

Management system of Agricultural Chemicals in Japan

Senior coordinator Y.Kitamura
Agricultural Chemicals Inspection Station (ACIS)
Food and Agricultural Materials Inspection Center (FAMIG)

Outline

I . Introduction

II . Overview of the management system of
agricultural chemicals in Japan

III . MRL system in Japan

I. Introduction

Basic knowledge and Role of agricultural chemicals

3

World Population Movements and Estimates: BC to 2050

Year	1000 of 1,000 years ago	7000 BC	600 BC	A.D. 1	1650	1750	1800	1850	1900	1950
Estimated population (100 million)	Emergence of humans	0.5	1	3	5.075	7.95	9.69	12.65	16.56	25.29

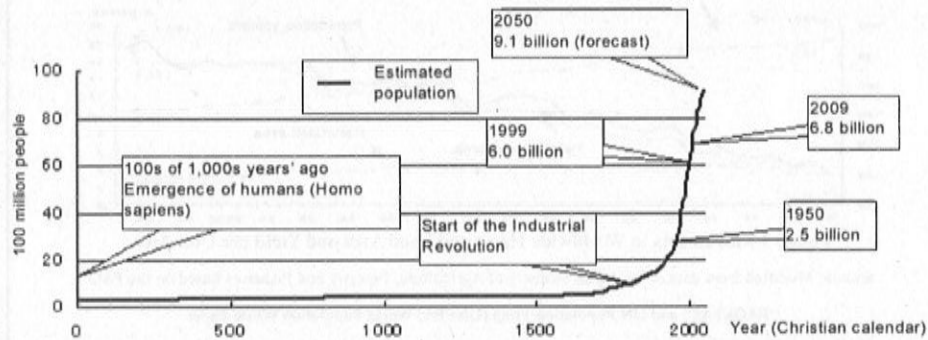
Year	1955	1960	1965	1970	1975	1980	1985	1990	1995	2000
Estimated population (100 million)	27.63	30.23	33.32	36.86	40.61	44.38	48.46	52.9	57.13	61.15

Year	2005	2010	2015	2020	2025	2030	2035	2040	2045	2050
Estimated population (100 million)	65.12	69.09	73.02	76.75	80.12	83.09	85.71	88.01	89.96	91.5

Source: Figures for 1900 and before are based on the UN, The Determinants and Consequences of Population Trends, Vol. 1, 1973. Figures for 1950 onwards are based on the UN, World Population Prospects: The 2008 Revision (medium estimate).

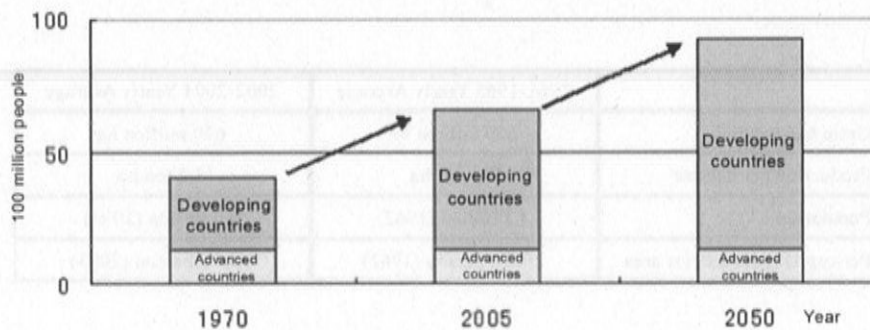
4

Population Movements from the Christian Era Onwards



5

Changes in World Population



6

Trend of yield per unit area

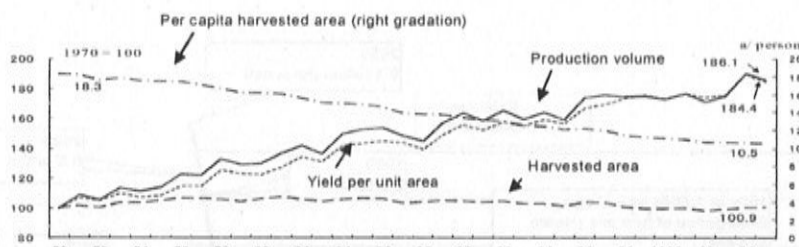


Figure 3 Movements in Worldwide Harvested Land Area and Yield per Unit Area

Source: Modified from data of the Japan Ministry of Agriculture, Forestry and Fisheries based on the FAO

"FAOSTAT" and UN Population Fund (UNFPA) World Population White Paper

7

Movements in Worldwide Grain Harvest Area and Production per unit area

	1961-1963 Yearly Average	2002-2004 Yearly Average
Grain harvest area	650 million ha	670 million ha
Production per hectare	1.4 ton/ha	3.2 ton/ha
Population	3.1 billion (1962)	6.3 billion (2003)
Per capita grain harvest area	20.8 a/person (1962)	10.7 a/person (2003)

8

Definition of Pesticides

FAO International Code of Conduct on the Distribution and Use of Pesticides:

“Pesticide means any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances which may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport.” 9

History of Pesticides

The history of modern synthetic pesticides dates back to the discovery that dichlorodiphenyl- trichloroethane (DDT) possessed powerful pesticidal ability by Paul Hermann Muller, an engineer of the Swiss pigment maker Geigy, in 1938.

10

Types of pesticides based on their purpose of use

- (1) Insecticides;
Chemical agents for controlling pests that damage agricultural crops
- (2) Fungicides;
Chemical agents for controlling diseases that damage agricultural crops
- (3) Insect-fungicides;
Chemical agents for simultaneously controlling harmful pests and diseases

11

Types of pesticides based on their purpose of use

- (4) Herbicides;
Chemical agents for controlling weeds
- (5) Rodenticides;
Chemical agents for controlling field rodents that damage agricultural crops
- (6) Plant growth regulators;
Chemical agents for accelerating or suppressing growth of agricultural crops

12

Types of pesticides based on their purpose of use

- (7) Attractants;
Chemical agents mainly for attracting harmful pests by odor, etc.
- (8) Repellents;
Chemical agents for repelling mammals and birds that damage agricultural crops
- (9) Spreading agents;
These are used with other pesticides in order to enhance the adherence of those chemicals.

13

Development of Pesticides

The development of new pesticides,

- ① High technical prowess
- ② Extremely long time: at least 10 years
- ③ Huge costs: 10-25 billion yen

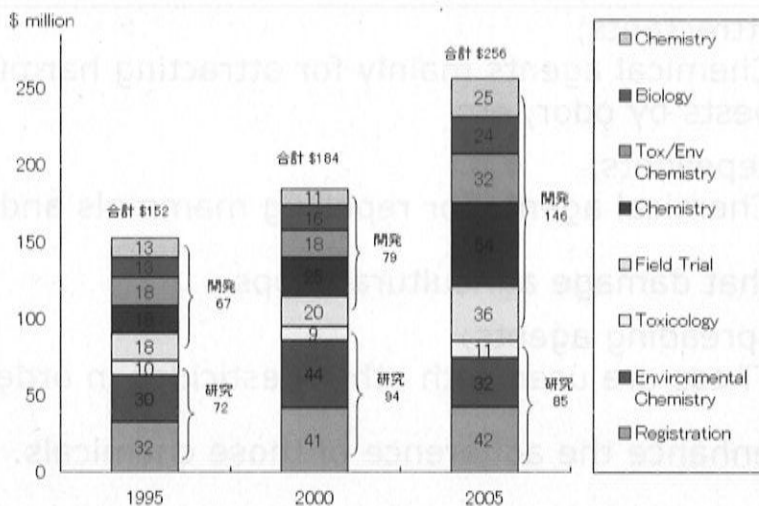
The chances of compounds being refined into pesticide,

Year 1975: 1 in 10,000 and 1 in 20,000 on average.

Now: 1 in 50,000 or less.

14

Costs of Exploration and Product Refinement of New Active Ingredients



15

Current Conditions of the Pesticides Industry

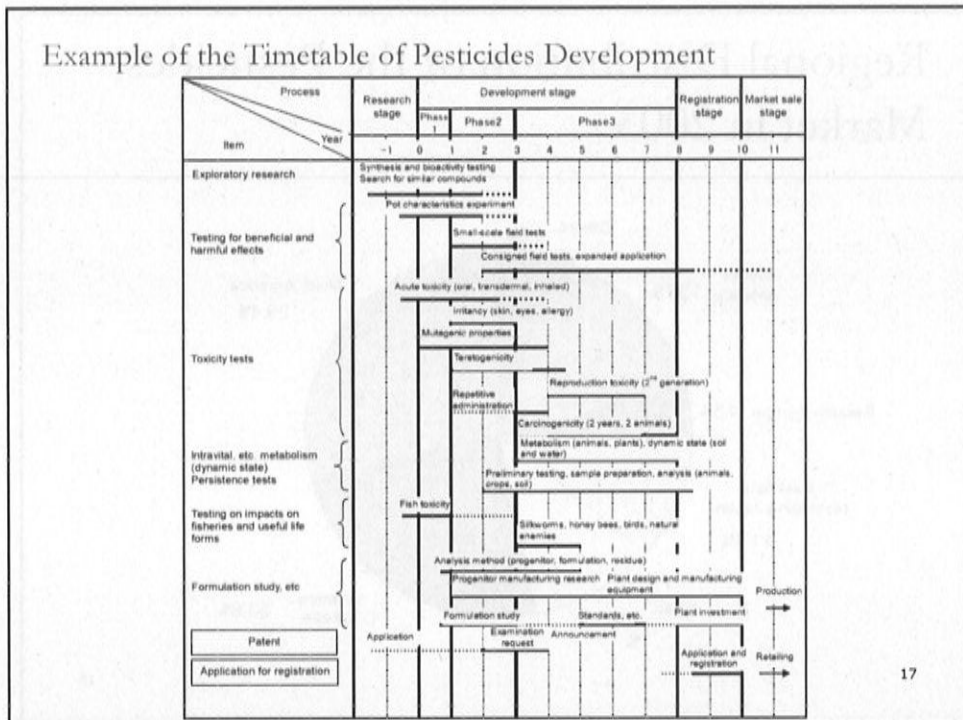
□ Pesticides market : 35 billion US dollars in 2005

