

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

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The *Detailed Rules on Pesticide Production Permit Evaluation* prepared by the Ministry in accordance with the *Regulations on Management of Pesticides* and the *Measures on Management of Pesticide Production Permit* is hereby promulgated and shall come into force as of October 10, 2017.

Ministry of Agriculture

September 3, 2017

Detailed Rules on Pesticide Production Permit Evaluation

Chapter I. General Provisions

Article 1. These Rules are prepared in accordance with the *Regulations on Management of Pesticides*, and the *Measures on Management of Pesticide Production Permits*, to regulate evaluation practices in relation to pesticide production permits.

Article 2. The pesticide production permit evaluation shall be conducted in a lawful, scientific and impartial manner.

Article 3. The pesticide production permit evaluation shall be conducted based on the applicants' scope of production applied for, and a conclusion shall be drawn for each item evaluated.

Chapter II. Requirements on Application Materials

Article 4. The application may be submitted for production of an active ingredient (technical concentrate) or of a formulation.

The application for production of an a.i (tc) shall be made based on the type of the a.i (tc). The application for production of a formulation shall be made based on the dosage form of the formulation, and the

application materials provided shall serve the purpose of application for production of the same pesticide.

Article 5. In case of applying for a pesticide production permit for the first time, or for expanding the scope of production described in the permit or changing the production address, applicants shall submit materials specified in Article 9 of the *Measures on Management of Pesticide Production Permits* and bound in a volume in sequence, and at the same time, submit the electronic copy of such materials.

In case of applying for production of more than two technical materials or preparations simultaneously, applicants shall bind the documents required under clauses 6, 7 and 9, paragraph 1 of Article 9 of the *Measures on Management of Pesticide Production Permits* in a separate volume based on the type or dosage form of the pesticides applied for.

Article 6. In case of applying for change of the name, legal representative (responsible person) or address of the pesticide producer during the validity period of the pesticide production permit, a copy of the updated business license shall be provided; in case of applying for change of the legal representative (responsible person), a copy of the ID card of the legal representative (responsible person) shall also be provided;

Article 7. In case of applying for extension of a pesticide production

permit, a summary report on production conditions, including any change in key technicians, equipment/facilities, process technology, quality assurance systems, and the production and sale of the pesticides involved shall be provided;

Chapter III. Evaluation Process

Article 8. Agricultural authorities at the provincial level shall organize the pesticide production permit evaluation.

Agricultural authorities at the provincial level may, where necessary, set up an evaluation team composed of experts in pesticide management, production process and quality control, to conduct technical evaluation or on-site inspection.

The evaluation team is composed of more than 3 persons, including one leader who assumes the overall responsibility for the whole team. The technical evaluation and on-site inspection may be conducted by different evaluation teams.

Article 9. Experts involved in pesticide production permit evaluation shall meet the following conditions:

(1) Be familiar with laws and policies concerning pesticide production management;

(2) Holding a bachelor's degree or above, or a senior professional title in pesticide, chemistry or chemical engineering or any relevant field,

be familiar with the pesticide production process, product quality standards or pesticide management, and having at least five-year experience in pesticide research, production, testing or management;

(3) Healthy and competent;

(4) Other conditions prescribed by the agricultural authorities at the provincial level.

Article 10. Members of the evaluation team shall practice a system of withdrawal. Members who have direct interest in the pesticide production permit application shall actively withdraw from the evaluation process.

Article 11. Agricultural authorities at the provincial level shall, upon receipt of application materials, timely organize paper examination and technical evaluation, and shall develop a report following the completion of the technical evaluation. The technical evaluation report shall include the following:

(1) Conclusion drawn from the technical evaluation;

(2) Major problems discovered;

(3) The Pesticide Production Permit Evaluation Form (to be filled out based on the pesticide production scope, refer to Appendix 1 and Appendix 2).

(4) Other matters to be described;

Article 20. Agricultural authorities at the provincial level shall

timely organize an on-site inspection under any of the following circumstances:

(1) Producers apply for a pesticide production permit for the first time;

(2) Non-chemical pesticide producers apply for adding pesticides into their scope of production;

(3) Producers apply for change of their production address or expand their scope of production;

(4) This is so suggested by the paper examination or technical evaluation.

Article 13. Where it is necessary to conduct an on-site inspection, agricultural authorities at the provincial level shall send 2 days' prior written notice to the applicant concerned and to their local counterpart in the place where the applicant is located. The local agricultural authority may send observers to participate in the on-site inspection.

Any objection of the applicant to any evaluator upon receipt of the on-site inspection notice shall be made in writing and submitted to the agricultural authorities at the provincial level in a timely manner.

