

Pesticide Regulation System in Japan

Atsuko HORIBE

1st Risk Assessment Division

Food Safety Commission Secretariat

Cabinet Office

atsuko.horibe@cao.go.jp

<http://www.fsc.go.jp/english/index.html>

Contents

- I. Food Safety Approach in Japan
- II. Pesticide Regulation
- III. Application of Import Tolerance
- IV. Positive List
- V. Official Journal of Food Safety Commission of Japan



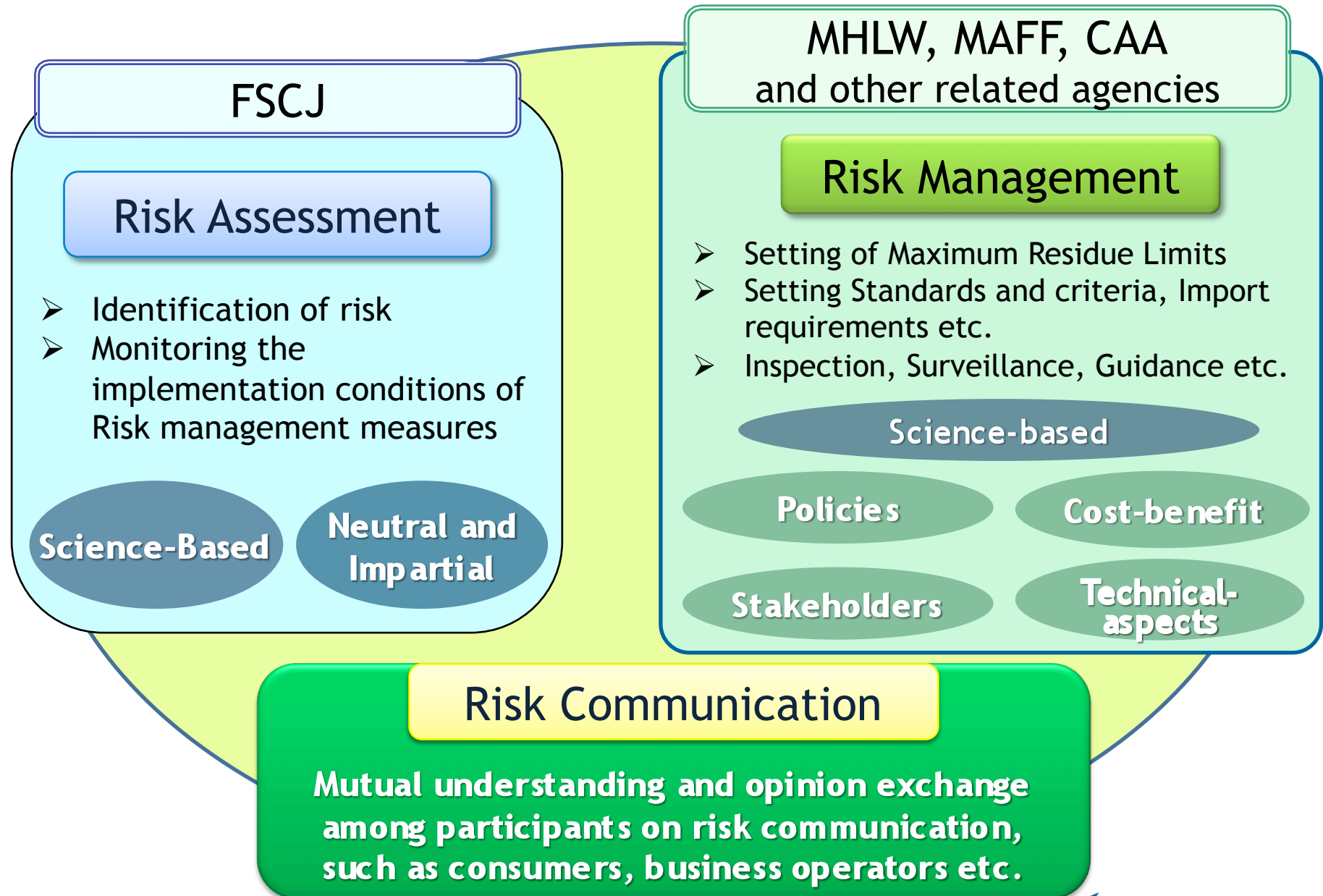
FOOD SAFETY APPROACH IN JAPAN



食品安全委員会
Food Safety Commission of Japan

内閣府

Risk Analysis for food safety in Japan



Food Safety Basic Act (Enforced 16 May 2003)



- Protection of the health of Japanese citizens is the top priority
- Introduction of Risk Analysis Principle to food safety administration
- Establishment of Food Safety Commission (FSCJ) as a part of Japanese Cabinet Office, independent from risk managing ministries (1 July 2003)
- FSCJ's Mission is to conduct science-based risk assessment in an objective, neutral and impartial manner

FSCJ Organization - Whole

Food Safety Commission of Japan(FSCJ): Commissioners

Susumu Kumagai (Chairperson)

Hiroshi Satoh (Deputy Chairperson), Yasushi Yamazoe (Deputy Chairperson),

Kunitoshi Mitsumori (Deputy Chairperson)

