

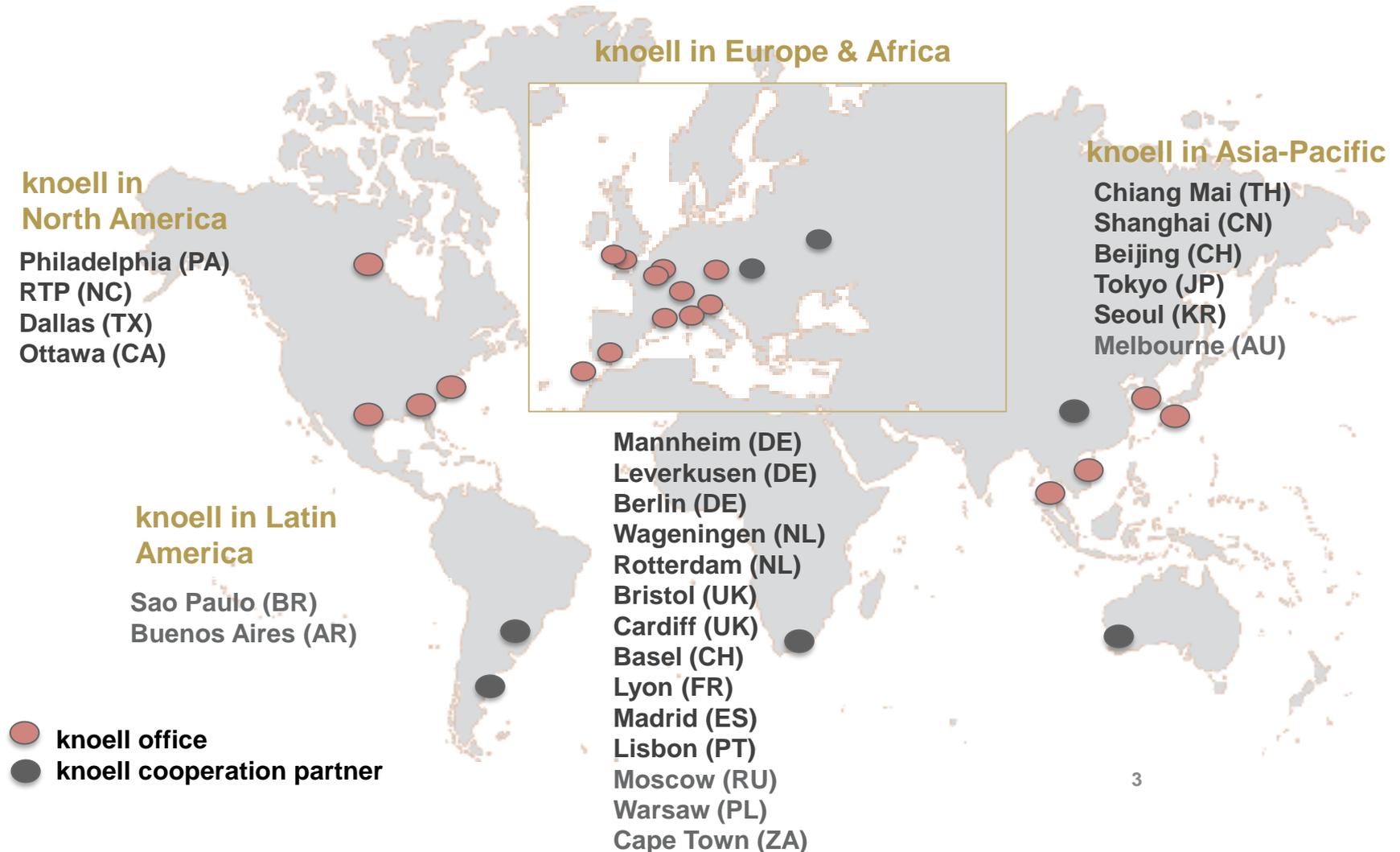
About knoell

- ▶ Independent service provider for regulatory sciences and registration for more than 20 years;
- ▶ Core business: **regulatory affairs, risk assessment, dossiers, product registration**
- ▶ Operating in different regulatory areas (plant protection and nutrition, import tolerance/MRLs, biocides, industrial chemicals/REACH, cosmetics, food and feed contact materials, medical devices, veterinary medicines);
- ▶ Privately owned company and no intentions to go public;
- ▶ Global services throughout our own companies (>550 employees) and an extensive network of cooperation partners in several countries.

