Inspection and confirmation of compliance with the standard provided for in Articles 5 to 19 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals

(Notification: 30 Shouan No.4215, issued on November 30, 2018 by Director-General, Food Safety and Consumer Affairs Bureau, the Ministry of Agriculture, Forestry and Fisheries)

Revision: 1 Shouan No.914, issued on June 28, 2019
Revision: 2 Shouan No.4310, issued on Jan 5, 2021
Revision: 3 Shouan No.3473, issued on Sep 27, 2024

Confirmation and Inspection on compliance with the standard provided for in Articles 5 to 19 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals

1 Purpose

Pursuant to Article 3, paragraph (2), Article 7, paragraph (1) or Article 8, paragraph (3) (including as applied mutatis mutandis pursuant to Article 34, paragraph (6)) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948; hereinafter referred to as "the Act"), the test results specified in Article 2 (hereinafter referred to as "Specified Test Results") of the "Ministerial Ordinance of the Good Laboratory Practice for Agricultural Chemicals" (hereinafter referred to as "Ministerial Ordinance") submitted for the registration, the registration of change or the reevaluation on agricultural chemicals, must be derived from tests conducted in accordance with the standard provided for in Articles 5 to 19 of the Ministerial Ordinance as necessary to ensure the reliability of the results (hereinafter referred to as "Agricultural Chemicals GLP Standards").

This notification is to provide for the procedures of the inspection and the confirmation of compliance with the Agricultural Chemicals GLP Standards.

2 Confirmation of GLP Compliance by the Director-General, Food Safety and Consumer Affairs Bureau

(1) Confirmation of compliance with the Agricultural Chemicals GLP Standards must be made in accordance with either (i) or (ii) below:

(i) The Director-General, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries (hereinafter referred to as the "Director-General, Food Safety and Consumer Affairs Bureau") confirms that the test facility conducting studies is in compliance with the Agricultural Chemicals GLP Standards (hereinafter referred to as a "Confirmation of GLP Compliance") in accordance with the area of expertise in the attachment at least once in every three years; or

(ii) A government agency or an organization representing it confirms that the test facility conducting studies is in compliance with standards of GLP (limited to the programs that have been confirmed to be in compliance with GLP principles of the Organization for Economic Co-operation and Development (OECD) or the programs of the countries which have concluded bilateral arrangements with Japan) in accordance with the area of expertise in the attachment, on the basis of which the Director-General, Food Safety and Consumer Affairs Bureau decides that the test facility conducting studies is in compliance with the Agricultural Chemicals GLP Standards.

(2) Regardless of (1), (i), if any doubt arises, as the result of the examination in Article 3, paragraph (4), Article 7, paragraph (2) or Article 8, paragraph (4) of the Act or on the basis of other information, as to the reliability of the specified test results provided in Article 3, paragraph (2), Article 7, paragraph (1) or Article 8, paragraph (3) of the Act, and when the notice thereof is issued by the Director-General, Food Safety and Consumer Affairs Bureau, the test facility must undergo a confirmation of GLP compliance by the Director-General, Food Safety and Consumer Affairs Bureau in order to eliminate the doubts regarding the reliability of the Specified Test Results.

3 Application for Confirmation of GLP Compliance

(1) When conducting studies subject to a Confirmation of GLP Compliance in 2, (1), (i), a person or, in case of a corporation, its representative (hereinafter referred to as "GLP Confirmation Applicant.") must submit the application for Confirmation of GLP Compliance of test facility (Appended Form 1) to the Director-General Food Safety and Consumer Affairs Bureau along with the following documents from (i) to (iv):

(i) Overview of the test facility (name, location, date of establishment, organizational and personnel composition (describe both the organizational affiliations in the facility and the organizational affiliations under the Agricultural Chemicals GLP Standards), site area and building area, internal

and external building layout, and the types and specifications of equipment);

(ii) Summary of the competence to conduct Specified Tests and the numbers of the specified test completed over the past three years;

(iii) List of Standard Operating Procedures and

(iv) Documents concerning Test Facility Management (Test Site Management, if applicable), Study Director, Principal Investigator, study personnel, personnel of Quality Assurance Unit and Archivist, which list the names, career backgrounds, research histories and names of academic societies and academic organizations to which they belong.

