Announcement of the Ministry of Agriculture of People's Republic of China

No. 2570

The *Rules on Evaluation of Pesticide Registration Testing Institutes* and the *Code for Pesticide Registration Testing Quality Management* prepared by the Ministry in accordance with the *Regulations on Management of Pesticides* and the *Measures on Management of Pesticide Registration Testing* are hereby promulgated and shall come into force as of October 10, 2017.

Appendixes: 1. Rules on Evaluation of Pesticide Registration Testing Institutes
2. Code for Pesticide Registration Testing Quality Management

Ministry of Agriculture
September 3, 2017

Appendix 1.

Rules on Evaluation of Pesticide Registration Testing Institutes

Article 1. These Rules are formulated in accordance with the *Regulations on Management of Pesticides* and the *Measures on Management of Pesticide Registration Testing*, for the purpose of regulating the evaluation of pesticide registration testing institutes.

Article 2. These Rules are applicable to the technical evaluation of pesticide registration testing institutes, including paper examination and on-site inspection.

The paper examination shall be conducted by the agency under the Ministry of Agriculture responsible for pesticide testing, and the on-site inspection shall be conducted under the unified arrangement of the Ministry of Agriculture.

Article 3. The tests required for registration of a pesticide includes tests on the chemical property, efficacy, toxicology, residue and environmental impact, among others.

Chemical tests include (all) components analysis test, physical and chemical property test, product quality test and storage stability test; Efficacy tests include tests on agricultural and forestry pesticides and tests on public health pesticides, etc.; Toxicity tests include acute toxicity test, repeated dose toxicity test, special toxicity test, metabolic and toxicological dynamics test, microbial pathogenicity test and exposure dose test. Residue tests include metabolism test, crop residue test and processed agricultural product residue test. Environmental impact tests include ecotoxicology test and environmental fate test.

In case of application for different tests, materials required for each test shall be provided. The evaluation result shall be given by the Ministry of Agriculture based on the application scope.

Article 4. The paper examination process involves the filling out the *Comments after Paper Examination of Pesticide Registration Testing Institutes.* Where there is any major defect with the organizational structure or quality management systems, or any person or facility or instrument is not in match with the tests applied for, or the test reports or raw data provided by applicants are not up to the requirements of the *Code for Pesticide Registration Testing Quality Management* Quality, the application materials shall be deemed to fall short of the registration requirements. The applicants shall be so informed, with reasons clearly stated.

Article 5. Where the application materials meet the registration requirements, the Ministry of Agriculture shall arrange an on-site inspection based on the application.

The on-site inspection shall be conducted by an evaluation team composed of more than 3 persons, including one leader who assumes the overall responsibility for the whole team, and where necessary, some experts in relevant fields. Any evaluator or expert who has any interest in applicants shall withdraw from the inspection process.

The Ministry of Agriculture shall be responsible for setting up an evaluator database and organizing training on evaluators.

Article 6. The Ministry of Agriculture shall send 3 days' prior written notice of the on-site inspection to the applicants and its counterpart at the provincial level in the place where the applicants are located.

Article 7. To conduct an on-site inspection, the evaluation team shall develop a work plan by following procedures below:

(1)The first meeting: Introduce members of the evaluation team, the purpose, basis, and scope of inspection, and the testing programs involved, nail down the schedule and announce disciplines and points for attention, and gain knowledge about the applicants.

(2) Inspection & Evaluation: Evaluators shall inspect items one by one based on the tests applied for and in accordance with the *Code for Pesticide Registration Testing Quality Management* through on-site inspection, consulting files, demonstration and interviews, and truthfully record problems discovered, and copy or take photos of relevant sites and documents as evidence. With respect to testing institutes that have multiple sites, the evaluation team shall check and evaluate each site.

(3) Internal exchanges: Upon completion of the on-site inspection, the evaluation team shall hold an internal meeting to exchange views on the inspection, and complete the *Form of Deviations Discovered in On-site Inspection of Pesticide Registration Testing Institutes,* as well as give comprehensive comments based on the tests applied for.

(4) The final meeting: The evaluation team shall hold a final meeting participated by key personnel of the applicants, to advise them of main problems discovered for their comments. Applicants shall sign the *Form of Deviations Discovered in On-site Inspection of Pesticide Registration Testing Institutes.*

Article 8. The conclusion drawn from the on-site inspection for a single item may be "compliant" "slightly defected", "non-compliant", or "N/A"; of which, "compliant" means the requirements of the *Code for Pesticide Registration Testing Quality Management* are met; "Slightly defected" means there are small deviations from the *Code for Pesticide Registration Testing Quality Management*, and they are accidental, isolated, and will not seriously impact the effectiveness of the testing program; "Non-compliant" means there are serious deviations from the *Code for Pesticide Registration Testing Quality Management*, and they could impact the effectiveness of the testing program and operation of quality management systems. "N/A" means the contents inspected have nothing to do with the tests applied for and there is no need to evaluate them.

Where the conclusion of "slightly defected" or "non-compliant" is drawn for a single item, explanations shall be given in the "Inspection Record" column.

Article 9. The overall conclusion drawn from an on-site inspection may be "qualified" "basically qualified" or "unqualified".

Article 10. If each item inspected is concluded to be "qualified", the overall conclusion shall be "qualified".

Article 11. The overall conclusion shall be "basically qualified" if all of the following conditions are met:

(1) No conclusion of “non-compliant” is drawn for any item;

(2) No conclusion of “slightly defected” is drawn for any key item;

(3) The number of items concluded to be “slightly defected” is less than 10% of the total number of items inspected for tests applied for;

Article 12. The overall conclusion shall be “unqualified” under any of the following circumstances:

(1) A conclusion of “non-compliant” is drawn for any item;

(2) A conclusion of “slightly defected” is drawn for any key item;

(3) The number of items concluded to be “slightly defected” is more than 10% of the total number of items inspected for tests applied for;

(4) The applicants are found to be practicing fraud during the on-site inspection.

Article 13. The evaluation team shall submit to the Ministry of Agriculture within 10 days following the completion of the on-site inspection, the *Form of Deviations Discovered in On-site Inspection of Pesticide Registration Testing Institutes*, the *Report on the On-site Inspection of Pesticide Registration Testing Institutes*, the inspection records and relevant supporting documents.

Article 14. Where the overall conclusion drawn from the on-site inspection is “basically qualified”, the applicants may conduct rectification based on requirements of the Ministry of Agriculture, and subsequently submit a rectification report and corresponding supporting documents. The rectification period is normally no more than 30 days.

Article 15. The evaluation team shall examine the rectification report and corresponding supporting documents submitted by applicants, while focusing on whether deviations are effectively rectified, whether reasons are rationally analyzed, and whether mistakes are properly corrected to prevent similar problems from happening again.

Article 16. The evaluation team shall fill out the *Comments on Rectification of Pesticide Registration Testing Institutes* based on actual conditions and develop a rectification inspection report. Where applicants fail to complete the rectification properly or within the specified time period, the conclusion drawn from the on-site inspection shall be “unqualified”.

Article 17.The Ministry of Agriculture shall conduct a comprehensive evaluation based on the results of paper examination and on-site inspection, and issue the certificate for pesticide registration testing institutes to applicants who meet the conditions, and notify applicants who fail to meet the conditions in writing, with reasons clearly stated.

Article 18. These Rules shall enter into force as of October 10, 2017.

