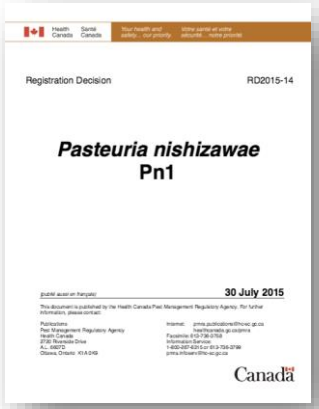

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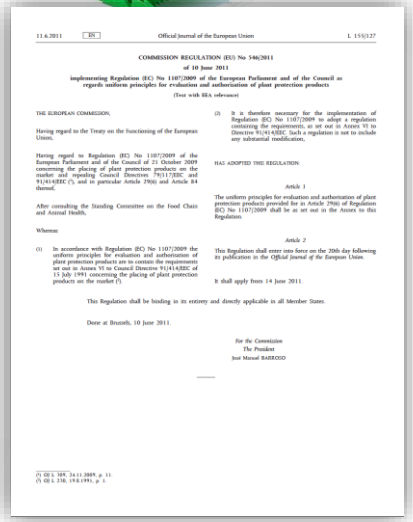

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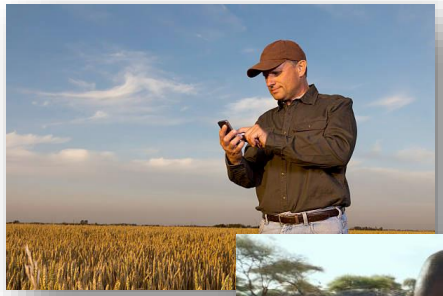

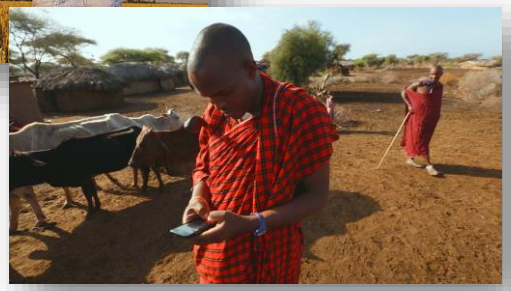

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- the solution
- the engagement