□ Pharmaceutical market: 605.1 billion US dollars in 2006

□ The pesticides market is roughly one-seventeenth of Pharmaceutical market

16

Example of the Timetable of Pesticides Development



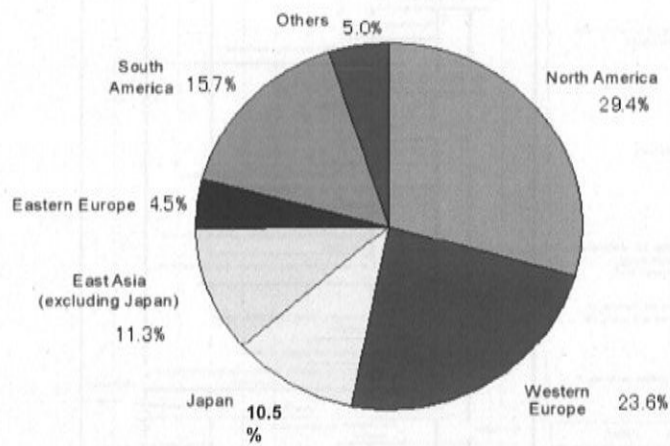
17

Market Share of the Top 9 Companies by Sales (2005)

Order	Company	Sales (million US\$)	Share (%)	Accumulated share (%)
1	Syngenta	6307	18	18
2	Bayer Holding Ltd.	6929	20	38
3	BASF	4104	12	50
4	The Dow Chemical Company	3058	9	58
5	Monsanto Company	3042	9	67
6	E. I. du Pont de Nemours and Company	2274	6	73
7	Makhteshim Agan Industries Ltd	1747	5	78
8	Sumitomo Chemical Co., Ltd	1644	5	83
9	Nufarm Limited	1191	3	87
10	Others	4704	13	100
	Total	35000	100	

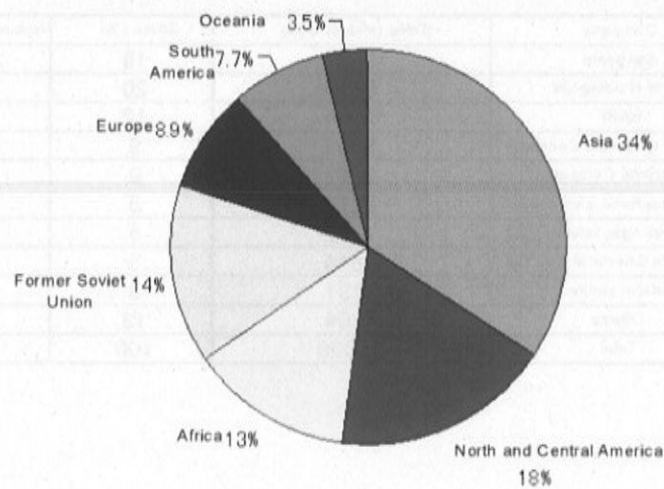
18

Regional Distribution of the Pesticides Market in 2003



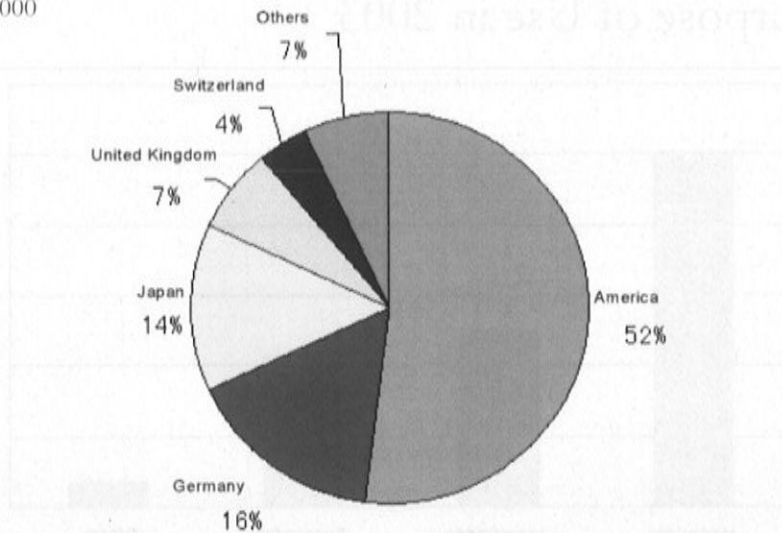
19

Distribution of Agricultural Land Area in the World in FY 1999



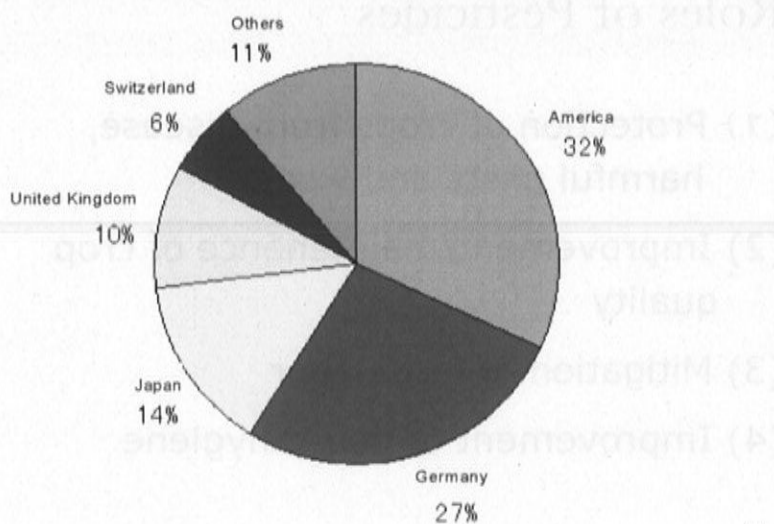
20

Number of Patents in the Pesticides and Peripheral Fields Registered with the United States Patent and Trademark Office between 1978 and 2000 and 2000



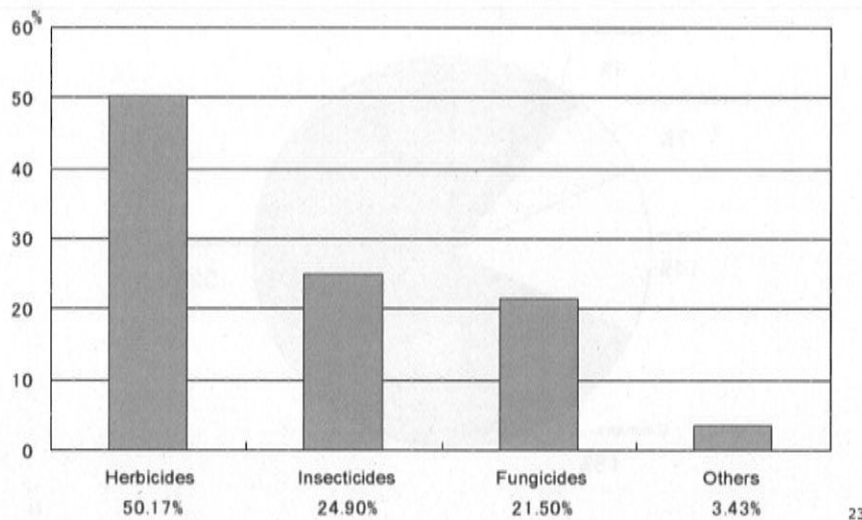
21

Number of Patents in the Pesticides and Peripheral Fields Registered with the European Patent Office between 1978 and 2000



22

Breakdown of World Pesticides Sales by Purpose of Use in 2003



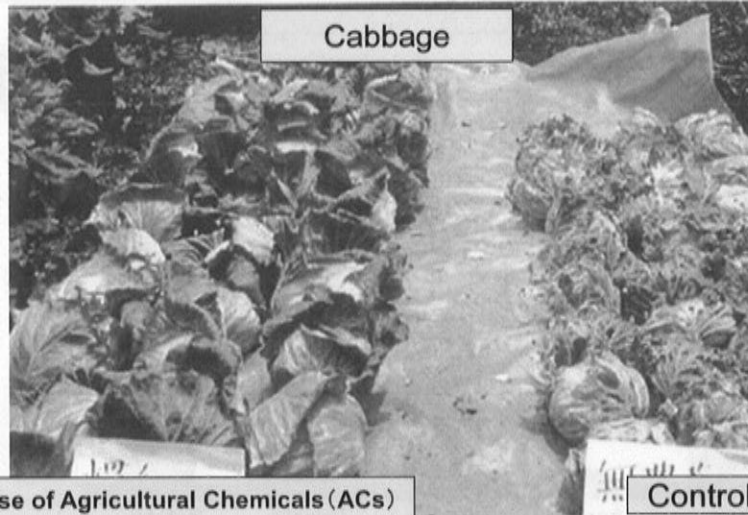
23

Roles of Pesticides

- (1) Protection of crops from disease, harmful pests and weeds
- (2) Improvement/maintenance of crop quality
- (3) Mitigation of farm labor
- (4) Improvement of public hygiene

24

Importance of plant protection



Use of Agricultural Chemicals (ACs)

Control

25

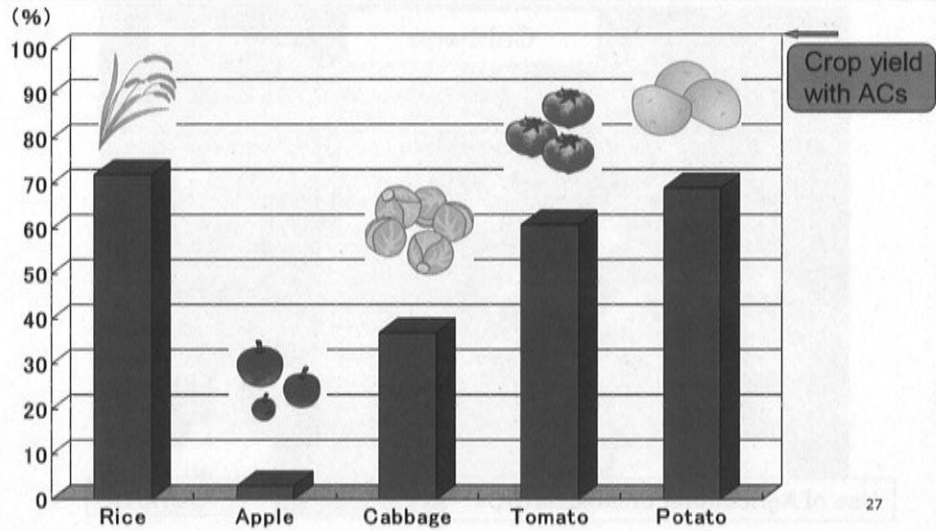
Decline in Revenue when Not Using Pesticides

(Survey by the Japan Plant Protection Association, 1990-2006)

Crop (number of surveyed cases)	Decline in Revenue (%)			Decline in Profit		
	Minimum	Maximum	Mean	Minimum	Maximum	Mean
Rice (14)	0	100	24	5	100	30
Wheat (4)	18	56	36	18	93	66
Soybeans (8)	7	49	30	18	63	34
Apples (8)	90	100	97	95	100	99
Peaches (4)	37	100	70	48	100	80
Cabbages (20)	10	100	67	18	100	69
Radish (12)	4	100	39	18	100	60
Cucumbers (5)	11	88	61	11	86	60
Tomatoes (7)	14	93	36	13	92	37
Potatoes (2)	22	44	33	22	64	43
Eggplants (2)	21	75	48	22	78	50

