

Pesticide development and registration in Japan

Joy Consulting Ltd.

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Service of Joy consulting Ltd.

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1. Characteristics of our contracted business

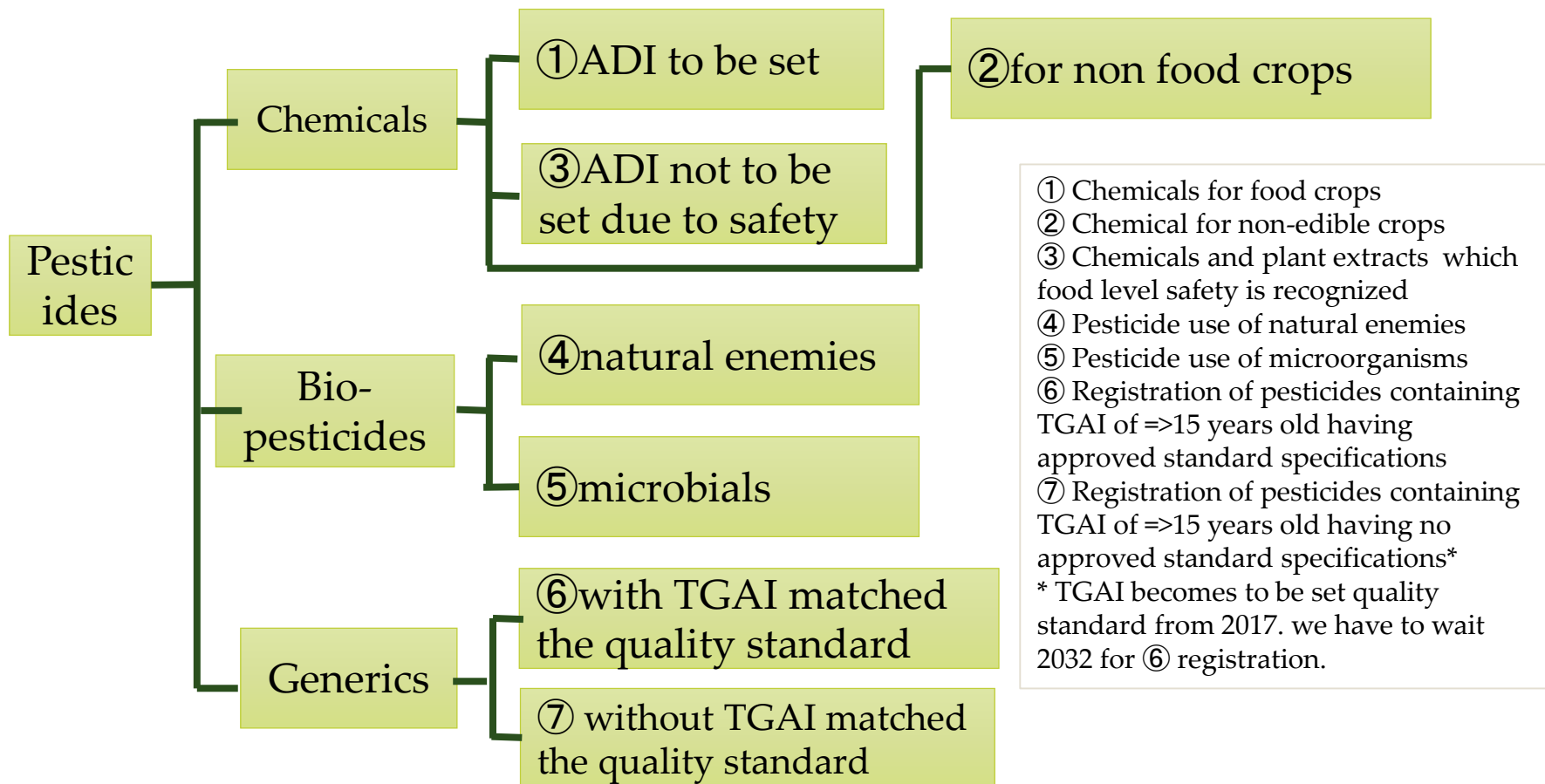
We undertake everything from planning and managing of JPPA/JAPR efficacy trials upto pesticide registration. That is, Joy consists of employees who have experienced all operations from chemical synthesis, efficacy evaluation, manufacturing, 5 batch analysis, toxicity evaluation, preparation of dossier, 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 inforamtion	○	○	○	○	○
products	Efficacy/phytotox.	○	○	○	○	○
TGAI	Acute toxicity	○	○	×	×	○
	Physical chemical property(pure compound)	○	○	×	×	○
	Sub-acute toxicity	○	○	×	×	○
	Teratology studies	○	○	×	×	○
	Reproduction study	○	×	×	×	○
	Chronic and carcinogenicity	○	×	×	×	○
	Gene toxicity	○	○	○(Ames)	×	○
RI	Environmental toxicities	○	○	×	×	○
	Environmental fate	○	○	×	×	×
	Animal metabolism	○	○	×	×	×
	Plant metabolism	○	×	×	×	×
Product	Crop residue studies	○	×	×	×	×
Product	Acute, irritation, sensitization	○	○	○	○	○
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) 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) 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 honey bees

