

Management Measures for the Production of Pesticides

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The "Management Measures for the Production of Pesticides" have been deliberated and passed by the Director's Meeting of the State Development and Reform Commission, and are hereby promulgated for implementation as of January 1, 2005. Meanwhile the "Management Measures for the Production of Pesticides" as promulgated by the previous State Economic and Trade Committee shall be concurrently annulled.

Director of the State Development and Reform Commission: Ma Kai
April 11, 2004

Management Measures for the Production of Pesticides

Chapter One General Principles

Article 1 For the purposes of strengthening the management of the production of pesticides and promote the healthy development of the pesticide industry, the present Measures are formulated according to the "Regulations on the Management of Pesticides".

Article 2 The present Measures are applicable to the production of pesticides in the People's Republic of China.

Article 3 The State Development and Reform Commission (hereafter shortened as SDRC) is responsible for the supervision and management of pesticide production in the country, and is also responsible for the examination and approval of pesticide production enterprises and the production of pesticide products.

Article 4 The department of development and reform in all the provinces, autonomous regions, and municipalities directly under the Central Government (or the administration for pesticide production such as the administration for economy and trade, hereafter referred as "provincial administration") shall supervise and manage the pesticide production in its own jurisdiction.

Article 5 The pesticide production should comply with the industrial policies of the state concerning the pesticide industry

Chapter Two The Examination and Approval of Pesticide Production Enterprises

Article 6 The establishment of pesticide production enterprises (including joint operations, the establishment of a branch factory, and the establishment of a pesticide production workshop by a non-pesticide production enterprise) should pass the initial examination of the provincial administration. An application should be submitted to the SDRC for examination and approval, after which the enterprise is allowed to apply for an operational license at the industrial and commercial administration or change the scope of business as specified in its existing industrial and commercial operational license according to law.

Article 7 The following conditions should be met at the time of application for examination and approval:

- (1) Having hired technicians and technical workers suitable for the pesticides to be produced;
- (2) Having factory plants, production facilities and hygienic environment suitable for the pesticides to be produced;
- (3) Having the facilities that comply with the state labor safety and hygiene standard and having corresponding labor safety and hygiene management systems;
- (4) Having product quality standard and product quality guarantee system;
- (5) The pesticide produced is a legally registered pesticide;
- (6) Having the pollution prevention facilities and measures that comply with the state environmental protection requirements, and the discharge of polluted materials complies with the state and local standards for such discharge.
- (7) Complying with other conditions as provided for by the SDRC.

Article 8 The following materials should be provided when applying for examination and approval:

- (1) The Application Form for Examination and Approval for Pesticide Production Enterprises (see attachment 1):
- (2) Copies of industrial and commercial operational license (for presently existent enterprise) or the "Notice of Advance Approval of Enterprise Name" (for newly established enterprise) issued by the industrial and commercial administration;
- (3) Project feasibility research report (for an original pesticide project, the report should be compiled by entities higher than a Level Two enterprise);
- (4) The examination and approval opinions from the local environmental protection department (above prefecture or city level) where the enterprise is situated (for an original pesticide project, an appraisal report for the environmental impact of the project and a review report for the appraisal should be provided);
- (5) Other materials as provided for by the SDRC.

Article 9 The applicant enterprise should submit the required materials to the provincial administration according to the provisions of Article 8 of these Measures. The provincial administration should conduct an initial examination of the submitted application materials, and submit the materials that have passed the initial examination to the SDRC.

Article 10 The SDRC should complete the examination and make a decision within 20 working days after receiving the application materials from the enterprise (excluding the time spent on on-site examination and expert examination). If a decision cannot be made within 20 days, an extension of 10 days can be obtained upon approval of the main leader in-charge of the SDRC.

For enterprises that have passed the examination and verification, the SDRC will grant them the right to pesticide production, and publicize such rights.

Application materials that have not passed the examination and verification will not be used as the basis for the next application.

Article 11 The term of validity for a pesticide production enterprise is 5 years. After the term expires and if the pesticide production enterprise wants to keep its right as a pesticide producer, it must apply at the SDRC 3 months before the expiration of the term.

