

Introduction of Biopesticide and Biofertilizer Regulations in APO Countries

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Outline

- 1. Terms**
- 2. Regulatory Agency and Laws**
- 3. Development Scheme**
- 4. Registration Process and Document Requirements**
- 5. Problems To Be Solved**

Terms

Term	R.O.C.	USEPA	OECD	EU
Pesticide	Pesticide denotes the chemicals or biologically-based formulations used for preventing and eliminating pests of crops and forest or the products thereof, regulating the growth of crops and forest or influencing the physiological functions, or for regulating the growth of beneficial insects.	Any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest. Any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant. Any nitrogen stabilizer.	A pesticide is any substance or mixture of substances that is used to prevent, destroy or control pests including vectors of human or animal disease, and unwanted species of plants or animals. Pesticides may cause harm during, or otherwise interfere with, the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs or that may be administered to animals so as to control insects, arachnids or other pests in or on their bodies.	A pesticide is something that prevents, destroys, or controls a harmful organism ('pest') or disease, or protects plants or plant products during production, storage and transport. The term includes, amongst others: herbicides, fungicides, insecticides, acaricides, nematicides, molluscicides, rodenticides, growth regulators, repellents, and biocides.

Terms

Term	R.O.C.	USEPA	OECD	EU
Biopesticide	<p>Biopesticides are biologically-based formulations including natural products, microbial pesticides, and biochemical pesticides. The product of biopesticide is an agent containing bacteria, fungi, viruses or protozoa, etc. used to control crop pests including microorganisms, insects and weeds or induce plant resistance. These microorganisms are isolated from nature, or further improved by artificial mutagenesis, artificial selection or genetic modification.</p>	<p>Biopesticides are certain types of pesticides derived from such natural materials as animals, plants, bacteria, and certain minerals. For example, canola oil and baking soda have pesticidal applications and are considered biopesticides. Biopesticides fall into three major classes including biochemical pesticides, microbial pesticides and plant-incorporated-protectants(PIPs).</p>	<p>Biopesticides include microbials - bacteria, algae, protozoa, viruses, fungi, pheromones and semiochemicals, macrobials/invertebrates such as insects and nematodes, and plant extracts/botanicals.</p>	<p>Biopesticides constitute a special group of active substances for plant protection that occur naturally or are nature-identical synthetic substances. They also include a number of living organisms(biocontrol organisms).</p>

Terms

Term	R.O.C.	USEPA	OECD	EU
Biofertilizer	Biofertilizer is an agent containing active or dormant spores of bacteria, actinomycetes, fungi, algae or its metabolites used to provide nutrient or promote nutrient utilization during crop production.	<p>No legal definition for the term “biofertilizer”.</p> <p>【 In some documents: The microorganism increases the growth of plants by replacing soil nutrients (i.e. by biological N2 fixation), by making nutrients more available to plants (i.e. by solubilisation of nutrients) or by increasing plant access to nutrients (i.e. by increasing the volume of soil accessed by the root system), as long as the nutrient status of the plant has been enhanced by the microorganism, it is the formulated product containing the microorganisms that is applied to the plant or soil that shall be named biofertilizer. 】</p>	<p>Biofertilizer is not specified.</p> <p>【 The words “use microbial organism as biofertilizer” are mentioned in document . 】</p>	<p>No legal definition for the term “biofertilizer”.</p> <p>【 In some documents: Biofertilizer contains biological-means, living organisms that synthesize the atmospheric plant nutrient in the soil or in the plant body, or create such an atmosphere in the soil or in the medium (in which the organisms are kept) which are helpful for the plants. 】</p>

Regulatory Agency for Registration

Type * Item	1	2	3	4	5
Biopesticide	Agency A	Agency A	Agency A	X	X
Biofertilizer		Agency B	X	Agency B	X

*Type of agency responsible for registration

1. Both biopesticide and biofertilizer are regulated by the same agency.
2. Biopesticide and biofertilizer are regulated by different agencies.
3. Regulatory agency is for biopesticide only.
4. Regulatory agency is for biofertilizer only.
5. No regulatory agency for biopesticide and biofertilizer.

