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## China - Peoples Republic of

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### **Administrative Measures on Seed Production and Operation License and Management Regulation for GM Cotton Production and Operation**

**Report Categories:**

Planting Seeds

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**Report Highlights:**

On September 2011, China's Ministry of Agriculture released the final document, "Administrative Measures on the License of Seed Production and Operation." The new policy increases the entry threshold for the seed sector. Compared with the draft version (please refer to GAIN [CH11004](#) for translation of the draft), the final document modified some of the requirements, such as assets, in order to receive a license. It also refrains from providing further guidance on how to acquire a license for genetically modified (GM) seed. On October 2011, MOA released "Regulations on the License of Production and Operation of Genetically Modified Cotton Seed," which provides information on to acquire a license only for GM cotton seed production and operation. This report is an unofficial translation of both documents.

## General Information:

On September 2011, China's Ministry of Agriculture released the final document entitled: “Administrative Measures on the License of Seed Production and Operation.” The new policy increases the entry threshold for the seed sector. Compared with the draft version (please refer to GAIN [CH11004](#) for translation of the draft), the final document modified some of the requirements, such as assets, in order to receive a license.

Major changes from the draft include:

1. Genetically modified (GM) seed is excluded in the document (see Article 35). On October 2011, MOA released, “Management Regulation on GM cotton Seed Production and Operation License” as an addendum to the “Administrative Measures” document on how to acquire a license for GM cotton production and operation (see appendix of the report for translation of the regulation). However, at the current time, there is no guidance for other GM seeds.
2. Some of the requirements needed to attain a license were modified. For example, some fixed asset requirements were changed or deleted, as well as number of experts, specifications for equipment, and the period of validity for the licenses. For example, to qualify for a hybrid corn and rice seed production license, a company needs to have assets (fixed and liquid) of at least RMB 30 million; however, the final document requires no fixed assets (originally the draft required at least RMB 15 million out of the RMB 30 million). For the hybrid corn and rice seed operation license, the fixed asset requirement was changed from RMB 15 million to RMB 10 million.

This report is NOT an official translation of this document.

## MEASURES FOR ADMINISTRATION OF PRODUCTION AND BUSINESS LICENSE OF CROP SEEDS

### CHAPTER I GENERAL PROVISIONS

**Article 1** These Measures are formulated to strengthen the administration of production and operation of crop seeds, and to regulate the orders of production and operation of crop seeds, in accordance with the relevant provisions of the *Seeds Law of the People's Republic of China*.

**Article 2** These Measures apply to the application, examination, issuance and supervision of the production and business licenses of crop seeds.

**Article 3** The agricultural administrative authorities of the people's governments at the county or higher level shall be in charge of collection of applications, examination, issuance and supervision of the crop seed production and business licenses.

**Article 4** The agricultural administrative authorities responsible for examining, verifying and issuing the crop seed production license and business license shall issue a public bulletin on the requirements and procedures for applying for the crop seed production and business licenses at the office site.

**Article 5** The agricultural administrative authorities shall issue the crop seed production license and business license according to law and based on the principles of being conducive to ensure the safety of agricultural production, enhance the level of selection, cultivation and production of crop varieties and promote the fair competition.

## CHAPTER II PRODUCTION LICENSE

**Article 6** A primary crop seed<sup>1</sup> production license (hereinafter referred to as “**Seed Production License**”) shall be lawfully obtained for the production of commercial seeds of primary crops.

A production license of primary crop hybrid seeds and their parental seeds, as well as the foundation seeds of conventional varieties, shall be examined by the agricultural administrative authorities of the people’s government at the county level of the production site and be issued by agricultural administrative authorities of the people’s government at the provincial level. A seed production license for other primary crops shall be issued by the agricultural administrative authorities of the people’s government at the county or higher level of the production site.

If a producer, who applies for a seed production license, has its non-primary crops at the production site but has its primary crops at any other province (autonomous region or municipality directly under the Central Government), the application shall be accepted and the production license shall be issued according to law by the agricultural administrative authorities at the production site.