Article 12 The enterprise that wishes to continue its right as a pesticide producer should provide the following materials:

- (1) An Application Form for Extending the Qualifications to Produce Pesticides (see attachment 2);
- (2) A copy of the industrial and commercial operational license;
- (3) The information about production, sales and financial of the enterprise in the recent 5 years;
- (4) The examination and verification opinions of the environmental protection administration where the enterprise is situated (at the prefecture and municipality level or above);
- (5) Other materials as provided for by the SDRC.

Article 13 The applicant enterprise should submit the required materials to the provincial administration according to the provisions of Article 12 of the present Measures. The provincial administration should conduct an initial examination of the submitted application materials, and submit materials that have passed the initial examination to the SDRC.

Article 14 The SDRC should examine whether the enterprise meets the conditions when it was first examined and approved, and should complete the examination and make a decision whether to renew the enterprise's right to produce pesticides within 20 working days after receiving the application materials (excluding time spent on on-site examination and expert examination), and publicize the decision. If a decision cannot be made within 20 days, an extension of 10 days can be obtained upon approval of the main leader in-charge of the SDRC.

If no continuation is applied for by the enterprise, then its obtained right as a pesticide production enterprise shall be deemed as being automatically cancelled, and the SDRC shall cancel its right to produce pesticides, and shall publicize such cancellation. The application materials that have not passed the examination and verification to renew the enterprise's right of production may not be used for the next application for renewal.

Article 15 If the pesticide production enterprise moves its site to another province, the move must be subject to the examination and approval of the SDRC. If the enterprise moves its site within the province, the move must be subject to the examination and approval of the provincial administration, and then be reported to the SDRC for filing.

Article 16 The change of name of a pesticide enterprise must be subject to the examination and approval of the industrial and commercial registration department, and then be reported to the SDRC for filing, and shall then be publicized.

Chapter Three Examination and Approval for the Production of Pesticides

Article 17 The production of any pesticide for which no state and industry standard have been formulated must be initially examined by the provincial administration, after which it must be reported to the SDRC for approval and the issuance of a certificate of approval for pesticide production. The enterprise may produce the approved product only after obtaining the certificate of approval for production.

Article 18 The following conditions should be met when applying for a certificate of approval:

- (1) Having obtained the qualification as a pesticide production enterprise;
- (2) The effective ingredients of the product being well-defined, and having legally registered the product as a pesticide product;
- (3) Having professional technicians, technically skilled workers, and measuring and inspection staff that can guarantee the product quality and routine production;
- (4) Having the technology, production facilities, plants, supportive facilities and means for measuring and quality inspection that can guarantee the product quality;
- (5) Having the safe production facilities, hygiene facilities, and the corresponding relevant management systems that are in match with the product;
- (6) Having the facilities and measures for dealing with the "three wastes" that are in match with the product, and the disposed polluting elements being up to the state and local standard for post-treatment disposal;
- (7) Other materials as provided for by the SDRC.

Article 19 The following materials should be provided when applying for a certificate of approval:

- (1) An application Form for Certificate of Pesticide Production (see attachment 3);

- (2) A copy of the industrial and commercial operation license;
- (3) The product standard and an account of the drafting thereof;
- (4) The product quality test report issued by relevant and qualified provincial quality test organization within one year before the application date;
- (5) For production facilities newly added to the original pesticides, a construction project feasibility research report formulated by an entity with the qualifications of Level Three or above must be provided, as well as the examination and approval opinions from other relevant departments;
- (6) The examination and approval opinions on agreeing to the project construction as issued by the environmental protection department where the production facilities are situated (if the product for which the application is submitted is the same form as an existing one, then the enterprise does not have to provide this opinion);
- (7) Source certification for the original chemicals used for processing product and re-mixing product within two years of the application (see attachment 8 for specimen);
- (8) Separate packaging authorization agreement for separate packaged products for the recent two years before the application;
- (9) Registration certificate for pesticides;
- (10) Other materials as provided for by the SDRC.

