

# Measures on the Management of Pesticide Registration

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## Chapter I General

**Article 1** To regulate pesticide registration practices, strengthen pesticide registration management, ensure the safety and effectiveness of pesticides, the Pesticide Registration Management Measures (hereinafter referred to as the Measures) are hereby developed in accordance with the Regulations on the Management of Pesticides.

**Article 2** The Measures shall apply to the registration of pesticides produced, operated and used in the territory of the People's Republic of China.

A pesticide for which a pesticide registration certificate is not obtained according to the law will be deemed as a fake pesticide.

**Article 3** The Ministry of Agriculture shall be responsible for pesticide registration management nationwide, organize the establishment of a pesticide registration review committee, and develop pesticide registration review rules.

The institution under the Ministry of Agriculture responsible for pesticide verification shall be in charge of specific work of pesticide registration nationwide.

**Article 4** Agricultural authorities under provincial people's governments (hereinafter referred to as agricultural authorities at the provincial level) shall be responsible for accepting applications for pesticide registration within their respective administrative regions, examine application data and give opinions on primary examinations.

The pesticide examination institutions under the agricultural authorities at the provincial level (hereinafter referred to as pesticide examination institutions at the provincial level) shall provide assistance in dealing with specific issues concerning pesticide registration.

**Article 5** Pesticide registration shall comply with science, fairness, equality, high efficiency and convenience principles.

**Article 6** The registration of safe, highly efficient and economical pesticides shall be encouraged, and the elimination of pesticides carrying high risks against agriculture, forestry, human and animal health, quality and safety of agricultural products and the environment shall be accelerated.

## Chapter II Basic Requirements

**Article 7** Pesticides shall be named in common names in Chinese or abbreviations thereof. Botanical pesticides may be named in the form of "plant name + extract", and public health pesticides for direct use shall be named in the form of function description expressions and formulations.

**Article 8** The content of active ingredient and formulation of a pesticide shall be determined in the principles of improving quality, protecting the environment and promoting the sustainable development of agriculture.

The formulas of formulated products shall be scientific, reasonable and convenient for use. For a single formulation with the same active ingredient and formulation type, the contents of active ingredients shall be no more than three. There should be no more than two kinds of active ingredients in the pesticide ready-mixture, and no more than three kinds of active ingredients in herbicide, seed treatment, and pheromones; for ready-mixtures with the same active ingredients and formulation type, the ratio shall be no more than three, and the content gradients of the same ratio shall be no more than three. Pesticides with a low content of active ingredients that are directly used other than through dilution or dispersing shall be classified separately, specific relevant requirements will be developed separately by the Ministry of Agriculture.

**Article 9** Based on the toxicity and harmfulness of pesticide adjuvants, the Ministry of Agriculture will timely publish and adjust the list and limited quantity of the prohibited/restricted adjuvants.

Where a specified adjuvant needs to be added in pesticides when used, corresponding testing data shall be submitted in the application for pesticide registration.

**Article 10** The dilution ratio or use concentration of pesticides shall match the techniques for applying pesticides.

**Article 11** Relevant data or materials submitted by the applicant shall meet the requirements of risk assessment, and demonstrate that its products are comparable or obviously superior to the registered products regarding safety, effectiveness, etc.

In the review of a product for which the registration is applied, it is required to refer to its risk assessment results and comply with the principle of maximum risks.

**Article 12** The applicant shall submit both paper and electronic files, and be responsible for the authenticity and legality of the data provided.

### Chapter III Application and Acceptance

**Article 13** The applicant shall be a pesticide production enterprise, an enterprise exporting pesticides to China or a new pesticide developer.

A pesticide production enterprise refers to a domestic enterprise holding a pesticide production permit. An enterprise exporting pesticides to China (hereinafter referred to as an overseas enterprise) refers to an enterprise exporting the pesticides produced overseas to China. A new pesticide developer refers to a Chinese citizen, legal person or other organization applying for a new pesticide registration.

For new pesticides jointly developed by several entities, one of the entities shall act as the applicant, specify other joint R&D institutions and provide supporting materials to prove the homogeneity of the relevant test samples. Other entities shall not make repeated applications.

**Article 14** A domestic applicant shall apply for pesticide registration to the agricultural authority at the provincial level where it is located. An overseas enterprise shall apply for pesticide registration at the Ministry of Agriculture.