(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

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 and crop residue trials

We can plan and manage registration exams as a window

- ✓ 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 test, environmental fate, environmental toxicity test

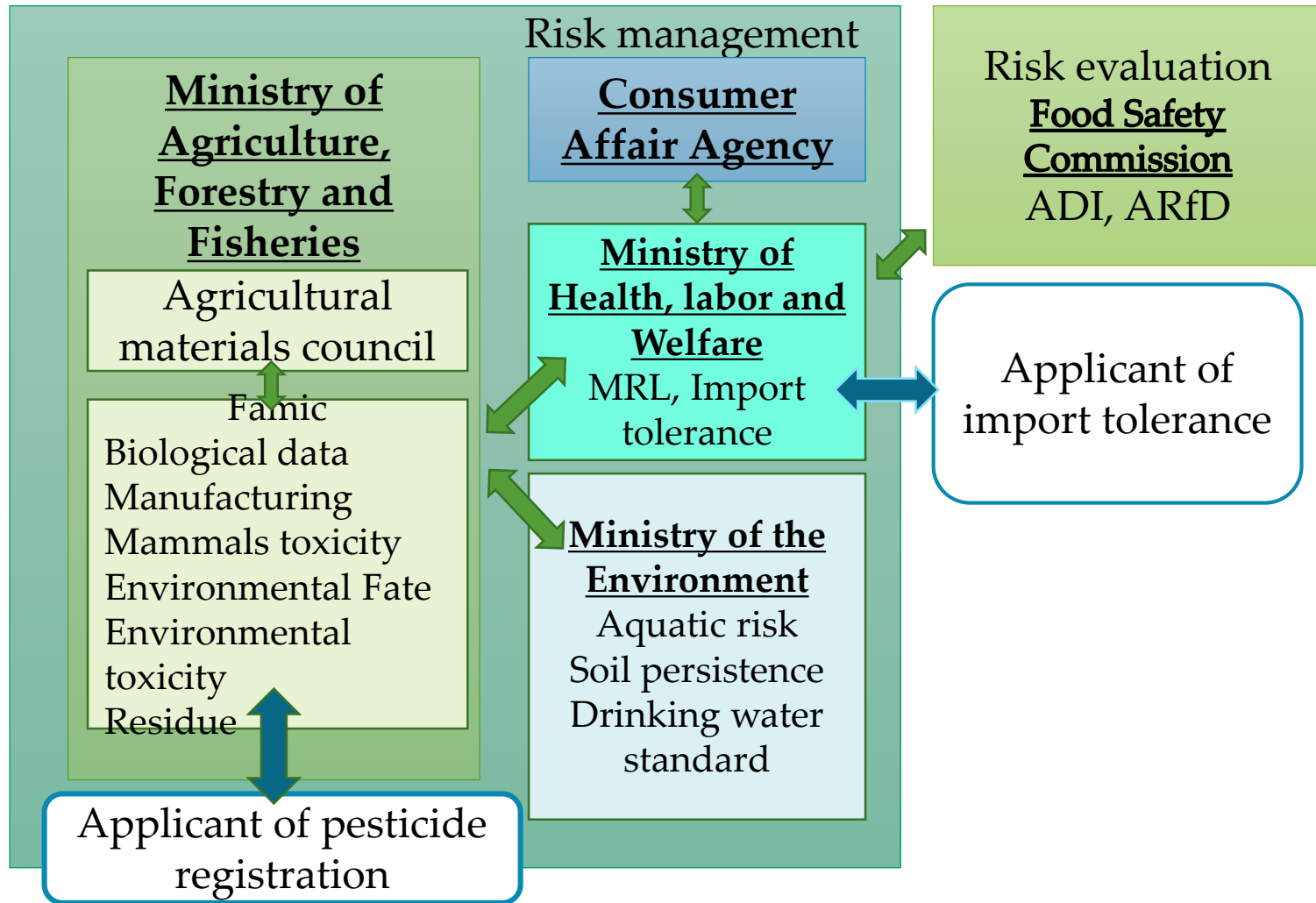
Chemical analysis of the formulation is not required to be GLP studies, but that of TGAI should be GLP studies. GLP studies are required for other studies except efficacy trials and some environmental toxicity studies. Both domestic and overseas laboratories can conduct it according to Japan's guidelines. Joy can plan and manage registration studies.

6. Development schedule

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

Studies/year	1	2	3	4	5	6	7	8
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 of registration for your products in Japan
- Inquiry to authority of special matters in your dossier
- Estimate of development cost of your products
- Maintenance of registration as an domestic agents
- Pesticide Market research in Japan
- Other various matters regarding pesticides and agriculture

President Seiji Takamura

Joy Consulting Ltd.

4-1-16 Edogawa-ku

Tokyo 133-0052 Japan

+81-3-3650-7593

E-mail: Seiji-takamura@joy-consulting.com