Appendixes:

1-1 Comments after Paper Examination of Pesticide Registration Testing Institutes

1-2 Form of Deviations Discovered in On-site Inspection of Pesticide Registration Testing Institutes

1-3 Comprehensive Comments after On-site Inspection of Pesticide

Appendix 1-1

Comments after Paper Examination of Pesticide Registration Testing Institutes

<table>
<tr><td>Name of applicant</td><td colspan="2"></td></tr>
<tr><td>Acceptance time</td><td colspan="2"></td></tr>
<tr><td>Acceptance number</td><td colspan="2"></td></tr>
<tr><td>File No.</td><td colspan="2"></td></tr>
<tr><td rowspan="4">Tests applied for</td><td>Product chemical test</td><td>□ (All) component analysis test
□ Physical and chemical property test
□ Product quality test/storage stability test</td></tr>
<tr><td>Efficacy test</td><td>□ Agricultural and forestry pesticide test:
□ Insecticide □ Fungicide □ Herbicide
□ Plant growth regulator □ Rodenticide
□ Public health pesticide test: □ Health insecticide
□ Rodenticide
□ Termicide □ Molluscicide
□ Stored grain pest control agent</td></tr>
<tr><td>Residue test</td><td>□ Metabolic test: □ Animal metabolism □ Plant metabolism
□ Crop residue test: □ Indoor test □ Field test
□ Processed agricultural product residue test</td></tr>
<tr><td>Toxicology test</td><td>□ Acute toxicity test □ Repeated dose toxicity test
□ Specific toxicity Test □ Metabolic and toxicology test
□ Microbiological pathogenicity test □ Exposure dose test</td></tr>
<tr><td></td><td>Environmental impact test</td><td>□ Ecological toxicology test (□ Class A □ Class B □ Class C □ Class D)
□ Environmental fate test (□ Class A □ Class B)</td></tr>
<tr><td>Application type</td><td colspan="2">□ First application
□ Application upon maturity
□ Organization division or merger
□ Change in address or significant change in facilities
□ Expand the scope
□ Other matters</td></tr>
<tr><td>Comments from experts</td><td colspan="2">Comments from the handler:
DD/MM/YY</td></tr>
</table>

	Comments from the person in charge: DD/MM/YY
Comments from the leader: DD/MM/YY	
Remarks	

Appendix 1-2

Form of Deviations Discovered in On-site Inspection of Pesticide Registration Testing Institutes

Task number:

Name of applicant	
Tests applied for	
Application type	□ First application □ Application upon maturity □ Organization division or merger □ Change in address or significant change in facilities □ Expand the scope □ Other matters
Descriptions about deviations and the corresponding clause number in the *Code for Pesticide Registration Testing Quality Management* (Additional page may be used if necessary)	
Signed by a member of the evaluation team: DD/MM/YY	
Signed by the leader of the evaluation team: DD/MM/YY	
Signed by the person in charge of the testing institute: (Official seal) DD/MM/YY	

Appendix 1-3

Comprehensive Comments after On-site Inspection of Pesticide Registration Testing Institutes

Task number:

Name of applicant	
Tests applied for	
Application type	□ First application □ Application upon maturity □ Organization division or merger □ Change in address or significant change in facilities □ Expand the scope □ Other matters
Comprehensive comments: (Additional page may be used if necessary)	
Signed by the evaluation team leader and member: DD/MM/YY	

Appendix 1-4

Comments on Rectification of Pesticide Registration Testing Institutes

Task number:

<table>
<tr><td>Name of applicant</td><td colspan="3"></td></tr>
<tr><td>Tests applied for</td><td colspan="3"></td></tr>
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□ Application upon maturity
□ Organization division or merger
□ Change in address or significant change in facilities
□ Expand the scope
□ Other matters</td></tr>
<tr><td>On-site inspection date</td><td></td><td>Rectification material submission date</td><td></td></tr>
<tr><td colspan="2">Deviations</td><td colspan="2">Rectification results</td></tr>
<tr><td colspan="2"></td><td colspan="2"></td></tr>
<tr><td colspan="2">Comments of the rectification verifier

(signature)

DD/MM/YY</td><td colspan="2">Comments of the evaluation team leader

(signature)

DD/MM/YY</td></tr>
<tr><td>Remarks</td><td colspan="3"></td></tr>
</table>

Appendix 1-5

Comments after Technical Evaluation of Pesticide Registration Testing Institutes

<table>
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<tr><td colspan="2">Tests applied for</td><td></td></tr>
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□ Application upon maturity
□ Organization division or merger
□ Change in address or significant change in facilities
□ Expand the scope
□ Other matters</td></tr>
<tr><td rowspan="3">Comments after technical evaluation</td><td colspan="2">Paper examination:</td></tr>
<tr><td colspan="2">On-site inspection:</td></tr>
<tr><td colspan="2">Comprehensive evaluation:</td></tr>
<tr><td colspan="2">Handled by:
DD/MM/YY</td><td>Approved by:
DD/MM/YY</td></tr>
<tr><td>Remarks</td><td colspan="2"></td></tr>
</table>

Appendix 1.

Pesticide Production Permit Evaluation Form

(Applicable to technical materials or concentrates)

1. Basic information about the producer

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
1 .1	Name of the producer	The name of the producer in the application shall be consistent with that in the business license;	Check the consistency between the application and the business license.	Qualified Unqualified	
1 .2	Legal representative	The legal representative (responsible person) in the application shall be consistent with that in the business license;	Check the consistency between the application and the business license.	Qualified Unqualified	
1 .3	Address of the producer	The address of the producer in the application shall be consistent with that in the business license;	Check the consistency between the application and the business license.	Qualified Unqualified	
1 .4	Production address*	Check whether the actual production address is consistent with that registered with the administration for industry and commerce (the actual production address shall be consistent with that in the business license; If not, it shall be consistent with that in the application)	Check the application and the business license.	Qualified Unqualified	

2. Requirements on Personnel

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
2. .1	Key managers of the producer shall have certain knowledge about pesticide management.	Key managers shall be familiar with the *Regulations on Management of Pesticides*, the *Measures on Management of Pesticide Production Permits* and other relevant laws, regulations and industrial policies.	Communicate with key managers to learn how much they know about relevant pesticide production policies.	Qualified Suggested for improvement Unqualified	
2. .2	Producers shall have suitable technical personnel*.	(1) Producers of a.i pesticides shall have at least five technicians with a bachelor's degree or above or an intermediate professional title or above in chemistry, chemical engineering, pharmacology or a relevant field and more than 2 years of work experience. (2) Producers of biological or non-chemical and non-a.i shall have at least two technicians with a bachelor's degree or above or an intermediate professional title or above in microbiology, plant protection, pharmacology, biochemistry or a relevant field and more than 2 years of work experience.	Check the personal files, academic certificates and employment contracts (where necessary, the receipts for social insurance payment) of relevant personnel against the application materials.	Qualified Unqualified	
2. .3	Producers shall have suitable operators.	(1) Operators engaged in pesticide production shall be provided with pre-job training and acquire the qualification needed for taking the post. (2) Operators involved in high-risk processes shall acquire relevant certificates before taking the post.	Check the files and training records of relevant personnel.	Qualified Suggested for improvement Unqualified	
2. .4	Producers shall have suitable quality inspectors*.	Pesticide producers shall have at least two quality inspectors with an associate's degree or having accepted and passed the professional training.	Check the personal files, academic certificates and employment contracts	Qualified Unqualified	

			(where necessary, the receipts for social insurance payment) and training records of relevant personnel against the application materials.		
2. .5	Personnel on the employment prohibition list*.	Producers shall not employ any person described in paragraph 1, Article 63 of the *Regulations on Management of Pesticides*.	Check against the credit files and administrative penalty records to verify whether producers have employed any such person.	Qualified Unqualified	