Katsue Ishii, Kiyoko Kamiyasuhira, Masatsune Murata

12 Expert Committees (218 experts, 1 Chair for each committee)

- Planning

- Food additives

- Pesticides

- Veterinary medicinal products

- Apparatus and containers/
packages

- Chemical and Contaminants

Chemical
Substances

- Microorganisms and Viruses

- Prions

- Natural toxins and mycotoxins

Biological
Materials

- Genetically modified foods

- Novel foods

- Feed, fertilizers

Novel
Foods

Secretariat

- Director-General

- Deputy Director-General

- General affairs Division

- First Risk Assessment Division

- Second Risk Assessment Division

- Information, Recommendation and Public Relations Division

- Director for Information Analysis

- Director for Risk Assessment Coordination

- Director for Risk Communication

Restructured in May 2013



PESTICIDE REGULATION

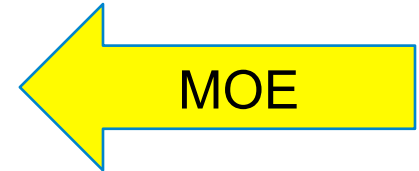
Laws concerning regulation of pesticides

Risk Management

- **Agricultural Chemicals Regulation Law**

→Registration of pesticides / Inspection of manufacturing sites, dealers and users

→Setting standards for water and aquatic organisms



- **Food Sanitation Law**

→Setting Maximum Residue Limits (MRLs)



Risk Assessment

- **Food Safety Basic Act**

→Setting toxicological reference values such as ADI and ARfD



Agricultural Chemicals Regulation Law

(Enforced 1 July 1948)

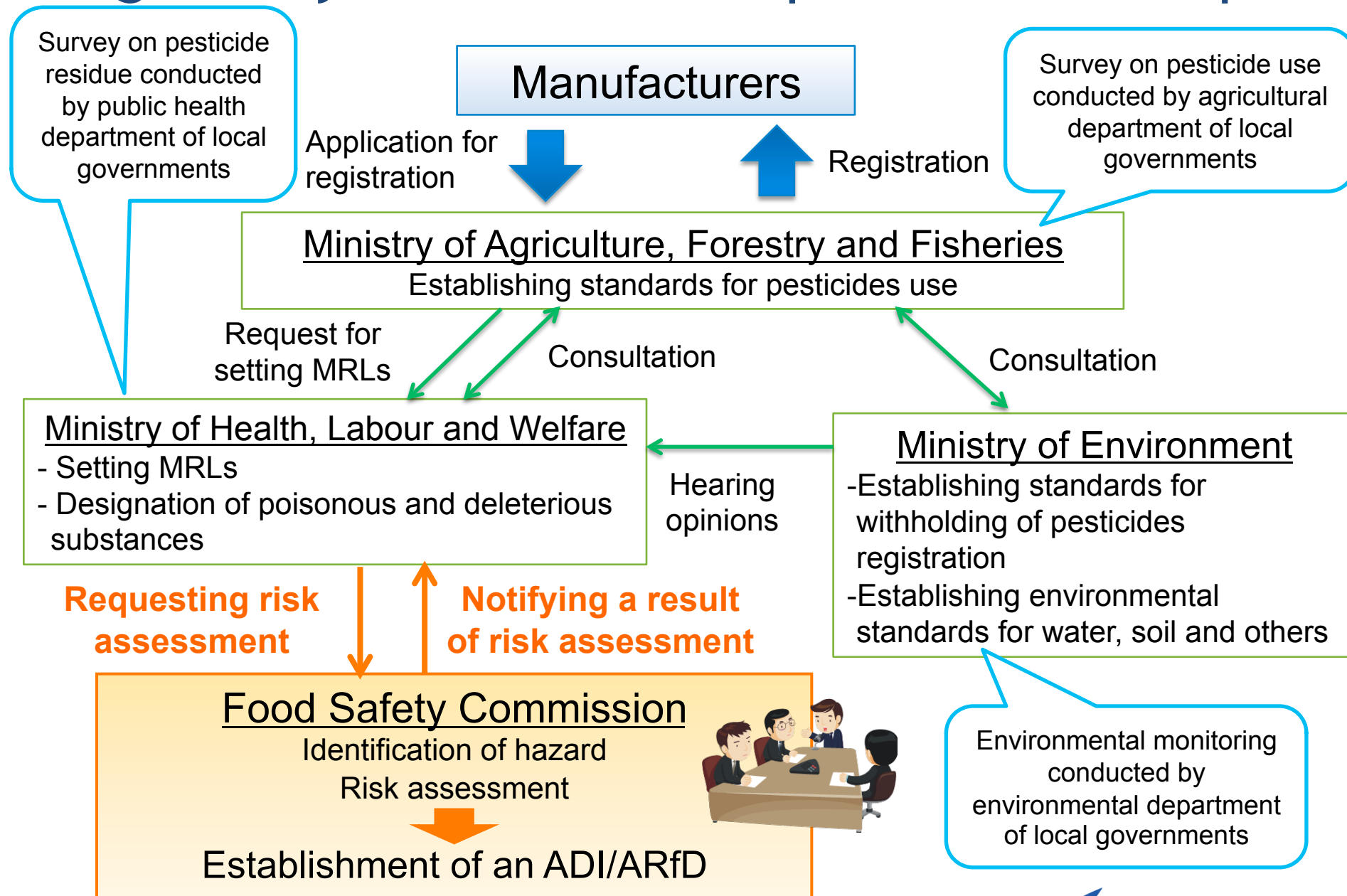
- To improve the quality of agricultural chemicals and to ensure their safe and proper use by introducing an agricultural chemical registration system to regulate their sale and use
- Contributing to the conservation of our living environment as well as the protection of human health and stable agricultural production