The knoell network

> 550 employees

19 offices: 11 in Europe, 4 in Asia and 4 in America



Worldwide Regulatory Agro Services

SERVICE	Europe	Asia	Africa	Latin America	North America
Agrochemicals	+	+	+	+	+
Import Tolerances/ MRL	+	+	+	+	+
Biopesticides	+	+	+	+	+
Fertilizers, Biostimulants	+	+			+
Study management and monitoring	+	+			+
Regulatory Strategy	+	+	+	+	+
Laboratory Services					+

Disclaimer

Certain views and opinions expressed in this presentation are those of the author and do not necessarily reflect the views of Dr. Knoell Consult GmbH, a knoell company.

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Basel, 24th October 2017

Outline

**Data Package for
Regulatory Approvals**

**Regulatory Process and
Policy Making**

**Science and Regulatory
Science**

Risk Perception

Data Package for Regulatory Approvals



Data package: the case for water

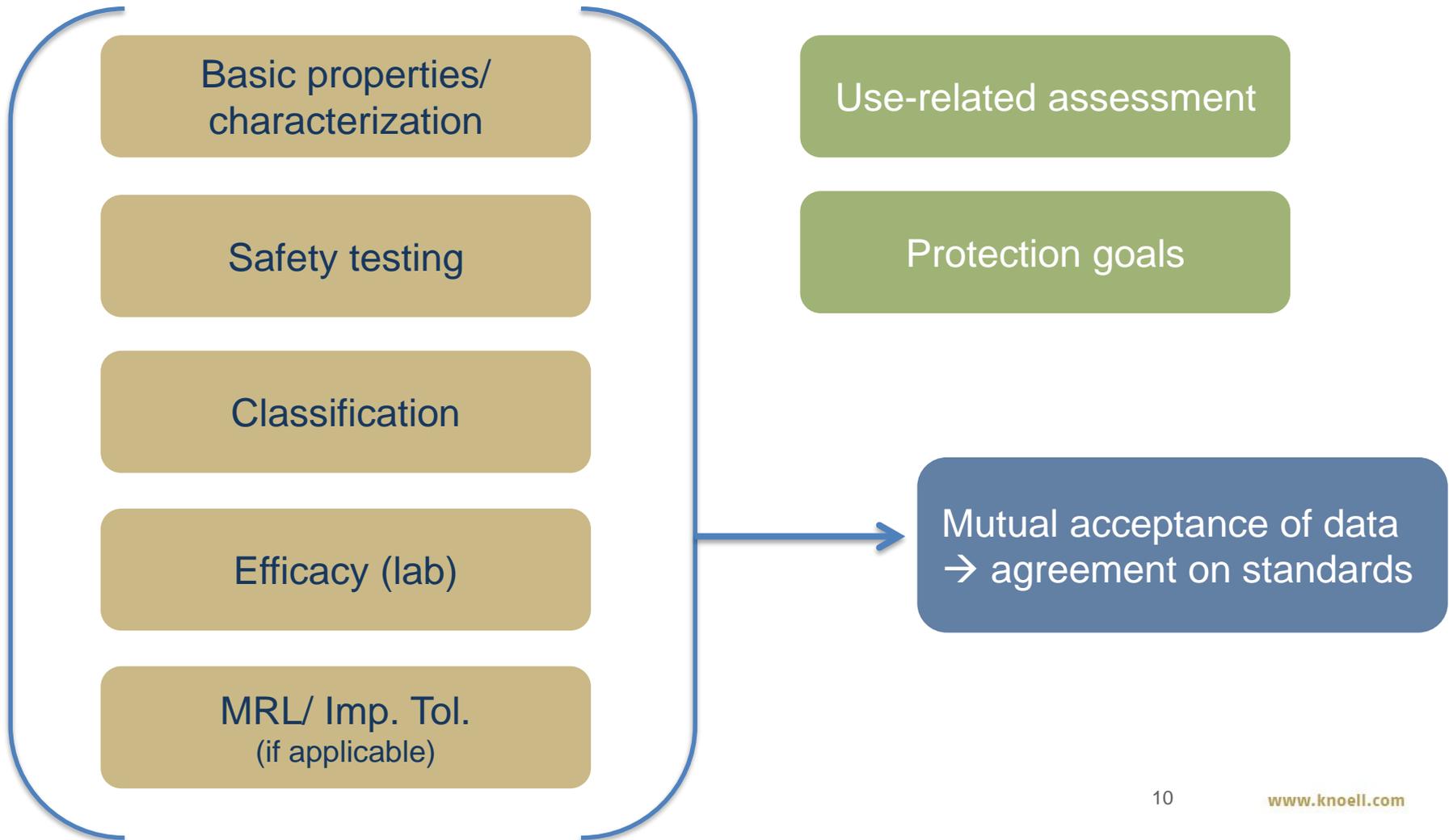


Data package: the case for the rest

	EU	USA	China	Brazil	Russia
Population (millions)	510	313	1,351	199	143
Area (km ²)	4,300,000	9,800,000	9,500,000	8,500,000	17,100,000
Density /km ²	115	34	141	24	8
Water (%)	3.1	6.8	0.3	0.7	13 ^(*)
Cultivated land (%)	30%	12%	16%	8%	7%

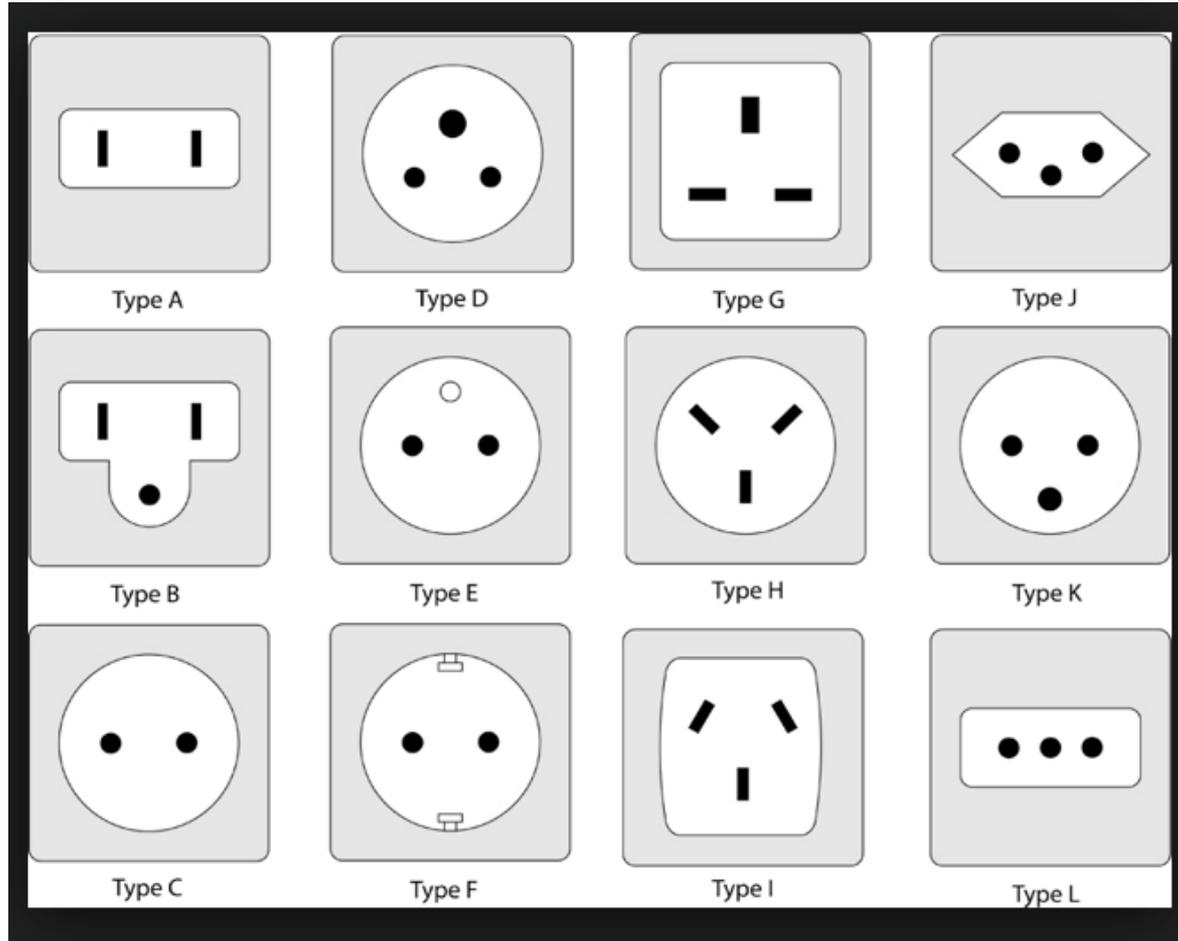
(*) including swamps

Data package



“This was another of our fears: that Life wouldn't turn out to be like Literature.”