**Article 15** The applicant shall submit product chemistry, toxicity, efficacy, residue, environmental impact as well as testing reports, a risk assessment report, samples of labels or instructions, product safety data sheet, relevant literature, application form, applicant qualification certificate, data authenticity declaration, and other applicant materials.

The pesticide application materials shall be authentic, standard, complete and valid, and specific requirements will be separately established by the Ministry of Agriculture.

**Article 16** A registration test report shall be issued by the registration test agency approved by the Ministry of Agriculture, or issued by a relevant overseas laboratory under the mutual recognition agreement between the relevant departments of government, provided that the efficacy, residue, environment and other tests closely related to environmental conditions as well as registration tests for unique biological species to China shall be completed in the territory of China.

**Article 17** The applicant, if applying for new pesticide registration, shall submit the registration applications for both new pesticide TC and new pesticide formulations, as well as reference samples of the pesticides.

Within six years upon registration of the new pesticide, where other applicants submit applications with the data obtained by themselves or authorized by the new pesticide registration certificate holder, it shall be deemed as a new pesticide registration application.

**Article 18** The complete registration data consistent with the registration data requirements and owned independently by the pesticide registration certificate holder may be used by other applicants if so authorized.

Where the pesticide registration data is transferred according to Article 14 of the Regulations on the Management of Pesticides, the transferee shall apply for pesticide registration by virtue of the transfer contract between the parties and the registration data consistent with registration data requirements.

**Article 19** For the application data submitted by the applicant, the Ministry of Agriculture or the agricultural authority at the provincial level shall treat it based respectively on the following circumstances:

- (1) Where no pesticide registration is required, the applicant shall be timely informed that its application is not accepted;
- (2) Where an error is found in the application data, the applicant shall be allowed to correct it 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 on site or one time 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 is complete, consistent with legal forms, or where the applicant submitted all supplemental or corrected data as required, the application shall be accepted.

## Chapter IV Review and Decision

**Article 20** The agricultural authorities at the provincial level shall perform a preliminary examination of the data submitted by an applicant within twenty working days upon acceptance of such application, give opinions of the preliminary examination, and report to the Ministry of Agriculture. If not qualified following the preliminary examination, a written notice indicating the reasons will be given to the applicant in accordance with the will of the applicant.

**Article 21** Upon acceptance of the application or receipt of the application data and preliminary examination opinions submitted by the agricultural authorities at the provincial level, the Ministry of Agriculture shall complete technical examinations on the chemistry, toxicity, efficacy, residue, environment impact and label sample of the product within nine months, give examination opinions, and submit them to the Pesticide Registration Reviewing Committee for review.

**Article 22** Upon receipt of the technical examination opinions, the Pesticide Registration Reviewing Committee shall give review opinions according to the registration review rules.

**Article 23** Upon acceptance of the pesticide registration application, the applicant may withdraw the registration application and submit a new application when supplementing and completing the relevant data.

The Ministry of Agriculture may require the applicant to supplement data based on the opinions of the Pesticide Registration Reviewing Committee.

**Article 24** During registration examination and review, the category of registration application submitted by the applicant and the technical requirements and review procedures that the applicant follows will not be affected by the other applicant's obtaining of a pesticide registration certificate during this period.

After a new pesticide is approved, the new pesticide registration application from any other applicant which has been accepted can continue to be subject to examination and review according to new pesticide registration approvals and review procedures. Other applicants may withdraw the application and file a new registration application.

**Article 25** The Ministry of Agriculture shall make a decision within twenty working days upon receipt of the review opinions. If the conditions are met, the pesticide registration certificate shall be issued, and if not, a written notice indicating the reasons shall be given to the applicant.

**Article 26** The pesticide registration certificate shall be uniformly printed and issued by the Ministry of Agriculture.

## Chapter V Change and renewal of Registration

**Article 27** The pesticide registration certificate shall be valid for five years.

**Article 28** The holder shall apply for change at the Ministry of Agriculture in the event one of the following circumstances occurs during the validity of the pesticide registration certificate:

- (1) the scope, method or use dosage of the pesticide is changed;
- (2) the components, except for the active ingredients, are changed;
- (3) the toxicity level of the product is changed;
- (4) the content of active ingredients in the TC is changed;
- (5) product quality standards are changed;
- (6) other circumstances specified by the Ministry of Agriculture.