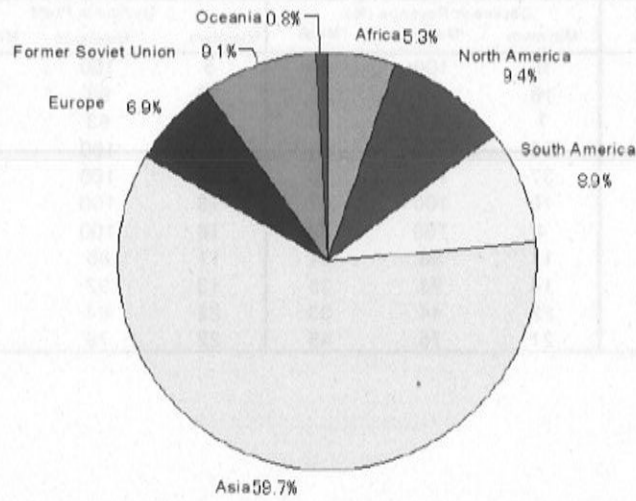
26

Decrease in Crop yield without using ACs



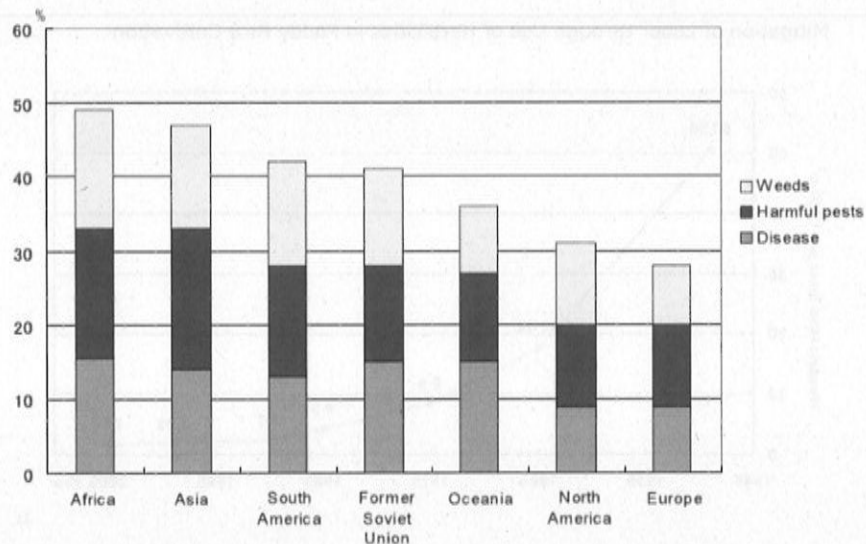
27

Value of Crop Losses Caused by Pest and Disease Damage and Weeds (US\$ billion)



28

Loss Rate of Crops Due to Disease, Pests and Weeds

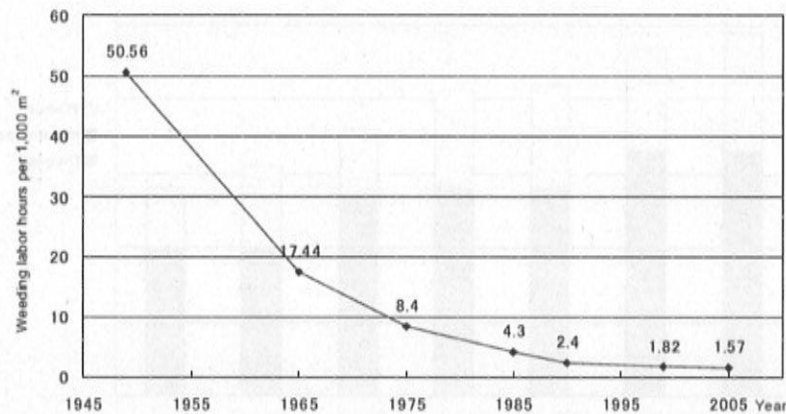


Improvement/maintenance of crop quality

- Typical example is the cultivation of seedless fruits through utilizing plant hormones.
- Prevention of rind puffing that causes skin to separate from fruit in Citrus
- Long-term prevention of post-harvest softening of fruit
- Picking of apples and other fruits
- Enlargement of tomatoes and eggplants
- Prevention of fruit dropping
- Acceleration of coloring and ripening of apples etc.

Mitigation of farm labor

Mitigation of Labor through Use of Herbicides in Paddy Rice Cultivation



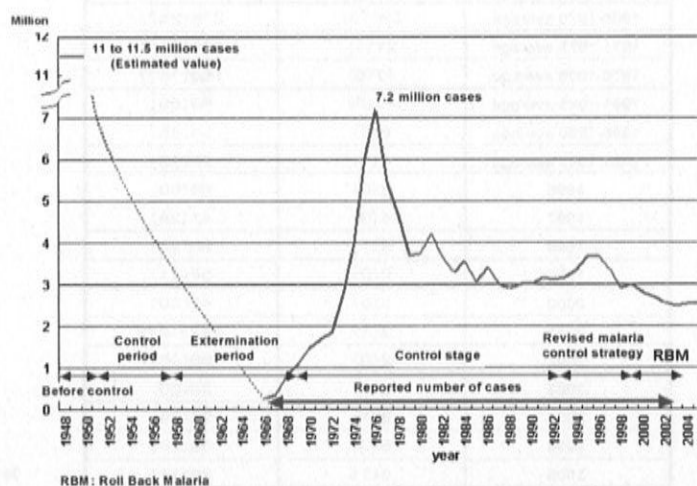
31

Improvement of public hygiene

- In Sri Lanka, thanks to the periodic spraying of DDT between 1948 and 1962, the number of malaria patients was reduced from approximately 2.8 million people per year to 17 people in 1963
- In Italy, DDT was used from 1947 with the objective of eradicating malaria, resulting in the country being declared free of the disease by the World Health Organization (WHO) in 1970.
- In Japan, phthiriasis was prevalent in the years following World War II, however, thanks to thorough prevention measures using DDT and so on, the public hygiene situation was greatly improved.

32

Malaria Countermeasures and Number of Infected Persons in Southeast Asia



33

Problems by Pesticides

- Adverse effect to farmers
- Negative impact to environment & ecosystem
- Short term & long term effect to consumer
- etc

34

Pesticide Poisoning Cases in Japan

Year	Fatalities (figures in parentheses indicate during spraying)	Poisoning (figures in parentheses indicate during spraying)
1957-1960 average	45	681
1961-1965 average	38 (20)	322 (296)
1966-1970 average	39 (15)	276 (252)
1971-1975 average	21 (4)	233 (216)
1976-1980 average	17 (6)	158 (147)
1981-1985 average	12 (3)	68 (59)
1986-1990 average	6 (3)	54 (45)
1991-1995 average	4 (1)	20 (13)
1996	2 (0)	66 (60)
1997	4 (0)	43 (29)
1998	3 (1)	50 (44)
1999	0 (0)	57 (41)
2000	0 (0)	42 (30)
2001	2 (1)	144 (132)
2002	2 (0)	56 (48)
2003	6 (1)	28 (25)
2004	2 (1)	54 (39)
2005	6 (0)	38 (26)
2006	6 (1)	28 (11)
2007	0 (0)	35 (26)

35

Differences between Pesticides and Pharmaceuticals

they differ greatly in terms of economy and their tolerance levels for harmful effects (side effects). Since pharmaceuticals are used with the objectives of curing diseases, mitigating symptoms and saving lives through their medicinal properties, the obtained effects are important and there is a certain tolerance level with respect to side effects. Moreover, in cases where such pharmaceuticals are directly concerned with human life, economy can be disregarded. Meanwhile, in the case of pesticides, cost effectiveness is the primary concern and the occurrence of harmful incidents (harmful effects or environmental pollution, etc.) is basically not tolerated.

36

Off-patent Active Ingredient Drug Products (Generic Products)

- The ratio of use of generic pesticides in developing countries is far higher than in advanced countries. For example, generic pesticides account for 75% of all the pesticides used in China.
- Generic pesticides have the same active ingredient compounds as original products, because they adopt different synthesizing techniques and use different plants, etc. in synthesis, the types and quantities of impurities generated.

37

Regional Breakdown of Generic Pesticides Makers (Top 100 Firms in Terms of Sales)

Region	Number of Companies
China	41
India	20
Europe (incl. Turkey and Israel)	19
South-east Asia (incl. Australia)	9
South America	7
North America	4
Total	100

38

Generic Pesticides Makers in the World (Top 30 Companies with Sales)

Company	Country	Annual Sales (million US\$)	Fiscal Year
1 Makhteshim-Agan	Israel	1581	2006
2 Nufarm	Australia	1253	2006
3 Cheminova	Denmark	680	2006
4 Sipsam-Oxon	Italy	378	2005
5 United Phosphorus	India	350	2006
6 Cerexagri	US	270	Unknown
7 Agripec	Brazil	198	Unknown
8 Isagro	Italy	196	2006
9 Amvac	US	194	2006
10 Red Sun	China	153	2005
11 Xinan Chemical	China	138	2005
12 Rallis	India	133	2006
13 Sanonda	China	120	2005
14 Tamino	Belgium	119	2006
15 Meshmani Organics	India	105	2007
16 Huaxing Chemical	China	100	Unknown
17 Rotam	Hong Kong	100	Unknown
18 Excel Crop Care	India	93	2007
19 Jiangshan Agrochemical	China	90	Unknown
20 AH Marks	UK	84	Unknown
21 Nagarjuna	India	80	2006
22 Sabero Organics	India	75	Unknown
23 Indofil	India	70	Unknown
24 Jiangsu Suhua Group	China	70	Unknown
25 Shenghua Biok	China	70	Unknown
26 Changxing Zhongshan	China	60	Unknown
27 Jingga Chemicals	China	60	Unknown
28 Punjab Chemicals	India	60	2006
29 Shandong Qiaochang Chemical	China	60	Unknown
30 IGV	Spain	58	2004

39

Imitation Products and Illegal Pesticides

In developing countries, as with other legislation, patent-related legislation had not made much progress until a few years ago. Accordingly, new active ingredients that were protected by law in advanced countries were not protected in developing countries due to the absence or inadequacy of legislation.

In developing countries, because the efficacy of controls isn't guaranteed, numerous imitation products continue to be manufactured and distributed. For example, according to the Report on the Survey of Imitation Product Suppression Activities Utilizing Trade Fairs in the Pesticide Industry, 2009 staged by JETRO Shanghai Center, in China, "the trade marks/trade names of original products continue to be unlawfully used on the labels of generic products and imitation products, and there are even cases where the labels of original products are forged (dead copies) and affixed to imitation products for sale."