Julian Barnes, *The Sense of an Ending*



Key messages

- **Data requirements** should be fit for purpose;
- **Data quality standards** need broader agreement, above country/region if we aim at mutual acceptance of data;
- **More dialogue** is needed to reach above-country agreements on data and trust-building regarding (already) performed assessments;
- **New technologies** should be subject to Risk-Assessment but taking into account their specificity because they cannot obey to laws not written for them.



Source: The New Yorker, 10th November 2014, page 62

Regulatory Science versus Science – the definitions

Biopesticide

(the definition problem)

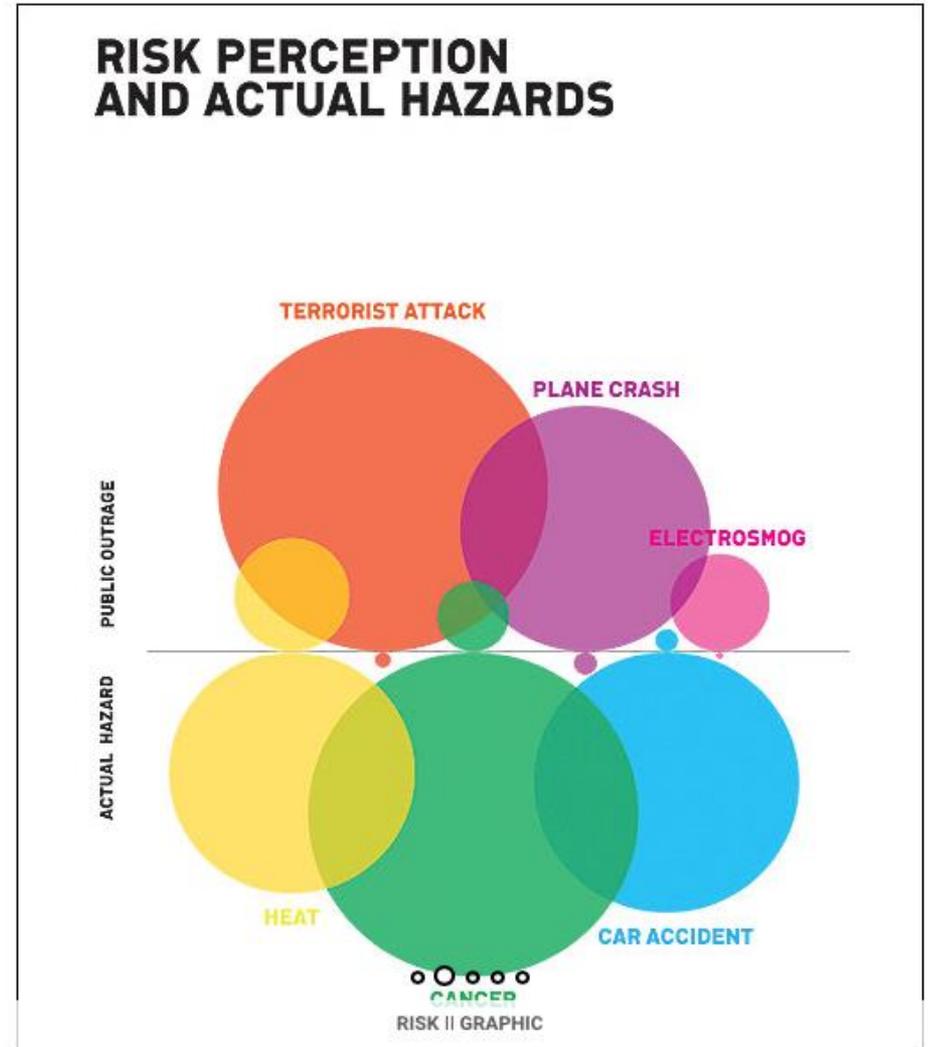
The term 'biopesticide', a contraction of the words biological and pesticide, has come to mean many things in different geographies, even though the term has historically been associated with biological control - and by implication - the manipulation of living organisms.

Regulatory positions in different regions/countries has been influenced by public perceptions of the use of plant protection products, agriculture practices and food safety-related issues.

Risk Perception: the arts

The discrepancy between the scenarios that we fear and those that are seriously harmful to us.