Regulatory Agency for Registration

Country	Agency	Regulating biopesticides	Regulating biofertilizers
Fiji	Biosecurity Authority of Fiji	√	√
India	Ministry of Agriculture	√	x
IR Iran	Plant Protection Organization	√	x
Malaysia	Ministry of Agriculture	√	√
Philippines	Fertilizer and Pesticide Authority	√	√
R.O.C.	Council of Agriculture	√	√
Thailand	Department of Agriculture	√	x
Vietnam	Ministry of Agriculture and Rural Development	√	√
U.S.A.*	US Environmental Protection Agency	√	x

*non-member

Laws for Regulating Biopesticides and Biofertilizers



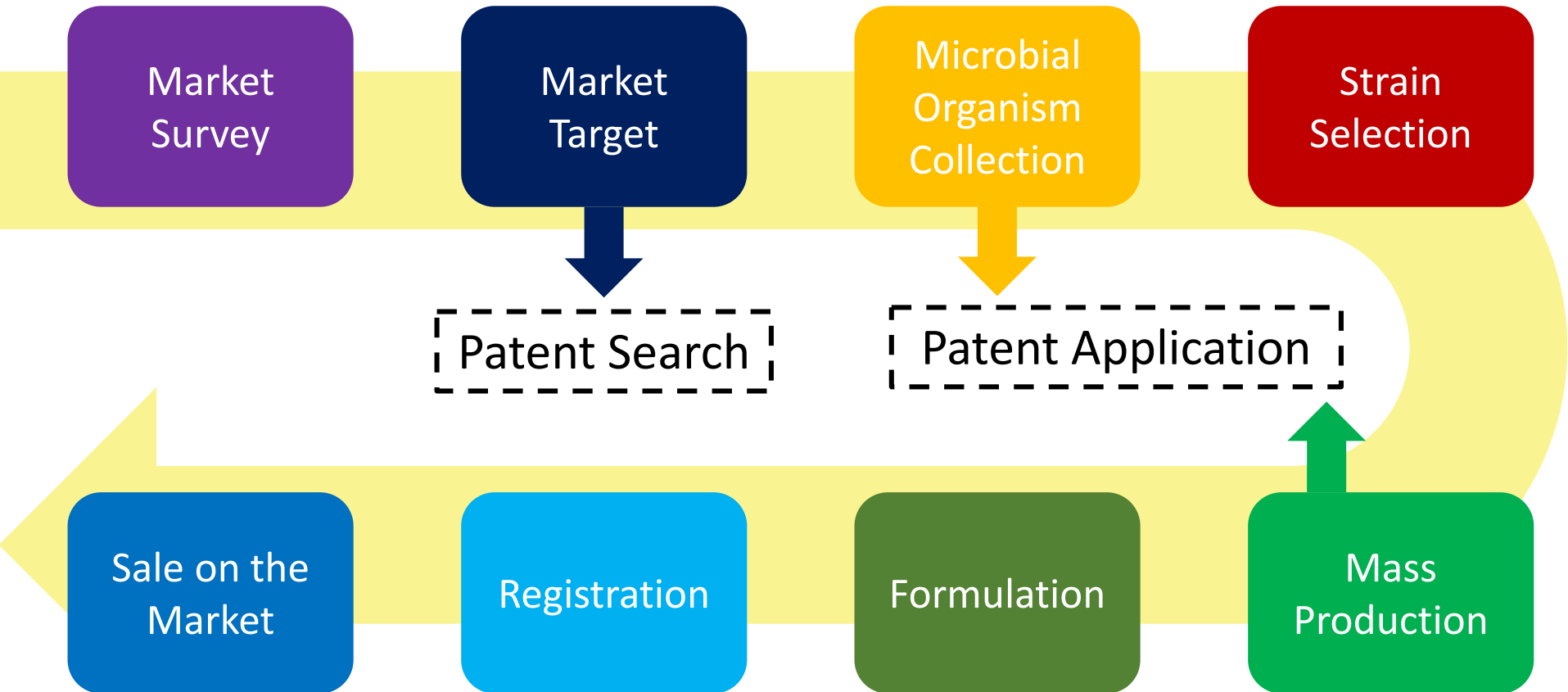
Country	Biopesticides	Biofertilizers
India	Insecticide Act (1968)	N.A.
IR Iran	Plant Protection Act	N.A.
Japan	Agricultural Chemicals Regulation Act	N.A.
Korea	Environmentally-friendly Agriculture Promotion Act	Environmentally-friendly Agriculture Promotion Act
Malaysia	Pesticide Act 1974	N.A.
Philippines	Republic Act 10068 Organic Agriculture Act	Republic Act 10068 Organic Agriculture Act
R.O.C.	Pesticide Management Act	Fertilizer Management Act
EU*	Regulation (EC) 1107/2009 Commission Regulation (EU) No 544/2011, No 545/2011, No 546/2011, 547/2011, Commission Implementing Regulation (EU) No 540/2011 & No 541/2011 Regulation (EC) No 396/2005 & No 178/2006	N.A.
U.S.A.*	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Federal Food Drug, and Cosmetic Act (FFDCA)	N.A.

