

Measures on the Management of Pesticide Registration Tests

Chapter I General

Article 1 To ensure the completeness, reliability and authenticity of pesticide registration tests and strengthen pesticide registration test management, the Measures on the Management of Pesticide Registration Tests (the Measures) is hereby developed in accordance with the Regulations on the Management of Pesticides.

Article 2 For the application of pesticide registration, registration tests shall be performed according to the Measures.

For pesticide registration tests, the applicant shall report to the agricultural authority under the provincial people's government (hereinafter referred to as agricultural authority at the provincial level) where it is to be put on record; the registration tests for new pesticides shall be additionally subject to review and approval of the Ministry of Agriculture.

Article 3 The Ministry of Agriculture shall be responsible for approval of new pesticide registration tests, recognition of pesticide registration test entities, supervision and management of registration tests; specific issues shall be handled by the institution responsible for the pesticide examination institute under the Ministry of Agriculture.

The agricultural authorities at the provincial level shall be responsible for relevant supervision and management work within their respective administrative areas; and specific issues shall be handled by the institution responsible for the pesticide examination institute under the Ministry of Agriculture.

Article 4 Agricultural authorities at the provincial level shall further digitalize the supervision and management, of the pesticide registration test, and timely upload the registration test record and supervision information to the pesticide management information platform specified by the Ministry of Agriculture.

Chapter II Recognition of Test Entities

Article 5 An entity which applies for undertaking pesticide registration test shall meet all the conditions below:

- (1) be an independent legal person, or individual authorized by the legal person to file such an application and commits to assume corresponding legal liabilities;
- (2) has its own testing place, suitable environment and facilities, test equipment and instruments, sample and file storage facilities, etc. matching the scope of the registration test for which it applies;
- (3) has professional technicians and management who are in legal labor or an employment relationship with it and able to undertake the registration tests within the scope for which it has applied for;
- (4) has a sound organization management system as well as persons in charge, a head of quality assurance, test project manager, file clerk, sample managers, corresponding testing personnel and other employees;
- (5) complies with quality management regulations for pesticide registration tests, and corresponding standard operation procedures are established;

(6) has sufficient experience in completing the test within the scope for which it applied for, and has been operating for more than 6 months in accordance with quality management regulations for pesticide registration tests;

(7) meets other conditions specified by the Ministry of Agriculture.

Article 6 The entity which applies for undertaking pesticide registration tests shall submit the following documents to the Ministry of Agriculture:

- (1) an application form for examination and recognition of the pesticide registration test entity;
- (2) a copy of legal person certificate or power of attorney issued by a legal person;
- (3) organizational structure setting and responsibilities;
- (4) list of quality management system documents (standard operation procedures) of the test entity;
- (5) supporting evidence for test place, test facilities and labs, and list of instruments and equipment;
- (6) list of professional technicians and management and relevant supporting documents;
- (7) statement of operations in compliance with quality management regulations for pesticide registration tests as well as typical test reports and copy of its original record.

The application data shall be submitted in both paper and electronic form.

Article 7 Where the application data submitted by the applicant is not complete or consistent with legal forms upon examination by the Ministry of Agriculture, the applicant shall be informed of all the contents that should be corrected or supplemented once and for all on the spot where the applicant submits his/her application or within five working days; where the application data are complete and consistent with legal forms, and all the supplemented or corrected data are submitted as required, the application shall be accepted.

Article 8 The Ministry of Agriculture shall finish its technical review within six months upon the date of acceptance, excluding the approval period.

Article 9 The technical review includes data review and field inspections.

Data review includes the applicant's organizational structure, test conditions, capacity suitability as well as the completeness, authenticity and suitability of quality management systems and relevant materials.

Field inspections include a compliance inspection of the applicant's implementation of quality management systems, the conditions of test equipment and facilities as well as testing capacities.

Detailed review rules shall be separately established by the Ministry of Agriculture.

Article 10 The Ministry of Agriculture shall within twenty working days state its approval or disapproval based on assessment results. If the conditions are met, the Ministry of Agriculture shall issue the pesticide registration test entity certificate, and if not, give a written notice indicating the reasons to the applicant.