Susanna Hertrich's works investigate the liminal space between the visible world and those things that normally remain hidden



Regulatory Science

(definition)

“The acquisition and analysis of data sufficient to inform decision making pertinent to the approval of safe and effective therapeutics, devices and cosmetics and ensuring the safety and nutritional value of the food supply.”

Garret FitzGerald, University of Pennsylvania School of Medicine (Fitzgerald, 2010)

“Regulatory science is a unique application of science, at all levels, to the societal decision process.”

Alan Moghissi, President, Institute for Regulatory Science (The Scientist, 2009)

“Regulatory Science relates the regulatory and legal requirements of product development to the scientific research needed to ensure the safety and efficacy of those products.”

Academic website for the University of Southern California School of Pharmacy (USC, 2010)

Science

(definition)

Could not find a consistent one, apologies for that!

“Science is a systematic enterprise that builds and organizes knowledge in the form of testable explanations and predictions about the universe.”

Regulatory Science vs Science

- ▶ Regulatory science is one step behind; **science has the freedom of no accountability.**
- ▶ Regulatory science has broader impact: decisions have an impact on agriculture productivity, society, farmers, consumers, food safety, food security, environmental and health protection, business and market-access.
- ▶ Regulatory agreements, particularly across borders, take much more time than a peer-review process of a scientific article.
- ▶ **Quality standards for mutual acceptance of data** are still being agreed upon.

Regulatory Processes and Policy

- the political agenda, the public, international trade

The agenda



Food and Agriculture Organization
of the United Nations



World Health
Organization



WORLD TRADE
ORGANIZATION



OECD

BETTER POLICIES FOR BETTER LIVES

ROTTERDAM
CONVENTION

Share Responsibility

STOCKHOLM
CONVENTION

Protecting human health and the environment
from persistent organic pollutants

BASEL CONVENTION

BASEL
CONVENTION

Controlling transboundary movements
of hazardous wastes and their disposal

Convention on
Biological Diversity

Nagoya Protocol

Cartagena
Protocol on
Biosafety

The public

CNN Health » Mad Cow Disease Fast Facts

Mad Cow Disease Fast Facts

CNN Library
Updated 1407 GMT (2207 HKT) June 22, 2016



Cancer row over GM foods as study says it did THIS to rats... and can cause organ damage and early death in humans

- French team claim bestselling brand of GM corn caused tumours and multiple organ damage
- Leading scientists have questioned the study and its results, claiming it has 'no value'

By SEAN POULTER FOR THE DAILY MAIL
PUBLISHED: 12:21 BST 19 September 2012 | UPDATED: 08:19 BST 20 September 2012



The French team has released shocking images of tumours in mice caused by exclusively eating GM corn. However, the research has been criticised as being of 'no value' by other scientists

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Glyphosate weedkiller, previously linked to cancer, judged safe by EU watchdog

Chemical used in the best-selling Roundup herbicide is cleared for public use following an EU licensing battle due to potential health risks



