Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals

(Ministerial Ordinance of Ministry of Agriculture, Forestry and Fisheries No. 76 of November 30, 2018
(Final amendment: April 1, 2024))

Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals

In accordance with the provisions of Article 3, paragraph (2) of the Agricultural Chemicals Regulation Act (Act No. 82 of 1948) (including as applied mutatis mutandis pursuant to Article 34, paragraph (6) of the said Act), the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals shall be established as follows:

Table of contents

Chapter 1 General Provisions

(Purpose)

Article 1 This Ministerial Ordinance specifies the test results and provides standards prescribed in Article 3, paragraph (2) of the Agricultural Chemicals Regulation Act (hereinafter referred to as “the Act”) (including Article 34, paragraph (6) of the Act, which applies the provision mutatis mutandis. The inclusion shall also apply in the following Article and Article 4).

Chapter 2 Specified Test Results

Article 2 The test results defined in the Ordinance of the Ministry of Agriculture, Forestry and Fisheries mentioned in Article 3, paragraph (2) of the Act shall be the test results listed below (Natural enemies deemed to be agricultural chemicals pursuant to the provision of Article 2, paragraph (2) of the Act are the test results set forth in item (iv).):

(i) of the test results listed in Article 2, paragraph (1), item (i) of the Regulation for Enforcement of the Agricultural Chemicals Regulation Act (Ordinance of the Ministry of Agriculture and Forestry, No. 21, 1951. Hereinafter referred to as the “Regulations”), test results regarding analysis of composition of an agricultural chemical TGAI (excluding analysis of dioxins);

(ii) test results listed in Article 2, paragraph (1), item (ii) of the Regulations (excluding test results regarding color, physical state and odor);

(iii) test results listed in Article 2, paragraph (1), item (v), (a) of the Regulations;

(iv) test results listed in Article 2, paragraph (1), item (v), (b) of the Regulations (excluding test results regarding exploration for detoxification methods or emergency medical treatment);

(v) of the test results listed in Article 2, paragraph (1), item (vi), of the Regulations (excluding test results regarding residues in crops [limited to crops with low production volume]

(vi) test results listed in Article 2, paragraph (1), item (vii) of the Regulations;

(vii) test results regarding behavior in soil, soil adsorption and behavior in water, listed in Article 2, paragraph (1), item (viii) of the Regulations;

(viii) of the test results listed in Article 2, paragraph (1), item (ix) of the Regulations, test results regarding adverse effects on aquatic and terrestrial organisms in environment (excluding test results regarding adverse effects of honeybee colonies); and

(ix) of the test results listed in Article 2, paragraph (1), item (x) of the Regulations, test results regarding analysis of composition of an agricultural chemical TGAI (limited to active ingredients and toxic impurities to be considered) , residues in crops and residues in livestock.

Chapter 3 Standards of Good Laboratory Practice for specified test results of Agricultural Chemicals

Section 1 General Provisions

(Definitions)

Article 3

(1) In this chapter, “test system” means any physical/chemical test system (system composed of measuring equipment used to obtain physical/chemical data. The same applies in Article 13, paragraph (1)) or biological test system (animals, plants, microorganisms, soil or components thereof to which a test item is administered or added, or controls thereof. The same applies in the paragraph (2) of said Article), or a combination of the systems.

(2) In this chapter, “raw data” means the result of observations obtained from a study, and records thereof.

(3) In this chapter, “specimen” means any material collected from a test system for examination or analysis.

(4) In this chapter, “test item” means an agricultural chemical or active ingredient of an agricultural chemical, or any related substance thereof to be evaluated in a study.

(5) In this chapter, “reference item” means any agricultural chemical or active ingredient of an agricultural chemical, or any chemical substance used for the purpose of comparison with the test item in a study.

(Standards of Good Laboratory Practice for specified test results of Agricultural Chemicals)

Article 4 The standards prescribed by Ordinance of the Ministry of Agriculture, Forestry and Fisheries provided for in Article 3, paragraph (2) of the Act are as prescribed in the following Article through Article 19.