Article 14. The on-site inspection by the evaluation team shall follow the following procedures:

(1) Informs the applicant concerned of members of the evaluation team, the contents and procedures of inspection, announces the

disciplines and gains knowledge about the producer concerned;

(2) Consults materials, inspects the site and conducts interviews, while focusing on the main problems discovered during the technical evaluation;

(3) Conducts internal exchange of views, to form a preliminary conclusion;

(4) Communicates the main problems discovered during the on-site inspection to the applicant for comments.

Article 15. The evaluation team shall timely prepare, following the completion of the on-site inspection and submit a report to the agricultural authority at the provincial level. The on-site inspection report shall include the following:

(1) Basic information about the applicant concerned;

(2) Conclusion drawn from the on-site inspection;

(3) Main problems to be communicated to the applicant;

(4) Main items, the conclusions for which are inconsistent with that drawn from the technical evaluation, and descriptions;

(5) The Pesticide Production Permit Evaluation Form (to be filled out based on the pesticide production scope);

(6) Other problems discovered during the on-site inspection;

Chapter IV. Contents of Evaluation

Article 16. The contents to be evaluated include but are not limited to, the basic information about the applicant concerned, information about his personnel, site layout, production process technology, production equipment, workshops, quality assurance systems, management systems and compliance with industrial policies.

Article 17. The basic information about the applicant shall be examined to identify the consistency between the name, the legal representative (responsible person) and the address of the applicant with whose in the business license, and consistency between the declared production address and the actual production address.

Article 18. The selection of the production address shall be in compliance with relevant provisions of the *Measures on Management of Pesticide Production Permits*.

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.

Article 19. Personnel of applicants include managers, technical personnel, operators and quality inspector, etc. Relevant training and appraisal records of such personnel shall be available; for posts having special technical requirements, corresponding qualification certificates shall be available.

(1) Managers Managers of pesticide producers shall be familiar with

the pesticide management laws, regulations and policies.

(2) Technical personnel Technical personnel shall have a bachelor's degree or above or at least an intermediate professional title in chemistry, chemical engineering, pharmacology, plant protection or a relevant field and more than 2 years of work experience. Producers of chemical pesticide technical materials shall have at least five technicians competent for production of the pesticides applied for; and other pesticide producers shall have at least two technicians of such kind.

(3) Operators Operators shall be provided with pre-job training. Operators involved in high-risk processes shall acquire relevant certificates before taking the post.

(4) Quality inspectors Pesticide producers shall have at least two quality inspectors with an associate's degree or above in relevant fields or having accepted and passed the professional training.

(5) Personnel engaged in special operations Personnel engaged in operations of pressure vessels, electric equipment, welding, crane, elevator, forklift truck and transportation of hazardous substances shall be properly trained and certified by the competent authority in accordance with law.

Applicants shall not employ any person described in paragraph 1, Article 63 of the *Regulations on Management of Pesticides*.

Article 20. Workshops, facilities and equipment include building

facilities, production units and equipment, fire safety facilities and “three wastes” disposal facilities, etc.

Article 21. The overall layout of the pesticide workshops shall be arranged in a scientific and rational manner.

The construction of workshops and auxiliary facilities shall be in line with the general layout plan, and meet the requirements of the production process, to ensure all links are well connected, materials appropriately and orderly delivered.

Applicants shall provide a list of main workshops, equipment, facilities and auxiliary facilities ensuring normal operations (refer to Appendix 3 for requirements on main production equipment for different scopes of production) based on the process flow diagram, the layout plan of production units, the production process flow diagram and process descriptions, and provide names, quantities and photos of facilities for tracing the pesticide products.

Article 22. The pesticide production workshops and facilities shall be arranged in a scientific and appropriate manner and meet the following requirements:

(1) The main production equipment and facilities shall meet the requirements for production of relevant pesticides and may be automatically operated (excluding some links or products that are not appropriate for automatic production for the time being).

(2) Products showing an obvious difference in dosage forms shall be produced with independent production units;

(3) Workshops producing herbicides, plant growth regulators and raticides shall be separated from workshops producing other pesticides to avoid cross-contamination;

(4) Raw materials, finished products and packaging materials shall be stored in separate areas.

Article 23. The quality inspection sites shall be arranged to meet the requirements for pesticide quality control, and the inspection equipment shall be relatively centralized, as opposed to the instrumental analysis room, the chemical analysis room, the balance room, the sample room and the heating room, which shall be separately located.

Article 24. With respect to product quality assurance systems, attention shall be paid to following aspects:

(1) The quality inspection unit shall be independently arranged;

(2) The quality testing instruments and equipment shall meet the requirements for ensuring products' compliance with the quality standards, and for in-process control and testing of raw materials; the legal dosing controls shall be subject to periodical inspection;

(3) Quality inspection and control systems, product quality standards, complete and effective operation procedures, ex-factory inspection and procedures for disposing substandard products.

Article 25. Management systems include systems concerning raw material procurement and control, production process control, equipment management, product storage and transportation, product sale management, traceability management, product recall, safe production, occupational health, environmental protection, waste recycling and disposal, personnel training, documentation and recording, etc.