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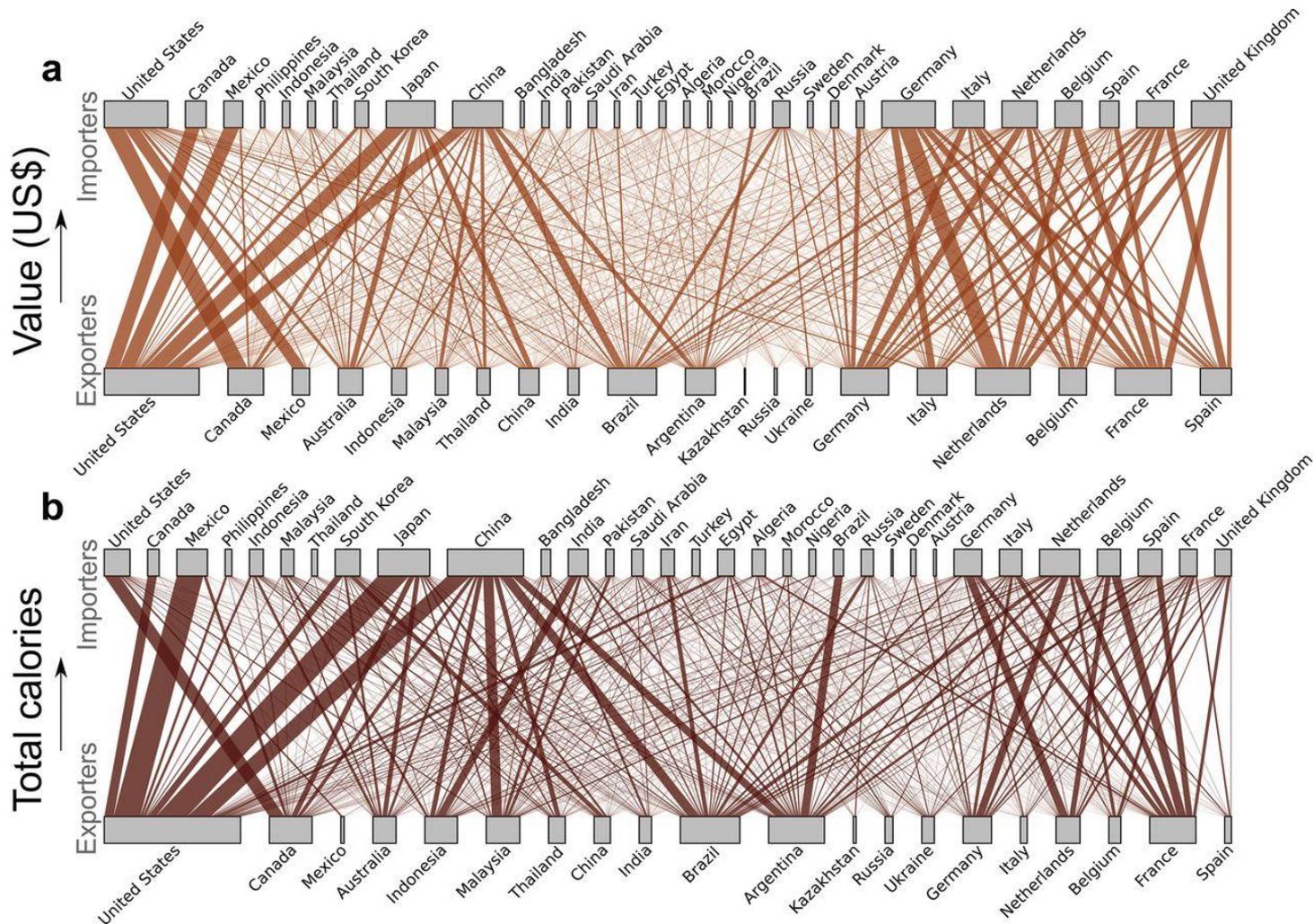
Across The Border by Laura He

China's new baby milk scandal to trigger tighter cross-border e-commerce rules

PUBLISHED : Thursday, 07 April, 2016, 4:38pm
UPDATED : Friday, 08 April, 2016, 12:50pm



International trade of crops – tolerances/MRLs



Graham K. MacDonald et al. BioScience 2015;65:275-289

The global agricultural trade for major importing and exporting countries in terms of (a) monetary value and (b) calories.

Regulatory Processes and Policy

- ▶ Provision for biopesticides definition, per category, in the regulation, i.e. regulatory figure clearly listed;
- ▶ Special regulatory process for approvals/authorisation of biopesticides.

- ▶ Priority to perform the assessment of biopesticides;
- ▶ Reduced fees;
- ▶ Less regulatory hurdles for maintaining registration (e.g. reviews, data calls, etc.).

Brazil – types of registrations



- ▶ Experimental Use Permits (EUP/RET)
- ▶ Technical material (new a.i.), proprietary data
- ▶ Formulated product, proprietary data
- ▶ Technical material by equivalence (TC)
- ▶ Formulated product by equivalence (FP)
- ▶ Minor Crops
- ▶ **Biological, Microbiological, Organic**
- ▶ **Semiochemical**
- ▶ **Atypical (copper, sulphur)**

Brazil – types of registrations



Type of registration	Approvals 2015	Approvals 2016	Evaluations pending	Estimated time (years)
Technical Material (new A.I.)	2	2	45	Not available
Technical Equivalence	43	160	1010	8.5
Formulation, new	15	28	1438	7
Formulation by equivalence	50	47		5
Biological/organic	29	38	5	1-2
Total	139	275		

China – types of registrations



▶ New registration of :

- ▶ Chemical pesticide
- ▶ **Bio-chemical pesticide**
- ▶ **Microbial pesticide**
- ▶ **Botanical pesticide**
- ▶ Pesticide for hygienic use
(non-crop)

▶ Registration amendment:

