



# Overview of OECD GLP and GLP programme for Agricultural Chemicals in Japan

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## History of GLP

Before GLP Programme was established

- Concerns raised about the validity of pre-clinical safety data.
- US Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) began investigations (1975).
- Some problems were found.

For example...

- Technical personnel were poorly trained and supervised
- Inadequate records
- Falsification of pathology reports

Etc.



**A system for ensuring the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical tests was sought.**

## OECD Council Acts on Good Laboratory Practice

- 1981 Council Decision on Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30/Final]
- 1989 Council Decision/Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87/Final]
- 1997 Council Decision on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data [C(97)114/Final]

## 1981 OECD Council Decision on Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30/Final]

### Part I

OECD Council:

*“Decides that data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and **OECD Principles of Good Laboratory Practice** shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment.”*

**Annex I OECD Test Guidelines**

**Annex II OECD Principles of Good Laboratory Practice**



## 1989 OECD Council Decision/Recommendation on Compliance with Principles of Good Laboratory Practice [C(89)87/Final]

### Part I GLP Principles and Compliance Monitoring

Decision and recommendation for country to conduct GLP inspection

### Part II Recognition of GLP Compliance among Member Countries

Decisions for country to recognise the assurance of the data generated in another country

### Part III Future OECD Activities

Instructions for committee to update and expand annexes as necessary

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## 1997 OECD Council Decision concerning the Adherence of non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals [C(97)114/Final]

*OECD Council decides*

*“that adherence to the Council Acts and participation in the part of the OECD Chemicals Programme related to the mutual acceptance of data shall be governed by the procedure set out in the Annex to this Decision, of which it forms an integral part.”*

### **Non members who are full adherents to MAD**

Argentina, Brazil, India, Malaysia, South Africa, Singapore

### **Non member who is a provisional Adherent to MAD**

Thailand

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## OECD Series on Principles of GLP and Compliance Monitoring

#	Document	Adopted	Revised
1	OECD Principles on GLP	1981	1997
2	Guides for Compliance Monitoring Procedures for GLP	1992	1995
3	Guidance for the Conduct of Laboratory Inspections and Study Audits	1992	1995
4	Quality Assurance and GLP	1992	1999
5	Compliance of Laboratory Suppliers with GLP Principles	1992	1999
6	The Application of the GLP Principles to Field Studies	1992	1999
7	The Application of the GLP Principles to Short-Term Studies	1993	1999
8	The Role and Responsibilities of the Study Director in GLP Studies	1993	1999

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## OECD Series on Principles of GLP and Compliance Monitoring

#	Document	Adopted	Revised
9	Guidance for the Preparation of GLP Inspection Reports	1995	-
10	The Application of the Principles of GLP to Computerised Systems	1995	-
11	The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP	1998	-
12	Requesting and Carrying Out Inspections and Study Audits in Another Country	2000	-
13	The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies	2002	-
14	The Application of the Principles of GLP to in vitro Studies	2004	-
15	Establishment and Control of Archives that Operate in Compliance with the Principles of GLP	2007	-

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## Overview of GLP programme in Japan

GLP Programme	Ministry	GLP Monitoring Authority
1) Pharmaceuticals and Medical Devices	MHLW	Pharmaceuticals and Medical Devices Agency (PMDA)
2) New Workplace Chemicals	MHLW	National Institute of Industrial Health
<b>3) Pesticides</b>	<b>MAFF</b>	<b>Food and Agricultural Materials Inspection Center (FAMIC)</b>
4) Feed Additives	MAFF	Food and Agricultural Materials Inspection Center (FAMIC)
5) Veterinary Medicinal Products and Veterinary Medical Devices	MAFF	National Veterinary Assay Laboratory (NVAL)
6) Industrial Chemicals		
① Toxicity	MHLW	National Institute of Health Sciences (NIHS)
② Bioaccumulation/Biodegradation	METI	National Institute of Technology and Evaluation
③ Ecotoxicity	MOE	-

MHLW : Ministry of Health, Labour and Welfare  
 METI : Ministry of Economy, Trade and Industry

MAFF : Ministry of Agriculture, Forestry and Fisheries  
 MOE : Ministry of the Environment

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## History of the Pesticide GLP in Japan

1948: Enactment of Agricultural Chemicals Regulation Law

1984: Establishment of GLP for Agricultural Chemicals

The area was **Toxicity/Mutagenicity**.

