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Draft Measures for Major Crops Seed Variety Registration

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Report Highlights:

On February 27, 2013, the Ministry of Agriculture of China (MOA) released the Draft Administrative Measures for Major Crop Seed Variety Registration for public comment. These Measures have not been notified to the World Trade Organization. The deadline for comment is March 31, 2013. This report provides an UNOFFICIAL translation of the draft measures.

General Information:

Executive Summary

On February 27, 2013, the Ministry of Agriculture of China (MOA) released the Draft Administrative Measures for Major Crop Seed Variety Registration for public comment. These Measures have not been notified to the World Trade Organization. The deadline for providing public comment is March 31, 2013. This report provides an UNOFFICIAL translation of the draft measures. Based on an initial review of the document, major changes from the 2001 measures entitled “Measures for Major Crop Variety Registration”

((Chinese text available at: http://www.scagri.gov.cn/zwgk/zcfg/gzgd/200807/t20080718_822.html) (no FAS GAIN report available)), as well as significant updates include:

1. Varieties will be tested in the same ecological zones at multiple locations for 2 years. Rice, wheat, corn, cotton, soybean, rape and potato seeds are subject to national or provincial variety registration.
2. Distinctness, Uniformity, and Stability (DUS) testing is required in addition to regional and production testing.
3. A process to withdraw varieties is required if conditions merit removal. However, the document does not clearly state the circumstances for determining when varieties do not meet certain requirements, or the responsible entity that identifies or reports these varieties to relevant authorities. The withdrawal process was not included in the previous measures.
4. Integrated seed enterprises (e.g. breeding, production, and marketing) that are certified by MOA can individually undertake regional and production testing for variety registration. However, the document provides no information on how an integrated operation, foreign or domestic, obtains MOA certification.

Comments can be addressed to:

Seed Administration Bureau
Ministry of Agriculture

Comments can be sent by email (zzjpzglc@agri.gov.cn) or fax ((86 10) 5919-2777).

BEGIN TRANSLATION

Administrative Measures for Major Crops Seed Variety Registration
(Draft for public comments)

Chapter I - General Provisions

Article 1. The Measure is formulated based on the Article 15 of the "Seed Law of the People's Republic of China (hereinafter referred to as the "Seed Law") to scientifically, impartially, and timely approve major crop varieties.

Article 2. The Measure applies to the major crop variety registrations in China.

Article 3. The term "major crops" used in the Measure refers to the crops specified in the Article 74-(1)-3 of Seed Law.

Chapter II - Variety Registration Committee

Article 4. Established by the Ministry of Agriculture, the National Variety Registration Committee is responsible for national crop variety registrations. Established by provincial agricultural administrative departments, the Provincial Variety Registration Committees are responsible for provincial crop variety registrations.

Article 5. Variety Registration Committee consists of professionals specialized in research, teaching, producing, marketing, management, and application, etc. The members should have senior professional titles or positions at division director level and above, generally below 55 years of age, for a term of five years.

Variety Registration Committee is supposed to have one Director and 2-5 Deputy Directors.

Article 6. Variety Registration Committee sets up an office, which is responsible for daily work of the Variety Registration Committee. The office is supposed to have one Director and 1-2 Deputy Directors.

Article 7. Special Committees by different crops shall be established under Variety Registration Committee. The Special Committee consists of 17-23 members with one Director and 1-2 Deputy Directors.

Article 8. Variety Registration Committee shall set up Director Committee, consisting of the Director and Deputy Directors of Variety Registration Committee, Directors of each Special Committees and the Director of the office.

Chapter III - Application and Acceptance

Article 9. The agents and individuals (hereinafter refers as the applicants), who apply for variety registration, can apply directly to National Variety Registration Committee or Provincial Variety Registration Committees.

The foreigners, foreign enterprises or other organizations with no habitual residence or place of business in China should entrust the agents with legal personality of the seed research, production, or operation if they want to apply for Variety Registrations in China.

Article 10. Rice, wheat, corn, cotton, soybean, rape and potato are subject to national or provincial variety registration. The applicants may apply for national and/or provincial registration, or apply to several provinces (autonomous regions and municipalities directly under the Central Government) for variety registration.

The major crop varieties determined by the provincial agricultural administrative departments apply to provincial approval.

The crop varieties introduced from abroad and genetically modified crop varieties shall follow the relevant provisions of the State Council.