40

Needs for Agricultural Chemicals (ACs)

- Ensuring stable crop yield
- Ensuring good quality of agricultural products
- Improving work efficiency

41

Basic concept of management of ACs

ACs are

- ① used for plants directly which would be foods
- ② released intentionally into the environment



Need for risk assessment and risk management for protecting human health and the environment

42

II. Overview of the current Management system of agricultural chemicals in Japan

43

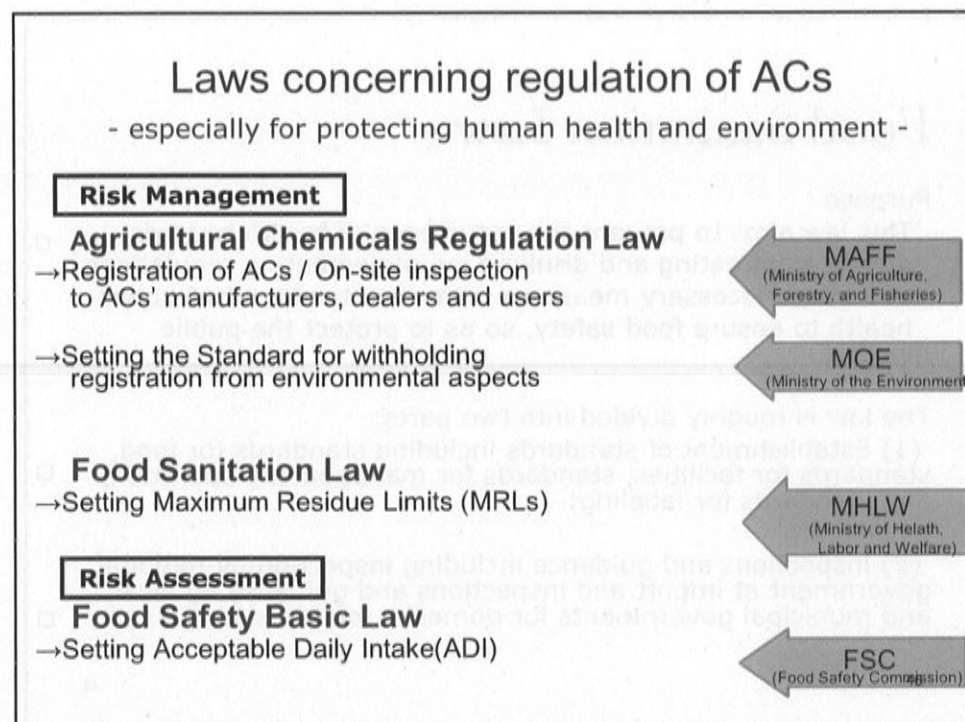
Food Safety Approach in Japan



44

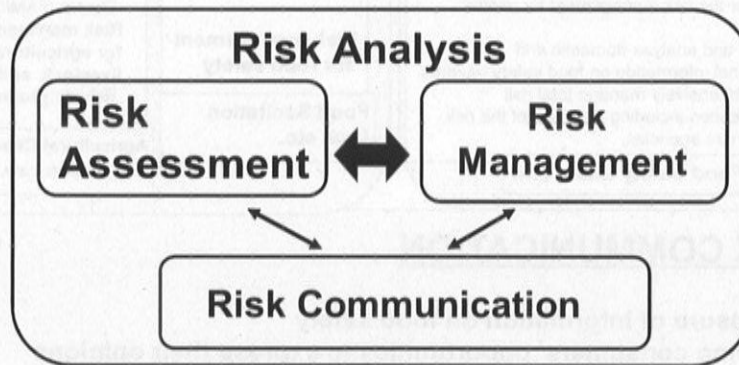


45



Food Safety Basic Law Enforced in July 2003

- Principles on Food Safety Administration
- Establishment of Food Safety Commission
- Responsibilities of Government, Food Producers and Consumers
- Application of Risk Analysis in Food Safety Administration



47

Food Sanitation Law

Purpose

This law aims to prevent the occurrence of health hazards arising from eating and drinking by implementing regulations and other necessary measures from the standpoint of public health to ensure food safety, so as to protect the public health.

The law is roughly divided into two parts:

(1) Establishment of standards including standards for food, standards for facilities, standards for management/operation, and standards for labeling;

(2) inspections and guidance including inspection by national government at import and inspections and guidance by local and municipal governments for domestic food businesses.

48

Agricultural Chemicals Regulation Law

Purpose

The ultimate purposes of the law are to make agricultural production stable and to prevent any adverse effect to human health and the environment caused by pesticide use.

This is done through a registration system.

Two ministries are mainly involved:

(1) Ministry of Agriculture, Forestry and Fisheries/ACIS

Examination based on criteria (i.e. "the registration Withholding Standards")
 false description in application, damage to crops, damage to users, designation misunderstanding efficacy, inferior efficacy, inconformity with official standards, persistency in crops, persistency in soil, water pollution and damage to aquatic animals and plants

(2) Ministry of the Environment

Establishment of the Standard on
 persistency in soil, damage to aquatic animals and plants, water pollution and persistency in crops

MRLs (Food Sanitation Law) are used as this standard.

49

Definition of Pesticides (agricultural chemicals) in the AC Regulation Law

Agricultural Chemicals (ACs)

Used on plants (e.g. crop, flower, tree, lawn and hay & grass)

against insects, disease and weeds

- Insecticide
- Fungicide
- Rodenticide
- Attractant
- Repellent
- Communication disruptor
- Herbicide

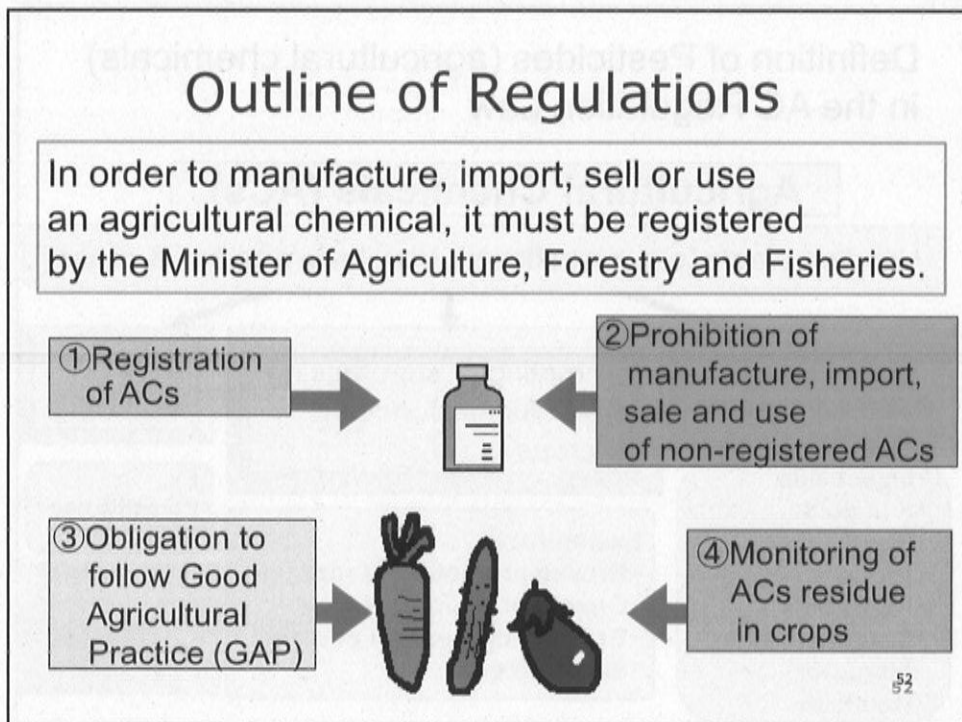
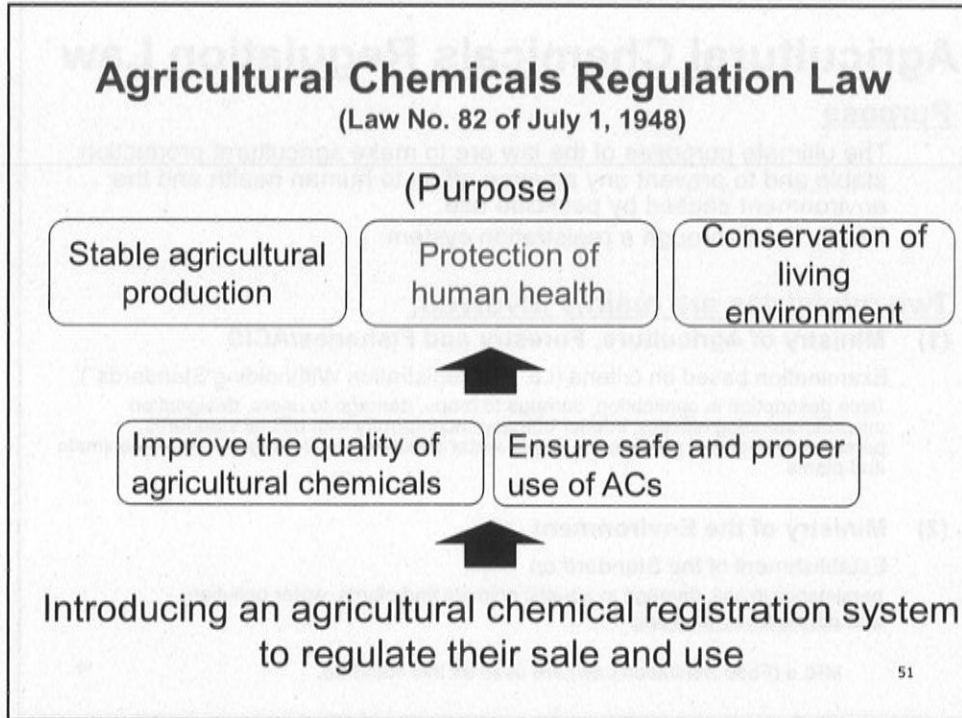
promoting or suppressing physiological functions of crops

- Examples:
- Growth promotion of root
 - Growth promotion of fruit
 - Growth suppression of stem
 - Seedless etc.

Natural enemies

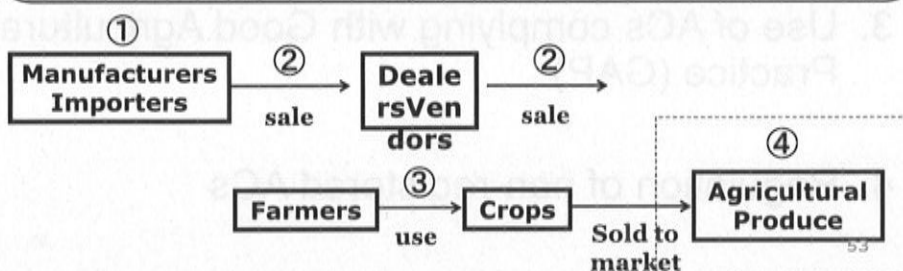
Ex.
Parasitic bee
Ladybug etc.