* non-member



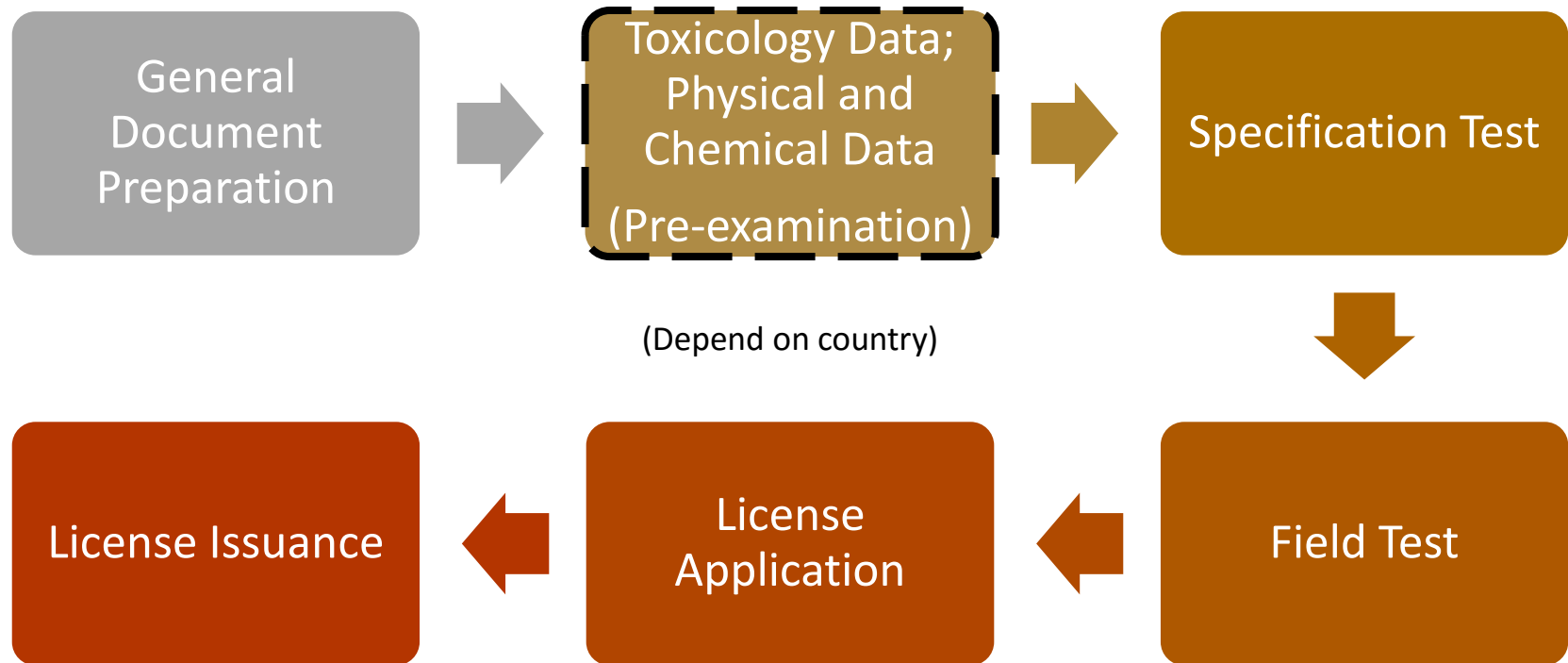


Development Scheme



bench scale production : < 50 L
small scale production : <1 ton
large scale production : < 20 ton

Registration Process



Document Requirements for Registration

General Information

- Application form
- Biological characteristics, chemical and physical properties for product

Toxicological Test

- Oral Toxicity
- Acute pulmonary toxicity
- Eye Irritation
- Dermal test

Field Data

- Efficacy

Environment Assessment (non-target organisms)

- Honeybee, silkworm, soil microbes, non-target insect
- Avian toxicity, freshwater fish