3. Requirements on Production Conditions (workshops, facilities and equipment)

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
3 .1	Requirements on the production address*	(1) New chemical pesticide producers or non-chemical pesticide producers wishing to expand the scope of production to include chemical pesticides or chemical pesticide producers wishing to add a production address shall have their workshops built within a chemical industrial park above the provincial level; (2) New non-chemical pesticide producers or household insecticide producers, or chemical pesticide products wishing to expand the	Check the approvals from the park where the producers are located or relevant proof.	Qualified Unqualified N/A	

		scope of production to include technical materials (concentrates) or non-chemical pesticide producers wishing to add a production address shall enter a chemical industrial park (industrial park) above the city level; (3) Chemical pesticide producers wishing to change the production address shall enter a chemical industrial park (industrial park) above the city level.			
3 .2	Requirements on the production site*	Applicants shall have obtained the land use right certificate or lease contract for the production site. The lease contract shall be valid for at least 5 years from the application date.	Check the land use certificate (including that of the leaser) and the lease contract.	Qualified Unqualified	
3 .3	Requirements on infrastructure and overall layout	(1) Producers shall have the general production layout plan;	Inspect the site, or check the application materials, the general plan and the production layout management regulations or descriptions	Qualified Suggested for improvement Unqualified	
		(2) The construction of workshops and auxiliary facilities shall be in line with the general layout plan;	Inspect the site, or check the application materials, the general plan and the production layout management regulations or descriptions	Qualified Suggested for improvement Unqualified	
		(3) Workshops producing herbicides, plant growth regulators and raticides shall be properly separated from workshops producing other pesticides to avoid cross-contamination. *	Inspect the site, or check the application materials, the general plan and the	Qualified Unqualified N/A	

			production layout management regulations or descriptions		
		(4) Raw materials, finished products and packaging materials shall be stored separately.	Inspect the site, or check the application materials	Qualified Suggested for improvement Unqualified	
		(5) Producers that produce other chemical products at the same time shall produce pesticides with separate equipment, and warehouses for finished products shall be set in isolated areas and clearly marked.	Inspect the site, or check the application materials	Qualified Unqualified N/A	
3 .4	Requirements on production units and equipment	(1) Applicants shall provide the production unit process flow diagram, process descriptions, and the layout plan of production units;	Check the process flow diagram and the layout plan, inspect the site or check the application materials	Qualified Suggested for improvement Unqualified	
		(2) The main production equipment and facilities shall meet the requirements for production of pesticides applied for;	Inspect the site, or check the application materials	Qualified Suggested for improvement Unqualified	
		(3) Producers shall have suitable workshops, equipment, facilities, and auxiliary facilities ensuring normal operations that may be automatically operated (excluding some links or products that are not appropriate for automatic production for the time being);	Inspect the site, or check the application materials	Qualified Suggested for improvement	

				Unqualified	
		(4) Microbial pesticide producers shall have seeding tanks, fermentation tanks, suitable preparation, package and storage facilities, and sterilization and disinfection equipment, and keep them properly separated from other pesticide workshops.	Inspect the site, or check the application materials	Qualified Unqualified N/A	
		(5) Botanical pesticide producers shall have crushers, extraction equipment, separation equipment, decompression & concentration equipment, solvent recovery equipment and the like.	Inspect the site, or check the application materials	Qualified Unqualified N/A	
		(6) Producers shall have facilities for tracing pesticide products that meet the management requirements.	Inspect the site, or check the application materials	Qualified Suggested for improvement Unqualified	

4. Requirements on Product Quality Standards and Quality Assurance Systems

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
4 .1	Quality Inspection and Quality Control Management	Producers shall establish and strictly comply with relevant quality inspection and control management systems, and maintain the management records.	Check the management systems and records	Qualified Suggested for improvement Unqualified	

4 .2	The quality inspection unit shall be arranged in accordance with relevant norms	(1) The quality inspection unit shall be independently arranged; (2) The instrumental analysis room, the chemical analysis room, the balance room, the sample room and the heating room shall be separately located.	Inspect the site, check the application materials, the layout plan and documents concerning independent quality inspections conducted.	Qualified Suggested for improvement Unqualified	
4 .3	Testing instruments*	Producers shall have testing instruments and means specified in the quality standards for production of the a.i (tc) applied for. Such instruments shall be highly functional and precise to support the production of qualified products, and be tested, calibrated and verified in accordance with regulations.	Inspect the site or check the application materials or the testing, calibration, verification and usage records; Check whether such instruments can meet the product quality standards;	Qualified Unqualified	
4 .4	Quality inspection of raw materials and products	(1) Producers shall establish relevant incoming inspection, in-process inspection and outgoing inspection procedures; (2) Producers shall test or inspect the raw materials, intermediates, semi-finished and finished products based on relevant control indexes and maintain the testing or inspection records to ensure product quality.	Check the systems and records	Qualified Suggested for improvement Unqualified	
4 .5	Product quality standards*	(1) Producers shall establish product quality standards or adopt national or industrial standards in accordance with product quality and safety management requirements; (2) Producers shall conduct quality inspection in accordance with product quality standards.	Check the effectiveness of standards and relevant inspection records	Qualified Unqualified	

5. Requirements on Management Systems

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
5 .1	Management systems of producers	Producers shall establish management systems and corresponding operation procedures (operation guide) for raw material procurement, process units, quality control, product sale, product accident reporting and recalling, product storage and transportation, safe production, occupational health, environment protection, traceability, pesticide waste recycling and disposal, personnel training, documents and records, among others.	Check whether the management systems are complete.	Qualified Suggested for improvement Unqualified	
5 .2	Raw material procurement and control	(1) Pesticide producers shall establish an incoming inspection system to examine production quality inspection certificates and other relevant proof, and shall not purchase or use raw materials that do not have a product quality inspection certificate or relevant proof required by law. (2) Pesticide producers shall establish a raw material purchasing and entry recording system, to truthfully record the name, relevant permit document numbers, quality certificates, specifications, quantity, supplier name and contact details, and entry date. Raw material purchasing and entry records shall be kept for no less than two years.	Check the management systems and relevant proof concerning raw materials, and check whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .3	Production process and management	(1) Producers shall have a list of process documents in relation to the scope of products, and the list shall be consistent with the actual process documents; (2) Producers shall have a process flow diagram;	Check the procedures, inspect the site, and check whether such management systems are complied with	Qualified Suggested for improvement	

		(3) Producers shall have sound and practical process management systems and assessment measures; (4) Producers shall set operation procedures for each process; (5) Producers shall set control indexes for main processes and establish control and assessment measures; (6) Producers shall establish a product labeling and packing management system; (7) Producers shall operate in strict compliance with the process parameters and operation procedures, and keep relevant production records.	based on original records of pilot production of three batches of pesticides applied for.	Unqualified	
5 .4	Facilities and equipment management	(1) Producers shall create files for main facilities and equipment and establish corresponding operation and maintenance systems; (2) Producers shall establish operation procedures for relevant facilities and equipment in light of actual production conditions. (3) Producers shall create operation records in light of actual production conditions.	Check equipment files and records, and serviceability rate records , and check whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .5	Quality control	Producers shall establish pesticide product quality management systems: (1) Producers shall regulate that produced pesticides to be sold must pass the quality inspections and attach the product quality inspection certificates; (2) Producers shall set explicit rules for controlling and disposing substandard products;	Check the systems and disposal records	Qualified Suggested for improvement Unqualified	