In case of change to the pesticide registration certificate holder, relevant proof shall be submitted to the Ministry of Agriculture for the re-issuing of a pesticide registration certificate.

**Article 29** Where the production of pesticides or export of pesticides to China needs to be continued upon expiration of the validity period, an application for renewal shall be made ninety days before expiration of the validity period. If no renewal is applied within such time limit, the application for registration shall be submitted again.

**Article 30** In case of application for change or renewal, the pesticide registration certificate holder shall submit such an application to the Ministry of Agriculture, fill in the application form and submit relevant data.

**Article 31** The Ministry of Agriculture shall finish the examination on the registration change within six months, give examination opinions, submit them to the Pesticide Registration Reviewing Committee for review, and make a decision within twenty working days upon receipt of the review opinions. If the application is qualified, the registration change will be permitted, with the registration certificate number and validity term unchanged; if not, a written notice indicating the reasons will be given to the applicant.

**Article 32** The Ministry of Agriculture shall examine the registration renewal application materials, and make a decision on whether the renewal should be allowed before expiration of the validity period. If any hidden danger or risk is found in safety and effectiveness, the materials shall be submitted to the Pesticide Registration Reviewing Committee for review.

## Chapter VI Risk Monitoring and Evaluation

**Article 33** Agricultural authorities above the provincial level shall establish a pesticide safety risk monitoring system, and organize pesticide verification institutions and plant protection institutions to monitor and evaluate the safety and effectiveness of the registered pesticides.

**Article 34** The content to be monitored shall include the impacts of pesticides on agriculture, forestry, human and animal safety, agricultural product quality and safety, the environment, etc.

The evaluations shall be organized and performed in case of any one of the following circumstances:

- (1) many crop phytotoxicity accidents occur;
- (2) the target biotic resistance is greatly raised;
- (3) the pesticide residue of agricultural products exceeds the standard value a number of times;
- (4) harmful events are caused to non-target species and natural enemy organisms, such as bees, birds, fish, silkworms, shrimps and crabs;
- (5) an adverse impact occurs in underground water, surface water and soil, etc.;
- (6) harm occurs to the health of pesticide users or the persons and animals exposed to the pesticide.

The agricultural authorities at the provincial level shall report the monitoring and evaluation results to the Ministry of Agriculture in a timely manner.

**Article 35** The pesticide registration certificate holder shall collect the information of and analyze the safety, efficacy change, product recall, accidents in production and use, etc. of pesticide products.

**Article 36** For pesticide products with a registration of more than fifteen years, the Ministry of Agriculture shall organize periodic evaluations based on the changes of production and use situations and industry policies.

**Article 37** If any registered pesticide is found to have caused serious harm or brings high risks to agriculture, forestry, human and animal safety, agricultural product quality and safety, the environment, etc., the Ministry of Agriculture shall organize the Pesticide Registration Reviewing Committee to perform reviews, cancel or alter the corresponding pesticide registration certificate based on the review results, and if necessary, the use shall be prohibited or restricted and an announcement shall be published.

## Chapter VII Monitoring and Management

**Article 38** In case of any of the following circumstances, the Ministry of Agriculture or agricultural authorities at the provincial level shall refuse to accept the pesticide registration application, and if having already accepted it, shall disapprove it if:

(1) the application data is not consistent with requirements regarding authenticity, completeness or standardization;

(2) the applicant is not qualified as specified in Article 13 of the Measures;

(3) the applicant is on the list of institutions with a history of serious dishonest acts as specified by competent authorities of the state and is restricted from obtaining an administrative permit;

(4) the pesticides for registration are clearly prohibited for production, operation and use by relevant national authority, or the pesticides are no longer registered according to the law by the Ministry of Agriculture;

(5) the registration test is against Paragraph III, Article 9 and Article 10 of the Regulations on the Management of Pesticides;

(6) other circumstances where the applicant shall not be accepted or approval shall not be granted.

Where an applicant conceals relevant facts or submits fake pesticide registration data and test samples, his/her application will not be entertained for one year; if the registration has been approved, the pesticide registration certificate shall be withdrawn and his/her application will not be entertained for three years. Where the pesticide registration certificate is revoked, his/her application will not be entertained for five years.