Food Sanitation Law (Enforced 24 December 1947)

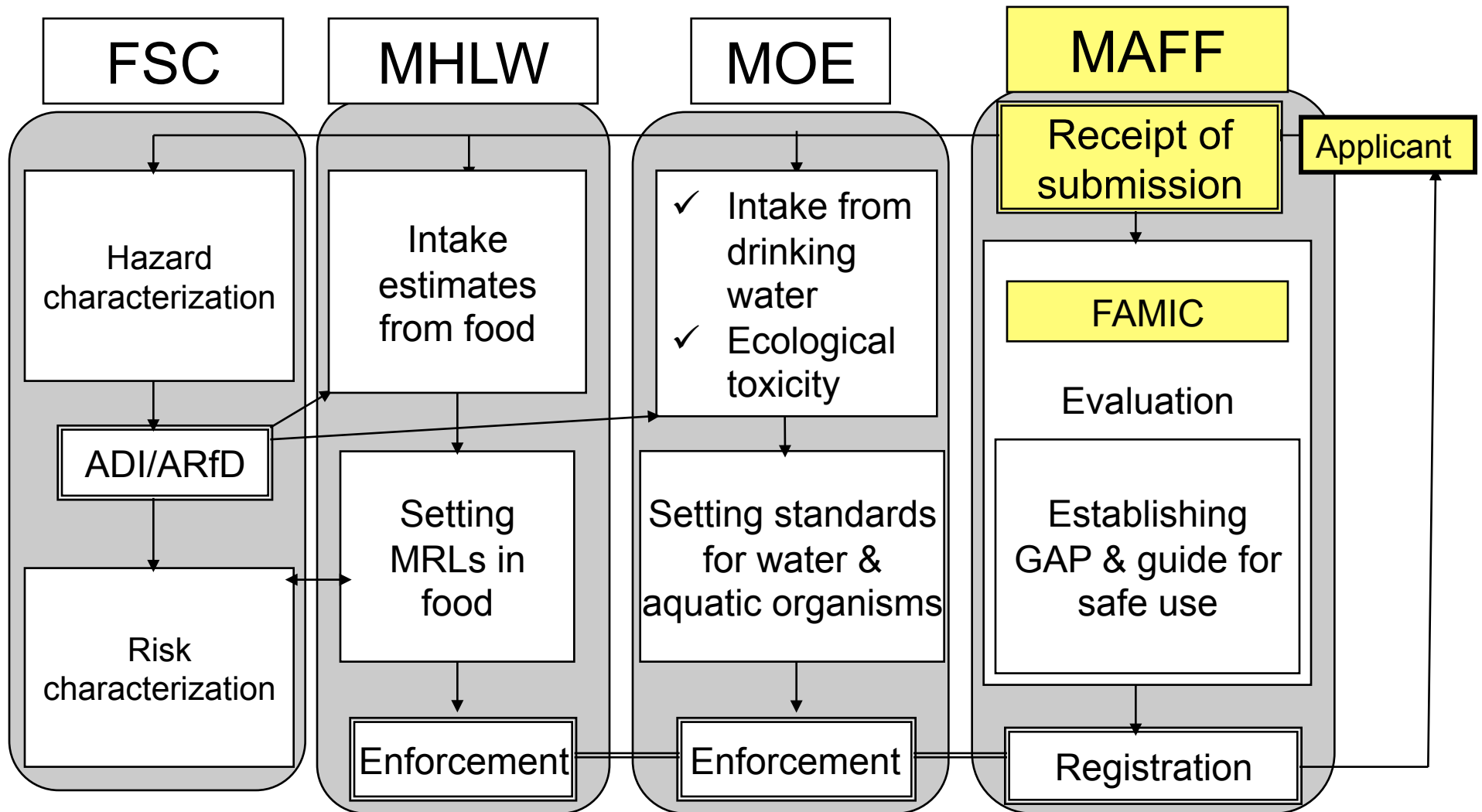
- To prevent the sanitation hazards resulting from eating and drinking by enforcing the regulations and other measures necessary, from the viewpoint of public health
- Ensure food safety and thereby to protect citizens' good health