		(3) Producers shall establish disposal systems for products involved in quality disputes.			
5 .6	Product sale management	(1) Producers shall have in place production account management systems to truthfully record production; (2) Producers shall have in place pesticide product entry and storage management systems to truthfully record product entry and storage; (3) Producers shall have in place factory sales recording systems to truthfully record the name, specifications, quantity, production date and batch number of pesticides, as well as product quality inspection information, name and contact details of purchasers and sales dates.	Check relevant systems and whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .7	Traceability management	Producers shall have in place a product tracing system.	Check relevant systems and whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .8	Product storage and transportation	Producers shall have in place and comply with pesticide storage and transportation management measures.	Check relevant systems and operation records	Qualified Suggested for improvement Unqualified	
5 .9	Safe production and occupational health	Producers shall have in place and comply with safe production and occupational health systems concerning pesticide production.	Inspect the site, or check systems or the application materials	Qualified Suggested for	

				improvement Unqualified	
5 .10	Environmental protection	(1) Producers shall have in place and comply with environmental protection systems concerning pesticide production. (2) Producers shall have in place and comply with waste recycling and disposal systems.	Check relevant systems and operation records	Qualified Suggested for improvement Unqualified	
5 .11	Product accident report and recall	Producers shall have in place product accident report and recall systems.	Check the accident report and recall systems.	Qualified Suggested for improvement Unqualified	
5 .12	Waste recycling and disposal	Producers shall have in place and comply with pesticide waste recycling and disposal systems.	Check the systems	Qualified Suggested for improvement Unqualified	
5 .13	Personnel training and management	(1) Producers shall have in place personnel training systems and assessment measures; (2) Producers shall provide training on operation skills, safety, environmental protection and occupational heath to relevant personnel, and provide training to and conduct assessment on site operators on a periodical basis. (3) Producers shall keep the training and assessment records.	Check the systems and records	Qualified Suggested for improvement Unqualified	
5 .14	Documentation and recording management	Producers shall have in place and comply with corresponding documentation and recording management systems.	Check the systems and records	Qualified Suggested	

				for improvement Unqualified	

6. Other requirements

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
6. .1	Registration of technical concentrates*	In case of application for production of a technical concentrate, the concentrate shall have been registered with the competent authority of China.	Check the technical concentrate registration	Qualified Unqualified N/A	
6. .2	Registration of new a.i pesticides*	In case of application for production of a new a.i pesticide, the new a.i shall have been registered with the competent authority of China.	Check the registration of the new pesticide	Qualified Unqualified N/A	
6. .3	The scope of production shall be expressed as the name of the pesticide, plus the dosage form*	In case of applying for direct production of preparations due to difficulties in producing technical materials (concentrates) caused by technology, safety or other reasons, a statement of reasons from the applicants as well as the registration of the pesticide shall be checked.	Check the registration of the pesticide	Qualified Unqualified N/A	

Note: Items marked with * means the key items to be checked

Appendix 2

Pesticide Production Permit Evaluation Form

(Applicable to formulations)

1. Basic information about the producer

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
1 .1	Name of the producer	The name of the producer in the application shall be consistent with that in the business license;	Check the consistency between the application and the business license.	Qualified Unqualified	
1 .2	Legal representative	The legal representative (responsible person) in the application shall be consistent with that in the business license;	Check the consistency between the application and the business license.	Qualified Unqualified	
1 .3	Address of the producer	The address of the producer in the application shall be consistent with that in the business license;	Check the consistency between the application and the business license.	Qualified Unqualified	
1 .4	Production address*	Check whether the actual production address is consistent with that registered with the administration for industry and commerce (the actual production address shall be consistent with that in the business license; If not, it shall be consistent with that in the application)	Check the application and the business license.	Qualified Unqualified	

2. Requirements on Personnel

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
2. .1	Key managers of the producer shall have certain knowledge about pesticide management.	Key managers shall be familiar with the *Regulations on Management of Pesticides*, the *Measures on Management of Pesticide Production Permits* and other relevant laws, regulations and industrial policies.	Communicate with key managers to learn how much they know about relevant pesticide production policies.	Qualified Suggested for improvement Unqualified	
2. .2	Producers shall have suitable technical personnel*.	(1) Producers of chemical pesticide formulations shall have at least two technicians with a bachelor's degree or above or an intermediate professional title or above in chemistry, chemical engineering, plant protection or biology or a relevant field and more than 2 years of work experience; (2) Producers of non-chemical pesticide technical materials shall have at least two technicians with a bachelor's degree or above or an intermediate professional title or above in biology, plant protection, pharmacology, biochemistry or a relevant field and more than 2 years of work experience.	Check the personal files, academic certificates and employment contracts (where necessary, the receipts for social insurance payment) of relevant personnel against the application materials.	Qualified Unqualified	
2. .3	Producers shall have suitable operators.	Operators engaged in pesticide production shall be familiar with relevant operation procedures and have accepted and passed the pre-job training.	Check the files and training records of relevant personnel.	Qualified Suggested for improvement Unqualified	
2. .4	Producers shall have suitable quality	Pesticide producers shall have at least two quality inspectors with an associate's degree in relevant fields or having accepted and	Check the personal files, academic certificates and	Qualified Unqualified	

	inspectors*.	passed the professional training, and be familiar with relevant standards, testing methods and in possession of relevant analysis and inspection skills.	employment contracts (where necessary, the receipts for social insurance payment) and training records of relevant personnel against the application materials.		
2. .5	Personnel on the employment prohibition list*.	Producers shall not employ any person described in paragraph 1, Article 63 of the *Regulations on Management of Pesticides*.	Check against the credit files and administrative penalty records to identify whether producers have employed any such person.	Qualified Unqualified	

3. Requirements on Production Conditions (workshops, facilities and equipment)

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
3 .1	Requirements on the production address*	The selection of production address shall be in compliance with relevant provisions of the *Measures on Management of Pesticide Production Permits*. (1) New chemical pesticide producers or non-chemical pesticide producers wishing to expand the scope of production to include chemical pesticides or chemical pesticide producers wishing to add	Check the approvals from the park where the producers are located or relevant proof.	Qualified Unqualified N/A	

		a production address shall have their workshops built within a chemical industrial park above the provincial level; (2) New non-chemical pesticide producers or household insecticide producers, or chemical pesticide products wishing to add a production address shall enter a chemical industrial park (industrial park) above the city level; (3) Chemical pesticide producers wishing to change the production address shall enter a chemical industrial park (industrial park) above the city level.			
3 .2	Requirements on the production site*	Applicants shall have obtained the land use right certificate or lease contract for the production site. The lease contract shall be valid for at least 5 years from the application date.	Check the land use certificate (including that of the leaser) and the lease contract.	Qualified Unqualified	
3 .3	Requirements on infrastructure and overall layout	(1) Producers shall have in place the general production layout plan; (2) The construction of workshops and auxiliary facilities shall be in line with the general layout plan;	Inspect the site, or check the application materials for consistency with the production layout and the general layout.	Qualified Unqualified	
		(3) Units producing herbicides, raticides, or plant growth regulators shall be arranged in separate areas, with appropriate measures in place, to avoid cross-contamination.	Inspect the site, or check the application materials	Qualified Unqualified N/A	
		(4) Producers that produce other chemical products at the same time shall produce pesticides with separate equipment, and warehouses for finished products shall be set in isolated areas and clearly marked.	Inspect the site, or check the application materials	Qualified Unqualified N/A	
3 .4	Requirements on	(1) Producers shall have suitable plants, and complete equipment	Inspect the site, or check the	Qualified	

	production units and equipment	and facilities meeting the process requirements as well as supporting auxiliary facilities.	application materials, or the production unit process flow diagram, process descriptions, and the layout plan of production units.	Suggested for improvement Unqualified	
		(2) Herbicides and plant growth regulators shall be produced with separate production equipment, and shall not share the same equipment with other pesticides.	Inspect the site, or check the application materials	Qualified Unqualified N/A	
		(3) Preparations shall be packaged automatically, and shall not be packaged with manual packaging (canning) equipment, excluding special products.	Inspect the site, or check the application materials	Qualified Suggested for improvement Unqualified	
3 .5	Traceability management	Producers shall have facilities for tracing pesticide products that meet the management requirements.	Inspect the site, or check the application materials	Qualified Suggested for improvement Unqualified	