For an application for newly added original pesticide products, the materials specified in items (1), (2), (3), (4), (5), and (6) of the preceding paragraph should be provided.

For an application for newly added processing and re-mixing products, the materials specified in items (1), (2), (3), (4), (6), and (7) of paragraph 1 should be provided.

For an application for newly added separate package products, the materials specified in items (1), (2), (3), (4), and (8) of paragraph 1 should be provided.

For an application for changing the certificate for pesticide production, the materials specified in (1), (2), (3), (4), (7), and (9) of paragraph 1 should be provided.

For an application for separate package products to change the certificate for pesticide production, materials specified in (1), (2), (3), (4), (5), (8), and (9) of paragraph 1 should be provided.

Article 20 If the pesticide will be the first to be produced in the country, the enterprise should first have the pesticide registered. For the products that have been registered by another enterprise, the enterprise should specify the name of the enterprise that has registered the product, the registration number, and the enterprise's own registration of the product on the application form, and may also apply for the certificate for production while registering the product.

Article 21 Procedures for Application and Approval:

- (1) The applicant enterprise should prepare the necessary materials according to Article 19 of the present Measures, and submit the application to the provincial administration;
- (2) The provincial administration is responsible for the organization of on-site examination and product quality sample test, and should accurately fill the Production Condition Examination Chart of the Certificate of Production for Pesticides (see attachment 4);
- (3) The provincial administration will conduct an initial examination on the application materials provided by the enterprise, and submit the application materials which have passed the initial examination together with the production condition examination chart of the certificate of production for pesticides to the SDRC;
- (4) The SDRC should complete the examination and make a decision within 20 working days after receiving the application materials. If a decision cannot be made within 20 days, an extension of 10 days can be obtained after the approval of the main leader in-charge of the SDRC. For the enterprises that have passed the examination, the certificate of production will be issued and publicized.

Article 22 For an application for the manufacturing of any product identical to any existing product, the on-site examination may be exempt for two years. But if any of the following conditions occurs, an on-site examination may be conducted:

- (1) A significant change has occurred in the production condition of the enterprise;
- (2) The provincial administration deems it necessary to conduct an on-site examination.

Article 23 When the provincial administration is accepting the enterprise's application, it should inform the applicant in writing whether an on-site examination and product quality sample test are required, and if so, the time needed to conduct the examination and test. The time needed to conduct the examination and test is not included in the legal time limit for the work.

Article 24 The on-site examination should be conducted by 3 or more workers and professional experts with experiences in production, quality, and safety. The on-site examination results are classified into three types: pass, basically pass, and fail. If the result of the on-site examination is basically pass or fail, the examination group should inform the enterprise on site of the reasons for the result, make suggestions for measures to reorganize or reform the enterprise, and should accurately record these in the production condition examination chart of the certificate of production for pesticides.

Article 25 Enterprises applying for the issuance of a pesticide production certificate should provide the product quality inspection report issued by a qualified entity; enterprises applying for the change of its pesticide production certificate should conduct a product quality sample test or provide a sample test report that is effective for one year. The taking and sealing of product samples for the product quality sample test will be done at the on-site examination by the provincial administration. The enterprise may select a qualified provincial quality inspection organization to perform the test and issue a test report.

Chapter Four Supervision and Management

Article 26 To let a pesticide product leave the factory, the product must be marked by an pesticide production certificate number.

Article 27 The term of the first pesticide production certificate is two years (test production period); the term for the reissued pesticide production certificate is 5 years for the original products, and 3 years for the remixed and processed products and the separately packaged products.

Article 28 When applying for changing the name on the pesticide production certificate, the enterprise should submit an application at the provincial administration. After the provincial administration has conducted an initial examination of the submitted materials, the application should be forwarded to the SDRC to be verified, after which a new certificate may be issued. The enterprise is required to provide the following materials:

- (1) An Application Form for changing the enterprise name on the pesticide production certificate (see attachment 5);
- (2) New and old business licenses or a copy of "Notice of Advance Approval of Enterprise Name" issued by the industrial and commercial administration;
- (3) The original pesticide production certificate.