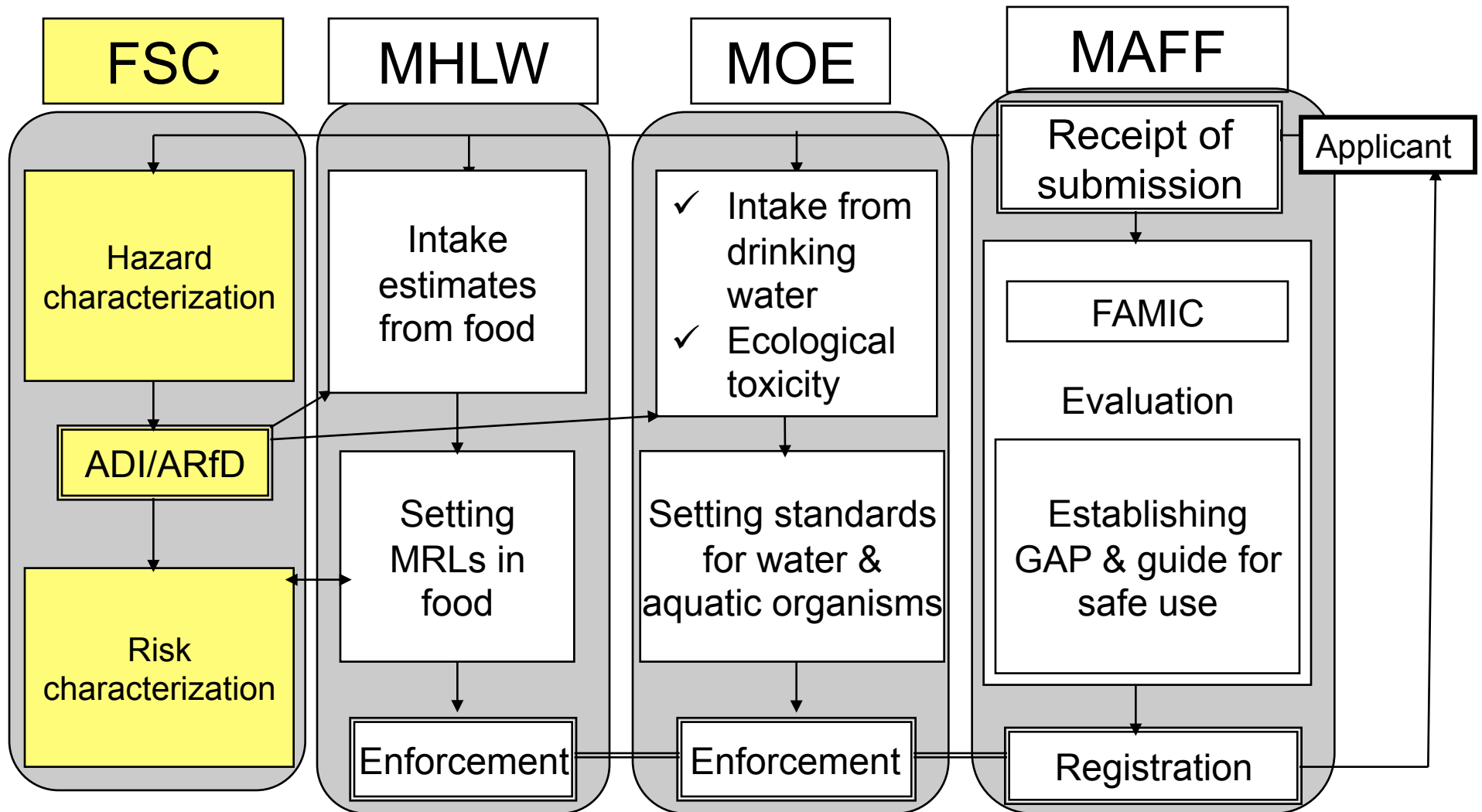
Regulatory framework for pesticides in Japan



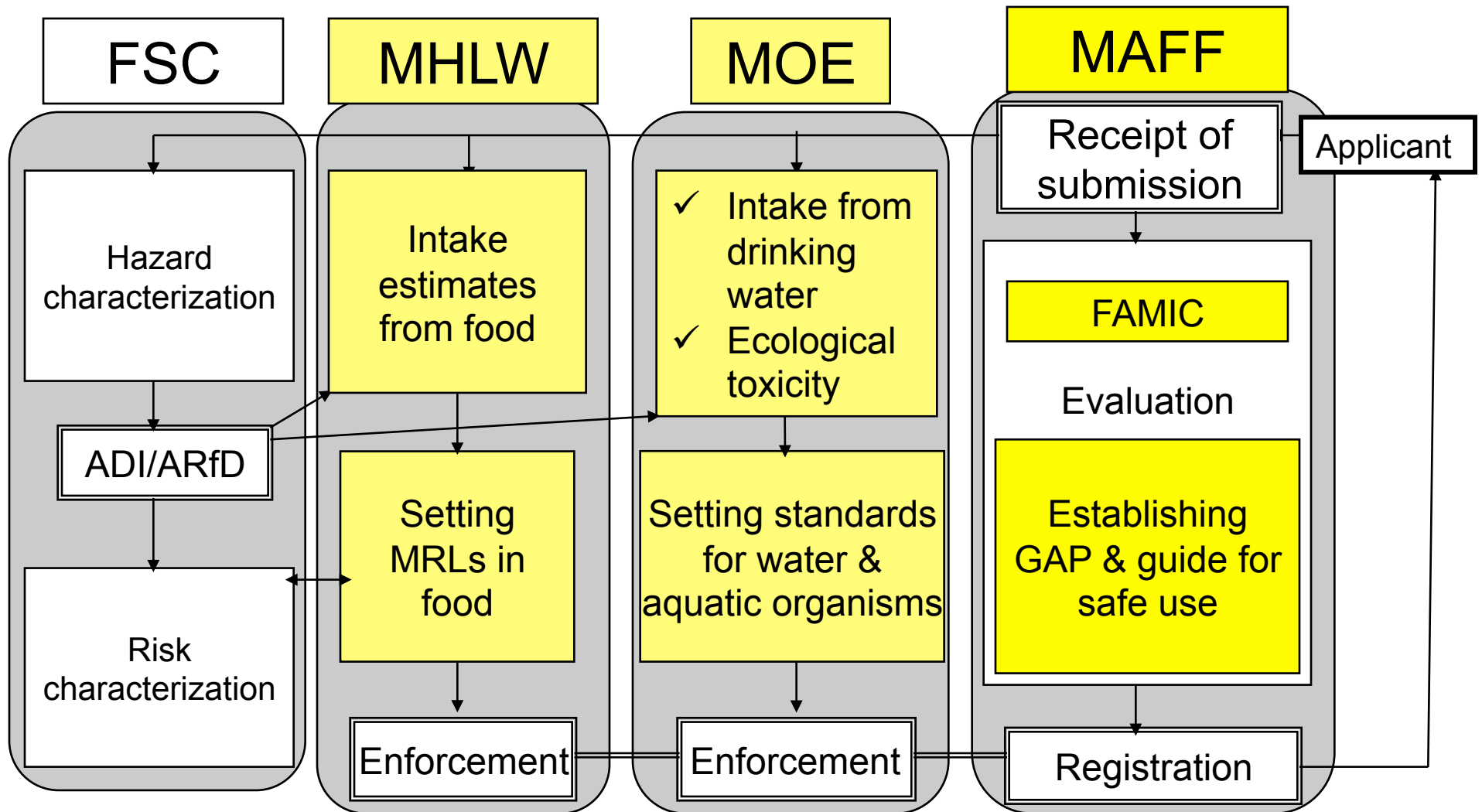
Domestic Procedure(1)