(2) Submission of the application for Confirmation of GLP Compliance of test facility and the relevant documents in (1), can be made via Independent Administrative Agency, Food and Agricultural Materials Inspection Center (hereinafter referred to as "FAMIC"). In this case, FAMIC may append comments, etc. to the application.

(3) The Director-General, Food Safety and Consumer Affairs Bureau may request a GLP Confirmation Applicant to submit further documents and other materials necessary for assessing GLP Compliance. In this case, the GLP Confirmation Applicant may submit them to the Director-General, Food Safety and Consumer Affairs Bureau via FAMIC.

4 Examination with document and Inspection

The Director-General Food Safety and Consumer Affairs Bureau examines the documents submitted in 3 above, and then, if it is found to be necessary to conduct an inspection, the Director-General may have either of the followings inspect the test facility:

(i) FAMIC;

(ii) Those appointed by the Director-General among those who have sufficient knowledge or experience on the inspection related to test results or specimens, etc.

5 Inspection Procedure

(1) Prior to the inspection, the Director-General, Food Safety Consumer Affairs Bureau notifies the GLP Confirmation Applicant of conducting the inspection. The personnel conducting the inspection (hereinafter referred to as the "Inspector") is separately to notify the GLP Confirmation Applicant of the date of the inspection and other necessary matters.

(2) Inspection is conducted in accordance with the following steps.

(i) Inspection of the overall management of the test facility;

(ii) Inspection of the facility and the maintenance of apparatus;

(iii) Inspection of operations;

(iv) Inspection of the documentation of study plan, Standard Operating Procedures, final report, etc.;

(v) Inspection of the activity of the Quality Assurance Unit;

(vi) Inspection of the management of retained raw data, specimen, etc.; and

(vii) Inspection and verification of raw data, specimens, final reports, etc. related to the studies for audit

(3) If it is deemed necessary for the inspection, the Inspector may request the test facility to submit samples of test item, etc., specimens, raw data, and other necessary materials.

(4) After the inspection is completed, the Inspector is to give advice or guidance on-site as necessary. The advice or guidance must be recorded.

6 Reporting the results of inspections and notification of results

(1) The Inspector must prepare an inspection report including the following items, and submit it to the Director-General, Food Safety and Consumer Affairs Bureau after conducting the inspection:

(i) Name(s) and affiliation(s) of the Inspector(s);

(ii) Name and Address of the test facility inspected;

(iii) Date(s) of inspection;
(iv) Purpose of the inspection;
(v) Overview of the test facility;
(vi) Type(s) of study audited;
(vii) Name(s) and affiliation(s) of personnel of the test facility who attended in the inspection;
(viii) Compliance with the Agricultural Chemicals GLP Standards on the test facility and studies inspected;
(ix) Conclusion; and
(x) Other items
- Improvement(s) relating to deviation(s) found in the last inspection;
- Implementable studies

(2) Based on the inspection report, the Director-General, Food Safety and Consumer Affairs Bureau verifies whether the test facility complies with the Agricultural Chemicals GLP Standards, and notifies the GLP Confirmation Applicant of the result. In this case, when the Director-General, Food Safety and Consumer Affairs Bureau intends to notify the GLP Confirmation Applicant of the results that the test facility subject to the inspection does not comply with the GLP standards for pesticides, he/she is to indicate the fact constituting the grounds for the said results (matters that are considered to deviate from the GLP standards for pesticides, etc.) and other necessary matters to the GLP Confirmation Applicant , and is to grant the GLP Confirmation Applicant an opportunity for explanation specifying a reasonable period of time.

(3) The Director-General, Food Safety and Consumer Affairs Bureau, upon notification under (2), is to give advice or instructions to the GLP Confirmation Applicant as needed. In addition, the Director-General, Food Safety and Consumer Affairs Bureau may, if deemed necessary, have the inspector give advice or instructions to the said GLP Confirmation Applicant.

