

Pesticide development and registration in Japan

Joy Consulting Ltd.

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1. Characteristics of our contracted business

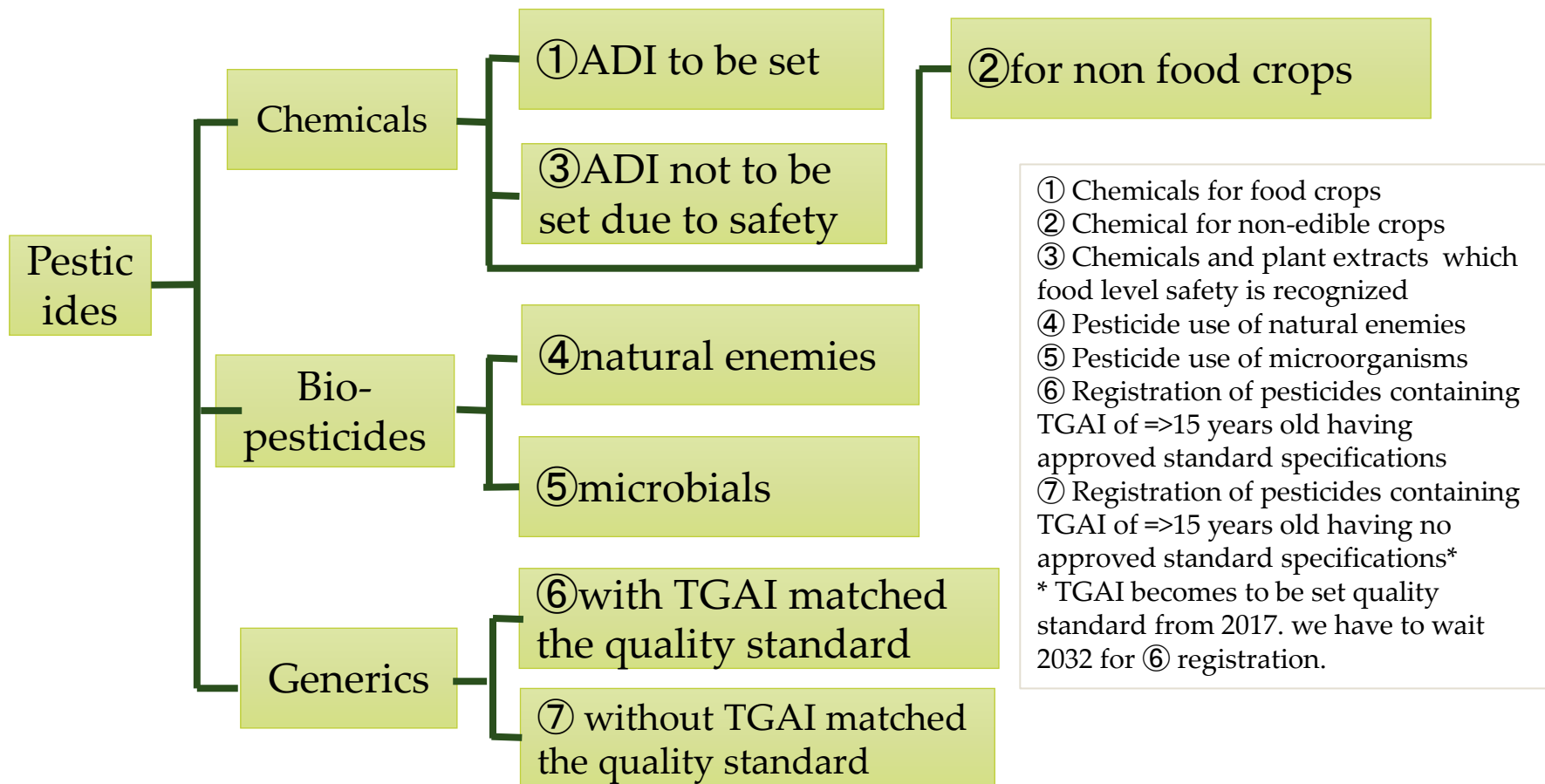
We undertake everything from planning and managing of JPPA/JAPR efficacy trials upto pesticide registration. That is, Joy consists of employees who have experienced all operations from chemical synthesis, efficacy evaluation, manufacturing, 5 batch analysis, toxicity evaluation, preparation of dossier, application, negotiation with authorities, up to registration, in Japan. Actually since 2002, when Joy was established , we have experienced many developments/registrations of insecticides, fungicides, herbicides, PGRs, bio-pesticides. Our characteristics are in one stop service from efficacy evaluation upto registration. Joy has also worked as a domestic agency to authority for the maintenance of pesticide registration.