4. Requirements on Product Quality Standards and Quality Assurance Systems

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
4 .1	Quality Inspection and Quality Control Management	Producers shall establish and strictly comply with relevant quality inspection and control management systems, and maintain the management records.	Check the management systems and records	Qualified Suggested for improvement Unqualified	
4 .2	The quality inspection unit shall be arranged in accordance with relevant norms	(1) The quality inspection unit shall be independently arranged; (2) The instrumental analysis room, the chemical analysis room, the balance room, the sample room and the heating room shall be separately located.	Inspect the site, check the application materials, the layout plan and documents concerning independent quality inspections conducted.	Qualified Unqualified	
4 .3	Testing instruments*	Producers shall have testing instruments and means specified in the quality standards for production of preparations applied for; Such instruments shall be highly functional and precise to support the production of qualified products, and be tested, calibrated and verified in accordance with regulations.	Inspect the site or check the application materials or the testing, calibration, verification and usage records; Check whether such instruments can meet the product quality standards;	Qualified Unqualified	
4 .4	Quality inspection of raw materials and products	(1) Producers shall establish relevant incoming inspection, in-process inspection and outgoing inspection procedures; (2) Producers shall test or inspect raw materials, intermediates/semi-finished and finished products based on relevant	Check the systems and records	Qualified Suggested for improvement	

		control indexes and maintain the testing or inspection records to ensure product quality.		Unqualified	
4 .5	Product quality standards*	(1) Producers shall establish product quality standards or adopt national or industrial standards in accordance with product quality and safety management requirements; (2) Producers shall conduct quality inspection in accordance with product quality standards.	Check the effectiveness of standards and relevant inspection records	Qualified Unqualified	

5. Requirements on Management Systems

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
5 .1	Management systems of producers	Producers shall establish management systems and corresponding operation procedures (operation guide) for raw material procurement, process units, quality control, product sale, product accident reporting and recalling, product storage and transportation, safe production, occupational health, environment protection, traceability, pesticide waste recycling and disposal, personnel training, documents and records, among others.	Check whether the management systems are complete.	Qualified Suggested for improvement Unqualified	
5 .2	Raw material procurement and control	(1) Pesticide producers shall establish an incoming inspection system to examine production quality inspection certificates and other relevant proof, and shall not purchase or use raw materials that do not have a product quality inspection certificate or relevant proof required by law. (2) Pesticide producers shall establish a raw material purchasing and entry recording system, to truthfully record the name, relevant permit document numbers, quality certificates, specifications, quantity, supplier name and contact details, and entry date. Raw material purchasing and entry records shall be kept for no less than two years.	Check the management systems and relevant proof concerning raw materials, and check whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .3	Production process and management	(1) Producers shall have a list of process documents in relation to the scope of products, and the list shall be consistent with the actual process documents; (2) Producers shall have a process flow diagram;	Check the procedures, inspect the site, and check whether such management systems are complied with	Qualified Suggested for improvement	

		(3) Producers shall have sound and practical process management systems and assessment measures; (4) Producers shall set operation procedures for each process; (5) Producers shall set control indexes for main processes and establish control and assessment measures; (6) Producers shall establish a product labeling and packing management system; (7) Producers shall operate in strict compliance with the process parameters and operation procedures, and keep relevant production records.	based on original records of pilot production of three batches of pesticides applied for.	Unqualified	
5 .4	Facilities and equipment management	(1) Producers shall create files for main facilities and equipment and establish corresponding operation and maintenance systems; (2) Producers shall establish operation procedures for relevant facilities and equipment in light of actual production conditions. (3) Producers shall create operation records in light of actual production conditions.	Check equipment files and records, and serviceability rate records, and check whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .5	Quality control	Producers shall establish pesticide product quality management systems: (1) Producers shall regulate that produced pesticides to be sold must pass the quality inspections and attach the product quality inspection certificates; (2) Producers shall set explicit rules for controlling and disposing substandard products;	Check the systems and disposal records	Qualified Suggested for improvement Unqualified	

		(3) Producers shall establish disposal systems for products involved in quality disputes.			
5 .6	Product sale management	(1) Producers shall have in place production account management systems to truthfully record production; (2) Producers shall have in place pesticide product entry and storage management systems to truthfully record product entry and storage; (3) Producers shall have in place factory sales recording systems to truthfully record the name, specifications, quantity, production date and batch number of pesticides, as well as product quality inspection information, name and contact details of purchasers and sales dates.	Check relevant systems and whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .7	Traceability management	Producers shall have in place a product tracing system.	Check relevant systems and whether such management systems are complied with based on original records of pilot production of three batches of pesticides applied for.	Qualified Suggested for improvement Unqualified	
5 .8	Product storage and transportation	Producers shall have in place and comply with pesticide storage and transportation management measures.	Check relevant systems and operation records	Qualified Suggested for improvement Unqualified	
5 .9	Safe production and occupational health	Producers shall have in place and comply with safe production and occupational health systems concerning pesticide production.	Inspect the site, or check systems or the application materials	Qualified Suggested for	

				improvement Unqualified	
5 .10	Environmental protection	(1) Producers shall have in place and comply with environmental protection systems concerning pesticide production. (2) Producers shall have in place and comply with waste recycling and disposal systems.	Check relevant systems and operation records	Qualified Suggested for improvement Unqualified	
5 .11	Product accident report and recall	Producers shall have in place product accident report and recall systems.	Check the accident report and recall systems.	Qualified Suggested for improvement Unqualified	
5 .12	Waste recycling and disposal	Producers shall have in place and comply with pesticide waste recycling and disposal systems.	Check the systems	Qualified Suggested for improvement Unqualified	
5 .13	Personnel training and management	(1) Producers shall have in place personnel training systems and assessment measures; (2) Producers shall provide training on operation skills, safety, environmental protection and occupational heath to relevant personnel, and provide training to and conduct assessment on site operators on a periodical basis. (3) Producers shall keep the training and assessment records.	Check the systems and records	Qualified Suggested for improvement Unqualified	
5 .14	Documentation and recording management	Producers shall have in place and comply with corresponding documentation and recording management systems.	Check the systems and records	Qualified Suggested	

				for improvement Unqualified	

6. Other requirements

No.	Contents of Evaluation	Key Points for Evaluation	Evaluation Method	Evaluation Result	Evaluation Record
6. .1	Whether the selected product is a a.i new pesticide*	In case of application for production of a new a.i pesticide, the pesticide shall have been registered with the competent authority of China.	Check registration of the technical concentrate	Qualified Unqualified N/A	

Note: Items marked with * means the key items to be checked

Appendix 2

Code for Pesticide Registration Testing Quality Management

Chapter I. General Provisions

Article 1. This Code is prepared in accordance with the *Regulations on Management of Pesticides* and the *Measures on Management of Pesticide Registration Testing,* for the purpose of strengthening the management of pesticide registration tests and regulating the pesticide registration testing practices, so as to ensure the integrity, reliability and authenticity of the pesticide registration test data, and ensure the pesticide registration and evaluation are conducted in a scientific and effective manner.