7 Voluntary Investigations

When it is deemed necessary to inspect the test facility that has been confirmed on the conformity under 6, the Director-General, Food Safety and Consumer Affairs Bureau may have a person listed in 4(i) or (ii) inspect the said test facility. When conducting the inspection, the inspector is to explain the purpose of the inspection, etc. to the testing facility in advance.

8 Others

(1) The representative of the test facility that has received the confirmation of the GLP compliance from the Director-General, Food Safety and Consumer Affairs Bureau under 2, (1), (i) is to submit a notification concerning the change of the application for Confirmation of GLP Compliance (Appended Form 2) to the Director-General, Food Safety and Consumer Affairs Bureau, in cases where any changes to the following items occur in the contents of the application for Confirmation of GLP Compliance of Test Facility (Appended Form 1):
(i) Address or name of the GLP Confirmation Applicant; or
(ii) Name or address of the test facility.

(2) The representative of the test facility that has received confirmation of GLP compliance from the Director-General, Food Safety and Consumer Affairs Bureau under 2, (1), (i) is promptly to submit the notification of business abolition (Appended Form 3) to the Director-General, Food Safety and Consumer Affairs Bureau, in cases where the GLP operation of a test facility is to be closed.

(3) A notification concerning the change of the application for Confirmation of GLP Compliance under (1) and a notification of business abolition under (2) to the Director-General, Food Safety and Consumer Affairs Bureau may be submitted via FAMIC.

Supplementary provisions (December 1, 2018)

1 This notification applies on December 1, 2018. However, it does not apply to the test results listed below.

(1) Following test results initiated before September 30, 1984: Acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation, eye irritation, skin sensitization, acute delayed neurotoxicity, 90-day repeated dose oral toxicity, 21-day repeated dose dermal toxicity, 90-day repeated inhalation toxicity, 28-day repeated dose delayed neurotoxicity, 1-year repeated dose oral toxicity, carcinogenicity, reproductive toxicity, teratogenicity and mutagenicity;

(2) Following test results initiated before August 28, 1997: Human safety of microbial pesticides;

(3) Following test results initiated before September 30, 1999: Properties, stability, degradability, etc. of active ingredient (excluding test results regarding color, shape and odor, and bioconcentration);

(4) Following test results initiated before January 31, 2001: Acute neurotoxicity, repeated dose oral neurotoxicity, detoxification methods or emergency medical treatment, metabolism in animals, metabolism in plants, behavior in soil, behavior in water, fish acute toxicity, Acute immobilization on daphnids, Reproduction on daphnids, and growth inhibition on algae;

(5) Following test results initiated before January 9, 2003: Analysis of composition of an agricultural chemical's TGAI, and analysis of dioxins in an agricultural chemical TGAI;

(6) Following test results initiated before March 31, 2005: Fish (incubated larvae) acute toxicity, Acute immobilization on daphnids (adults), effects of coexisting organic substances on fish acute toxicity / acute swimming inhibition of the genus Daphnia, Acute toxicity on freshwater shrimps (Paratya compressa compressa and Paratya compressa improvisa) and amphipoda, and Acute immobilization on chironomid larvae;

(7) Following test results initiated before October 1, 2007: Bioconcentration;

(8) Following test results initiated before March 31, 2011: Residues in crops;

(9) Following test results initiated before November 13, 2014: Residues in livestock; and

(10) Following test results initiated before March 31, 2017: Analysis of composition of an agricultural chemical TGAI used in toxicity tests, toxicity for additives and impurities, and Analysis methods on an agricultural chemical TGAI

2 “The Good Laboratory Practice for Agricultural Chemicals” (The notification: 11 Nousan No.6283, issued on October 1, 1999 by Director-General of Agricultural Production Bureau, the Ministry of Agriculture, Forestry and Fisheries; hereinafter referred to as the “former notification”) is hereby abolished.