Outline of Regulations

- Prohibition of manufacture, importation, sale and use of non-registered AC(①、②、③)
- Order to recall illegal and/or unsafe AC(②)
- Obligation to follow GAP (③)
- Monitoring/Enforcement of MRLs by the Food Sanitation Law(④)



Currently Registered Pesticides

(As of 30 September 2013)

Currently registered Formulations (Active ingredients)	4,342 (555)
Cumulative No. (formulation)	23,358

Distinction of Agricultural Chemicals

- Formulations (e.g. granular, emulsion)
- Contents of A.I. (e.g. 5% and 10% A.I.)
- Mixture with other A.I.(e.g. A.I. "A" and A.I. "B")
- Trade marks

54

How ACs are regulated in Japan?

1. Registration application and evaluation
2. Risk assessment and risk management
3. Use of ACs complying with Good Agricultural Practice (GAP)
4. Regulation of non-registered ACs

55

Registration application and evaluation

Documents and Samples required for Application

- **Application form stating the items required in the law**
- **Documents showing the test results concerning efficacy, phytotoxicity, toxicity and persistency of the ACs** (※ Ref. "Data requirements for Supporting Registration of ACs")
- **Samples of ACs**



56

Data requirement for ACs registration

Study report shall be made in accordance with
 "Data Requirements for Supporting Registration of ACs"
 (Notification No. 12-Nouan-8147, 24th November, 2000)

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

Examples:

- 1 Efficacy / Phytotoxicity
- 2 Residues (crops / soil)
- 3 Metabolism (crop / animal)
- 4 Toxicity (acute/ chronic)
- 5 Environmental effects (aquatic organisms, pollinators...)

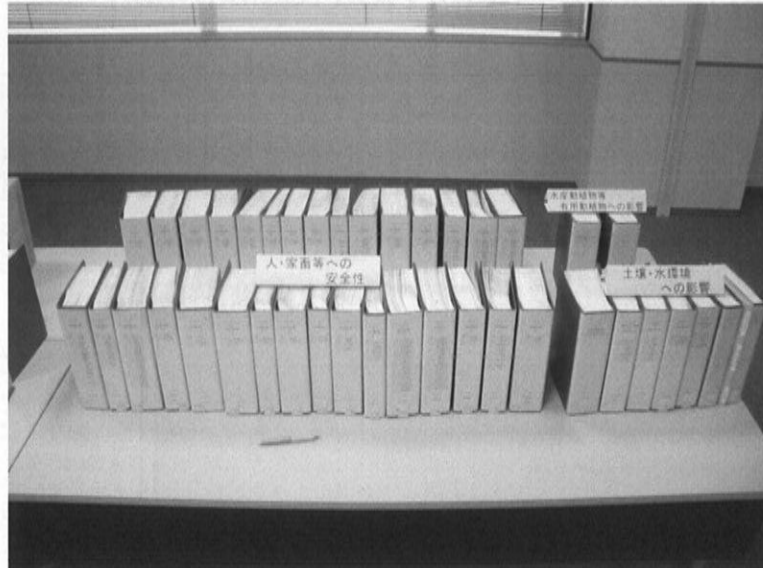


Examples of application materials (new applications)



58

Examples of application materials (new applications)



59

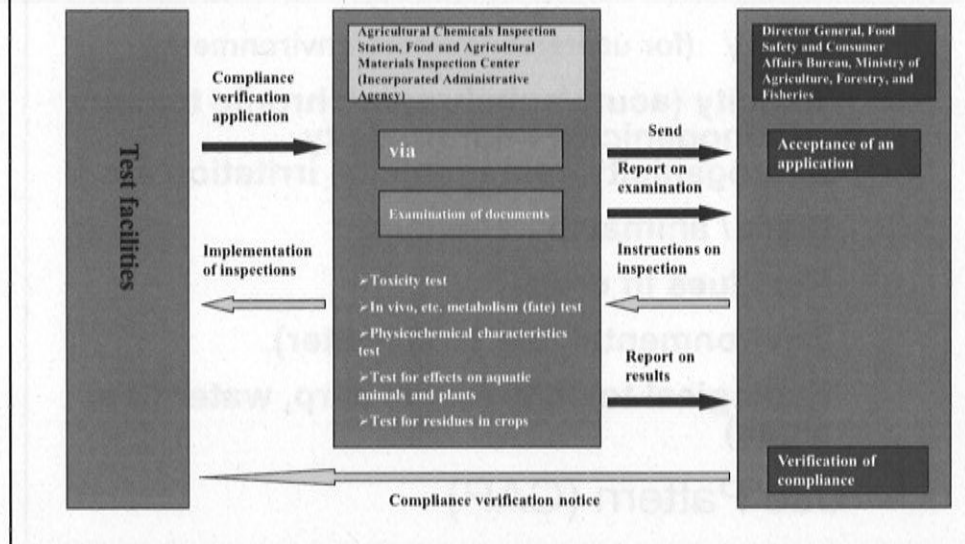
GLP System and Inspections

- GLP (Good Laboratory Practice)
 - “Standards for GLP”
 - “Standard Operating Procedures at Good Test Facilities”
 - Auditing system for test facilities to ensure the reliability of test studies
 - Inspection of equipment, instruments, test procedures, and recording/storage at test facilities
 - Inspection of test studies
 - Target test range

Toxicity test	32 items
In vivo, etc. metabolism (dynamics) test	4 items
Physicochemical characteristics test	15 items
Test for effects on aquatic animals and plants	10 items
Test for residues in crops (except translocation to milk)	

60

Mechanism of Verification of GLP Compliance



Required Data for Registration (1)

- Quality of AC formulation
 - Active ingredient & auxiliary substances (content, method of analysis)
 - Physical and chemical properties
 - Specification & samples (technical grade, formulation(s))
 - Stability
- Efficacy / Phytotoxicity
 - Field test results

Required Data for Registration (2)

■ Safety (for users/consumers/environment)

Toxicity (acute/subchronic/chronic toxicity, carcinogenicity, neurotoxicity, teratogenicity, mutagenicity, irritation etc.)

Plant / animal metabolism

Residues in crops

Environmental fate (soil, water)

Ecological toxicity (small carp, water flea, algae)

■ Use Pattern (GAP)

Withholding of ACs registration (1)

- any misstatements in the application;
- trade name causes misunderstanding of the active ingredient and the efficacy;
- effect of the AC is not sufficient;
- specification is out of official specification;

When an AC may cause:

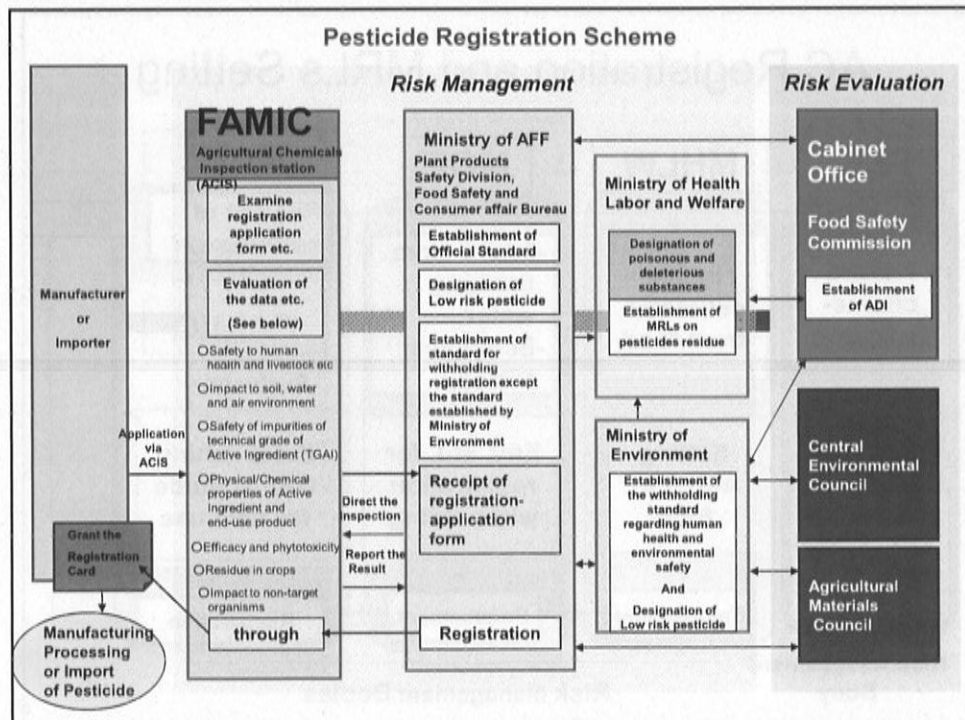
- damages to applicable crops when used according to the proposed use pattern; or
- significant adverse effects the health of human and livestock even if taken any appropriate risk management measures

Withholding of ACs registration (2)

When an AC may cause:

- significant adverse effects on the health of human and livestock caused by the residues in applicable crops (and due to the persistency in soil);
- significant adverse effects on aquatic organisms; or
- water pollution which leads to adverse effects on the health of human and livestock