**Article 7** An applicant who applies for a seed production license shall meet the requirements as follows:

- (1) It shall have the registration capital of no less than RMB 30 million for the application of a seed production license for hybrid rice seed, hybrid corn seed and their parental seeds; and have the registration capital of no less than RMB 5 million for the application of a seed production license for other primary crops;
- (2) The produced variety shall have passed the variety registration; the production of seeds with new plant variety right shall also have obtained the written consent of the variety owner;
- (3) It shall have at least one set of purity analysis desk, electronic scale, counting and planting equipment, electrophoresis system, electrophoresis tank, sample muller, oven, bio-microscope and refrigerator respectively in good conditions, at least one set of electronic balance (reciprocal sensibility 1/100, 1/1000 and 1/10000), and at least two sets of sampling devices, sample distributors and germination boxes respectively; for the application of a hybrid rice or hybrid corn seed production license, the applicant shall have at least one set of PCR amplification instrument, pH meter, high-pressure sterilizing pot, magnetic stirring apparatus, constant temperature water bath, high-speed refrigerated centrifuge and complete pipette respectively;
- (4) It shall have a laboratory of more than 100m<sup>2</sup>; for the application of a seed production license for hybrid rice seed, hybrid corn seed and their parental seeds, the applicant shall have a laboratory of more than 150m<sup>2</sup>;
- (5) It shall have a warehouse of more than 500m<sup>2</sup>, a drying yard of more than 1,000m<sup>2</sup>, or an equivalent seed dryer or equipment;
- (6) It shall employ at least three full-time seed production technicians, storage technicians, and seed inspectors (covering farm test, sampling and indoor test similarly hereinafter) who have successfully passed an exam by the agricultural administrative authorities of the people’s government at the provincial or higher level respectively; moreover, for the production of hybrid rice seed, hybrid corn seed and their parental seeds, the applicant shall employ at least five seed production technicians and seed inspectors respectively;
- (7) It has no harmful quarantine organism at the production site;

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<sup>1</sup> According to Seed Law of China, primary crops refer to rice, wheat, corn, soybean, cotton. The Seed Law also authorizes the Ministry of Agriculture and provincial agricultural authorities to further add one to two local primary crops to the definition. For example, the Ministry of Agriculture has also added rapeseed and potato as primary crops.

(8) It shall comply with the separation and production conditions required by the good seed production practices; and

(9) Other requirements prescribed by the Ministry of Agriculture.

**Article 8** An applicant who applies for the seed production license shall submit the following materials:

(1) A crop seed production license application form;

(2) The photocopy of the capital verification report or the certificate of registered capital, such as the annual accounting statements and the audit report issued by the intermediary within one year prior to the date of application; a list of seed inspection equipment and other equipments, and photocopy of purchase invoices thereof; photocopy of the property certificate of the seed laboratory and warehouse in the province (autonomous region or municipality directly under the Central Government) at the production site; photocopy of the certificate of title (or lease agreement) of the drying yard in the province (autonomous region or municipality directly under the Central Government) at the production site; or photocopy of the certificate of title of the seed dryer and equipment; photocopy of the testing certificate of the inspection equipment involving the measurement issued by the measurement testing institution; and description and field photos of the relevant facilities and equipment;

(3) Photocopy of qualification certificates and labor contracts of the seed production, storage and inspection technicians;

(4) Quarantine certificate of the seed production site;

(5) Photocopy of variety registration certificate;

(6) For the production of any seed with a new plant variety right, the written consent of the variety right holder is required;

(7) Description of the safety separation and production conditions for seed production; and

(8) Other materials required by the Ministry of Agriculture.

Where the applicant of a seed production license has obtained a seed business license of the corresponding crop, the applicant shall be exempted from submitting the materials required in the preceding Paragraph (2) as well as the photocopy of qualification certificates and labor contracts of the seed storage and inspection technicians, but the photocopy of the seed business license is required.

**Article 9** The examining authority shall complete the examination within 20 working days after accepting the application. During the examination, the examining authority shall conduct a field survey on the production site, drying yard, drying facilities and equipments, storage facilities, inspection facilities and equipments, and shall examine the relevant certificates and materials (only conduct a field survey on the production site if the applicant has obtained the seed business license of the corresponding crops). If all requirements prescribed herein are satisfied, the examining authority shall sign an examining opinion and submit it to the issuing authority; if the examination is not passed, it shall give a written notice to the applicant explaining reasons.

The issuing authority shall complete the issuance within 20 working days after receiving the examining opinion and the application materials. If the issuing authority considers it necessary, it may conduct a field survey. If all requirements prescribed herein are satisfied, it shall issue a seed production license and make an official announcement; otherwise, it shall give a written notice to the applicant explaining reasons.

**Article 10** The seed production license shall indicate the license number, name, domicile, legal representative and registered capital of the license holder, the name of issuing authority, announcement number, date of issuance, as well as the varieties of crop seeds produced, variety name, registration number, new plant variety right code, production site and valid term of

the license etc.

The license number shall be in the format of “\_\_ (X) Nong Zhong Sheng Xu Zi (X) No.X”. Here, the content in the first bracket shall be the abbreviation of the issuing authority; the second bracket shall be the year of first issuance; the third number shall be the serial number in four digits; “\_\_” shall be filled in with the type of the crop seed produced, of which, b represents hybrid rice seeds, hybrid corn seeds and their parental seeds, and c represents other primary crop seeds.

**Article 11** The valid term of a seed production license is three years. During the valid term of the seed production license, if the same license holder submits an application to the same issuing authority for any additional variety of similar crops, the issuing authority shall add the new plant variety on the original license and will not issue a separate seed production license.

Upon expiration of a seed production license, if the seed producer intends to apply for a new license with the same issuing authority, it shall submit a new application at least 70 days prior to the expiration of the seed production license.