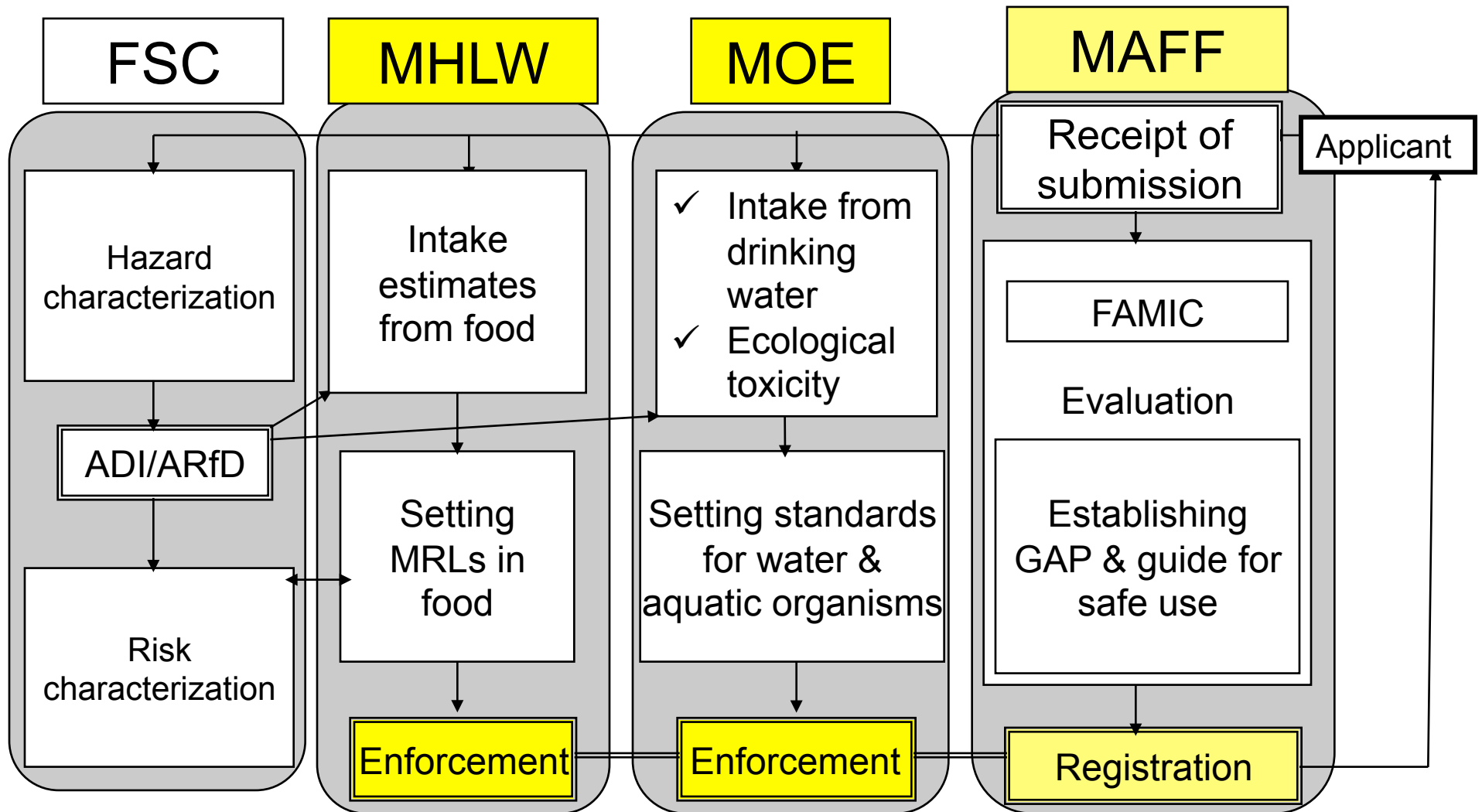
Domestic Procedure(2)



Domestic Procedure(3)