Article 29 If the enterprise's pesticide production certificate is missing or is unintelligible because of damage, the enterprise may apply to the provincial administration for reissuing a certificate.

After the provincial administration has conducted an initial examination to the application materials, the application should be forwarded to the SDRC for reissuing a pesticide production certificate.

To apply for reissuing a pesticide production certificate, the following materials are needed:

- (1) Application Form for the Reissuance of Lost Pesticide Production Certificate (see attachment 6);
- (2) A copy of the industrial and commercial business license.

Article 30 To process the applications for changing the enterprise name on the pesticide production certificate or for reissuing a pesticide production certificate, the provincial administration should complete the initial examination to the application materials and the forwarding of the materials within 20 working days after receiving the application. For application materials that have met relevant requirements, the SDRC should complete the relevant work within 5 working days.

Article 31 The pesticide production enterprises should conduct their production according to pesticide product quality standard and technical procedures, and should keep complete and accurate production records. Before February 15 every year, the enterprise should truthfully fill out the Pesticide Production Yearly Report (see attachment 7) which reflects the enterprise's pesticide production situation for the previous year, and submit the report to the provincial administration. The provincial administration should gather all the yearly reports for the enterprises and forward them to the SDRC.

Article 32 The applicant enterprise should truthfully submit relevant materials to the competent administrative organs which reflect their true situation, and should be responsible for the truthfulness of the content of the application materials.

Chapter Five Principles of Punishment

Article 33 If any of the following situation occurs, the enterprise's qualification for pesticide production will be cancelled by the SDRC:

- (1) The actual situation of an approved enterprise is in serious conflict with that described in its application materials;
- (2) Unlawfully changing any of the examination and approval content.

Article 34 If any of the following situation occurs, the SDRC shall revoke or cancel the enterprise's pesticide production license:

- (1) The enterprise no longer meets the requirements for the license upon re-examination;
- (2) The product quality having failed the random test done by a supervision and management department above the provincial level for two consecutive times;
- (3) Transferring the pesticide production license for the use of another enterprise or another product;
- (4) The state has decided to stop the production of certain product within the pesticide production license valid period for that product;
- (5) Producing and selling fake, shoddy or unqualified pesticides;

Article 35 If the organization in charge of pesticide product quality control violates relevant regulations and employs trickery, the provincial administration or the SDRC shall ask relevant departments to cancel the organization's qualification to control the pesticide product quality.

Article 36 The pesticide administrators who abuse their power, neglect their duties, employ trickery to gain personal benefits, or solicit for or accept bribes shall be punished for their criminal activities according to relevant stipulations in the Criminal Law on the abuse of power, dereliction of duties, or accepting bribes. Those who are not punishable by criminal laws shall be given an administrative punishment.

Chapter Six Supplementary Provisions

Article 37 The SDRC may not ask the applicants to provide any "other materials" as mentioned in Article 7, 8, 12, 18, or 19 of the present "Measures" until the SDRC has announced it to the public about those materials for at least half a year.

Article 38 The results of verification and approval of the pesticide production enterprises and the

examination and approval of the pesticide production certificate, and relevant announcements and industry policies concerning the management of pesticide production shall be publicly announced on the official SDRC website.

Article 39 The power to interpret the present “Measures” shall remain with the SDRC.

Article 40 The present “Measures” shall be implemented as of January 1, 2005. Meanwhile the “Pesticide Production Management Measures” as publicized by the previous state Economic and Trade Committee shall be concurrently annulled.

Attachments:

1. The Application Form for Examination and Approval for Pesticide Production Enterprises (omitted);
2. Application Form for Extending the Qualifications to Produce Pesticides (omitted);
3. Application Form for Certificate of Pesticides Production (omitted);
4. Production Condition Examination Table for the Certificate of Production for Pesticides (omitted);
5. Application Form for Changing the Enterprise Name on the Pesticide Production Certificate (omitted);
6. Application Form for the Reissue of Lost Pesticide Production Certificate (Omitted)
7. The Pesticide Production Yearly Report (omitted)
8. Form for the Source certification for the Pesticide Original Chemicals (omitted);