### **CHAPTER III BUSINESS LICENSE**

**Article 12** A crop seed business license (hereinafter referred to as “**Seed Business license**”) shall be lawfully obtained for the operation of crop seeds.

A business license of primary crop hybrid seeds and their parental seeds, as well as the foundation seeds of conventional varieties, shall be examined by the agricultural administrative authorities of the people’s government at the county level of the production site and be issued by agricultural administrative authorities of the people’s government at the provincial level.

The following seed business licenses shall be examined by the agricultural administrative authorities of the people’s government at the provincial level of the domicile of the seed operator and shall be issued by the Ministry of Agriculture:

- (1) The seed business license to be held by a company, who engages in the business of seeds importing and exporting; and
- (2) The seed business license to be held by a company, who carries out the integrated businesses of breeding, production and operation and has the registered capital of more than RMB 100 million.

A seed business license for other crops shall be issued by the agricultural administrative authorities of the people’s government at the county or higher level of the domicile of the seed operator.

**Article 13** An applicant who applies for a seed business license of the hybrid rice seed, hybrid corn seed and their parental seeds shall meet the following requirements:

- (1) It shall have the registered capital of no less than RMB 30 million and have the fixed assets of no less than RMB 10 million;
- (2) It shall have at least one set of purity analysis desk, electronic scale, counting and planting equipment, electrophoresis system, electrophoresis tank, sample muller, oven, bio-microscope and refrigerator respectively in good conditions, at least one set of electronic balance (reciprocal sensibility 1/100, 1/1000 and 1/10000), at least two sets of sampling devices, sample distributors and germination boxes respectively, at least one set of PCR amplification instrument, pH meter, high-pressure sterilizing pot, magnetic stirring apparatus, constant temperature water bath, high-speed refrigerated centrifuge and complete pipette respectively, and have a laboratory of more than 150m<sup>2</sup>;
- (3) It shall have the seed warehouse, drying yard or other appropriate drying facilities and equipments meeting the requirements prescribed in Paragraph (5) of Article 7 above, and have a business office of more than 300m<sup>2</sup>;
- (4) It shall have the whole-set seed processing equipment with total processing capacity of no less than 10 t/h for hybrid corn

seeds, 5 t/h for hybrid rice seeds, and a processing workshop of more than 500m<sup>2</sup>;

(5) It shall have at least five full-time seed processing technicians, at least three full-time seed storage technicians, and at least five seed inspectors who have passed the exam of the agricultural administrative authorities of the people's government at the provincial or higher level; and

(6) Other requirements prescribed by the Ministry of Agriculture.

**Article 14** An applicant who applies for a seed business license of the crop seeds other than the hybrid rice seed, hybrid corn seed and their parental seeds, if such crop seeds shall be processed and packed, shall meet the following requirements:

(1) For a primary crop seed business license, it shall have the registered capital of no less than RMB 5 million and the fixed assets of no less than RMB 2.5 million; for the non-primary crop seed business license, it shall have the registered capital of no less than RMB 2 million and the fixed assets of no less than RMB 1 million;

(2) It shall have at least one set of purity analysis desk, electronic scale, counting and planting equipment, electrophoresis system, electrophoresis tank, sample miller, oven, bio-microscope and refrigerator respectively in good conditions, at least one set of electronic balance (reciprocal sensibility 1/100, 1/1000 and 1/10000), at least two sets of sampling devices, sample distributors and germination boxes respectively, and have a laboratory of more than 100m<sup>2</sup>;

(3) For the operation of primary crop seeds, it shall have the seed warehouse, drying yard or other appropriate drying facilities and equipments meeting the requirements prescribed in Paragraph (5) of Article 7 above, and have a business office of more than 200m<sup>2</sup>; for the operation of non-primary crop seeds, it shall have a seed warehouse of more than 300m<sup>2</sup>, a drying yard of more than 500m<sup>2</sup> or other appropriate dryers and equipments, and have a business office of more than 200m<sup>2</sup>;

(4) For the operation of conventional rice and wheat seeds, it shall have the whole-set seed processing equipment with the processing capacity of 10 t/h or higher; for operation of soybean seeds, it shall have the whole-set seed processing equipment with the processing capacity of 3 t/h or higher; for operation of cotton seeds or canola seeds, it shall have the whole-set seed processing equipment with the processing capacity of 1 t/h or higher; for operation of other crop seeds, it shall have the appropriate seed processing equipment;

(5) For operation of primary crop seeds, it shall have a seed processing workshop of more than 500m<sup>2</sup>; for operation of non-primary crop seeds, it shall have a seed processing workshop of more than 200m<sup>2</sup>; and

(6) It shall have at least three full-time seed processing technicians, three full-time seed storage technicians, and three seed inspectors who have passed the exam of the agricultural administrative authorities of the people's government at the provincial or higher level.