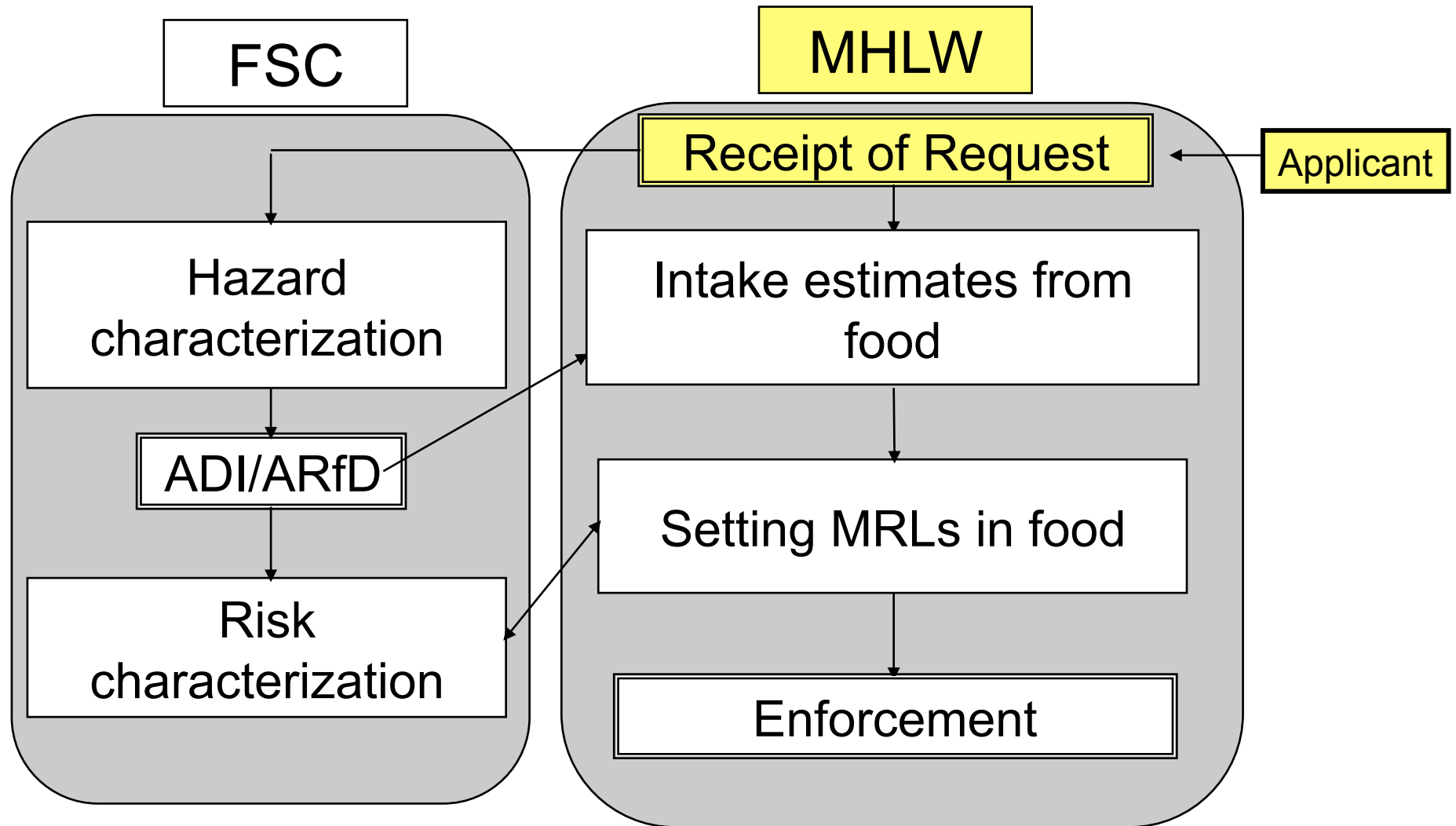
Domestic Procedure(4)