Article 11 The pesticide registration test entity certificate is valid for five years and shall indicate the full name, legal representative (person in charge), domicile, location of laboratory, testing scope, certificate number, validity and other details about the test entity.

Article 12 Within the validity of the pesticide registration test entity certificate, in case of any change to the name of the pesticide registration test entity, the name or domicile of the legal representative (person in charge), an application for such change shall be filed to the Ministry of Agriculture, together with an application form for change and other supporting documents. The Ministry of Agriculture shall approve or disapprove the change within twenty working days upon acceptance of the application.

Article 13 Within the validity of the pesticide registration test entity certificate, in the event of any of the following circumstances, a re-application shall be made to the Ministry of Agriculture:

- (1) the testing entity is divided or merged;
- (2) any change to the location of the laboratory or any major change to facilities occurs; or
- (3) the test scope is expanded;
- (4) others.

Article 14 Upon expiration of the validity of the pesticide registration test entity certificate, if the test entity intends to continue pesticide registration testing, it shall re-apply to the Ministry of Agriculture at least six months prior to such expiration.

Article 15 If the pesticide registration test entity certificate is lost or damaged, the entity shall state the reasons, provide relevant supporting documents, and apply to the Ministry of Agriculture for re-issuance in a timely manner.

Chapter III Test Filing and Approval

Article 16 Before any pesticide registration test to be conducted, the test shall be recorded with the agricultural authority at the provincial level where the registration test will be carried out, stating the filer, product description, test items, test site, test entity, test time, safety protection measures, etc.

Article 17 Where any new pesticide registration test needs to be carried out, an application shall be submitted to the Ministry of Agriculture with the following documents accompanied:

- (1) new pesticide registration test application form;
- (2) domestic and foreign R&D and foreign registration;
- (3) scope of test, test site (test area) and other statements;
- (4) chemical information of product and a product quality conformance inspection report;
- (5) toxicological information;
- (6) crop safety information;
- (7) environmental safety information;
- (8) existing or potential safety hazards in the test;
- (9) safety protection measures to be taken in the test;
- (10) identity documents of the applicant.

The application data shall be accompanied with paper and electronic files.

Article 18 Regarding the application data submitted by the applicant, the Ministry of Agriculture shall treat them based on the following circumstances:

- (1) where no approval is required for the pesticide registration test, the applicant shall be informed in a timely manner that the application is not accepted;
- (2) where any error is found in the application data, the applicant shall be allowed to make any correction on site;
- (3) where the application data is not complete or consistent with legal forms, the applicant shall be informed of all the contents that should be corrected or supplemented once and for all on the spot where the applicant submits his/her application or within five working days; if the applicant is not informed within the aforesaid period, the data is deemed as accepted upon receipt of the application data;
- (4) where the application data are complete, consistent with legal forms, or the applicant submits all supplemental or corrected data as required, the application shall be accepted.

Article 19 Within forty working days upon acceptance of the application, the Ministry of Agriculture shall examine the test's safety risks and prevention measures and make a decision on its approval or disapproval. If the conditions are met, the Ministry of Agriculture shall approve the registration test and issue a new pesticide registration test approval certificate, and if not, give a written notice to the applicant indicating the reasons.

Article 20 The new pesticide registration test approval certificate shall clearly state the name of the test applicant, pesticide name, formulation type, active ingredients and content, test scope, test certificate number, validity period and others.

The type of new pesticide registration test approval certificate will be determined by the Ministry of Agriculture. The certificate number shall be expressed as "SY + Year + Serial No"; "Year" means the year in which the certificate is issued and shall be expressed by four Arabic numerals; the serial number shall be expressed by three Arabic numerals.

The new pesticide registration test approval certificate is valid for five years. If no test is carried out within five years, a re-application shall be made.

Chapter IV Basic Requirements for Registration Tests

Article 21 The sample of the pesticide registration test shall be a sophisticated finished product and accompanied with product identification methods, quality control indicators and testing methods.

The applicant shall be responsible for the authenticity and consistency of the test sample.

Article 22 The applicant shall submit the test sample to the Provincial Pesticide Examination Institution where it is located for sealing, and provide the pesticide name, active ingredients and contents, dosage form, sample production date, specifications and quantity, storage conditions, warranty period and other information together with a quality consistency test report and relevant spectrogram.