For application of a crop seed business license without requirement of processing and packaging as prescribed by the Ministry of Agriculture, the registered capital and fixed assets of the applicant shall meet the requirements prescribed in Paragraph (1) of Article 14 above, and the specific requirements regarding seed inspection, storage facilities and equipments and personnel shall be prescribed by the agricultural administrative authorities of the people's government at the provincial level and be reported to the Ministry of Agriculture for filing.

**Article 15** A company who engages in the businesses of importing and exporting seeds and applies for a seed business license shall meet the following requirements:

(1) It shall have the registered capital of no less than RMB 30 million and have the fixed assets of no less than RMB 10 million;

(2) Other requirements for issuance of the corresponding crop seed business license provided for herein.

**Article 16** A company who carries out the integrated businesses of breeding, production and operation, has the registered capital of more than RMB 100 million and applies for a seed business license shall meet the following requirements:

- (1) It shall have the fixed assets of no less than RMB 50 million;
- (2) It shall have at least two sets of purity analysis desk, electronic scale, counting and planting equipment, electrophoresis system, electrophoresis tank, sample muller, oven, bio-microscope and refrigerator respectively in good conditions, at least two sets of electronic balance (reciprocal sensibility 1/100, 1/1000 and 1/10000), at least three sets of sampling devices, sample distributors and germination boxes respectively, at least two sets of PCR amplification instrument, pH meter, high-pressure sterilizing pot, magnetic stirring apparatus, constant temperature water bath, high-speed refrigerated centrifuge and complete pipette respectively, and have a laboratory of more than 200m<sup>2</sup>;
- (3) For the operation of primary crop seeds, it shall have a seed warehouse of more than 1,500m<sup>2</sup>, a drying yard of more than 3,000m<sup>2</sup> or other drying facilities and equipments, and have a business office of more than 500m<sup>2</sup>; for the operation of non-primary crop seeds, it shall have a seed warehouse of more than 300m<sup>2</sup>, a drying yard of more than 500m<sup>2</sup> or other drying facilities and equipments, and have a business office of more than 300m<sup>2</sup>;
- (4) For the operation of hybrid rice seeds, hybrid corn seeds and their parental seeds, it shall have the seed dryer and equipment matching its seed operation scale, the whole-set processing equipment for hybrid rice seeds and their parental seeds with the total processing capacity of more than 10 t/h, the whole-set processing equipment for hybrid corn seeds and their parental seeds with the total processing capacity of more than 20 t/h and the processing workshop of more than 800m<sup>2</sup>; for the operation of other crop seeds, its processing capacity and processing workshop shall meet the requirements specified in Paragraph (4) and Paragraph (5) of Article 14 above;
- (5) It shall have at least five full-time seed production, processing and storage technicians respectively, and five seed inspectors who have passed the exam of the agricultural administrative authorities of the people's government at the provincial or higher level;
- (6) It shall have a specialized breeding department, full-time breeding personnel and operating budget; the annual R&D spending shall be no less than 10% of the annual profit of the applicant; it shall have an independently owned research lab of more than 300m<sup>2</sup> and a stable breeding land of more than 100 *mu*, of which, it shall have more than three testing places at more than three different ecological zones nationwide respectively and have more than 10 *mu* of testing land and the appropriate sowing, harvesting and testing facilities and equipments in each testing place; it shall have at least five full-time breeding researchers holding the professional qualification of intermediate or higher level (or at the bachelor degree or higher in the relevant subject area); for production and operation of primary crop seeds, it shall have at least one full-time breeding researcher holding the professional qualification of senior level (or at the master degree or higher in the relevant subject area) for each variety of crop;
- (7) It shall have a stable seed production base. Including a base of more than 5,000 *mu* for operation of primary crop seeds, and a base of more than 500 *mu* for operation of other crop seeds.
- (8) It shall have a sound after-sale service system;
- (9) For operation of primary crop seeds, it shall have two or more varieties that have been filed an application in its own name and have passed the national variety registration, or five or more varieties that have been filed an application in its own name and at least three of them have passed the variety registration at the province (or autonomous region or municipality directly under the Central Government) level; for operation of non-primary crop seeds, it shall have five or more varieties that have been granted the new plant variety right in its own name;
- (10) For operation of crop seeds, the business volume of the subject seed shall account for more than 1% of the national market share of such crop seed in more than one year of the three years (excluding the year of application) prior to the date

of application, and the business volume of the varieties in which the applicant has its independent intellectual property right shall account for more than 10% of the applicant's total business volume;

(11) Other requirements prescribed by the Ministry of Agriculture.

**Article 17** An applicant who applies for the seed business license shall submit the following materials:

(1) A crop seed business license application form;

(2) Photocopy of the capital verification report or the certificate of registered capital and fixed assets, such as the annual accounting statements and the audit report issued by the intermediary within one year prior to the date of application; the certificate regarding the basic information of the applicant, such as the business nature and composition of capitals;

(3) A list of seed inspection and processing facilities and equipments, and photocopy of purchase invoices thereof; photocopy of property certificate of the seed laboratory, processing workshop and warehouse; photocopy of the certificate of title (or lease agreement) of the drying yard; or photocopy of the certificate of title of the seed dryer and equipment; photocopy of the testing certificate of the inspection and packaging equipment involving the measurement issued by the measurement testing institution; and description and field photos of the relevant facilities and equipment;

(4) Photocopy of qualification certificates and labor contracts of the seed inspection, processing and storage technicians; and

(5) Other materials required by the Ministry of Agriculture.