Article 2. This Code applies to tests conducted based on data provided for application of pesticide registration, including but without limitation, the product chemical, efficacy, toxicology, residue and environmental impact tests.

Article 3. The pesticide registration testing institutes shall comply with this Code when conducting relevant tests.

Chapter II. Organization and Personnel

Article 4. The pesticide registration testing institutes (hereinafter referred to as the “testing institutes") shall establish sound organizational management systems, and be staffed with persons in charge of the testing institutes, test program leaders (technical supervisors), and sufficient numbers of quality assurance personnel, test personnel, file clerks and sample keepers, etc.

Article 5. The person in charge of a testing institute shall be the legal representative of the testing institute or a person authorized by the legal person. He is expected to assume the following duties:

(1) be fully responsible for the construction and organizational management of the testing institute, and ensure its compliance with this Code;

(2) provide facilities, equipment, materials and personnel required for timely implementation of relevant tests;

(3) establish a filing system that is managed by a specially designated person to keep records of qualifications of all workers and of their training, experience and job responsibilities;

(4) specify duties of all workers and strengthen business training;

(5) organize preparation and revision of standard operating procedures, and keep all versions and their revision records, and ensure that the latest version is implemented;

(6) establish a quality assurance department staffed with competent quality assurance personnel, and ensure that they perform their duties in an appropriate manner;

(7) develop and timely update the master test schedule, learn about the progress of each test program, appoint one leader before the start of each test program or sub-leaders in case of tests involving multiple sites;

(8) ensure smooth communication among the test program leader, the sub-leaders, the quality assurance personnel and the test personnel;

(9) supervise the test program leader, approve test plans in writing and provide them to the quality assurance personnel;

(10) establish computer systems, and conduct system verification, operation and maintenance in accordance with this Code;

(11) provide sound safety measures;

(12) sign an entrustment agreement or contract with the entrusting party, nail down the test plan and the deadline etc., and timely upload the agreement or contract, the number of the sealed samples and the product name, the test program name, the program leader, expected start and end dates, the test location and other information onto the pesticide management information platform designated by the Ministry of Agriculture.

Article 6. The test program leader shall be responsible for the whole testing process and the final test report, and is expected to assume the following duties:

(1) examine and approve a test plan and ensure it meets the technical requirements of the entrusting party; and verify the test conditions, to ensure that they meet the test requirements;

(2) timely submit a copy of the test plan to the quality assurance personnel and maintain effective communication with such personnel during the test;

(3) ensure that the test personnel have access to the test plan at any time, and carry out the test in accordance with corresponding standard operating procedures or test guidelines and ensure the safety precautions are in place;

(4) keep abreast of deviations from the test, examine and approve any action that may affect the quality and integrity of the test, assess the impact of any deviation, and take appropriate corrective action if necessary;

(5) ensure that the equipment and computer systems in use are calibrated or verified, and the raw data records are true and reliable;

(6) approve the final test report and ensure that the test report completely, truly and accurately reflect the test process and results;

(7) ensure that the test plan, the final test report, the raw data and related materials are filed immediately following the completion of the test (including the termination of the test);

(8) ensure the test plan and the final test report involving multiple sites clearly describe each test site and the role of each sub-leader;

(9) complete the test independently, and under special circumstances necessitating subcontracting, choose a qualified testing institute recognized by the Ministry of Agriculture and sign an agreement or contract with it;

(10) ensure the revised test plan, if any, meets requirements in paragraphs (1), (2) and (3).

Article 7. The sub-leaders of a test program are mainly expected to assume the following duties:

(1) be responsible for any part of the test program entrusted by the test program leader and conduct the test in accordance with the test plan and requirements of this

Code;

(2) timely record and report to the test program leader any deviation from the test plan or the standard operating procedures occurred during the course of the test;

(3) submit a part of the final test report to the test program leader; and

(4) timely submit to the test program leader or put on file materials and samples in relation to the part of the test they conducted; If these materials and samples are filed, inform the test program leader of where and when such materials and samples are filed; No material and sample shall be disposed of in any way without the written consent of the test program leader.

Article 8. The quality assurance personnel are mainly expected to assume the following duties:

(1) stay on top of the test progress, have at hand all approved or revised test plans, copies of the then-current standard operating procedures and the latest master test schedule;

(2) review standard operating procedures and determine whether requirements of this Code are met;

(3) check a test plan to verify whether it contains the contents required by this Code, and record the findings in writing;

(4) check whether all tests are implemented in accordance with this Code, and whether the test personnel have easy access to, or are familiar with or comply with the test plan and relevant standard operating procedures or test guidelines;

(5) review the final test report to confirm whether the test method, test procedures and test phenomena are recorded in a comprehensive and confirmable manner, and whether the test results correctively and fully reflect the raw data;

(6) report the checking results in writing to the person in charge of the testing institute, the test program leader, sub-leaders and relevant managers;

(7) sign a quality assurance statement in the final test report and describe the inspection conducted and notification of results;

(8) monitor the compliance of computer systems with this Code and access data via computer systems.

Article 9. The testing personnel are mainly expected to fulfill the following duties:

(1) know about the quality management requirements related to the tests they conduct;

(2) be familiar with the test plan and relevant standard operating procedures or test guidelines and conduct tests in accordance with requirements;

(3) timely and accurately record raw data, and be responsible for the authenticity of such data;

(4) record any deviation found in the test in writing and report it directly to the test program leader or sub-leader concerned;

(5) comply with regulations concerning safety precautions to reduce possible physical harm caused by tests and timely report their health condition to relevant personnel.

Article 10. File clerks are mainly expected to assume the following duties:

(1) manage files in accordance with standard file management and operating procedures to prevent possible damage, deterioration and loss of data;

(2) accept, classify and file documents, materials, samples, raw data and final reports in an orderly manner to facilitate retrieval;

(3) truthfully record the borrowing and return of documents, materials, samples and raw data.

Article 11. Sample keepers are mainly expected to assume the following duties:

(1) manage samples in accordance with standard operating procedures and control the conditions of sample storage facilities;

(2) accurately record the sample receipt information, clearly mark samples, and store samples in accordance with their respective storage requirements;

(3) be responsible for the circulation and keeping of samples during the test period;

(4) timely file and process samples.

Chapter III. Quality Assurance

Article 12. Testing institutes shall have in place a written quality assurance plan to ensure tests are conducted in accordance with this Code.

Article 13. The person in charge of the testing institutes shall appoint a person familiar with the test procedures as the quality assurance specialist to take charge of quality assurance. The quality assurance specialist is directly responsible to the person in charge of the testing institutes.

Article 14. The quality assurance specialist shall not participate in any test for which he is responsible for quality assurance.

Article 15. With respect to tests involving multiple sites, the quality assurance specialist shall ensure the whole test process in each site complies with this Code.

Chapter IV. Test Facilities

Article 16. Requirements on test sites:

(1) The test sites shall be large enough and reasonably arranged, with mutually effecting zones effectively isolated to avoid disturbance;

(2) Electrical piping, lighting systems and other facilities shall be designed in a manner that is conducive to the implementation of tests and in line with safety requirements;

(3) Environmental conditions shall meet the test requirements, and environmental factors that would affect the test results shall be properly monitored, controlled and recorded;

(4) Fire, safety protection, waste collection and disposal facilities shall be available to ensure the site safety and personnel health;

(5) Important test sites shall be under the administration of a specially designated person.

Article 17. Requirements on test substances, reference substances, samples, chemical reagents and storage facilities:

(1) Test substances, reference substances, samples shall be kept in independent

rooms or areas to ensure that their property, concentration, purity and stability do not change;

(2) Chemical reagents and dangerous substances shall be stored safely in accordance with relevant requirements of the state.