3 With regard to an application for the confirmation of the GLP compliance based on 4 of the former notification filed prior to the enforcement of this notification, and for which no notification has been made for the results of the confirmation of the GLP compliance on 7, (2), of the former notification, the procedure for the confirmation of the GLP compliance then in force must remain applicable.

4 With regard to test results that may not be in compliance with the standards set out in Articles 5 to 19 of the Ministerial Ordinance on GLP for Agricultural Chemicals under the provision of paragraph (2) of the supplementary provisions of the Ministerial Ordinance on GLP for Agricultural Chemicals, and that are subject to the Agricultural Chemicals GLP Standards in the former notification (other than those listed in 1, (1) to (10)), the provisions of the former Notification (including the attached standards) is to remain in force.

Supplementary provisions (June 28, 2019)

1 This notification applies on July 1, 2019.

2 Notwithstanding the provisions of the preceding paragraph, the provisions for revising relating to the following studies applies on April 1, 2020: Physical and chemical properties of formulation products in the physical and chemical properties area; dermal absorption and Exposure of operator to agricultural chemicals applying them in the field in the toxicity area; growth inhibition on algae and cyanobacteria, growth inhibition on Lemna sp., acute oral toxicity on avian, acute dermal toxicity on honeybees (adults), acute oral toxicity on honeybees (adults), chronic oral toxicity on honeybees (adults), oral toxicity on honeybees (larvae) and residues in pollen and nectar in the adverse effects on aquatic and terrestrial

organisms area; provided however, that it does not preclude the application of the provisions of the revised notification on the Confirmation of GLP Compliance, etc. to these studies on or before March 31, 2020.

Supplementary provisions (September 27, 2024)

This notification applies on October 1, 2014.

Appended Form 1

Application for Confirmation of GLP Compliance of Test Facility

Date:

To the Director-General, Food Safety and
Consumer Affairs Bureau, the Ministry of
Agriculture, Forestry and Fisheries,

Address: (For corporate body, the address of the main office)
Name: (For corporate body, its name and the name of its representative)
Contact point: (phone / fax number, e-mail address, department / name of person in charge)

I hereby apply for the confirmation (on-site inspection) of the below-mentioned test facility in accordance with the provisions of 3 of "Inspection and Confirmation of compliance with the standard provided for in Articles 5 to 19 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals" (Notification: 30 Shouan No.4215, issued on November 30, 2018 by the Director-General, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries). Attached are documents required in 3.

1 Name of test facility:
2 Address of test facility:
3 Area(s) of the studies:
4 If there has been confirmation of GLP compliance in the past, the date of confirmation and the Area(s) of the studies:

(Japanese Industrial Standard A4)

Remarks

(Note 1) The documents, etc. provided in "3: Application for Confirmation of GLP Compliance" are to be attached as related documents.

(Note 2) For Notes 1 and 2 above, write them in English alongside.

(Note 3) Refer to attachment for the area in 3 and 4 above.

Appended Form 2

Notification of Change to Application for Confirmation of GLP Compliance of Test Facility

Date:

To the Director-General, Food Safety and
Consumer Affairs Bureau, the Ministry of
Agriculture, Forestry and Fisheries,

Address:
Name: (For corporate body, its name and the name of its representative)

I hereby notify change(s) in the information stated in the Application for Confirmation of GLP Compliance of test facility as shown below, in accordance with the provisions in 8 (1) of "Inspection and confirmation of compliance with the standard provided for in Articles 5 to 19 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals."

1 Name of test facility:
2 Content(s) of change(s):
3 Reason for change(s):
4 Date that change was made:

(Japanese Industrial Standard A4)

Appended Form 3

Notification of Business abolition

Date:

To the Director-General, Food Safety and
Consumer Affairs Bureau, the Ministry of
Agriculture, Forestry and Fisheries,

Address:
Name: (For corporate body, its name and the name of its representative)

I hereby notify the discontinuation of the business of GLP test facility as follows, in accordance with the provisions in 8 (2) of “Inspection and Confirmation of compliance with the standard provided for in Articles 5 to 19 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals”.