**Article 18** When a company engaged in integrated business of breeding, production and operation applies for a crop seed business license to be issued by the Ministry of Agriculture, shall also submit the following materials, in addition to the materials prescribed in Article 17 above:

(1) Description of its breeding department; photocopy of the property certificate and field photos of its own researching and breeding facilities and equipments; photocopy of the transfer agreement with a term of more than five years for the researching, breeding and variety testing lands;

(2) Photocopy of the certificate of professional title (or academic degree ) and the labor contract of its breeding personnel;

(3) Photocopy of the annual accounting statements and the audit reports issued by the intermediary within three years prior to the date of application;

(4) Photocopy of the variety registration certificate or new plant variety right certificate, and the certificate of its independent variety production and operation right; description and relevant certificates of seed business volume, business amount and share on the national market of the subject crop within three years prior to the application date; description and relevant certificate of the business volume and business amount of the variety in which it has independent intellectual property right;

(5) Certificates regarding its seed production bases within three years prior to the application date, including the seed production places (with the detailed name of villages), seed production area, contacts at the base village (or group) and the phone list of the commissioned seed growers, and photocopy of ten seed production contracts, or photocopy of the land transfer agreement;

(6) Certificates of sound after-sale service system, including the description of after-sale service system and construction of after-sale service network;

(7) In case of a renewal application prior to the expiration of the existing seed business license, it shall also submit the certificates regarding the seed production, operation, researching and breeding during the valid term of the existing license.



**Article 19** The examining authority shall complete the examination within 20 working days after accepting the application. The examining authority shall conduct a field survey on the business office, processing and warehousing facilities, inspection facilities and equipments, and examine the originals of the relevant certificates. If all requirements prescribed herein are satisfied, the examining authority shall sign an examining opinion and submit it to the issuing authority; if the examination is not passed, it shall give a written notice to the applicant explaining reasons.

The issuing authority shall complete the issuance within 20 working days after receiving the examining opinion and the application materials. If the issuing authority considers it is necessary, it may conduct a field survey. If all requirements prescribed herein are satisfied, it shall issue a seed business license and make an official announcement; otherwise, it shall give a written notice to the applicant explaining reasons.

**Article 20** The seed business license shall indicate the license number, name, domicile, legal representative and registered capital of the license holder, the name of issuing authority, announcement number, date of issuance, as well as the scope of permitted crops, operation mode, applicable territory and valid term of the license etc.:

(1) The license number shall be in the format of “\_\_ (X) Nong Zhong Jing Xu Zi (X) No.X”. Here, the content in the first bracket shall be the abbreviation of the issuing authority; the second bracket shall be the year of first issuance; the third number shall be the serial number in four digits; “\_\_” shall be filled in with the type of operation, of which, a represents issuance by the Ministry of Agriculture, where the license holder engages in the integrated businesses of breeding, production and operation; b represents hybrid rice seeds, hybrid corn seeds and their parental seeds; c represents primary crop seeds other than hybrid rice seeds and hybrid corn seeds; d represents non-primary crop seed; and e represents seeds importing and exporting businesses;

(2) With respect to the scope of business crop, it shall be filled in with the name of crops in case of primary crops, or indicated as vegetable, flower or bast fiber plant in case of non-primary crops;

(3) With respect to the seed operation mode, it shall be filled in with processing, packaging, wholesale, retailing or import & export;

(4) With respect to the applicable territory, it shall be the actual administrative region, but not beyond the jurisdiction of the issuing authority as determined by the issuing authority.

**Article 21** The valid term of a seed business license is five years. If there is any change to any particular contained in a license during its valid term the license holder shall complete the change procedures same as the original application procedures and shall provide the relevant supporting materials.

If a license holder intends to continue its seed operation after expiration of the seed business license, it shall submit a new application at least six months prior to expiration.

**Article 22** If a seed operator engages in the special business of packed seeds without requirement of further sub-packaging, or is authorized by a seed operator with a valid seed business license in written form to distribute the latter's seeds, it is not required to obtain a seed business license, but it shall have its fixed business office.

If a seed operator engages in the special business of packed seeds without requirement of further sub-packaging, it shall sign a purchase and sale contract with another seed operator with a valid seed business license when it is purchasing the seeds.

If a seed operator is authorized by another seed operator with a valid seed business license to sell the seeds, it shall sign a commission contract with another seed operator.