Article 18. Requirements on file facilities:

(1) File facilities shall provide sufficient space to store files (including test plans, raw data, final test reports and samples);

(2) Facilities and environmental conditions shall meet the requirements for long-term safe preservation of data;

(3) A file management system shall be established to facilitate file classification, retrieval and access.

Article 19. Requirements on waste disposal facilities:

(1) Dedicated waste classification, collection and storage facilities shall be available;

(2) Waste disposal shall not in any way affect the integrity of any test;

(3) Relevant waste collection, storage, disposal and transportation regulations shall be complied with.

Chapter V. Instruments, Materials and Reagents

Article 20. Instruments and equipment required for tests and meeting environmental requirements shall be provided. There shall be sufficient space to place instruments and equipment (including computer systems and environmental control equipment).

Article 21. The instruments and materials used for testing shall not interfere with any test system.

Article 22. The installation, operation and performance verification of instruments and equipment shall be carried out in accordance with the standard operating procedures, and their inspection, cleaning, maintenance, verification/calibration shall be conducted on a regular basis and properly recorded for future reference. The verification/calibration shall be conducted based on national standards as far as possible.

Article 23. The test substances, reference substances, reagents and solutions shall be marked with such information as the validity period, storage requirements, source, preparation time and stability.

Chapter VI. Test Systems

Article 24. Requirements on physical/chemical test systems:

(1) The instruments used for testing physical/chemical properties shall be properly placed to meet the test requirements;

(2) The integrity of physical/chemical test systems shall be maintained.

Article 25. Requirements on biological test systems:

(1) The environmental conditions shall meet the requirements for preservation, treatment and breeding of biological test systems to ensure the test systems and test data are not affected;

(2) The newly received biological test systems shall be timely quarantined and evaluated for health condition. Organisms died unnaturally or with any disease shall not be used for testing, and shall, where necessary, be treated in a humanitarian manner.

(3) Biological test systems shall be given a period to adapt to the environment before first administration;

(4) The test systems shall be in good condition before being tested. During the test, interactions between different test systems and between groups given different dosages shall be avoided. All ill and injured test systems shall be quarantined and treated in time; all abnormal injuries, illnesses and treatment before and during the test shall be recorded, and all organisms shall be properly handled at the end of the test.

(5) The source, variety, quantity, status and date of receipt of the biological test systems and their feed, litter and culture materials shall be properly recorded and maintained;

(6) The feeding cages or containers of biological test systems shall be clearly marked with the test information, and individual biological test systems in each cage or container shall also be properly marked;

(7) The containers for breeding and treating test systems shall be cleaned and disinfected on a regular basis. Any material in contact with any test system shall not contain any contaminant (if unavoidable, the contaminant concentration shall not be up to the level that may interfere with the test);

(8) The animal litter and culture materials shall be replaced regularly in accordance with regular breeding management practices, and the insecticidal sterilization shall be properly recorded.

Chapter VII. Test Substances, Reference Substances and Samples

Article 26. Requirements on receipt, collection, storage and treatment:

(1) Records of properties of the test substances, reference substances and samples, as well as their receipt time, validity period, quantity received and quantity used in tests shall be available;

(2) Procedures shall be established for receipt, collection and storage of test substances, reference substances and samples to ensure uniformity and stability, and prevent contamination or confusion;

(3) The storage containers shall be marked with the identification information, the validity period and special storage requirements;

(4) Procedures shall be established for processing test substances and samples, and relevant processing records shall be available.

Article 27. Requirements on characterization:

(1) The test substances, reference substances and samples shall be clearly marked;

(2) The properties of each batch of test substances and reference substances used for each test shall be clearly known to relevant personnel, including batch number, purity, composition, concentration or other characteristics;

(3) The testing institutes shall timely confirm the properties of the test substances with the entrusting party;

(4) The stability of the test substances and reference substances under storage and test conditions shall be found out;

(5) If any solvent is needed at the time of administration or application of any test substance, the concentration, uniformity and stability of such substance in the solvent shall be determined;

(6) Samples of each batch of test substances used for tests (except short-term tests) shall be kept for future reference.

Chapter VIII. Standard Operating Procedures

Article 28. The testing institutes shall prepare standard operating procedures in writing. The preparation and revision of standard operating procedures shall be subject to approval of the person in charge of the testing institutes. The preparation, revision, distribution, recovery and destruction of standard operating procedures shall be properly documented and filed.

Article 29. The departments to which the testing institutes belong shall timely obtain the latest version of the standard operating procedures. Relevant personnel shall timely get acquainted with the newly prepared or revised standard operating procedures.

Article 30. Publicly published standards, textbooks, analytical methods, papers and manuals may serve as supplements to the standard operating procedures.

Article 31. Any deviation from the standard operating procedures in the test shall be confirmed and recorded in writing by the test program leader or the sub-leader.

Article 32. The standard operating procedures shall include the following:

(1) preparation, revision and management of standard operating procedures;

(2) appointment, selection, change and training of personnel;

(3) preparation and revision of test plans;

(4) tests and deviations from the test plans;

(5) inspections to be conducted by the quality assurance specialist , inspection scheme preparation and implementation, inspection recording and reporting;

(6) receipt, identification, marking, access, storage and disposal of test substances, reference substances and samples;

(7) Instruments, materials and reagents:

1. Instruments: purchase, acceptance inspection, use, maintenance, verification/calibration;

2. Computer systems: purchase, acceptance inspection, verification, operation, maintenance, security, change management and backup;

3. Materials and reagents: purchase, acceptance inspection, preparation, identification, storage and disposal.

(8) Generation, retrieval and storage of records and reports: test data acquisition and analysis (including the use of computer systems), report preparation rules and filing methods, test code and composition and use of the index system.

(9) Test systems:

1. Requirements on room conditions and environment;

2. Receipt, transfer, storage, characterization, identification, grouping and feeding and cultivation management;

3. Positioning and arrangement in test areas;

4. Pre-test preparation, in-test observation and recording, disposal of unnaturally died, dying or dead test organisms;

5. Specimen/sample collection, identification and disposal (including autopsy, physiological and biochemical tests and histopathological examination).

(10) Other standard operating procedures that need to be developed.

Chapter IX. Test Implementation

Article 33. Requirements on test plans:

(1) A written test plan shall be prepared before any test is conducted;

(2) The test plan shall be examined and approved by the quality assurance specialist, signed and dated by the test program leader, and if necessary, approved by the person in charge of the testing institutes and the entrusting party;

(3) The revision of any test plan shall be made based on reasonable ground, signed and dated by the test program leader and, if necessary, approved by the entrusting party. The revised test plan shall be kept together with the original plan;

(4) Any deviation from the test plan shall be recorded, signed and dated by the test program leader or sub-leader concerned, and kept together with the original data, or be notified to the entrusting party as the case may be;

(5) Short-term tests may be conducted based on an approved test plan, which shall be attached with specific requirements for each test.

Article 34. A test plan shall include the following:

(1) Basic contents of the test program:

1. Name of the test program;

2. Nature and purpose of the test;

3. Name, code of and other basic information about the test substance:

4. The reference substance to be used and its source.

(2) Information about the entrusting party and testing institute:

1. Name or address of the entrusting party:

2. Name and address of the entrusting party and of the test sites involved:

3. Name of the test program leader:

4. Name of sub-leaders, the part of the tests they are responsible for and their roles.

(3) Dates:

1. Dates when the test program leader, the person in charge of the testing institute and the entrusting party approve/confirm and sign the test plan;

2. Expected test start and end dates

(4) Test methods: proposed methods, including national standards, industrial standards, other test guidelines and methods regulated by recognized international organizations.