Article 23 The sealed test samples shall be retained by the Provincial Pesticide Examination Institution and the applicant, one for each, for at least two years, and the remained samples shall be sent to the registration test entity for testing.

Article 24 Where the sealed test samples are insufficient for testing needs or the storage life has lapsed for the test samples, if it is still necessary to carry out the test, the applicant shall re-seal the samples according to the Measures.

Article 25 The applicant shall provide the pesticide registration test entity with the information regarding the pesticide test sample's name, content, dosage form, production date, storage conditions, quality warranty period as well as risk prevention measures. In case of a new pesticide, the copy of a new pesticide registration test approval certificate shall also be provided.

The pesticide registration test entity shall check for the completeness of sealed samples and the compliance of sample information.

Article 26 If the pesticide registration test entity is engaged by the applicant to carry out the registration test, the entity shall enter into an agreement with the applicant to define their rights and obligations.

Article 27 The pesticide registration test shall be carried out according to legal technical standards and methods for pesticide registration tests. In absence of such legal technical standards and methods, they shall be determined by the applicant and the registration test entity through consultation with the scientific soundness and accuracy of the tests guaranteed.

In cases where any material safety risks occurs in the process of the pesticide registration test, the test entity shall immediately cease the test and take all reasonable measures to prevent further expansion of risk, report such case to the agricultural authority at the provincial level where it is located, and notify the applicant.

Article 28 Upon completion of the test, the pesticide registration test entity shall issue a standard test report to the applicant as agreed upon in the agreement.

Article 29 The pesticide registration test entity shall keep the test plan, original data, specimen, tested samples and contrasts, test report and other documentary materials regarding the test for at least seven years after completion of the test, and may hand over the same material to the applicant upon expiry of the period. The applicant shall keep the material for at least five years after the pesticide is withdrawn from the market.

The storage life of perishable specimen, tested samples, contrast samples, etc. shall be subject to a period of effective evaluation.

The test entity shall keep indefinitely the organizational structure, personnel, quality assurance department check record, master schedule, standard operation instructions and other records regarding operation activities and quality management of the test entity.

Chapter V Supervision and Inspection

Article 30 The agricultural authority at the provincial level and the Ministry of Agriculture shall supervise and inspect the pesticide registration test entities and the registration test process, and focus on the following items:

- (1) change of the qualification conditions of the test entities;
- (2) important test equipment and facilities;
- (3) whether the test site, test items and other recorded information are consistent;
- (4) whether the test process is consistent with statutory technical rules and methods;
- (5) the safety risks of registration tests and the implementation of their prevention measures;
- (6) other circumstances where the quality management specification requirements on pesticide registration tests are not met or the registration test quality is affected.

In case any uncontrollable safety risk is found in the test process, the test shall be promptly ordered to cease or terminate and a risk report sent to the Ministry of Agriculture.

In case any test entity is found no longer consistent with the specified conditions, the authority shall call for corrections to be made within a specified period; if the test entity refuses to make the corrections or fails to meet the requirements even after correction, the Ministry of Agriculture will revoke the test entity's testing certificate.

Article 31 The pesticide registration test entities shall submit reports on implementation of quality management regulations for pesticide registration tests to the Ministry of Agriculture each year.

Article 32 Agricultural authorities above the provincial level shall arrange for supervision and inspection on the conformity and consistency of pesticide test samples sealed for registration tests, and report any problem found during supervision and inspection to the Ministry of Agriculture.

Article 33 If the pesticide registration test entity issues any false registration test report, it shall be subject to sanctions according to Article 51 of the Regulations on the Management of Pesticides.

Chapter VI Supplementary Provisions

Article 34 Test items in which the existing registration test entities are unable to undertake shall be undertaken by the entity designated by the Ministry of Agriculture.

Article 35 The Measures shall be enacted as from August 1, 2017.

The pesticide registration test entities announced publicly by the Ministry of Agriculture prior to the enactment of the Measures may continue pesticide registration tests within their validity terms; where the registration tests need to be continued after the expiration of the validity term, an application for recognition of the test entity shall be filed according to the Measures.