

China: Biopesticides, Opportunities and Challenges

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- We are:
 - Regulatory consultancy wholly owned by Dentons
 - 25 years old, 130 of scientific & regulatory experts
- We are located in:
North America; Europe; Multi-National
- Our Staff
 - **Scientists:** Chemistry, toxicology, eco-toxicology, microbiology, exposure assessment, environmental & metabolic fate
 - **Regulatory experts:** Ex-regulatory agency officials – US EPA, UK, EU and US member states, Experienced company regulatory specialists
 - **High level problem solvers:** High value consultants and competitively priced teams

China – Fast Growing & Still Developing

- Fast growing; 2nd largest economy; #121 in PPP rank
- One of the largest agrochemical producing and import/export countries
- Of > 30,000 registered pesticide products only about 650 chemicals
- Will gradually phase out highly toxic chemicals, and establish a withdrawal mechanism for old pesticides



Biopesticides in China

- Had been treated somewhat similarly to conventional chemicals in data requirement
- A revision is underway
- Current definition of the **Special Pesticides**:
 - **Microbial pesticides**
 - **Biochemical pesticides**
 - **Botanical pesticides**
 - Semiochemicals (e.g. insect pheromones)
 - Enzymes (proteins)
 - Natural plant regulators and insect growth regulators
 - **Macro Pest Enemy organism**
 - **Transgenic organism/ GMO with anti-pesticidal activity**

Biopesticides in China

- Of 650 registered A.I.s, 105 are biopesticides (~16.2%)
- Of 30,000 registered products, 12% are biopesticides (and only 3% excluding antimicrobials)

Type	A.I.s	Formulations
Antimicrobial	17	2668
Microbial	32	365
Biochemical	34	415
Botanical	20	204
Natural Enemy	2	3
Total	105	*3655

***34% are mixtures**

Opportunities for Western Companies

- The policy of phasing out highly toxic and old chemicals opens doors for biopesticides
- Currently > 80% of biopesticides registered are antimicrobials/microbials
- Most of > 2,000 agrochemical companies are conventional chemical manufactures
- Chinese government is making an effort to harmonize with OECD regulations, i.e. pesticide definitions, data requirements, GLP compliance



Regulatory Differences from OECD Countries

- **Data: MOA/ICAMA requires in-China studies at authorized facilities for:**
 - **Product chemistry**
 - **Efficacy**
 - **Toxicity**
 - **Residue**
 - **Environmental**
- **Data from OECD countries under GLP could be considered – case by case basis**
- **Study protocols might not be consistent with those developed by the registrants**

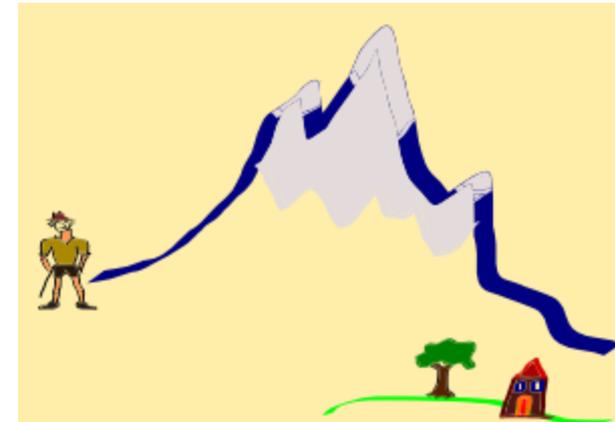
Challenges – Regulatory

	EPA/OPP	China
Data Source	Registrants	ICAMA* laboratories and its designated testing facilities
Data Requirement	Specific & clearly defined	Certain issues could be unclear or vague
Regulatory Status	Online Publication	Online – yes & no; always double check for each registration application

*** Institute for the Control of Agrochemicals,
Ministry of Agriculture, P.R. China**

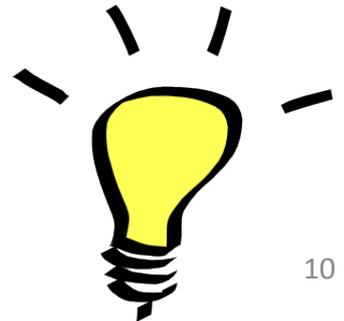
Challenges – Regulatory

- **Published regulations might not be all current; “current” policies might not all be able to find online**
- **Changes may be random and based on individuals decisions**
- **Registration timeline – case by case**



Doing Business in China

- Understand the regulation, culture, and politics
- Build positive relationships with regulatory agencies
- Discuss product registration or import/export issues case by case
- Find good consultants with integrity and “know how”



Doing Business in China

- Gather market intelligence & know your potential partner well before a signing contract, **i.e. toll manufacturers, local agents, distributors, local employees**
- Regularly audit toll manufacturers
- Be prepared to protect yourself and your products
- Beware of Intellectual Property issues



Thank You!

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