Registration of Domestic Products (I)

Application Form

- General information
- Physical and chemical properties
- Identification method
- Toxicity data
- Field data

**Submission for
Application**

Regulatory
Agency

For Example: Japan, Korea, R.O.C.

Registration of Domestic Products (II)

Application Form

- General information
- Physical and chemical properties
- Identification method
- Toxicity data

Pre-examination
by Regulatory
Agency

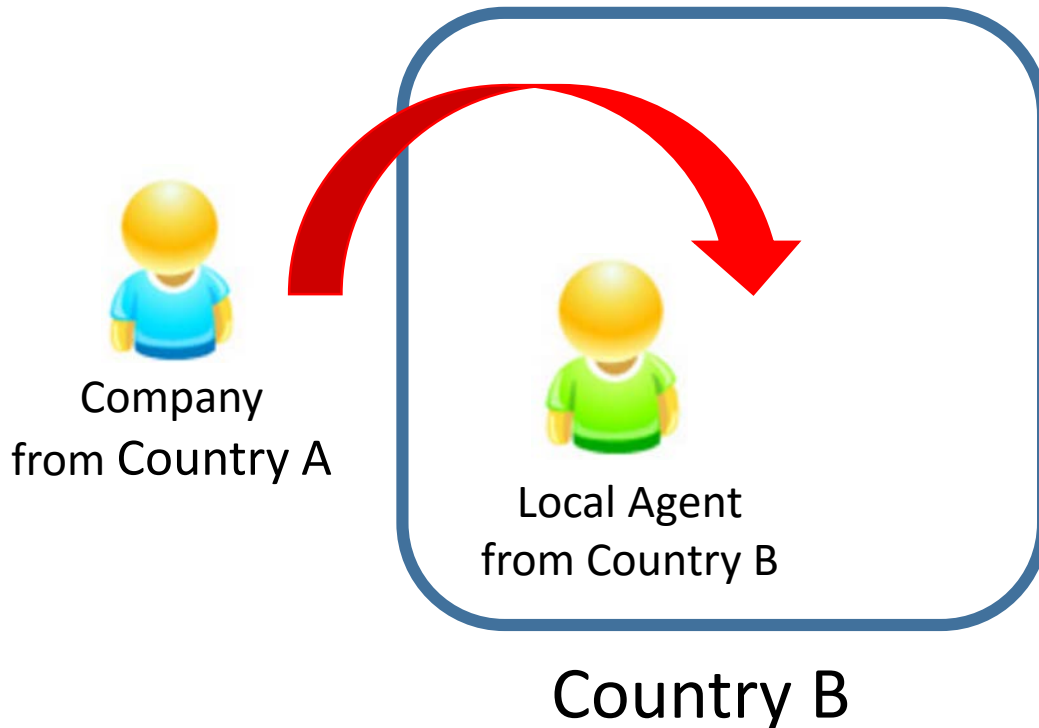
Field Test

Submission for
Application

Regulatory
Agency

For Example: Egypt(non-member), Turkey(non-member)