1999: Fundamental revision of the notification

**Physical/chemical property** was added in the scope.

2000: The following areas were added.

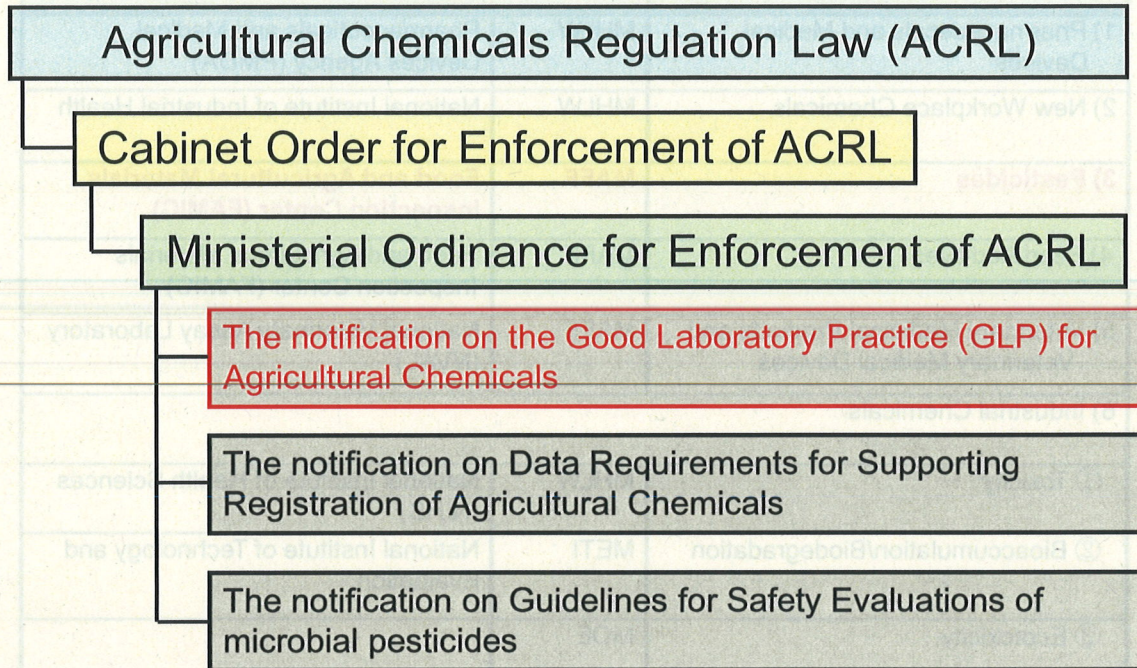
① **Metabolism in animals and plants and behavior in soil and water**