Article 26. Original records of pilot production of three batches of pesticides include: inspection records of incoming raw materials, inspection or checking records of raw materials, intermediate/semi-finished and finished products, main production records and finished product warehouse entry records, etc.

Evaluators shall conduct a comprehensive evaluation of the completeness, scientific base, validity and effectiveness of corresponding documents concerning quality assurance systems and management systems by taking into account the original records of pilot production of three batches of pesticides applied for.

Chapter V. Conclusion from the Evaluation

Article 27. Conclusion drawn from a technical evaluation or an on-site inspection may be a conclusion for a single item or a comprehensive conclusion.

Article 28. The conclusion for a single item may be “qualified”,

“suggested for improvement”, “unqualified” or “N/A”.

“Qualified” means relevant regulations are met. “Suggested for improvement” means there is an accidental and isolated problem of general nature that can be further improved. “Unqualified” means there is at least one regional or systematic problem; “N/A” means the contents inspected have nothing to do with the scope of the production applied for and there is no need to evaluate them.

Any conclusion for a single item of “unqualified” or “N/A” shall be accompanied by a statement of reasons.

Article 29. A comprehensive conclusion may be “qualified” or “unqualified”.

The comprehensive conclusion shall be “qualified” if the following conditions are met:

- (1) No conclusion of “unqualified” is drawn for any item inspected;
- (2) The total number of items deemed “suggested for improvement” is less than 5.

Article 30. Where the conclusion drawn from the on-site inspection is different from that drawn from the technical evaluation, the former shall govern.

Article 31. When applicants apply for production of more than two technical materials or preparations simultaneously, but the conditions are not fully met as discovered in inspections, agricultural authorities at the

provincial level shall issue the permit for the part that meets the conditions, and inform the applicants of the part that fails to meet the conditions in writing, with reasons clearly stated.

Chapter VI. Supplementary Provisions

Article 32. Applicants that have obtained the pesticide registration certificate permit prior to the effective date of the *Measures on Management of Pesticide Production Permits*, but have not obtained the pesticide production certificate or the pesticide production permit, shall be evaluated as new pesticide producers when applying for a pesticide production permit.

Article 33. When applicants apply for production of a technical concentrate or a new pesticide technical material, the registration of the pesticide shall be checked.

Article 34. When applicants apply for direct production of preparations due to difficulties in producing technical materials (technical concentrates) caused by technology, safety or other reasons, the registration of the pesticide, as well as the conditions for production of technical materials (technical concentrates) and preparations shall be checked, and the scope of production shall be expressed as the name of the pesticide, plus the dosage form.

Article 35. These Rules shall come into force as of October 10,

2017.

Appendixes:

1. Pesticide Production Permit Evaluation Form (applicable to a.i or tc)
2. Pesticide Production Permit Evaluation Form (applicable to formulations)
3. Requirements on Pesticide Production Equipment

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 <i>Regulations on Management of Pesticides</i> , the <i>Measures on Management of Pesticide Production Permits</i> 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 <i>Regulations on Management of Pesticides</i> .	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	

		<p>(3) Producers shall have sound and practical process management systems and assessment measures;</p> <p>(4) Producers shall set operation procedures for each process;</p> <p>(5) Producers shall set control indexes for main processes and establish control and assessment measures;</p> <p>(6) Producers shall establish a product labeling and packing management system;</p> <p>(7) Producers shall operate in strict compliance with the process parameters and operation procedures, and keep relevant production records.</p>	based on original records of pilot production of three batches of pesticides applied for.	Unqualified	
5.4	Facilities and equipment management	<p>(1) Producers shall create files for main facilities and equipment and establish corresponding operation and maintenance systems;</p> <p>(2) Producers shall establish operation procedures for relevant facilities and equipment in light of actual production conditions.</p> <p>(3) Producers shall create operation records in light of actual production conditions.</p>	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	<p>Producers shall establish pesticide product quality management systems:</p> <p>(1) Producers shall regulate that produced pesticides to be sold must pass the quality inspections and attach the product quality inspection certificates;</p> <p>(2) Producers shall set explicit rules for controlling and disposing substandard products;</p>	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 health 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	
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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 <i>Regulations on Management of Pesticides</i> , the <i>Measures on Management of Pesticide Production Permits</i> 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 <i>Regulations on Management of Pesticides</i> .	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 <i>Measures on Management of Pesticide Production Permits</i> . (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	

		<p>a production address shall have their workshops built within a chemical industrial park above the provincial level;</p> <p>(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;</p> <p>(3) Chemical pesticide producers wishing to change the production address shall enter a chemical industrial park (industrial park) above the city level.</p>			
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	<p>(1) Producers shall have in place the general production layout plan;</p> <p>(2) The construction of workshops and auxiliary facilities shall be in line with the general layout plan;</p>	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 standards* quality	(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	

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