2. Strategy of development

- We make it a rule to please our customers before everything that clients can acquire pesticide registration with the shortest and minimum budget, and at the time of application, we always keep track of changes in guidelines to comply with the latest pesticide registration guidelines.
- If you have any possible gap between requirement of Japanese pesticide registration and your dossier, be sure to submit an inquiry to authority, negotiate in writing and fix the necessary data and then start the development work.
- We are a member of the Japan Plant Protection Association and the Japan Plant Regulator Research Association, and perform successfully the above-mentioned works by grasping the latest information of authorities and Agricultural Chemical Industry Association.

3.1 Classification of pesticide registration and data requirement

Pesticides are classified as below from the standpoint of data requirement:



3.2 Classification of pesticide registration and data requirement

Data requirementk		①	②	③	⑥	⑦
		ADI to be set	For non food crops	ADI-not set (safe AI)	Generic-with TGAI standard	Generic-without TGAI standard
TGAI	Manufacturing info.	○	○	○	○	○
products	Product information	○	○	○	○	○
products	Efficacy/phytox.	○	○	○	○	○
TGAI	Acute toxicity	○	○	×	×	○
	Physical chemical property(pure compound)	○	○	×	×	○
	Sub-acute toxicity	○	○	×	×	○
	Teratology studies	○	○	×	×	○
	Reproduction study	○	×	×	×	○
	Chronic and carcinogenicity	○	×	×	×	○
	Gene toxicity	○	○	○(Ames)	×	○
	Environmental toxicities	○	○	×	×	○
RI	Environmental fate	○	○	×	×	×
	Animal metabolism	○	○	×	×	×
	Plant metabolism	○	×	×	×	×
Product	Crop residue studies	○	×	×	×	×
Product	Acute oral/dermal irritation, sensitization	○	○	○	○	○
Product	Inhalation	△	△	△	△	△
Product	Aquatic toxicity	○	○	△	○	○

○: necessary, △: conditional, ×: not necessary

3.3 Classification of pesticide registration and data requirement 3

Microbials

Product manufacturing information

1. Data concerning specification and properties of microbial pesticides

(1) Name and taxonomic position of microbe (2) Biological properties of microbe (3) Composition of technical grade of the active ingredient (4) Production method for technical grade of the active ingredient (5) Composition of end-use product (6) Production method for end-use product

2. Information of use method

(1) Efficacy trial reports

(2) Use label and directions

3. toxicological studies for human safety*1

(1) Acute oral toxicity/infectivity study

(2) Acute dermal toxicity/ irritation study

(3) Acute pulmonary toxicity /infectivity study

(4) Acute intravenous toxicity/infectivity study

(5) Eye irritation study

(6) Skin sensitization study

4. Information of hypersensitive reactions that occurred in production and use of microbial pesticides

5. Results of studies of residual microbial viability on crop plants (conditional requirement)

6. Environmental toxicity studies*1

(1) Toxicity study on freshwater fish

(2) Toxicity study on freshwater invertebrates

(3) Avian toxicity study

(4) Study of effects on non-target plants

(5) Study of effects on non-target insects

(6) Study of effects on honeybees

(7) Study of effects on silkworms

(8) Study of effects on soil microbes

7. Results of studies of fate in the environment

*In case of toxicity/infestation found, higher tier studies may become necessary

*1 Test guidelines for microbials is very special to Japan.

Natural enemies

Data on specification properties: name and taxonomic location, biological properties (related species information for introduced species), maintenance and propagation method, composition of product, manufacturing method

Efficacy and use label

Information concerning safety to humans (literature, cases of allergies, safety tests, etc. on consideration on safety to humans)

Information on impact to environment

4. Local studies of efficacy (non-GLP) and crop residue trials (GLP)

These studies should be tested in Japan.