- ▶ Expanding application scope
(e.g. crop, control target, etc.)
- ▶ Change of application method
- ▶ Change of application rate

New regulations China: Pesticide Registration Management Measures (MOA Order 2017 No.3, entry into force on August 1st, 2017) and **Data Requirements for Pesticide Registration** (MOA Announcement No.2569, will enter into force on **November 1st, 2017**)



European Union – types of registrations

Complex framework: No official definition, but different “categories” when you look at **supplementary law** (guidance documents) for registration:

- Semiochemicals/Pheromones
- Microbials (living organisms) – also included in secondary law (Regulation)
- Botanicals/Plant Extracts
- *(Macro-organisms are excluded from plant protection regulation 1107/2009)*

Data requirements (secondary law)*:

- Chemicals
- Microbials

Regulatory process (secondary law):

- No difference for biopesticides (e.g. no official fast-track procedure) but for Basic substances and **Low-Risk active substances**.

Risk/Uses (secondary law):

- Active substances (Safeners and Synergists)
- Low-risk active substances
- Basic Substances

But the low-risk figure is not restricted to naturally occurring substances, but also includes synthetic molecules.

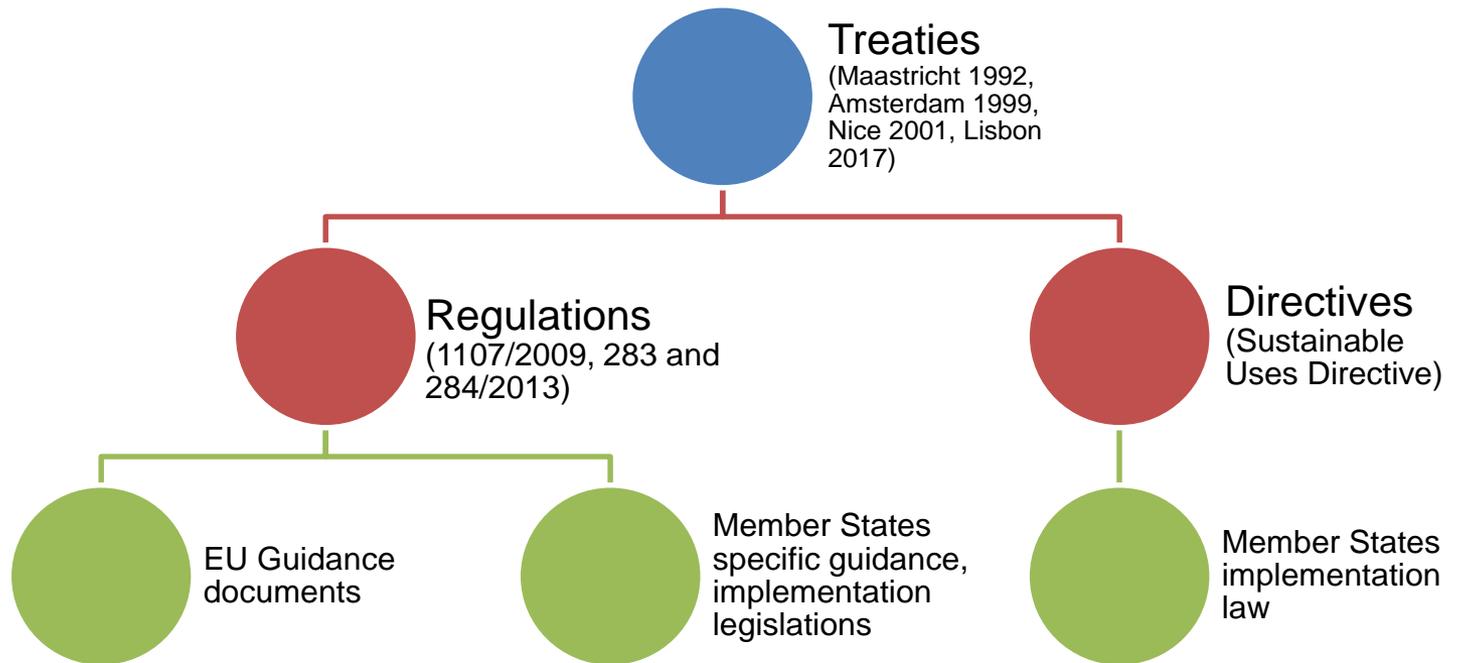
* Only in Regulation (EC) 283/2013 and Reg (EC) 284/2013 (data requirements) are provisions for microbials described (but not for other types of biopesticides)

The European Union: legislative hierarchy

Primary law

Secondary law:
direct effect or
indirect effect

Supplementary law: to implement
primary and
secondary law



And Regulation (EC) 1107/2009 does not accommodate the “biopesticide” figure in its text.