② **Aquatic organism effects**

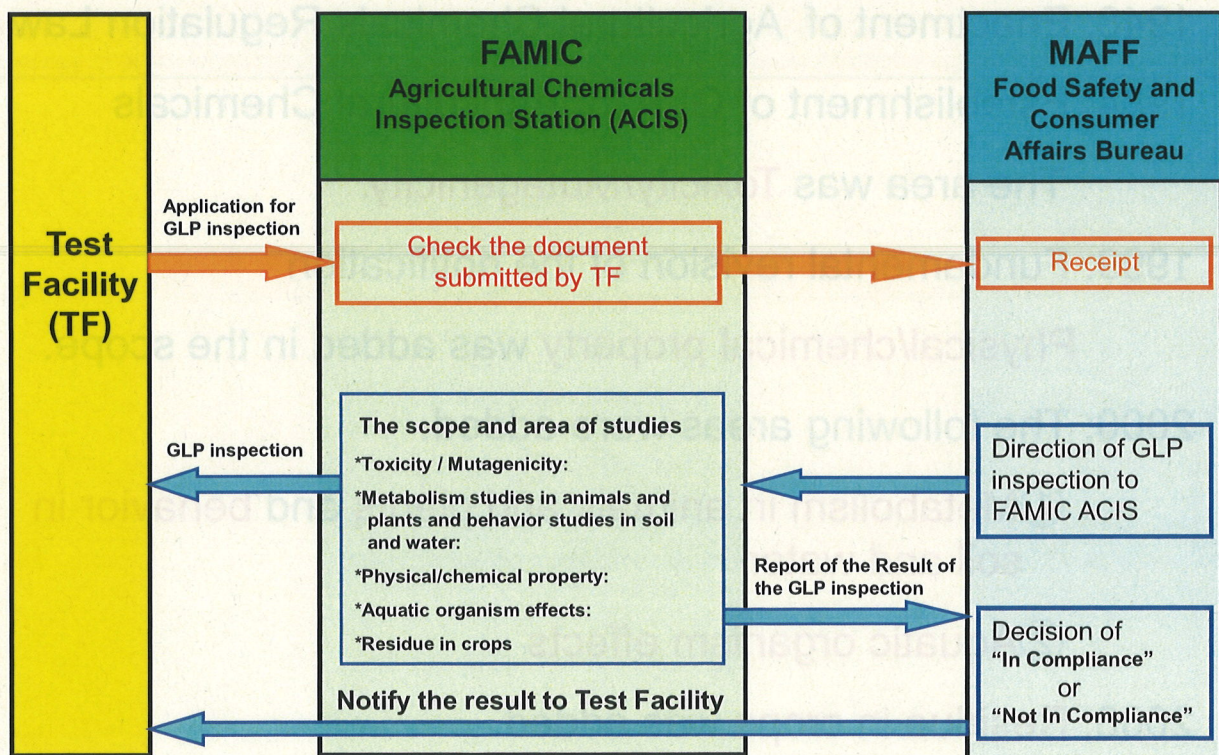
2008: **Residue in crops** was added.

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## Pesticide Legislation in Japan



## Flow of compliance accreditation for the pesticide GLP





## Number of inspection concerning the pesticide GLP

Fiscal Year	Number of GLP inspection	Type of Scope				
		①	②	③	④	⑤
2005	19	11	2	8	5	-
2006	18	10	4	8	7	-
2007	15	4	2	8	6	-
2008	14	9	2	7	1	2
2009	19	9	3	7	5	4
2010	23	6	2	8	6	9
2011	23	8	2	7	2	10
2012	20	9	3	8	5	5

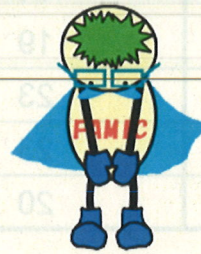
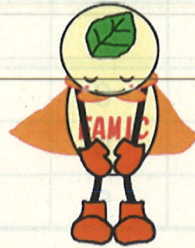
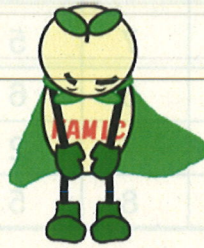
- ① Toxicity / Mutagenicity
- ② Metabolism studies in animals and plants and behavior studies in soil and water
- ③ Physical/chemical property
- ④ Aquatic organism effects
- ⑤ Residue in crops



## Number of Test Facilities which were compliant with the pesticide GLP

Fiscal Year	'07	'08	'09	'10	'11	'12
Test Facility	44	45	48	52	55	56

# Thank you for your attention



\*FAMIC official mascots

## Number of Test Facilities which were compliant with the pesticide GLP

Fiscal Year	2007	2008	2009	2010	2011	2012
Test Facility	44	45	48	52	55	58