Section 2 Personnel and Organization of Test Facility

(Responsibilities of Test Facility Management)

Article 5 The test facility management (an individual who is responsible for the operation and management of the test facility; the same applies hereinafter) shall conduct the following activities:

(i) to have in place a document attesting to the status of test facility management in the test facility;

(ii) to designate, for each study, an individual responsible for operating, recording and reporting the study and other related activities whenever the study is conducted (hereinafter referred to as the “Study Director”);

(iii) to designate, if a study is conducted at a test site (the location(s) at which a phase(s) of a study is conducted, the same applies hereinafter), an individual responsible for the operation and management of the test site (hereinafter referred to as the “test site management”) as needed, and an individual responsible for operating, recording and reporting of the phase of the study (hereinafter referred to as the “Principal Investigator”) as needed;

(iv) to designate personnel of the unit which assures that studies being conducted at the test facility comply with the provisions of this Ministerial Ordinance (hereinafter referred to as the “Quality Assurance Unit”); an individual responsible for the management of the archive(s) (hereinafter referred to as the “Archivist”); an individual responsible for managing test and reference items (referred to as the “Test item management” in item (iii) of the following Article); and an individual responsible for managing apparatus (referred to as the ”Apparatus management” in the said item and Article 12, paragraph (2));

(v) to ensure that the personnel of the Quality Assurance Unit appropriately fulfil their activities;

(vi) to ensure that sufficient personnel, facilities, apparatus and materials are available to appropriately conduct studies;

(vii) to provide the necessary education and training for personnel;

(viii) to prepare and maintain documents on education and training programs provided for personnel and their work experience, and documents that clearly describe specific job assignments;

(ix) to ensure that the study plan has been prepared and signed or affixed the name and seal by the Study Director;

(x) to approve and maintain the Standard Operating Procedures prepared by personnel;

(xi) to ensure and retain that the master schedule (a document that contains the information necessary for evaluating the workload associated with all the studies in the test facility or manage the progress of those studies. Hereinafter the same applies in this section and Article 19, paragraph (1), item (iii)) has been properly prepared;

(xii) to establish a communication scheme in order to ensure that the Study Director, Principal Investigator(s)

and study personnel and the Quality Assurance Unit(s) are closely coordinating if the study is conducted in a test site;

(xiii) to ensure that the characteristics of the test and reference items are identified and ensure that the study is appropriately conducted;

(xiv) to establish procedures pertaining to verification that electronic data processing system properly operate and the appropriate operation and maintenance if the electronic data processing system are to be used; and

(xv) to perform other activities for operating and managing the test facility.

(Responsibilities of the Test Site Management)

Article 6 The Test site management shall conduct the following activities for the test site for which the test site management is responsible:

(i) to have in place a document attesting to the status of test site management in the test site;

(ii) to designate a Principal Investigator as necessary;

(iii) to designate the personnel of the Quality Assurance Unit, Archivist, Test item management and Apparatus management;

(iv) to ensure that the personnel of the Quality Assurance Unit appropriately fulfil their activities;

(v) to ensure that sufficient personnel, facilities, apparatus and materials are available to effectively conduct studies;

(vi) to provide the necessary education and training for personnel;

(vii) to prepare and maintain documents on education and training programs provided for personnel and their work experience, and documents that clearly describe specific job assignments;

(viii) to approve and maintain the Standard Operating Procedures prepared by personnel;

(ix) to ensure and retain that the master schedule (limited to the parts related to the test site) has been properly prepared;

(x) to ensure that the characteristics of test and reference items are identified and ensure that the study is appropriately conducted;

(xi) to establish procedures pertaining to verification that electronic data processing system properly operate and the appropriate operation and maintenance if the electronic data processing system are to be used; and

(xii) to perform other activities for operating and managing the test site.