**Article 23** Before establishment of a branch in the applicable territory defined in the seed business license, the seed operator

shall register the branch with the local competent administration of industry and commerce, and shall file with the local agricultural administrative authorities of the people's government at the county level and the original issuing authority for reference within 15 days upon receipt or change of the business license. For the purpose of file, the seed operator shall submit the photocopy of its seed business license and business license, as well as the certificates regarding the domicile, operation mode, name of responsible person and contact telephone of the branch, etc.

#### **CHAPTER IV SUPERVISION AND MANAGEMENT**

**Article 24** Primary crop seed producers shall organize the production of seeds in accordance with their seed production licenses. Each seed producer shall set up a seed production archive, report information such as production sites, names of varieties and production area to the local agricultural administrative authorities of the people's government at the county level within 30 days after sowing. The agricultural administrative authorities of the people's government at the county level shall summarize the production information and report it to the Ministry of Agriculture level by level.

**Article 25** The seed operator shall set up a seed operation archive, recording the source of seed, brief description of seed processing, storage, transportation and quality inspection, as well as responsible persons and identities of purchasers, etc.

The seed operator shall report the main operation activities in the previous year to the issuing authority before the end of May in each year. The issuing authority shall summarize the seed operation information and report it to the Ministry of Agriculture.

**Article 26** The agricultural administrative authorities of the people's government at the county or higher level shall supervise and inspect the seed production and operation activities carried out by the seed producers and operators.

**Article 27** Upon occurrence of any of the following circumstances during the valid term of a license, the issuing authority shall cancel the license and publicly announce the cancellation:

- (1) Any seed producer or operator have suspended its production or operation activities for more than one year; or
- (2) Any seed producer or operator fails to meet the requirements specified herein, and still fails to meet such requirements after rectification within a prescribed time period.

**Article 28** If an applicant conceals related information or submits falsified materials in applying for a seed production or business license, the agricultural administrative authority shall reject the application and make a notification on related situation. The said applicant may not submit another application for a seed production or business license within one year subsequently.

If an applicant acquires a seed production or business license by improper means, such as fraud or bribery, the agricultural administrative authority shall revoke its license and make a notification on related situation. The said applicant may not submit another application for a seed production or business license within three years subsequently.

**Article 29** The superior agricultural administrative authorities shall supervise and inspect the activities of granting and issuing the seed production and business licenses carried out by the inferior agricultural administrative authorities. Upon occurrence of any of the following circumstances, it shall be ordered to make correction, and the directly responsible persons-in-charge and other directly responsible persons shall be imposed an administrative sanction according to law; where it constitutes a criminal offence, it shall be transferred to the judicial authorities for prosecution of criminal liabilities:

- (1) Any seed production or business license is issued beyond the authority of examining and issuing authority;
- (2) Any seed production or business license is issued as per the lower examining and approving standard without authorization; or

(3) Any seed production or business license is issued illegally.

**Article 30** Where an agricultural administrative authority suspends, revokes or cancels the seed production or business license held by an offender, it shall, within five working days upon its decision, notify the competent administration for industry and commerce to cancel or change the business license of the offender according to law.

**Article 31** The agricultural administrative authorities shall establish an online inquiry system for the management of seed production and business licenses and shall publish the relevant license issuing information, except for the information subject to confidentiality requirement under the laws.

The agricultural administrative authorities and their working personnel shall lawfully keep confidentiality of any and all trade secrets received from the seed producers and operators during the administrative activities hereunder.

## **CHAPTER V SUPPLEMENTARY PROVISIONS**

**Article 32** “Seed Production” referred to herein shall mean the activities relating to planting, harvesting, air drying or stoving of seeds.

“Seed Business” referred to herein shall mean the activities relating to processing and treatment of the produced seeds through conditioning, grading, drying and coating, as well as packaging, labeling and marketing.

**Article 33** “Whole-set Seed Processing Equipment” referred to herein shall mean the seed processing system, in which the host machine and auxiliary system are compatible with each other and installed in a processing workshop to fulfill the flow processes and functions of seed conditioning, measurement and packaging. The host machine mainly includes Air Screen Cleaner (the air separation unit shall be equipped with front and rear suction channels and twin deposition chambers; the screening unit shall be equipped with more than three layers of sieve plates), gravity separator, computerized measuring, packaging and code spraying equipment; and the auxiliary system mainly includes the conveyor system, storage system, duster system, impurity removal system and electric control system. The whole-set processing equipment for hybrid rice seeds shall also include a pocket cylinder separator that can complete separating operation for length. .

“Fixed Assets” referred to herein shall mean the non-monetary assets that are held by enterprises for production of products, rendering of services, leasing or business management and have a service life of more than 12 months, including premises , buildings, machines, machinery, transport vehicles and other equipments, instruments and tools relating to the production and operation activities.

**Article 34** The seed researching, production, processing, inspection and storage personnel referred to herein shall have signed labor contract with their employers for a term of more than three years.

The seed production, processing and inspection facilities and equipments, and the seed laboratory, warehouse, seed drying facilities and equipments referred to herein shall be the properties owned by the applicants respectively.