Article 11. The varieties applying for registration should meet the following requirements:

- (1) Artificially bred/discovered and improved;

- (2) Distinct from existing varieties (registered varieties or varieties whose application have been accepted by the peer Crop Variety Registration Committee);
- (3) Stable genetic traits;
- (4) Consistent morphological and biological characteristics;
- (5) A name complying with “Rules on Naming Agricultural Plant Varieties”;
- (6) A two-years and multi-locations variety comparison trials shall be completed in the same type of ecological zones. For rice, wheat and corn varieties applying for national variety registration, it requires no less than 20 testing sites per year for comparison trials; For cotton, soybean, rape, potato varieties applying for national variety registrations, it requires no less than 10 testing sites per year for comparison trials, or more than two provincial testing reports. For rice, wheat and corn varieties applying for provincial variety registrations, it requires no less than 10 testing sites per year for comparison trials; for cotton, soybean, rape, potato and the provincially-determined major crop varieties applying for provincial variety registrations, it requires no less than 5 testing sites per year for comparison trials.

All applications from the applicant would be rejected in three years if the applicant has any deception, bribery or other improper behavior during the application process.

Article 12. Applicants applying for variety registration shall submit the following documents to the office of Variety Registration Committee:

- 1) Application Form. The Application Form includes crop species and variety name (with a written guarantee that the applied variety name is consistent with the name used for New Plant Variety Right and Safety Assessment of Agricultural Genetically-Modified Organisms); applicant name, address, post code, contact, phone number, fax, nationality; agents or individuals responsible for variety breeding (hereinafter referred to as “breeders”);
- 2) Variety Breeding Report. The report includes the combination of parent lines and the parental relationship of the hybrids, breeding method, characterization of generations; the trait characterization of varieties (including the parent lines of hybrids), standard images, proposed testing area and key points of cultivation; main defects of the variety and the problems that should be paid attention to;
- 3) Variety Comparison Trial Report. The report includes test purpose, test varieties, test design, implementation agent, resistance identification, quality analysis, yield result, as well as the data of each test site and summarized result;
- 4) Letter of Commitment for the Authenticity of Variety and Application Material;
- 5) Test Report of GMO Detection. Genetically modified variety shall also provide Ag-GMO Biosafety Certificates.

Article 13. Within 60 days after receiving the application, the office of Variety Registration Committee shall make the decision to accept the application or not, and inform the applicants.

For those applications compliant with Article 11 and 12 of this Measure, the applications should be accepted and the applicants should be informed to provide test seeds within 30 days. The office shall arrange variety testing for those who provide test seeds; while the application shall be deemed as withdraw for those who fail to provide test seeds in time.

For those applications incompliant with Article 11 or 12 of this Measure, the applications should be rejected. Within 60 days after receiving the notice, the applicants may present their opinions or do amendment; while the application shall be deemed as withdraw for those who fail to reply in time. The applications shall be rejected if they are still incompliant with related articles after amending.

Article 14. The office of Variety Registration Committee should reserve the reference sample from the test seeds provided by applicants, and submit to MOA-assigned institute for storage.

Chapter IV – Variety Trials

Article 15. Variety trials include DUS testing, regional testing and production testing. The trials of GMO varieties should be implemented within the safe planting area specified by Ag-GMO Biosafety Certificate.

Article 16. DUS testing shall be conducted by MOA New Plant Variety Test Center; regional testing and production testing at national level shall be implemented by National Agricultural Technology Extension and Service Center; regional test and

production test at provincial level shall be implemented by provincial seed management organization.

Article 17. DUS testing shall identify Distinctness, Uniformity and Stability of the variety.

Synchronization of DUS testing and regional testing follows related crop test guideline.

Article 18. Regional testing is supposed to identify the variety agronomic traits such as yield ability, yield stability, stress tolerance and quality, as well as DNA fingerprint testing and GMO detection.

The regional testing of each variety must be no less than two production cycles, with no less than 3 test replicates; The test sites in the same ecological zone must be no less than 10 for national level and no less than 5 sites for provincial level.

Article 19. The production testing should be implemented in the same ecological zone after the regional test. The production test is supposed to further validate the yield ability, yield stability and stress tolerance of each variety following the local production practice under the condition close to field production.

For each variety, the production testing sites should be no less than the sites for the regional test. The planting area for each test site should be no less than 300 m², no more than 3000 m²; and the test time should be no less than one production cycle.