(Responsibilities of the Study Director)

Article 7 The Study Director shall perform the following activities:

(i) to send a copy of a study plan, when it was prepared or amended, to the Quality Assurance Unit;

(ii) to make Standard Operating Procedures and study plans available to study personnel;

(iii) to ensure that each study is conducted in accordance with the Standard Operating Procedures and study plan; when there has been any deviation from the matter of specified by the Standard Operating Procedures or study plan, to take appropriately improvement measures if necessary, after evaluating potential consequences of any deviations from the Standard Operating Procedures or study plan; and also to prepare and retain the documents on the ensuring, deviations and corrective actions;

(iv) to ensure that raw data are recorded accurately;

(v) to ensure in advance that the electronic data processing system appropriately operate, if the electronic data processing system are to be used;

(vi) to retain the study plan, final report, raw data and other materials related to the study in archives after the completion of the study; and

(vii) to perform other activities pertaining to the management of conducting, recording and reporting the study.

(Responsibility of the Principal Investigator)

Article 8 The Principal Investigator shall perform the activities listed in all the items of the preceding Article (excluding item (i)) for the delegated phases of the study.

(Responsibilities of the Study Personnel)

Article 9 The study personnel shall fulfill the following matters:

(i) to conduct studies in accordance with the provisions of this Ministerial Ordinance, the Standard Operating Procedures applicable for the study that they are engaged in and study plan; when there has been any deviation from the provisions of this Ministerial Ordinance, procedures and study plan, to record the details of any deviations and reasons for their occurrence, and to report them to the Study Director (or the Principal Investigator if is appointed. Hereinafter the same applies in this section.);

(ii) to record raw data promptly and accurately; and

(iii) to ensure own safety and health, and to report any health problem that may affect the performance of the study to the Study Director.

(Responsibilities of the Quality Assurance Unit)

Article 10

(1) The test facility shall have a Quality Assurance Unit consisting of individual(s) who are familiar with the study procedures and designated by the test facility management.

(2) The individual(s) of the Quality Assurance Unit shall perform the following activities:

(i) to retain copies of the Standard Operating Procedures, master schedule and study plans;

(ii) to inspect that the study plan is prepared in accordance with the provisions of this Ministerial Ordinance, and retain the inspection records;

(iii) to inspect that the studies have been conducted in accordance with the provisions of this Ministerial Ordinance, the Standard Operating Procedures, and the study plans, and retain the inspection records;

(iv) to inspect that the study methods used are accurately described in the final report and that the raw data are accurately reflected;

(v) to regularly inspect the equipment and management of the test facility, and retain the inspection records;

(vi) to report the inspection results provided in items (ii) through the preceding item in writing to the test facility management (or test site management if the test site management is appointed; hereinafter the same applies in the following item) and the Study Director;

(vii) to prepare a document that contains the dates and results of the inspections provided in items (ii) through (iv) and the dates when these results were reported to the test facility management and the Study Director (referred to as the “Quality Assurance Statement” in Article 18, paragraph (3)), and to sign or affix the name and seal on the document; and

(viii) to perform any other activities necessary to assure that the studies are conducted in accordance with the provisions of this Ministerial Ordinance.

(3) The individual(s) of the Quality Assurance Unit who are designated to be responsible for each study, shall not be engaged in the conduct of such study.

Section 3 Test Facilities, Apparatus, Materials and Reagents

(Test Facility)

Article 11 The test facility shall satisfy the following requirements:

(i) to have the necessary areas and construction for conducting the study;

(ii) to have a structure that allows distinct operations to be separately performed and a sufficient number of rooms or areas in order to ensure that each study is appropriately performed;

(iii) to have rooms or areas for the diagnosis, treatment and control of diseases;

(iv) to separately maintain the rooms or areas where studies are conducted, and the rooms or areas where the apparatus are stored;

(v) to separately maintain the rooms or areas where the test or reference items are received and stored, and the rooms or areas where the vehicle (a substance used to mix, disperse or solubilize test or reference item in order to be easily administered or added to a test system. The same applies in Article 14, item (vi)) are mixed with the test item;

(Apparatus, Materials and Reagents)

Article 12

(1) The apparatus used to prepare study reports, apparatus used to maintain the environment of the facility and other apparatus necessary for conducting the studies (hereinafter referred to simply as the "apparatus") shall be properly designed, have sufficient processing capacity, and be properly placed.