(5) Other matters (dependent upon the test to be conducted):

1. Reasons for choosing a particular test system:

2. Characteristics of the test system, including species, line (sub-line), source, quantity, weight, sex, age and other relevant information;

3. Administration or application method and reasons;

4. Dose/concentration, times and intervals of administration or application;

5. Detailed information about the test design, including schedule, methods, materials and conditions of the test, and indicators and frequency that need to be measured, observed and tested, as well as statistical analysis methods to be used for different indicators.

(6) Records: List of records that shall be kept.

Article 35. Requirements on test implementation:

(1) Each test shall be assigned with a unique number, which can be used to trace the test substances, samples, specimens, test results and other data.

(2) Each test shall be conducted in accordance with the test plan;

(3) All data generated from tests shall be recorded in a direct, timely, accurate and clear manner, and signed and dated by the recorder;

(4) Any change to any raw data shall be made in the prescribed manner, with reasons clearly stated and shall not alter, or cover the previous record, and shall be signed and dated by the person who made such change.

(5) Data directly entered into the computer shall be confirmed by the person who made such entry, and the computer system shall be able to display all modifications and verifications made to the data, which shall not cover the original data. All modifications shall be provided with reasons and be properly dated.

Chapter X. Test Reports

Article 36. Basic requirements:

(1) Each test shall generate one final test report, and the final report for any short-term test may consist of a standard report and a test-specific report;

(2) The name of the person who prepared the report, either a test program leader or a sub-leader shall be given in the report;

(3) The test program leader shall sign and date the final test report and be responsible for the validity, authenticity and completeness of its data, as well as describe how the Code and the test plan are complied with, and the effect of any deviation upon the test results;

(4) Any modification or supplement to the test report shall contain a statement of reasons, and signed and dated by the test program leader;

(5) If the format of any test report needs to be adjusted in order to meet the pesticide registration requirements, no content of the report shall be amended, added or supplemented;

(6) Upon request of the entrusting party, the testing institutes may issue a copy of the final test report, provided that it shall be consistent with the original report.

Article 37. The final test report shall include the following contents:

(1) Basic information about the test program:

1. Qualification certificate of the testing institutes (a copy of such certificate);

2. A copy of the registration test entrustment agreement/contract;

3. Name and number of the test program;

4. Record information and number of the new pesticide registration test approval certificate;

5. Number of the sealed sample of the test substance;

6. Basic information about the effective constituents, including their common names in Chinese and English, US CAS registry number, chemical name, molecular formula, structural formula, relative molecular weight, appearance, solubility, stability, biological activity and source;

7. Basic information about the test substance, including its name, nominal value, dosage form, sample batch number, appearance, weight, production date, effective date, date of receipt, manufacturing enterprise, manufacturer address and storage conditions;

8. Basic information about the reference substance, including its generic name, chemical name, appearance, purity, source, batch number, date of manufacture, effective date, date of receipt, storage conditions, and valuation methods.

(2) Information about the entrusting party and the testing institute;

1. The name and address of the testing institute;

2. All the names and addresses of the testing institutes and test sites involved;

3. Name of the test program leader:

4. Name of test program sub-leaders, the part of the tests they are responsible for.

5. Name of other relevant persons.

(3) Test start and end dates

(4) Quality assurance statement: List the inspection type, inspection contents, inspection results, and dates on which the inspection report is delivered to the person in charge of the testing institutes, the test program leader, or the sub-leader concerned, and confirm the extent to which the final test report reflects the raw data.

(5) Instruments, reagents, materials and methods;

1. The instruments, reagents, materials and methods used;

2. Referred national standards, industrial standards, other test guidelines and methods regulated by recognized international organizations.

(6) Results:

1. Summary;

2. All information and data required by the test plan;

3. Statistical software and statistical methods used, and analysis results;

4. Detailed discussion about the biological significance of the test results and impact of any variation from the test plan, key factors and data given based on current standards, comments and conclusion.

(7) Filing: Materials to be filed include test plans, test substances, reference substances, specimens, samples, raw data, final test reports, and descriptions about the place where such materials are filed.

Chapter XI. Filing and Maintenance

Article 38. The following materials shall be put on file:

(1) Information about test plans, raw data, test substances, reference substances, samples and specimens, the final test report and the master schedule;

(2) All inspection records of quality assurance specialists;

(3) Personnel qualifications, training, experience, job duties and appointment documents;

(4) Records of instruments, including records and reports of instrument purchase, acceptance inspection, maintenance, use, verification/calibration;

(5) Valid confirmation documents for computer systems;

(6) All versions of standard operating procedures and revision records;

(7) Environment monitoring records;

(8) Other documents that need to be filed.

Article 39. The final processing of any test material shall be documented in writing. When any test substance or reference substance, or specimen or sample needs to be disposed prior to the expiry of the regulated maintenance period due to some reason, such reason shall be stated and documented.

Article 40. Materials shall be filed based on their classification to facilitate retrieval and search efforts. The final disposal of any filed material shall be documented in writing.

Article 41. Only those who are authorized by the person in charge of the testing institutes may access the file room, and the receipt and borrowing of any filed material shall be properly recorded.

Article 42. If any testing institute or the filing contractor is bankrupt and there is no legal successor, these files shall be incorporated into files of the entrusting party.

Chapter XII. Supplementary Provisions

Article 43. The terms and definitions used in this Code are as follows:

(1) Tests: refer to a test or a set of tests conducted in a lab or field on a certain substance to gain data about its characteristics, effectiveness and safety.

(2) Test sites: refer to sites where a part or parts of the test are conducted.

(3) Person in charge of the testing institutes: refers to the person with managerial authority in organization and function of the testing institutes.

(4) Test program leader (technical supervisor): refers to the person who is responsible for the implementation and management of a test.

(5) Test program sub-leader: refers to the person who is responsible for a part of the test involving multiple sites.

(6) Quality assurance systems: refer to systems independent of any test that are designed to ensure that the testing institutes comply with the quality management practices, covering organization, regulations, and personnel.

(7) Standard operating procedures: refer to documented procedures that describe how to carry out a test or test activity.

(8) Master schedule: refers to a summary of progress, workload and time arrangement of tests to be conducted by the testing institutes.

(9) Short-term tests: refer to tests conducted within a short period using conventional technology.

(10) Test plans: refer to any text document that specifies the purpose and design of the test and contains all revisions made to such purpose and design.

(11) Test systems: refer to any biological, chemical or physical system alone or in combination used to test organisms (typically including test organisms and their specific living conditions).

(12) Test substances (materials): refer to pesticide samples to be tested in a test program.

(13) Reference substances (materials): refer to pesticides or other compounds to be tested for base values for comparison with the test substances.

(14) Samples: refer to test materials used to inspect and analyze test systems.

(15) Specimens: refer to any animal or plant or any part of it collected during the test process and that is processed for long-term preservation while maintaining its original shape or characteristics for purposes of identification, research or examination or otherwise.

(16) Raw data: refer to original records and related documents or certified copies with respect to a test, such as the observation records, test records, photos, negatives, chromatograms, microfilms, magnetic carriers, computer printing materials, automated instrument recording materials.

(17) Test start date: refers to the date of first acquisition of test data.

(18) Test end date: refers to the date of last acquisition of test data.

(19) Test program start date: refers to the date on which the test program leader signs the test plan.

(20) Test program end date: refers to the date on which the test program leader signs the final test report.

Article 44. This Code shall come into force as of October 10, 2017.