**Article 35** The measures for the seed production and business license of GM crops shall be otherwise formulated by the Ministry of Agriculture.

**Article 36** With respect to any district (or county or city) which does not have an agricultural administrative authority, all applications for the seed production and business license shall be examined by the agricultural administrative authority of the people’s government at the prefecture (or municipal) level.

**Article 37** The crop seed production and business licenses shall be uniformly printed and the relevant forms shall be uniformly formulated by the Ministry of Agriculture.

**Article 38** These Measures shall be enacted as of September 25, 2011. The *Measures for Administration of Production and Business license of Crop Seeds* (No.48 Decree of the Ministry of Agriculture) promulgated on February 26, 2001 and revised on July 1, 2004 by the Ministry of Agriculture shall be abolished as of enactment date of these Measures. In case of any discrepancies between these Measures and the measures regarding the production and business license of seeds promulgated by the Ministry of Agriculture prior to the enactment of these Measures, these Measures shall prevail.

For license holder whose crop seed production license has been issued prior to the enactment date of these Measures and the valid term of which will expire after the enactment date of these Measures but before April 1, 2012, the valid term of such seed production license shall be automatically extended to April 1, 2012; for license holder whose crop seed business license which has been issued and the valid term of which will expire after the enactment date of these Measures but before September 25, 2012, the valid term of such seed business license shall be automatically extended to September 25, 2012.

## Appendix

### **Regulations on the License of Production and Operation of Genetically Modified Cotton Seed**

**Article 1** To strengthen the license management of GM cotton seed production and operations, in conformity with Seed Law of the People's Republic of China, the Regulations on Safety Management of Agricultural Genetically Modified Organisms (GMO), and the Measures for Administration of Production and Operation License of Crop Seeds, the regulations is formulated.

#### **Article 2**

Production and operation license of GM cotton seed shall be examined by the agricultural administrative authorities of the people's government at the provincial level and be issued by the Ministry of Agriculture.

**Article 3** An applicant who applies for a GM cotton seed production license shall meet the requirements as follows:

- (1) It shall have the registration capital of no less than RMB 30 million;
- (2) The produced variety shall acquire Biosafety Certificate and have passed the variety registration; the production of seeds with new plant variety right shall also have obtained the written consent of the variety owner;
- (3) It shall have at least one set of purity analysis desk, electronic scale, counting and planting equipment, electrophoresis system, electrophoresis tank, sample muller, oven, bio-microscope and refrigerator respectively in good conditions, at least

one set of electronic balance (reciprocal sensibility 1/100, 1/1000 and 1/10000), and at least two sets of sampling devices, sample distributors and germination boxes respectively; at least one set of PCR amplification instrument, pH meter, high-pressure sterilizing pot, magnetic stirring apparatus, constant temperature water bath, high-speed refrigerated centrifuge, complete pipette, enzyme labeling instrument, plate washer, and imaging system respectively; testing room should be more than 150m<sup>2</sup>;

(4) It shall have a warehouse of more than 500m<sup>2</sup>, a drying yard of more than 1,000m<sup>2</sup>, or an equivalent seed dryer or equipment;

(5) It shall employ at least three full-time seed production technicians, storage technicians, and seed inspectors who have successfully passed an exam by the agricultural administrative authorities of the people's government at the provincial or higher level respectively; at least one full-time manager of agricultural GMO safety;

(6) Production site should be within the regions approved by Agricultural Biosafety Certificate; and no harmful quarantine organism;

(7) It shall comply with the separation and production conditions required by the cotton seed production practices and GM cotton seed production safety;

(8) It shall have relevant agricultural GMO safety management and prevention measures;

(9) Other requirements prescribed by the Ministry of Agriculture.

**Article 4** An applicant who applies for GM cotton seed production license shall submit the following materials:

(1) A GM cotton seed production license application form;

(2) The photocopy of the capital verification report or the certificate of registered capital, such as the annual accounting statements and the audit report issued by the intermediary within one year prior to the date of application; a list of seed inspection equipment and other equipments, and photocopy of purchase invoices thereof; photocopy of the property certificate of the seed laboratory and warehouse in the province (autonomous region or municipality directly under the Central Government) at the production site; photocopy of the certificate of title (or lease agreement) of the drying yard in the province (autonomous region or municipality directly under the Central Government) at the production site; or photocopy of the certificate of title of the seed dryer and equipment; photocopy of the testing certificate of the inspection equipment involving the measurement issued by the measurement testing institution; and description and field photos of the relevant facilities and equipment;

(3) Photocopy of qualification certificates and labor contracts of the seed production, storage and inspection technicians; Description and photocopy of labor contract of the manager of agricultural GMO safety.

(4) Quarantine certificate of the seed production site;

(5) Photocopy of variety registration certificate;

(6) For the production of seed with a new plant variety right, the written consent of the variety right holder is required;

(7) Description of the safety separation and production conditions for seed production; and

(8) Photocopy of Biosafety Certificate;

(9) Descriptions on management and prevention measures of agricultural GMO safety.