(2) The Apparatus management shall ensure that the apparatus is regularly maintained, inspected, cleaned and calibrated according to the Standard Operating Procedures, and prepare and retain the records of the results thereof.

(3) Apparatus and materials used in a study shall not adversely affect the test systems.

(4) Reagents and solutions (hereinafter referred to as the "reagents, etc." in this paragraph) shall be appropriately labeled to indicate name, storage conditions, expiry date and other information necessary to identify the reagents, etc..

Section 4 Operation and Handling of Test Items, etc.

(Test Systems)

Article 13

(1) Apparatus used for obtaining physical chemical data as a part of the physical chemical test system shall be appropriately arranged or designed and provided with sufficient data processing capability, and their functions shall be maintained.

(2) The biological test systems shall satisfy the following requirements:

(i) the appropriate conditions for the storage, containment, handling and management of the test systems shall be defined properly in order to ensure the reliability of data;

(ii) newly received test systems shall be isolated until their health status has been evaluated;

(iii) if any unusual mortality or disease occurs in the test systems, this lot shall not be used in studies;

(iv) at the experimental starting date (the day when raw data was first obtained in the study. The same applies in Article 16, paragraph (1), item (vii) and Article 18, paragraph (1), item (viii)), test systems shall be free from any disease or pathological condition that may interfere with the purpose or performance of the study;

(v) if test systems are affected by a disease or injured during the course of a study, it shall be isolated and treated if it is necessary to maintain the integrity of the study;

(vi) any diagnosis and treatment of any disease before or during a study shall be recorded;

(vii) records of source, date of arrival, and arrival condition of test systems shall be maintained;

(viii) test systems shall be acclimated to the study environment for a period of time before the first administration or application of the test or reference item;

(ix) all information for identifying the test systems shall be indicated in its housing or containers (limited to housing or containers sufficiently cleaned at appropriate intervals to maintain hygienic conditions), and individual test systems shall be identified by additional appropriate indications, if necessary; and

(x) test systems used in field studies shall not be affected by spray drift or past usage of agricultural chemicals.

(Test and Reference Items)

Article 14 Test and reference items shall satisfy the following requirements:

(i) records including test and reference item characterization, date of receipt, expiry date, quantities received and used in studies shall be maintained;

(ii) test and reference items shall be checked for homogeneity and stability when they are handled, sampled and stored, and procedures for preventing contamination or mix-up shall be provided;

(iii) identification information, expiry date and storage instructions of the test and reference item shall be indicated on storage container(s) of these;

(iv) test and reference items shall be identified necessary to allow for distinction of their lot;

(v) in case where the test item is supplied by the Sponsor (the entity who commissioned the study to the test facility; the same applies hereinafter), a collaborative scheme shall be established between the Sponsor and the test facility to verify the identity of test item to be used in study;

(vi) when the test item is administered or applied in a mixture with a vehicle, the homogeneity, concentration and stability of the test item in that vehicle shall be determined; and

(vii) a sample for analysis shall be retained from the lot of test item to be used in study (excluding those whose experimental period is less than 4 weeks).

(Standard Operating Procedures)

Article 15

(1) The Standard Operating Procedures shall describe the operational methods and procedures for the following tasks:

(i) management of test and reference items;

(ii) use, maintenance, cleaning and calibration of apparatus;

(iii) management of electronic data processing system;

(iv) preparation and labeling of materials, reagents and solutions;

(v) recording, reporting, storage and search of records;

(vi) management of the test systems;

(vii) inspection activities related to the studies and facilities to be performed by the Quality Assurance Unit; and

(viii) other necessary matters.