We can plan and manage registration trials using below associations:

- ✓ Japan Plant Protection Association (JPPA) trials: Fungicide, insecticide, environmental toxicity test (non-GLP), crop residual test (GLP)
- ✓ Japan Plant Growth Regulator Association (JAPR) trials: Herbicide, Planting growth regulators, crop residual test (GLP)

5. Chemical analysis, toxicity tests, environmental fate studies, environmental toxicity test

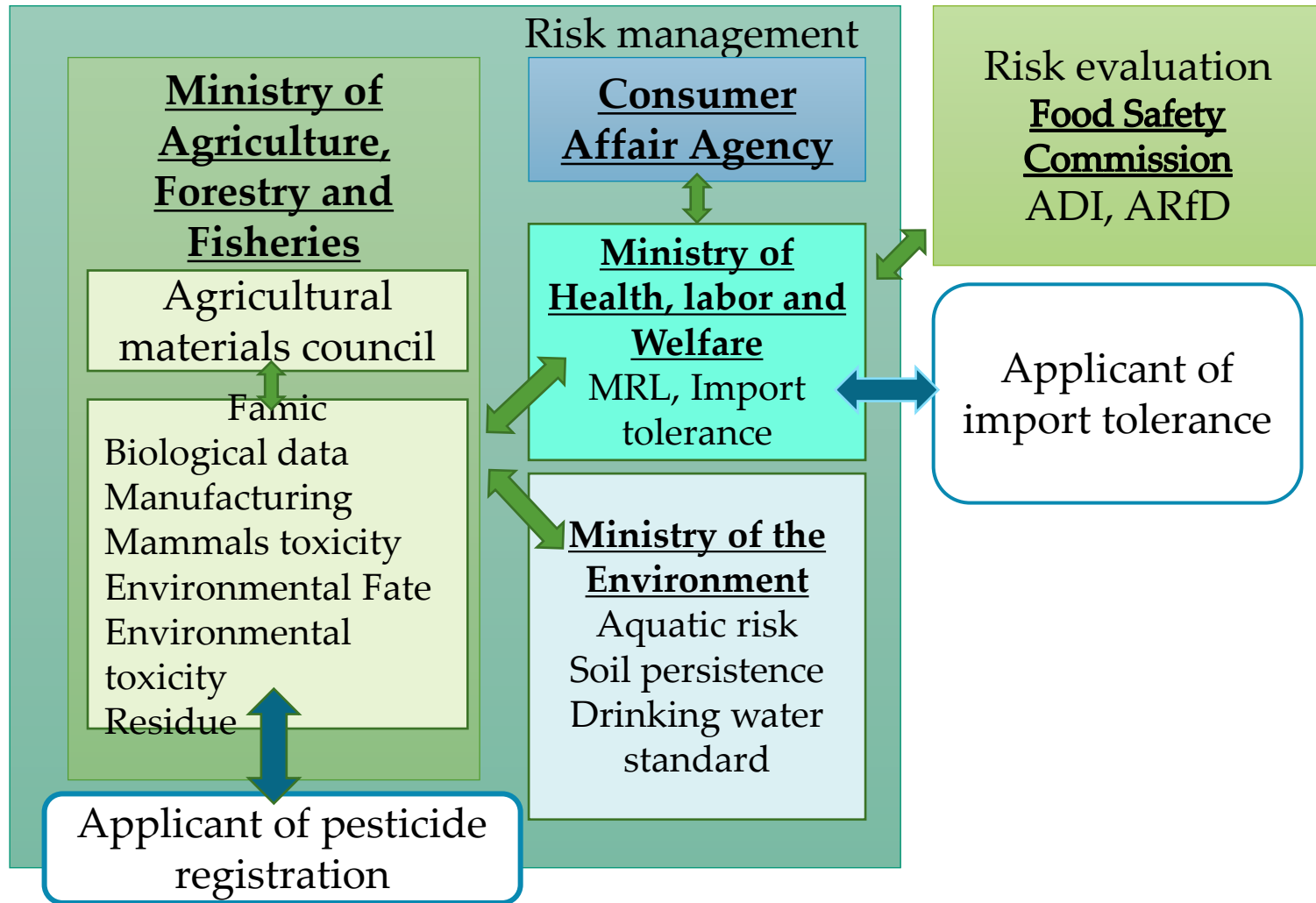
GLP studies are required for all studies by laboratories of OECD, and OECD-MDA countries.

6. Development schedule

Below is a standard schedule for pesticides of ADI setting. It will be shorter for pesticides of non-food crop use, no-ADI-setting and bio-pesticides.

Studies/year	1	2	3	4	5	6	7
5 batch analysis and specification of TGAI	█						
Efficacy trials	█						
Toxicological studies		█	█				
Metabolism and environmental fate		█	█				
Soil residue and crop residue		█	█				
Application and evaluation				█	█	█	
Registration and sales							█

Evaluation system of pesticides



7. Joy's service regarding pesticide registration

- Possibility check of registration of your products in Japan
- Inquiry to authority of special matters in your dossier
- Estimate of development cost of your products
- Maintenance of registration as a domestic agent
- Pesticide Market research in Japan
- Other various matters regarding pesticides and agriculture

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