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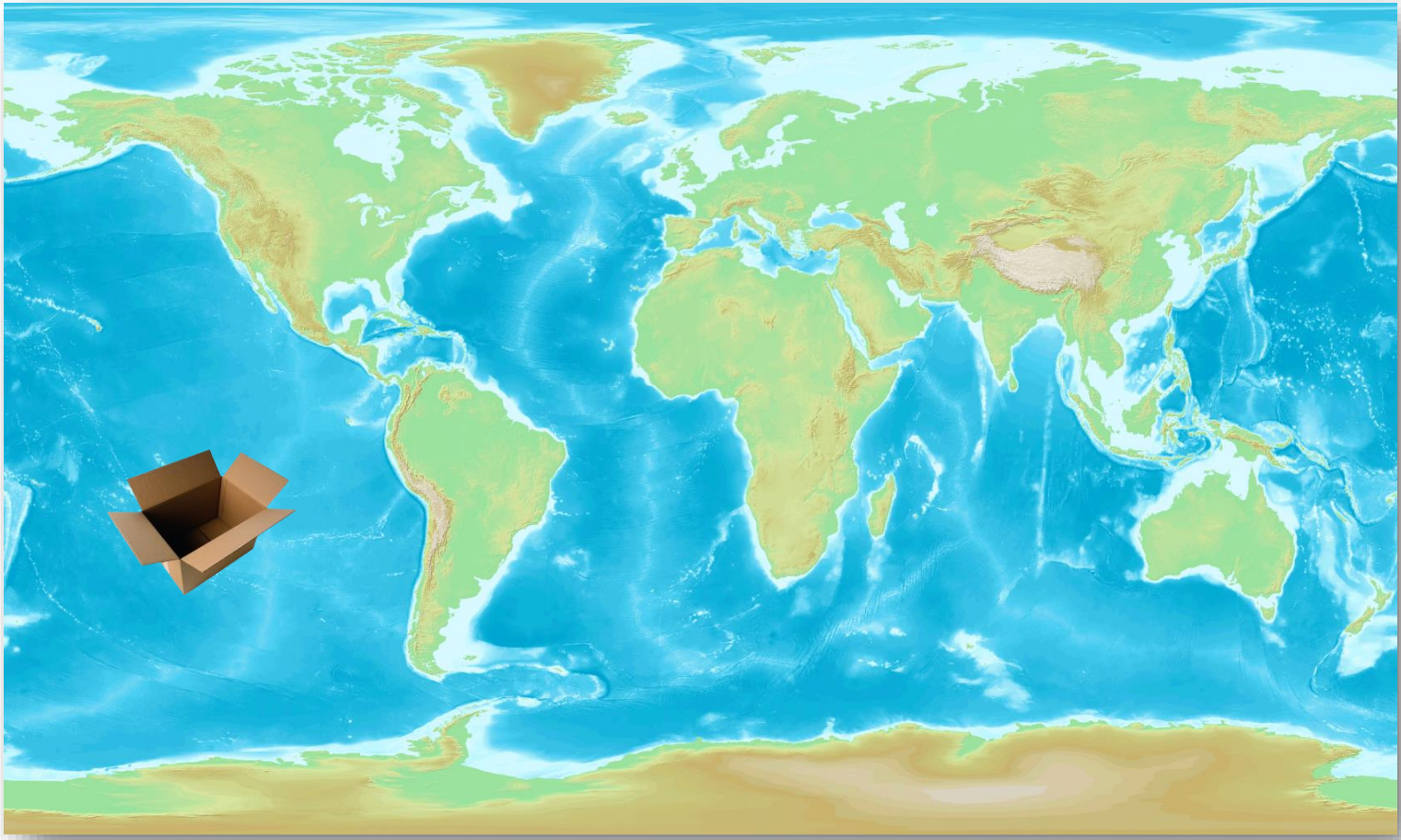

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risk mitigation

regulatory decision

national label legalization

Homologa™

OECD 50
BETTER POLICIES FOR BETTER LIVES

GMUS-3
Third Global Minor Use Summit
Fairmont Queen Elizabeth Hotel
Montreal, Quebec, Canada

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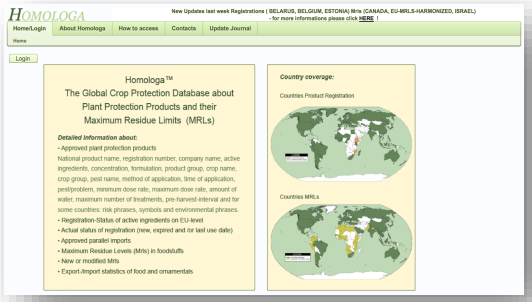
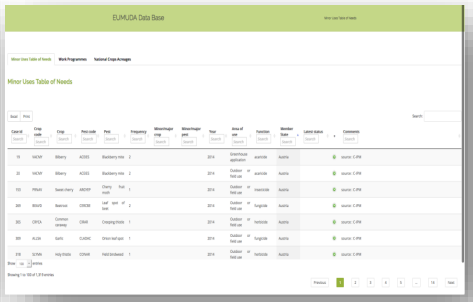
IDRG