(10) Other materials required by the Ministry of Agriculture.

Where the applicant of a GM cotton seed production license has obtained a GM cotton seed operation license, the applicant shall be exempted from submitting the materials required in the preceding Paragraph (2) as well as the photocopy of qualification certificates and labor contracts of the seed storage and inspection technicians, but the photocopy of GM cotton seed business license is required.

**Article 5** An applicant who applies for a seed operation license of GM cotton seed, shall meet the following requirements:

(1) It shall have the registered capital of no less than RMB 30 million and have the fixed assets of no less than RMB 10 million;

(2) The produced variety shall acquire Biosafety Certificate and have passed the variety registration; the production of seeds with new plant variety right shall also have obtained the written consent of the variety owner;

(3) It shall have the seed testing facilities and equipments, warehouse, drying yard or other appropriate drying facilities and equipments meeting the requirements prescribed in Paragraph (3) and (4) of Article 3 above; a business office of more than 300m<sup>2</sup>; whole-set seed processing equipments with total processing capacity over 1 ton/hour; equipments for chemical delinting of cotton seed; processing workshop of more than 500 m<sup>2</sup>.

(4) It shall employ at least three full-time seed production technicians, storage technicians, and seed inspectors who have successfully passed an exam by the agricultural administrative authorities of the people's government at the provincial or higher level respectively; at least one full-time manager of agricultural GMO safety;

- (5) It shall have relevant agricultural GMO safety management and prevention measures;
- (6) Business site should be within the regions approved by Agricultural Biosafety Certificate;
- (7) Other requirements prescribed by the Ministry of Agriculture.

**Article 6** An applicant who applies for GM cotton seed operation license shall submit the following materials:

- (1) A GM cotton crop seed operation license application form;
- (2) Photocopy of the capital verification report or the certificate of registered capital and fixed assets, such as the annual accounting statements and the audit report issued by the intermediary within one year prior to the date of application; the certificate regarding the basic information of the applicant, such as the business nature and composition of capitals;
- (3) A list of seed inspection and processing facilities and equipments, and photocopy of purchase invoices thereof; photocopy of property certificate of the seed laboratory, processing workshop and warehouse; photocopy of the certificate of title (or lease agreement) of the drying yard; or photocopy of the certificate of title of the seed dryer and equipment; photocopy of the testing certificate of the inspection and packaging equipment involving the measurement issued by the measurement testing institution; and description and field photos of the relevant facilities and equipment;
- (4) Photocopy of qualification certificates and labor contracts of the seed inspection, processing and storage technicians; Description and photocopy of labor contract of the full-time manager of agricultural GMO safety.
- (5) Photocopy of variety registration certificate and biosafety certificate; For the operation of GM cotton seed with a new plant variety right, the written consent of the variety right holder is required;
- (6) Descriptions on management and prevention measures of agricultural GMO safety.
- (7) Other materials required by the Ministry of Agriculture.

**Article 7** The examining authority shall complete the examination within 20 working days after accepting the application, sign the examination result and report to the issuing authority. The examining authority shall conduct a field survey on the business office, processing and warehousing facilities, inspection facilities and equipments, and examine the originals of the relevant certificates.

The issuing authority shall complete the issuance within 20 working days after receiving the examining opinion and the application materials. If the issuing authority considers it is necessary, it may conduct a field survey. If all requirements prescribed herein are satisfied, it shall issue a GM cotton seed production/operation license and make an official announcement; otherwise, it shall give a written notice to the applicant explaining reasons.

**Article 8** GM cotton seed production license number shall be in the format of “\_\_ (X) Nong Zhong Sheng Xu Zi (X) No. X”. Here, “\_\_” shall be filled in “G”, the content in the first bracket shall the abbreviation of the issuing authority; the second bracket shall be the year of first issuance; the third number shall be the serial number in four digits; GM cotton seed operation license number shall be in the format of “\_\_ (X) Nong Zhong Jing Xu Zi (X) No. X”. Here, “\_\_” shall be filled in “G”, the content in the first bracket shall the abbreviation of the issuing authority; the second bracket shall be the year of first issuance; the third number shall be the serial number in four digits;

**Article 9** The valid term of GM cotton seed production license is three years, and operation license is five years. Meanwhile, it cannot exceed the valid term of biosafety certificate.

**Article 10** Other items of GM cotton seed production/operation license shall be implemented according to relevant rules formulated in the Measures for Administration of Production and Operation License of Crop Seeds.

**Article 11** These Regulations shall be enacted as of October 7, 2011. For license holder whose GM cotton seed production/operation license has been issued prior to the enactment date of these Regulations and the valid term of which will expire after the enactment date of these Regulations but before October 7, 2012, the valid term of such licenses shall be automatically extended to October 7, 2012; however, if its biosafety certificate will expire before October 7, 2012, the valid term of GM cotton seed production/operation license will be subject to the valid term of biosafety certificate.