(2) The test facility management shall have the Standard Operating Procedures in place in all the rooms or areas where the tasks listed in the preceding items are undertaken.

Section 5 Study Plan and Conduct of Study

(Study Plan)

Article 16

(1) The Study Director shall prepare a study plan for every study containing the following information and make the study plan be verified by the Quality Assurance Unit:

(i) a title, type and purpose of the study;

(ii) information concerning the test and reference item;

(iii) name and address of the Sponsor;

(iv) name and address of the test facility;

(v) name and affiliation of the Study Director;

(vi) name and affiliation of the Principal Investigator(s), and the phase(s) of the study delegated to the Principal Investigator(s) by the Study Director if the study is to be conducted at test site(s);

(vii) the date scheduled for the study initiation date (the date when the signature or affixation of the name and seal are given as provided in item (xii). The same applies in Article 18, paragraph (1), item (viii)) and the proposed experimental starting date and completion date (the last date when raw data is obtained from the study. The same applies in the said item);

(viii) information on the study guidelines to be referred to;

(ix) information on the test system;

(x) information on the study methods;

(xi) information on the records to be retained;

(xii) signature or affixation of the name and seal of the Study Director with the date; and

(xiii) other necessary matters.

(2) If the study plan is to be changed, the Study Director shall record the date, the part, and the reason for the change in writing, sign or affix the name and seal, and retain the document with the study plan.

(Conduct of Study)

Article 17

(1) the indication to identify each study shall be done, and specimens shall be indicated to confirm their origin.

(2) The study shall be conducted in accordance with the study plan under the supervision of the Study Director.

(3) The study personnel shall promptly and accurately record all the data obtained during the conduct of the study, together with the dates, and sign or affix the name and seal on the related documents.

(4) If the study personnel change the raw data, the change shall be given so that the data before the change is not obscured, write the reason for the changes and the date when the changes are given, and sign or affix the name and seal on the related documents.

(5) The Study Director shall verify that the paperwork provided in the preceding two paragraphs are properly fulfilled, write the dates when the verification is done, and sign or affix the name and seal on the related documents.

(6) If the study data is managed by the electronic data processing system, the following requirements shall be satisfied:

(i) electronic data processing system shall be designed so that the data can be changed without obscuring the data before the changes; and

(ii) when the data is input into the electronic data processing system, the individual(s) responsible for the data input shall verify the data at the time of input.

Section 6 Reporting and Archiving

(Final Report)

Article 18

(1) The Study Director shall prepare a final report for every study that contains the following information:

(i) a title, date of preparation of final report and type and purpose of the study;

(ii) information concerning the test and reference item;

(iii) name and address of the Sponsor, if the study is conducted at its request;

(iv) name and address of the test facility;

(v) name and affiliation of the Study Director;

(vi) name and affiliation of the Principal Investigator(s) and the phase(s) of the study delegated to the Principal Investigator(s) by the Study Director if the studies are conducted at the test site(s);

(vii) name and affiliation of Experts (referred to as the “Expert” in the following paragraph) having contributed reports to the final report, if applicable;

(viii) study initiation date, experimental starting date and experimental completion date;

(ix) description of materials and test methods used in the study;

(x) information on study guidelines consulted;

(xi) a summary, evaluation and discussion of the study results, and other matters related to the study results;

(xii) information on archiving the study plan, samples of the test and reference item, specimens, raw data and final report;

(xiii) statement that the study was conducted in accordance with this Ministerial Ordinance;

(xiv) signature, or affixation of the name and seal of the Study Director with the date; and

(xv) other necessary matters.

(2) Any reports prepared by the Principal Investigator or Expert shall contain the date when they were prepared, be signed or affixed the name and seal by those persons, and be attached to the final report provided in the preceding paragraph.