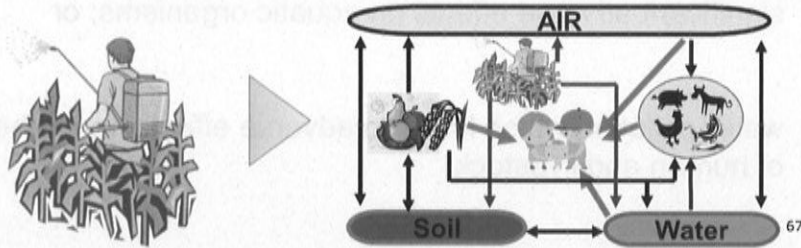
65



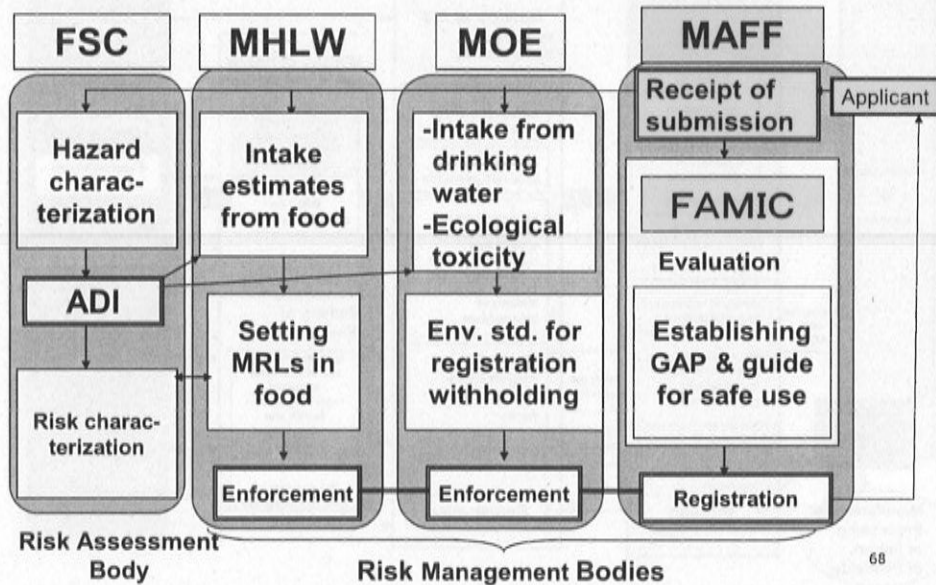
Risk assessment & Risk management

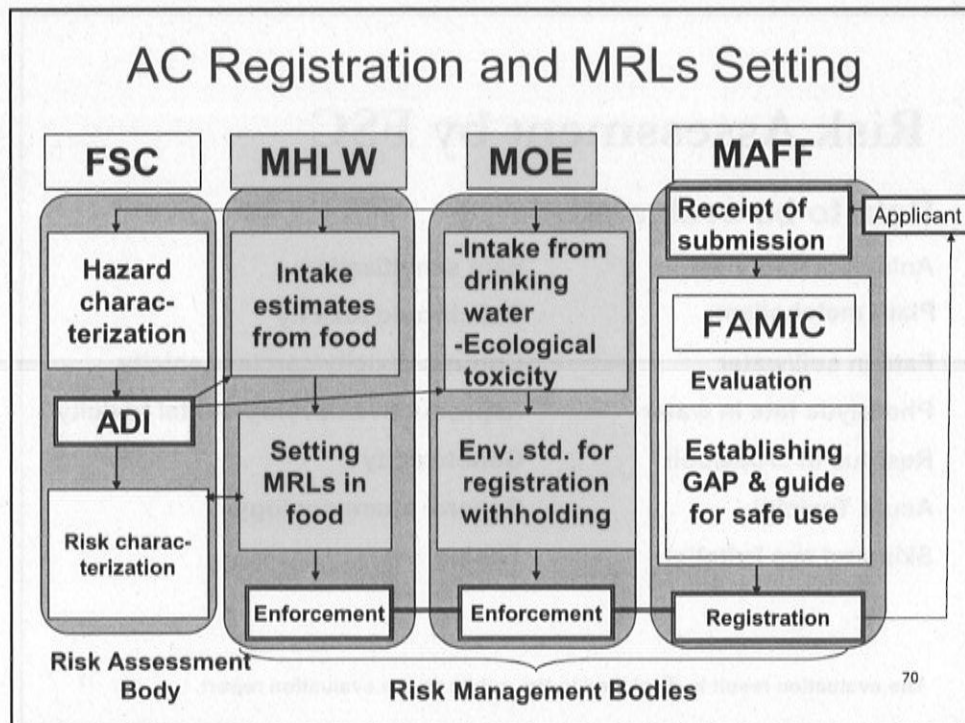
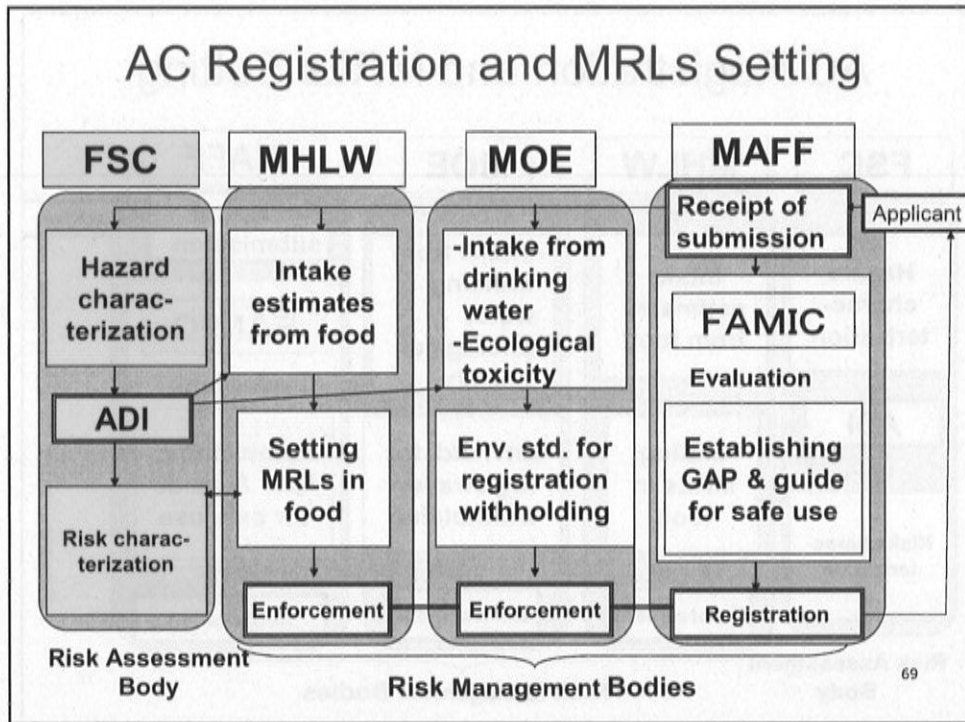
Safety of human health

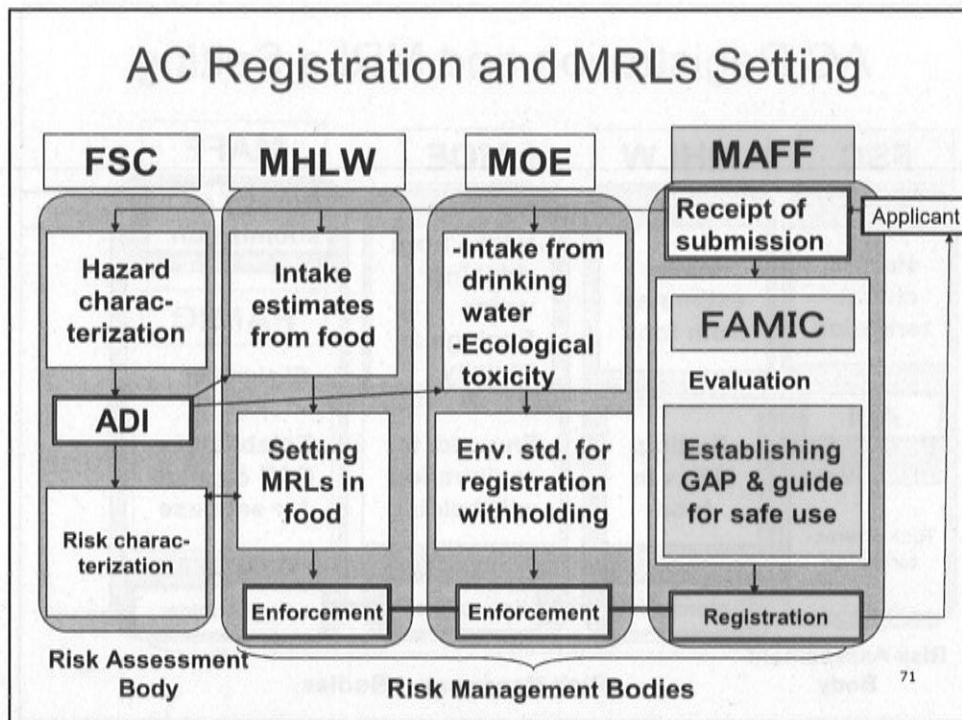
- ACs user
(Farmer, pest control conductor etc.)
- Consumer



AC Registration and MRLs Setting







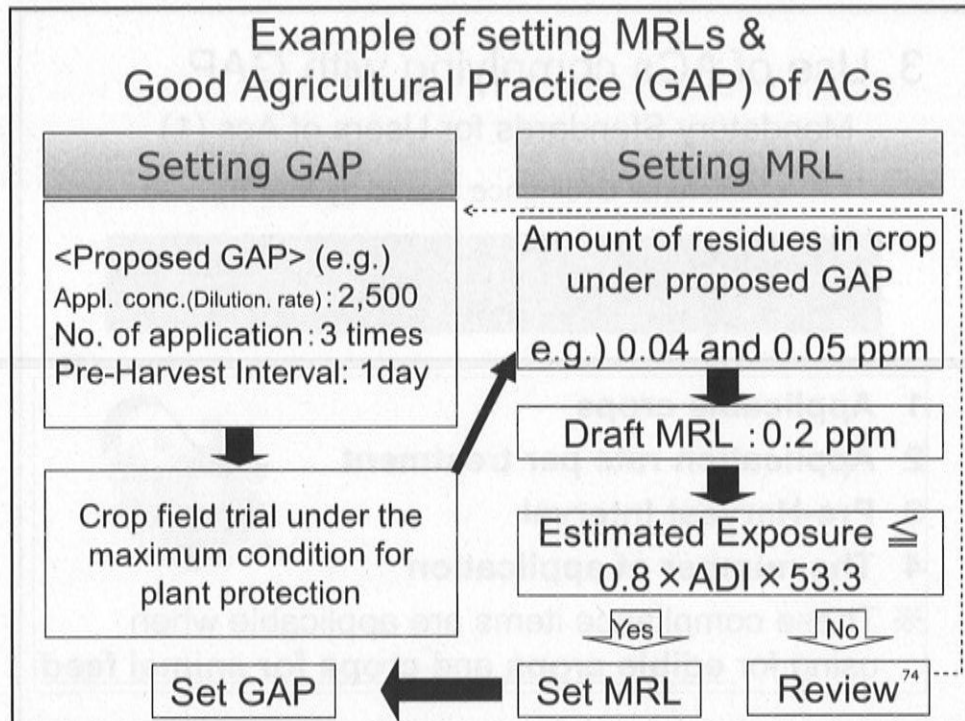
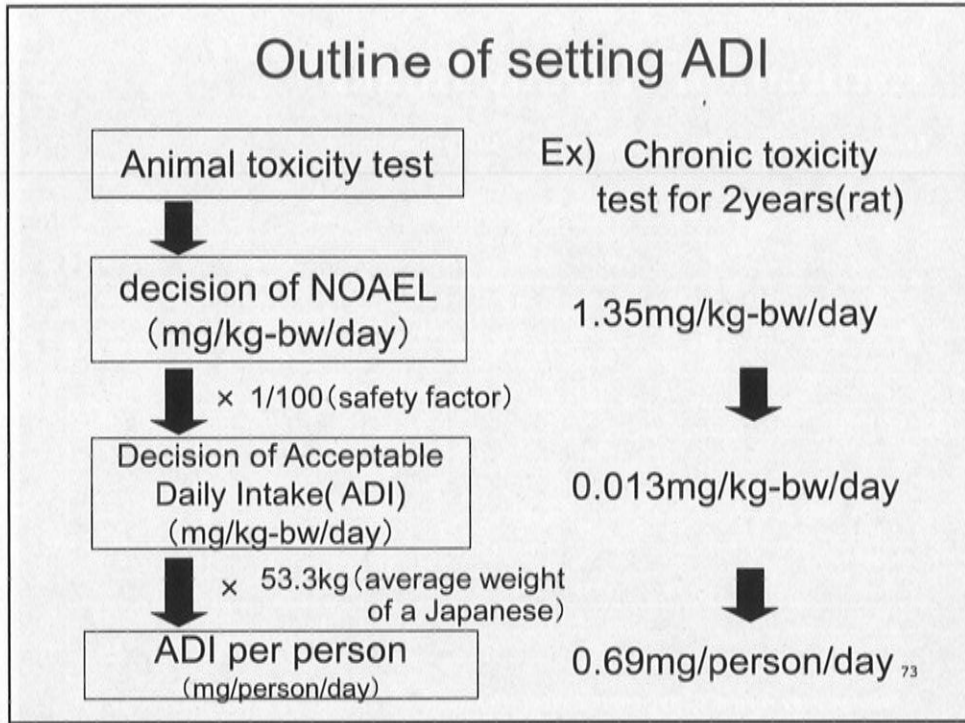
Risk Assessment by FSC