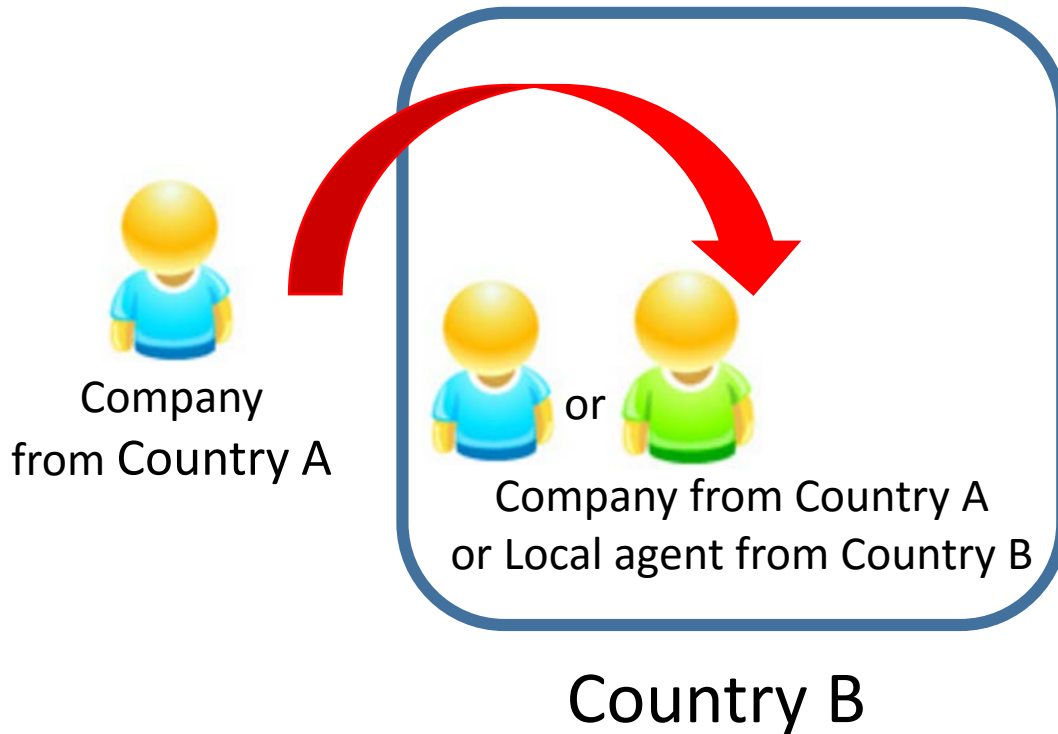
Registration of Foreign Products (I)



- ✓ The company from country A intends to register product in country B.
- ✓ Registration is handled by local agent from country B.
- ✓ Required documents for registration are provided by the company or local agent.
- ✓ Registered product is sold by local agent.



Registration of Foreign Products (II)



- ✓ The company from country A intends to register product in country B.
- ✓ Registration is handled by the company itself.
- ✓ Required documents for registration are provided by the company.
- ✓ Registered product is sold by the company or through local agent from country B depending on the company.

Problems To Be Solved

- Insufficient information with regard to the laws and regulations for registration and application of biopesticides and biofertilizers in APO member countries.
- Harmonization of laws and regulations in relation to biopesticides and biofertilizers in APO member countries.
- Promotion of the application and industrial development of biopesticides and biofertilizers.

Thanks for Your Attention!



ASIAN PRODUCTIVITY ORGANIZATION