(3) The Study Director shall attach the Quality Assurance Statement prepared by the Quality Assurance Unit to the final report provided in paragraph (1) (including the reports attached in accordance with the provisions of the preceding paragraph).

(4) If the final report provided in paragraph (1) is to be amended, the Study Director shall record the date, the specific part and the reason for the amendment in writing, sign or affix the name and seal, and retain the document with the final report.

(Storage and Retention of Records and Materials)

Article 19

(1) The test facility management shall appropriately retain the following materials for 10 years (for the matters set forth in item (i), the shorter period of either 10 years or the period from the study completion date(the date when the final report is signed or affixed the name and seal by the Study Director as provided in paragraph (1), item (xiv) of the preceding Article; hereinafter the same applies in this paragraph) until the date when the

evaluation of the samples or specimens becomes difficult) starting from the study completion date in the archives:

(i) samples of test and reference items, and specimens;

(ii) the study plan, raw data and the final report of each study;

(iii) the master schedules and records of all inspections performed by the Quality Assurance Unit;

(iv) records of qualifications, training, experience, and job descriptions of personnel;

(v) records of the maintenance and calibration of apparatus;

(vi) documents on the validation of electronic data processing system;

(vii) Standard Operating Procedures; and

(viii) environmental monitoring records.

(2) If the materials set forth in item (i) of the preceding paragraph are to be disposed of, the reasons or other necessary matters shall be documented before their disposal can be done.

(3) The Archivist shall make an index on the materials to be retained in the archives so that the materials can be easily retrieved.

(4) Only the Archivist and persons who are authorized by the Archivist have access to the archives.

(5) The Archivist shall record the access of the persons specified in the preceding paragraph and movement of material in and out of the archives.

(6) If the test facility is abolished, the test facility management shall transfer the materials on the studies conducted in the test facility to the entity who succeeds its business or the Sponsors of the studies (referred to as the "Material Successor" in the following paragraph).

(7) The provisions of paragraphs (1) through (5) shall apply mutatis mutandis to the Material Successor.

Supplementary Provisions

(Effective Date)

(1) This Ministerial Ordinance shall come into force as from the date of enforcement (December 1, 2018) of the Act Partially Amending the Agricultural Chemicals Regulation Act (Act No. 53 of 2018).

(Transitional Measures)

(2) Of the study reports from the studies that are started before the date of enforcement of this Ministerial Ordinance, the study reports that fall under one in all the items of Article 2 may not comply with the standards set out in Articles 5 through 19.

Supplementary Provisions (Ministry of Agriculture, Forestry and Fisheries, Ordinance No. 11 on June 28, 2019)

(Effective Date)

(1) This Ministerial Ordinance shall come into force as from the date of enforcement (April 1, 2020) of the provisions set forth in Article 1, item (ii) of the Supplementary Provisions to the Act (Act No. 53 of 2018) Partially Amending the Agricultural Chemicals Regulation Act. The amendments to Article 11, paragraph (1), item (i); Article 13 and Article 19, paragraph (1), item (i) of the Regulation for Enforcement of the Agricultural Chemicals Regulation Act, as provided in Article 1, however, shall come into force on the date of promulgation.

(Transitional Measure)

(2) Prior provisions may continue to govern the study reports from the studies started before the date of enforcement of this Ministerial Ordinance, notwithstanding the provisions of Article 2 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals, as amended by Article 2 of this Ministerial Ordinance.

Supplementary Provisions (Ministry of Agriculture, Forestry and Fisheries, Ordinance No. 25 on April 1, 2024)

(1) This Ministerial Ordinance shall come into force as from October 1, 2024, and the amended provision of Article 2 of the Ministerial Ordinance on Good Laboratory Practice for Agricultural Chemicals shall be applied to the application for the registration of Article 3, paragraph (1) of the Agricultural Chemicals Regulation Act which is submitted on or after October 1, 2024.