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

IDRG

farmer / processor / trader





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IDRG

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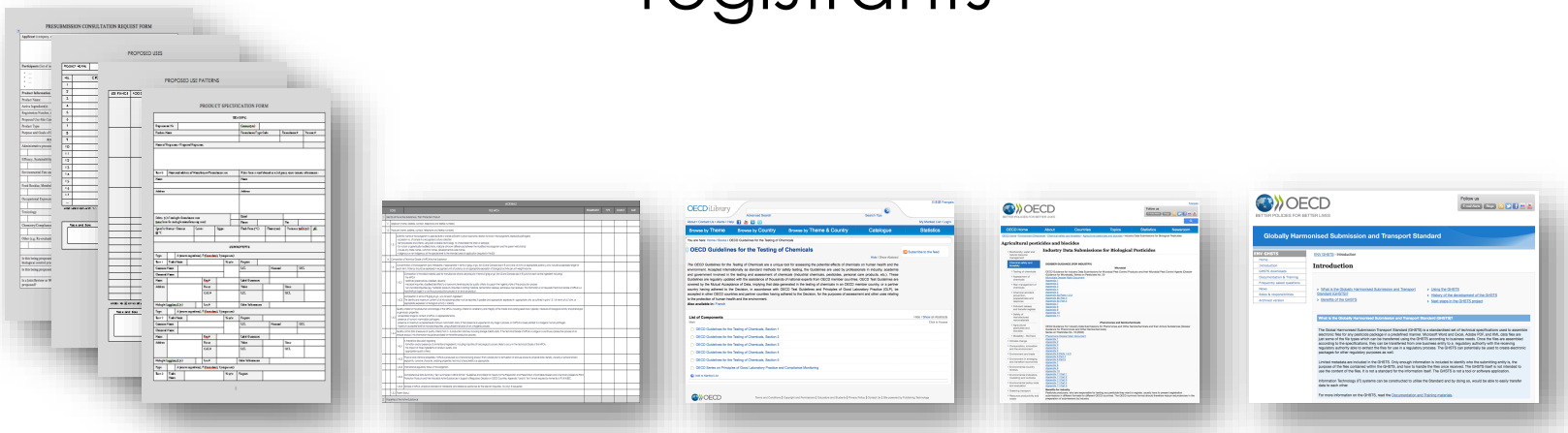
II. Registrants and Contract Research Organizations: conduct a global presubmission consultation, build a global data package in cooperation with companies in other countries and allow regulators to communicate with each other

IDRG

registrants



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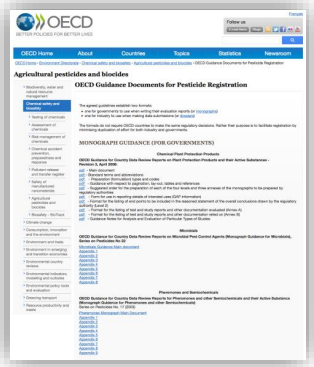
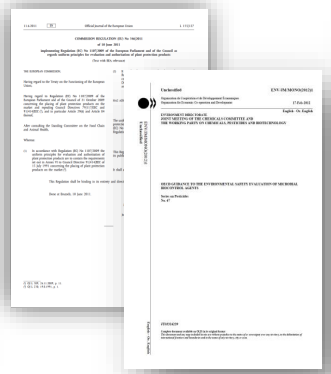
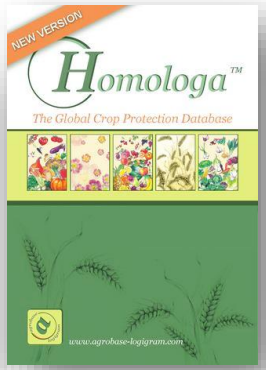
III. Regulators: exchange review reports and communicate with each other to reach compatible decisions whenever identical decisions can not be reached

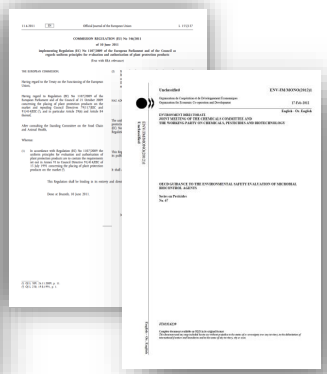
IDRG

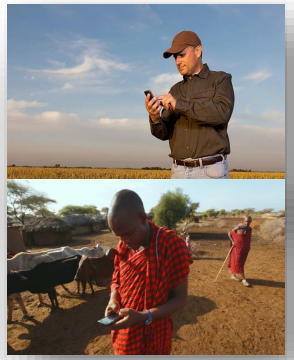
regulators











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