However,

No special regulatory process but in the preamble of Regulation 1107/2009:

(35) To ensure a high level of protection of human and animal health and the environment, plant protection products should be used properly, in accordance with their authorisation, having regard to the principles of integrated pest management **and giving priority to nonchemical and natural alternatives** wherever possible.

Article 3: Definitions: For the purpose of this Regulation, the following definitions shall apply:“

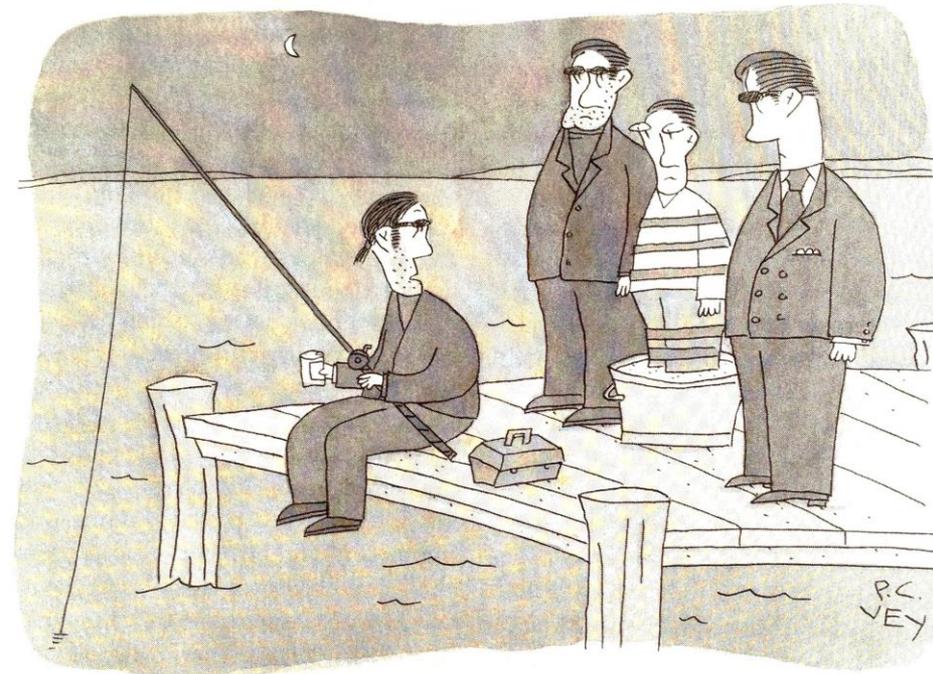
(2) ‘Substances’ means chemical elements and their compounds, **as they occur naturally or by manufacture**, including any impurity inevitably resulting from the manufacturing process;

- **Reduced fees:** IT, FR, ES, NL, DE, DK, SE, FI, NO
- **National pieces of legislation or policy:** FR, UK, NL, PT, FI, SE, DK
- **Fast-track:** some of them



Key messages

- **Progress** has been made albeit slower than business wished for;
- **Decisions on fast-tracking, fee structure, timelines** for reviews are a policy decision;
- Regulatory frameworks should accommodate and **embrace new technologies**: today the biologicals, but what about tomorrow?
- Is the current regulatory system (individual product approvals) suitable in an IPM context?



“Tonight? I thought it was tomorrow night.”

Source: The New Yorker, 19th January 2014, page 42

Regulatory windows for innovation



Canada PMRA defines three types of biopesticides: microbial, semiochemical and **non-conventional pest control products** (Note: this excludes the USA class of Plant-Incorporated-Protectants, PIPs).



.The UK/HSE Biopesticide scheme considers four categories/classes:

- Products based on **pheromone** and other semiochemical (for mass trapping or trap cropping);
- Products containing a **microorganism** (e.g. bacterium, fungus, protozoa, virus, viroid);
- Products based on **plant extracts**;
- **Other novel alternative products**: potential products which do not easily sit within a specific category and as such the data requirements will have to be assessed on a case by case basis.

Thank you



Eve Sussman / Brooklyn

Source: Benedikt Partenheimer, "Turnaround" series, dealing with the relationship between "internal" and "external" space.

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