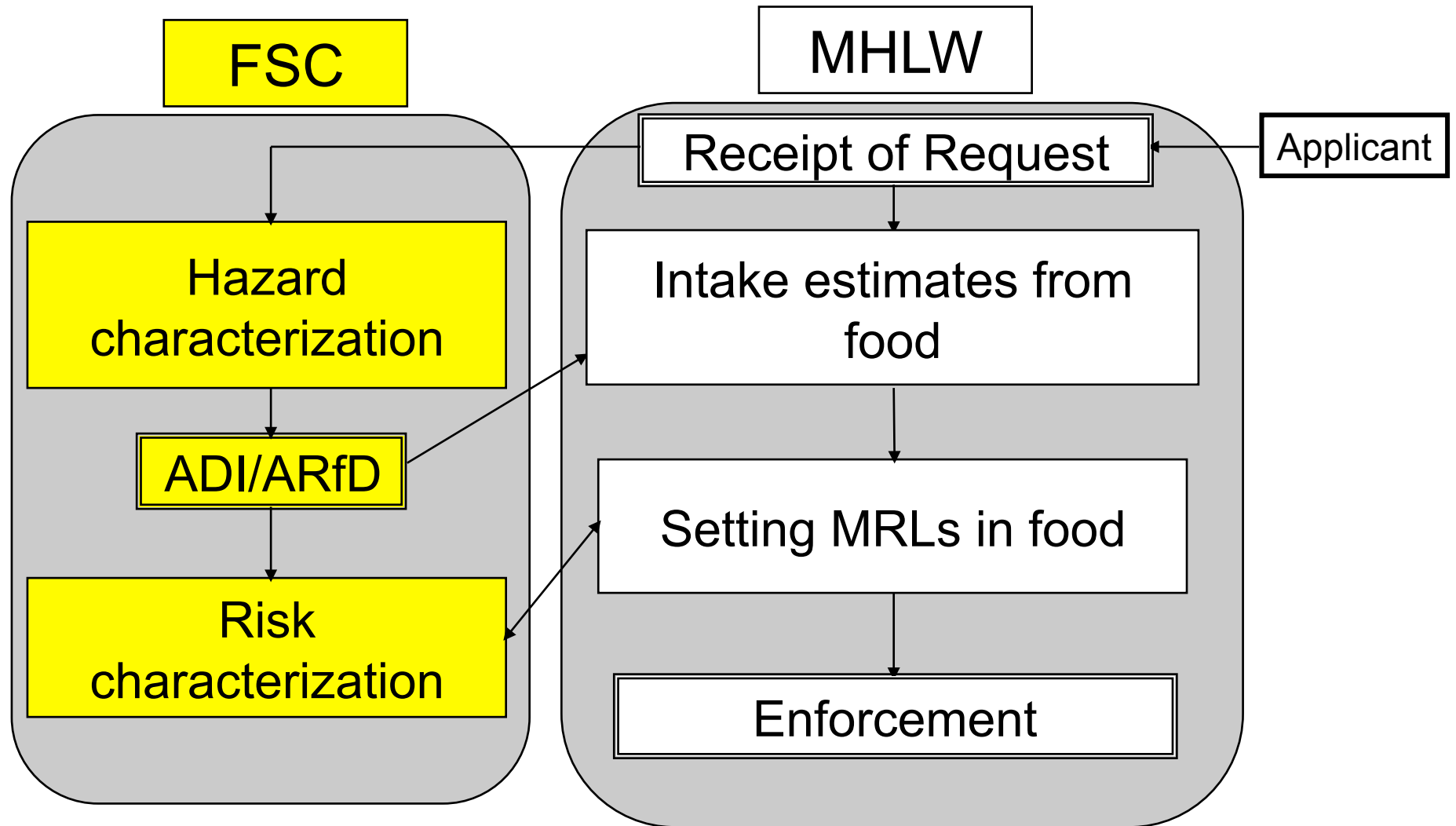
APPLICATION OF IMPORT TOLERANCE



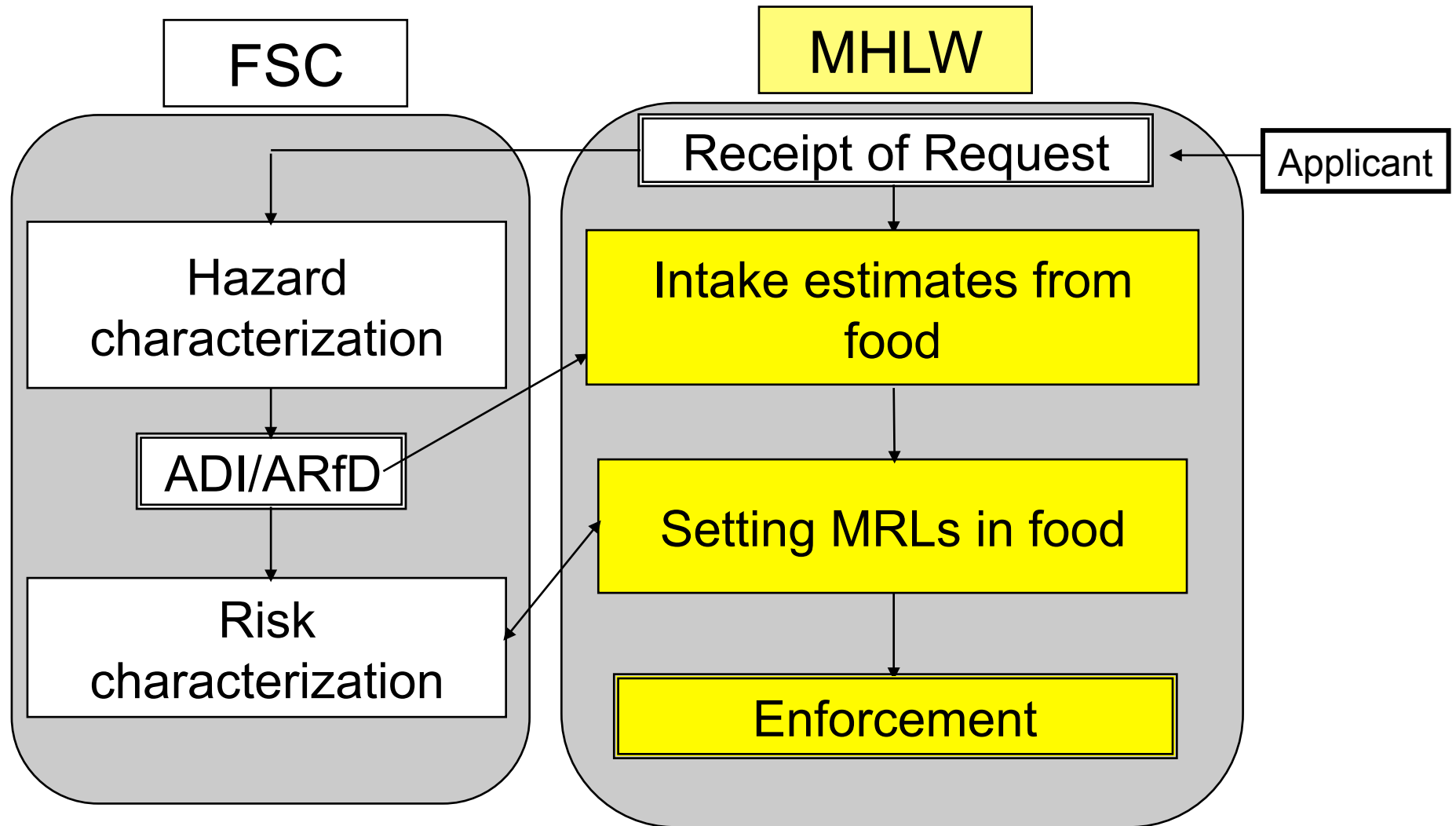
MRLs Setting for Import Tolerances(1)