**Article 39** The Ministry of Agriculture will list the tainted information of the applicant submitting fake data and test samples into the integrity record and publish it.

**Article 40** The Ministry of Agriculture shall cancel the pesticide registration certificate and publish the fact in any of the following circumstances:

(1) the application for renewal is not filed upon expiration of the validity term;

(2) the pesticide registration holder is terminated according to law or not qualified as a pesticide registration application;

(3) the pesticide registration data has been transferred according to law;

(4) other circumstances where the pesticide registration certificate shall be canceled.

**Article 41** The Ministry of Agriculture promotes the construction of a pesticide registration information platform, gradually realizes online handling of registration applications, and publishes the pesticide registration certificate issuing, renewal, changes, withdrawals and cancellation information, as well as the approved label information about the quality standard code, residue limit and testing methods of pesticide products through the website of the Ministry of Agriculture or by issuing a pesticide registration announcement.

**Article 42** Where any member of the Pesticide Registration Reviewing Committee seeks personal benefits during the application process, the Ministry of Agriculture will remove the member from the Pesticide Registration Reviewing Committee; where the member is a state functionary, he/she shall be submitted to the relevant authority for punishment according to the law; where his/her act constitutes a crime, he/she shall be held liable criminally.

**Article 43** The Ministry of Agriculture, agricultural authorities at the provincial level and their personnel engaged in pesticide registration shall perform their duties according to the law, give scientific, objective and fair examination and review opinions, and are obligated to keep confidential the registration data submitted by the applicant, and unpublished examination and review results and opinions. If the government authority or personnel has any personal relation with or any special interest regarding any applicant or the corresponding products (data), he/she shall avoid participating in pesticide production and operation activities.

**Article 44** Where any personnel engaged in pesticide registration fails to perform their duties, misuses their authority, plays favoritism and commits irregularities, or asks for, accepts properties, or seeks other interests, the personnel shall be punished accordingly; upon the day when the punishment is made, the personnel shall not be engaged in pesticide registration work for five years.

**Article 45** If any unit or individual finds any circumstance against the Measures, it has the right to report to the Ministry of Agriculture or agricultural authority at the provincial level. The Ministry of Agriculture or agricultural authority at the provincial level shall verify such reporting and deal with the circumstance in a timely manner. Furthermore, the Ministry of Agriculture shall keep confidential the information of the informer. If the case is verified to be true, plays an active role in production safety or saves great loss, a reward or award shall be given according to relevant national regulations.

## Chapter VIII Supplementary Provisions

**Article 46** For the registration of pesticides used for special minor crops, grouped registration management shall apply to the expanded use scope. The scope of special minor crops is determined by the Ministry of Agriculture.

For special minor crops or new pests to which no registered pesticides are available, the agricultural authorities at the provincial level may take temporary pesticide application measures based on local actual situation and submit them to the Ministry of Agriculture for recording.

**Article 47** The terms used in the Measures shall be defined as follows:

- (1) a new pesticide refers to the pesticide that contains any active ingredient not approved and registered in China, including new pesticide TC (TK) and new pesticide formulations;
- (2) TC refers to the product obtained from the production process and composed of active compounds and relevant impurities, and if necessary, containing a small volume of additives;
- (3) TK refers to the product obtained from the production process, composed of active compounds and relevant impurities, and possibly containing a small volume of necessary additives and moderate diluents;
- (4) formulation refers to stable pesticide products processed from TC (TK) and appropriate adjuvants or processed by way of biological fermentation, phytoextraction, etc.;

(5) adjuvant refers to any substance (other than the active compound) composed of a single component or several components which is added into a pesticide product and has no pesticide activity and active compound functions in itself, but is able or helpful to improve or enhance the material properties of pesticide products.

**Article 48** The registration management of the pesticides only used overseas shall be subject to separate regulations under the Ministry of Agriculture.

**Article 49** The Measures are enacted as from August 1, 2017.

Before June 1, 2017, temporary pesticide registration certificates already obtained will not be renewed upon expiration. The pesticide registration applications that are already accepted but not yet approved will be subject to relevant provisions in the Regulations of the Management of Pesticides.