1 Name of test facility:
2 Contents of abolishment:
(1) Reason for abolishment:
(2) List of place of transfers of final reports, specimens, raw data, etc. after abolishment:
(3) (Scheduled) date of abolishment:

（Japanese Industrial Standard A4）

Remarks
(Note) About 2 (2), the list may be submitted as an attached document of the application.

Attachment

Area of expertise	Name of study
Analysis of the technical grade active ingredient (TGAI)	Analysis of composition of an agricultural chemical TGAI
	Analysis methods on an agricultural chemical TGAI
Physical and chemical properties	Melting point
	Boiling point
	Density
	Vapor pressure
	Spectrum
	Solubility in water
	Solubility in organic solvents
	n-Octanol /water partition coefficient
	Hydrolysis
	Photolysis in water
	Dissociation constant
	Thermal stability
	Fineness
	Particle size
	Stability of stock solution
	Stability of diluted solution or Wettability
	Water solubility or Solubility in water
	Suspension rate
	Storage stability
	Other studies required for the formulation products※
Toxicity	Acute oral toxicity
	Acute dermal toxicity
	Acute inhalation toxicity
	Skin irritation
	Eye irritation
	Skin sensitization
	Acute neurotoxicity
	Acute delayed neurotoxicity
	90-day repeated dose oral toxicity
	21/28-day repeated dose dermal toxicity
	90-day repeated dose dermal toxicity
	28-day repeated inhalation toxicity
	90-day repeated inhalation toxicity
	Repeated dose oral neurotoxicity

Area of expertise	Name of study
Toxicity	28-day repeated dose delayed neurotoxicity
	Chronic toxicity
	Carcinogenicity
	Combined of Carcinogenicity and Carcinogenicity
	Reproductive toxicity
	Developmental toxicity
	Developmental neurotoxicity
	Detoxification methods or emergency medical treatment
	Dermal absorption
	Exposure of operator to agricultural chemicals applying them in the field
	metabolism in animals
	Acute oral toxicity / infectivity
	Acute dermal toxicity / infectivity
	Acute pulmonary toxicity / infectivity
	Acute intravenous toxicity / infectivity
	Cell culture
	Repeated dose toxicity / infectivity
	Viral carcinogenicity
	Immunodeficiency inducing
	Histopathological specimen preparation
Mutagenicity	Reverse mutation
	Chromosomal aberration
	Micronucleus
	Gene mutation or DNA damage
Residues	Metabolism in plants
	Residues in crops
	Analysis methods on residues in crops
	Residues in processed commodities
	Metabolism in livestock
	Residues in livestock
	Analysis methods on residues in livestock
	Stability in stored commodities
Environmental behavior	Aerobic flooding soil
	Aerobic soil
	Anaerobic soil
	Soil adsorption
	Hydrolysis

Area of expertise	Name of study
Environmental behavior	Photolysis in water
	Bioconcentration
Ecotoxicity	Fish acute toxicity
	Acute immobilization on daphnids
	Acute immobilization on daphnids (adults)
	Reproduction on daphnids
	Adverse effects of coexistent organic substances on fish acute toxicity and daphnids acute immobilization
	Acute toxicity on freshwater shrimps (Paratya compressa compressa and Paratya compressa improvisa) and amphipoda
	Acute immobilization on chironomid larvae
	Growth inhibition on algae and cyanobacteria
	Growth inhibition on Lemna sp.
	Acute oral toxicity on avian
	Residues in seeds
	Acute dermal toxicity on honeybees (adults)
	Acute oral toxicity on honeybees (adults)
	Chronic oral toxicity on honeybees (adults)
	Oral toxicity on honeybees (larvae)
	Residues in pollen and nectar

※ "Other studies required for the formulation products" refers to the tests shown in 2 [11] of Table 2 "Test results regarding stability, degradability and other physical and chemical properties" in the notification “Data Requirements for Registration of Agricultural Chemicals”(The notification No.30-Shouan-6278, issued on March 29, 2019 by Director-General, Food Safety and Consumer Affairs Bureau, Ministry of Agriculture, Forestry and Fisheries).