Data to be evaluated

- | | |
|--------------------------|-------------------------------------|
| Animal metabolism | Skin sensitization |
| Plant metabolism | Subchronic toxicity |
| Fate in soil/water | Chronic toxicity/carcinogenicity |
| Photolytic fate in water | Reproductive/developmental toxicity |
| Residue in crops/soil | Genotoxicity |
| Acute Toxicity | General pharmacology |
| Skin and eye irritation | Others |

The evaluation result is disclosed to the public as the evaluation report.

72



Estimation of Daily Intake

Example of Theoretical Maximum Daily Intake (TMDI) estimation

Name :AAAA

Food	Proposed MRL (mg/kg)	ug/man/day							
		Entire nation		Infant (1 to 6 years old)		Pregnant women		Elderly (65 years old or over)	
		ff	Intake	ff	Intake	ff	Intake	ff	Intake
Corn	0.05	2.5	0.13	4.3	0.22	2.7	0.14	0.8	0.04
Beans, dry	0.5	1.4	0.70	0.5	0.25	0.1	0.05	2.7	1.35
Cabbage	2	22.8	45.60	9.8	19.60	22.9	45.80	19.9	39.80
Tomato	0.5	24.3	12.15	16.9	8.45	24.5	12.25	18.9	9.45
Egg plant	0.5	4.0	2.00	0.9	0.45	3.3	1.65	5.7	2.85
Lettuce	2	6.1	12.20	2.5	5.00	6.4	12.80	1.2	2.40
***	***	**	***	**	***	**	***	**	***
Cherry	1	0.1	0.10	0.1	0.10	0.1	0.10	0.1	0.10
Strawberry	0.5	0.3	0.15	0.4	0.20	0.1	0.05	0.3	0.15
Grape	3	5.8	17.40	4.4	13.20	1.6	4.80	3.8	11.40
Total			336.8		171.8		287.8		377.0
ADI%			2.3		4.0		1.9		2.6

ff: Food factor

Average body weight: 53.3kg(entire nation), 15.8kg(infant), 55.6kg(pregnancy), 54.2kg(elderly)

3. Use of ACs complying with GAP

Mandatory Standards for Users of Acs (1)

(Ministerial Ordinance issued by MAFF)

Matters to be complied with

(violation of the followings will result in penalty)

- 1 Applicable crops
- 2 Application rate per treatment
- 3 Pre-Harvest Interval
- 4 The number of application



※ These compliance items are applicable when using for **edible crops** and **crops for animal feed**.

Mandatory Standards for Users of ACs (2)

Recommendations (Voluntary actions)

- 1 **Not use ACs** over **expiry date** of quality guarantee,
- 2 **Record date** and **place** of ACs application, **name** of ACs and **amount** of the use,
- 3 **Pay attention to drift of ACs on aerial spray** and **spray near/in residential area**,
- 4 Comply with **term for preventing runoff of water of paddy field** in which ACs are applied.
- 5 Comply with **term for covering soil** and **take some actions to prevent volatilization**, when soil fumigant is applied.

77

Information written on Label of ACs

- Registration number**
- ACs category** (e.g. insecticide), **trade name, physical and chemical properties, active and other ingredients** (name and content),
- Amount** in ACs container
- Use pattern**(Applicable crops and target organisms, application methods and times of use etc.)

78

Information written on Label of ACs

- Precautions, toxic information and information of detoxification to humans or livestock
- Precautions and toxic information to aquatic organisms
- Information concerning flammable, explosive, or harmful effect to skin
- Precautions for use or storage
- Name and address of manufacturing plant
- Expiry date of quality guarantee

79

Example of Label on ACs product

The image shows a detailed view of a pesticide label with the following components and annotations:

- Registration number:** Located at the top center.
- Use pattern table:** A table on the right side of the label detailing application methods.
- ACs group:** Indicated by a box on the left side.
- Trade name:** '殺虫剤' (Insecticide) and 'DDVP乳剤' (DDVP Emulsion) are listed.
- Toxicity and inflammability classification:** '500m入' (500ml container) is noted.
- Manufacturing plant and company:** '株式会社' (Company) is visible at the bottom.
- Date of quality guarantee:** Located at the bottom center.
- Pictogram concerning user safety:** A circular pictogram on the right side.
- Precaution concerning efficacy and phytotoxicity:** Text on the right side.
- Precaution concerning user safety:** Text on the right side.
- Detoxication:** Text on the right side.
- Precaution concerning aquatic organisms:** Text on the right side.

80

Example of GAP

(Formulation type : Emulsifiable Concentrate)

Crop	Pest or group of pests controlled	Spray Conc. (dilution fold)	PHI (Pre-harvest Interval) (day)	Number of application	Method of application
Cabbage	Aphids Cabbage moth	1,000	30	2	Spray
	Green Caterpillar	1,500			
Tomato	Aphids spider mite	1,000	1		

81

Examples of Guide for Safety Use

- When spraying it in paddy fields, stop the flow of irrigation water for at least 7 days after its application in order to avoid contamination of canal / river water.
- Do not use rice straw as feed after the application.
- Do not harvest baby leaves as vegetables after soil application.
- Do not use it in areas of beekeeping.

82

Monitoring on Compliance with GAP

- Enforcement of MRLs according to the Food Sanitation Law
 - Local governments monitor residues of ACs in foods on the market
 - MHLW compiles and publishes data
- Monitoring program on proper use of ACs by MAFF

83

Monitoring survey on proper use of ACs

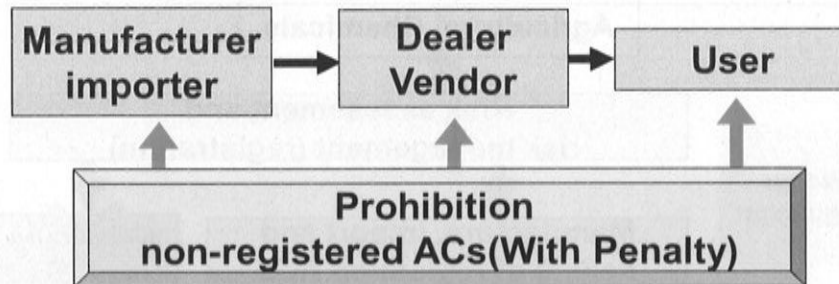
4,000 farmers in Japan (chosen every year)
(orchard, vegetables, tea, and rice etc.)

Monitor on proper use of ACs

- ACs residue analysis in crops
on 1,400 out of 4000 farmers
- Promotion of record of ACs use

84

4. Regulation on non-registered Acs and inappropriate use of Acs



For physical person :
Imprisonment of up to three years,
or a fine of up to one Million Yen.

For juristic person :
A fine of up to one hundred Million Yen.

85

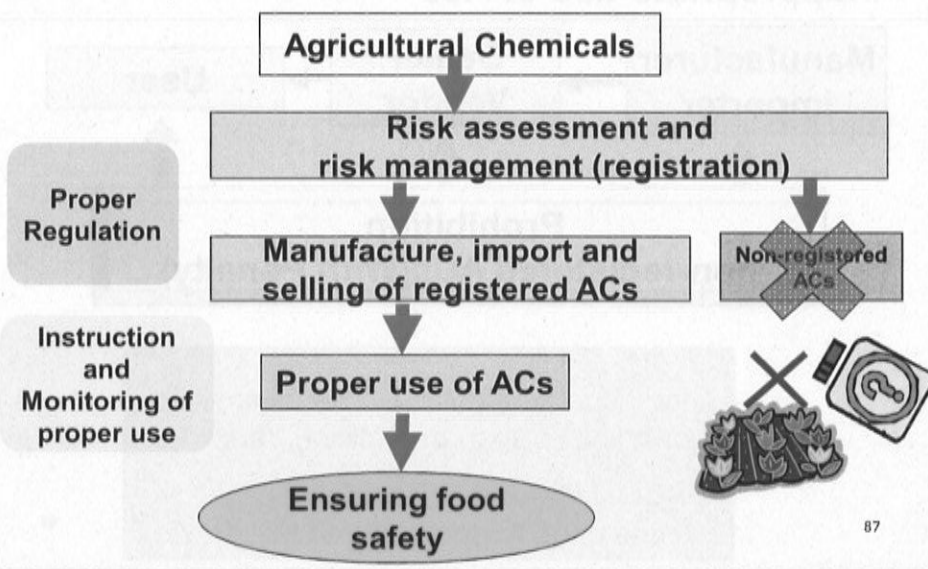
Inspections of Manufacturing Site

- 70-80 factories each year
- Check production line and QC
- Check samples of formulation
 - concentration of AI
 - physico-chemical property
 - label

86

Summary:

Regulation of Agricultural Chemicals in Japan



MRLs for Food and Feed

MRLs for Foods in Japan

- Responsibility of MHLW
- “Positive List”: pesticide / commodity combination to be tested
- Use of
 - Codex
 - National MRL (registered pesticides)
 - MRLs in AU, CA, EU, NZ and US
- Harmonization with Codex MRLs as much as possible
- For some commodities, portions to which MRLs apply are not the same as Codex MRLs

89

Positive List System for Pesticide Residue in Food

90

Summary of the Positive List System for Agricultural Chemical Residue in Food

- Residues in foods resulting from the use of Veterinary Drugs, Feed Additives and Pesticides

Food in which residue of agricultural chemical exceeds a certain level, "Default Level", shall not be marketed.