MRLs Setting for Import Tolerances(2)



MRLs Setting for Import Tolerances(3)



Guideline for “Import Tolerances”

- Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan

(Notification No. 0205001, 5 February 2004 from Director-General, Department of Food Safety, MHLW)

<http://www.mhlw.go.jp/english/topics/foodsafety/residue/index.html>

Application of Import MRL

Any person may apply to the Minister of Health, Labour and Welfare for the establishment or revision of MRLs for an agricultural chemical in the case that the chemical is approved in a country for foods exported to Japan.

If the applicant is abroad, an appropriate contact person in Japan should be identified to handle the application.

Data Requirements

<Establishment of MRLs>

- A set of toxicity data and residue data given in “Data Requirements for Supporting Registration of Pesticides” (excluding effects of aquatic animals and plants, effects on beneficial creatures other than aquatic animals and plants, and study data on water contamination)

(Notification No. 12-Nouan-8147, 24 November 2000 from Director-General, Agricultural Production Bureau, MAFF)

<http://www.acis.famic.go.jp/eng/shinsei/index.htm>

<Revision of MRLs>

- Residue data on target commodities
- If new findings on safety and residue of the applied pesticide have been obtained after MRL was established, documents on the findings should be submitted.
- * Applicant must have toxicity data, but the submission shall be made upon request of the MHLW.

- GLP Compliance

In principle, studies should comply with the GLP requirements.

If data quoted from studies not conducted by the applicant, prior permission should be obtained from the study authors unless they have been publicized in scientific journals.

- Language

The executive summary should be in Japanese. Other accompanying documents, such as study reports may be written in English.

Documents in other languages are not acceptable.

POSITIVE LIST



“Positive List” System

Pesticides, Feed Additives & Vet. Drugs

Chemicals for which MRLs are established

Establishment of provisional MRLs for agricultural chemicals containing Codex Standards, Japanese registration withholding limits, and other standards establishing based upon scientific evaluation

+

Acceleration of the establishment of MRLs

Foods containing chemicals above the MRLs are enjoined from domestic distribution

Chemicals for which MRLs are not established

Establishment of a certain level that is determined to pose no adverse health effects (Uniform limit)

0.01 ppm

Foods found to contain chemicals above the level are enjoined from domestic distribution

Chemicals designated by MHLW

Chemicals that do not pose adverse health effects

Not subject to the positive list system



食品安全委員会

Food Safety Commission of Japan

Previous Regulation

Pesticides, Feed Additives & Vet. Drugs

Chemicals for which MRLs are established

MRLs for 250 pesticides and 33 vet. drugs



Foods containing chemicals above the MRLs are enjoined from domestic distribution

Chemicals for which MRLs are not established



Basically, even foods found to contain chemicals are not enjoined from distribution

Advertisement



Official Journal of Food Safety Commission of Japan

Available on J-Stage <https://www.jstage.jst.go.jp/browse/foodsafetyfscj>

Food Safety is...

A peer-reviewed open-access electronic online journal in English published by the FSCJ.

(published quarterly)

This journal features four types of articles;

- Original articles
- Short communications
- Reviews
- Risk assessments conducted by FSCJ.

Papers dealing with the following areas are particularly welcome:

1. pathogenicity or toxicity of biological, physical, or chemical agents concerning food safety;
2. occurrence of biological, physical, or chemical agents in the food chain with emphasis on food safety;
3. epidemiology or control of food-borne illnesses;
4. safety evaluation of novel foods including nanomaterials, genetically modified organisms, etc.



For further information, please visit our website:

http://www.fsc.go.jp/english/topics/fsc_journal_e1.html

**食品安全委員会**
Food Safety Commission of Japan
内閣府

ホーム サイトマップ English page
サイト内検索 検索
文字サイズ拡大表示 A~A



食品安全委員会(FSC)とは 会議開催予定と委員会の実績 FSC Views 食品健康影響評価(リスク評価) 意見・情報の交換(リスクコミュニケーション)

ホーム > Food Safety - The Official Journal of Food Safety Commission of Japan


Official Journal of Food Safety Commission

20 November 2013

Food Safety - The Official Journal of Food Safety Commission of Japan
Website: Japan Science and Technology Information Aggregator, Electronic (J-STAGE)
<https://www.jstage.jst.go.jp/browse>

Food Safety - The Official Journal of Food Safety Commission of Japan - Vol. 2: 25 March 2014 -
<https://www.jstage.jst.go.jp/browse/foodsafety/fscj>

[From Editor-in-chief\(PDF\)](#)
[Instructions for Authors\(PDF\)](#)
[Scope of the journal\(PDF\)](#)

〒107-6122 東京都港区赤坂 5-2-20 赤坂パークビル22階 TEL 03-6234-1166 FAX 03-3584-7390
Copyright © 2006 - 2011 Food Safety Commission. All Right Reserved.

**食品安全委員会**
Food Safety Commission

Thank you for your attention!