But the case that the MRL for the residue is established and the residue level does not exceed the MRL is exclusive.

- The regulation applies to domestic and import foods.

- The regulation has been enforced since 29 May 2006.⁹¹

Positive List System for Agricultural Chemical Residues

[Previous Regulation]

Pesticides, Feed Additives, and Veterinary Drugs

Chemicals for which MRLs are established

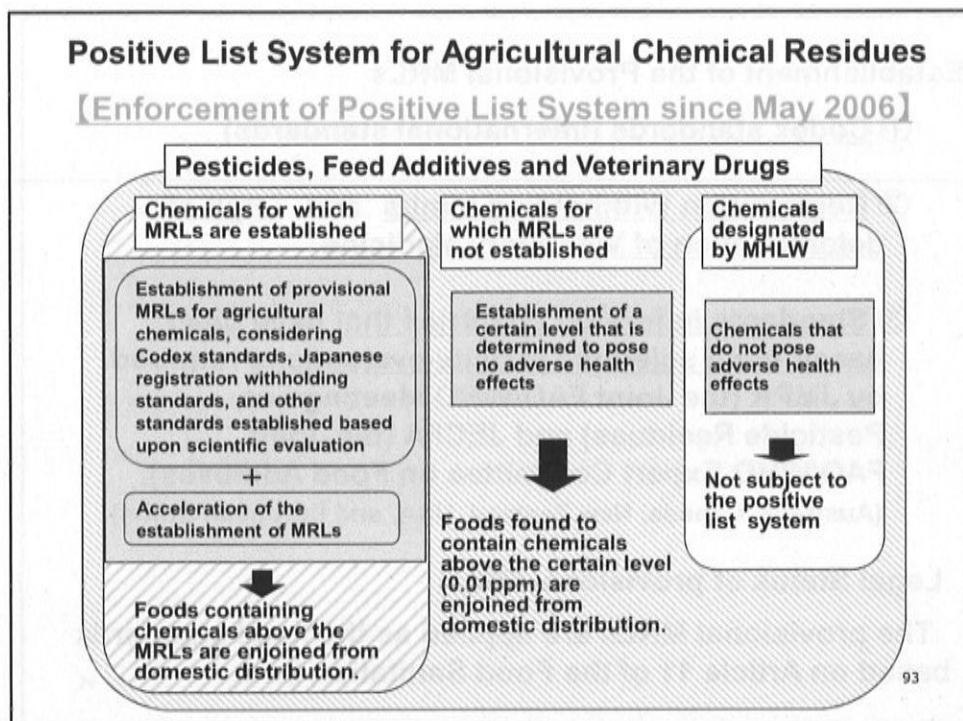
MRLs for 250 pesticides and 33 Veterinary Drugs

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.

92



Government Notifications on 29 November 2005 related to the Positive List System

- No. 497 **Default Level**
0.01ppm is established as the default level.
- No. 498 **Substances exempted from the system**
65 substances are listed.
- No. 499 **Provisional MRLs (for 758 substances) and other provisions for the system are established.**

Establishment of the Provisional MRLs

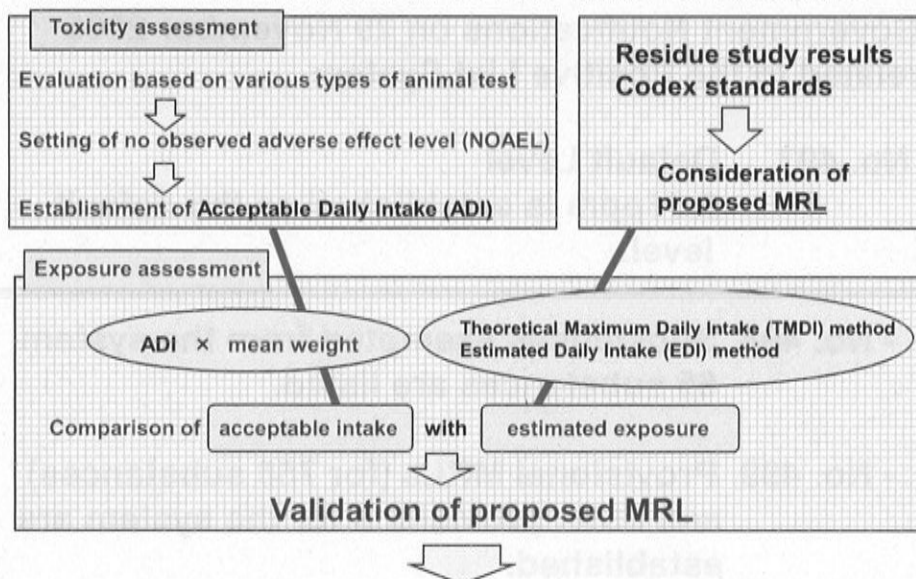
- ① Codex standards (International standards)
- ② Registration Withholding Limits and Limit of determination of Veterinary Medicine
- ③ Standards in foreign countries that have been based upon scientific toxicity evaluations required by JMPR (the Joint FAO/WHO Meetings on Pesticide Residues) and JECFA (the Joint FAO/WHO Expert Committee on Food Additives).
(Australia, Canada, New Zealand, USA, and European Union)

Legal Status of provisional MRLs

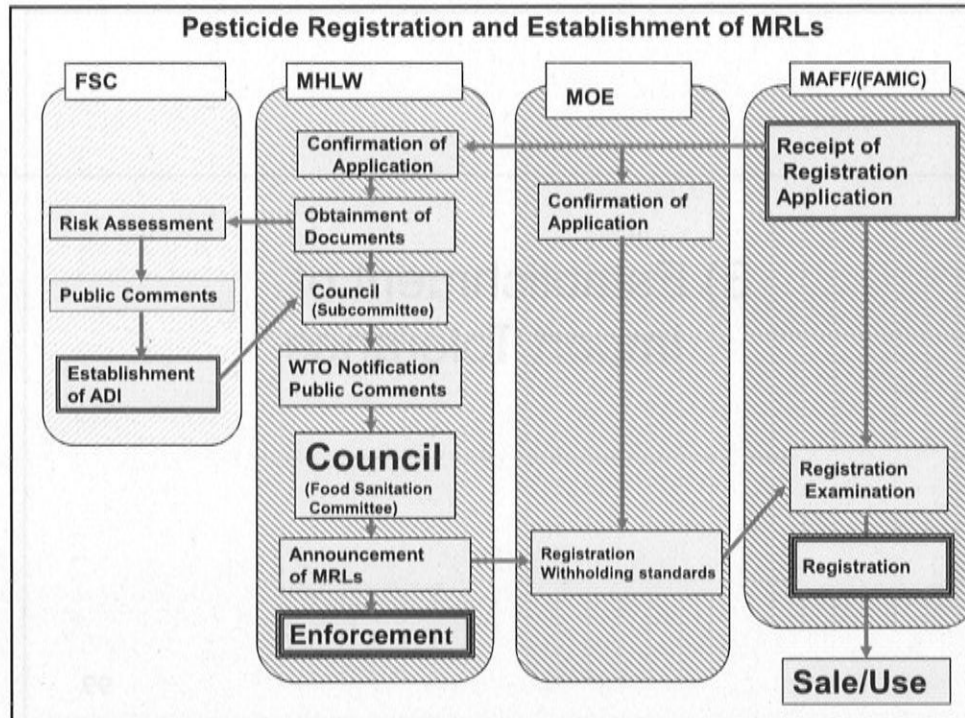
The provisional MRLs are applied as the legal standards based on Article 11 of the Food Sanitation Law.

95

Establishment of maximum residue limits for pesticides



96



MRLs for Feeds and Foods of Animal Origin

- MRLs for feeds
 - Under the responsibility of MAFF
 - Estimated in the same manner as those for foods of plant origin
 - Expressed in mg/kg as Codex
- MRLs for foods of animal origin
 - Estimated by MAFF following the JMPR method
 - Using the animal feeding table and residue concentrations in Japan
 - Submitted to MHLW for legalization

3) Establishment of Import Tolerance

99

Import Tolerance

- Established for
 - Pesticide registered in a country (not in Japan)
 - Food for feed crops
 - ✓ For which the pesticide can be used
 - ✓ In which residues were expected
 - ✓ Expected to be exported to Japan
 - Foods from animals fed the above mentioned feeds and exported to Japan
- Established upon application to the Minister of Health, Labor & Welfare (food) or DG of Food Safety & Consumer Affairs (feed)

100

Required Data for IT(1)

- Similar to those for registration
- No need for efficacy / phytotoxicity studies
- Studies on operator safety and by-stander safety are not required
- ITs for feeds
 - Livestock metabolism and livestock feeding studies are required
 - Studies on environmental safety are not required

101

Required Data for IT(2)

- Compliance with GLP
- Language
 - Monograph in Japanese
 - ✓ Negotiable in case of IT for feed
 - Individual study reports can be in English or Japanese
- ITs for feeds
 - ITs are limited to imports from AU, CA & US as imports from these countries account for ca. 90% of the total import
 - Estimated using the JMPR method

102

Application of IT for Food

Submit to:

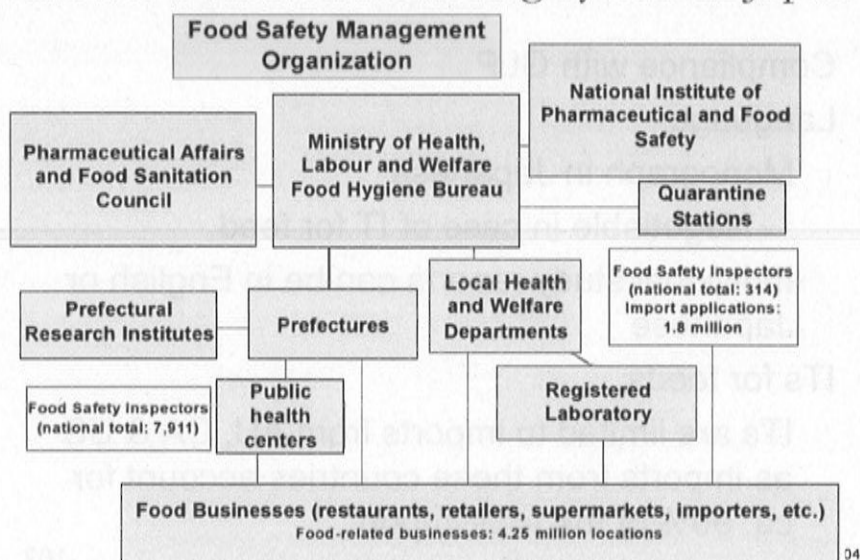
Food Safety Department of MHLW

For details, access the following URL
(English version):

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

103

Pesticides Residue Monitoring System in Japan



Thank you for your attention.

105

106