Article 20. The check variety for regional testing and production testing should be the representative registered variety with same producing period in the same ecological zone. The check variety shall be proposed by the testing implementation institution and approved by Special Committee of Variety Registration Committee. The check variety shall be changed timely based on the agriculture development requirements.

The check variety for provincial regional test and production test shall be reported by provincial Crop Variety Registration Committee to national Crop Variety Registration Committee for the record.

Article 21. The unit undertaking regional test or production test should have independent legal personality with the corresponding test sites, equipment, and technical personnel.

The technician for variety trials should have relevant professional college education or professional titles of intermediate or above, with more than three years work experience in variety trials and regularly receiving related technical training.

The testing institutions assigned by Variety Registration Committee shall be responsible for stress resistance identification, quality analysis, DNA fingerprint test and GMO detection.

Article 22. Along with the office of Variety Registration Committee, the specific implementation institution should regularly organize the investigation of variety trials to examine the trial quality and evaluate the variety performance.

Article 23. The specific implementation institution should hold a wrap-up meeting within 60 days after each production cycle. According to the test summary and investigation result, the Special Committee of Variety Registration Committee decides either to terminate the trial or to continue for registration submission. The office of Variety Registration Committee shall inform applicants the final decision of the variety application.

Article 24. The seed enterprises certified by MOA as “Integration of Breeding-Production-Marketing” may implement the regional testing and production testing of own crop varieties, with testing conditions and standards no lower than national level regional testing and production testing. The specific measures shall be developed by the National Crop Variety Registration Committee.

Chapter V – Registration and Announcement

Article 25. For the variety completing the procedure of DUS testing, regional testing and production testing, the data of each test site and summary result should be submitted to the office of Variety Registration Committee by the specific

implementation institution of variety trial within 60 days, and submitted by the office of Variety Registration Committee to Special Committee of Variety Registration Committee within 30 days for preliminary examination. The Special Committee should complete the preliminary examination within 60 days.

Article 26. During the preliminary examination, each Special Committee should convene a plenary meeting. The meeting is considered as valid if more than $\frac{2}{3}$ of the total members attend the meeting. According to registration criterion, the variety preliminary examination applies with secret ballot. The variety is considered as passed if approval votes achieve $\frac{1}{2}$ and above of the total number of members.

Article 27. The preliminary examination applies with avoidance system. The office of Variety Registration Committee decides the avoidance of the director of Special Committee; and Special Committee decides the avoidance of other members.

Article 28. For the variety that passes the preliminary examination, the review comments of preliminary examination as well as the data of each site and summary result shall be published by the office of Variety Registration Committee on the official website for exposure. The public exposure duration should be more than 15 days.

Article 29. After public exposure, the review comments of preliminary examination as well as exposure result should be submitted by the office of Variety Registration Committee to the Director Committee of Variety Registration Committee for examination. The Director Committee should complete the examination within 30 days. The variety gets the approval if it passes the examination.

Article 30. For the variety with approval, the Variety Registration Committee shall designate an identifier, issue the certificate, and the peer agricultural administrative department shall publish the notice.

For the varieties with provincial approval, the provincial agricultural administrative departments should submit the information such as variety name to MOA for public exposure before the public notice.

Article 31. The registration number consists of abbreviation of approval committee, abbreviation of crop species, the year and series number, wherein the series number is three-digit.

Article 32. The public notice includes: registration number, variety name, applicants, breeders, variety history, morphological characteristic, growth stage, yield, quality, resistance to stress, key points of cultivation techniques, suitable planting area and notes.

The provincial Variety Registration Committee should report to the National Crop Variety Registration Committee for the record within 30 days of public notice.

The published variety name in the public notice should be the common name of the variety, which is not allowed with unauthorized alterations during the process of production, operation and marketing.

Article 33. The registration certificate includes registration number, variety name, applicants, breeder, variety history, registration comments, public notice number and certificate number.

Article 34. For the variety that fails to pass the registration, the office of Variety Registration Committee shall inform the applicant within 30 days. The applicant may apply to the same Variety Registration Committee for re-examination within 30 days of receipt of the notification date. Variety Registration Committee should review the re-examination reason, previous registration document and previous registration procedure during the following registration meeting. Variety Registration Committee may arrange another production cycle of variety trial if necessary, and inform the applicant of the review result.

Article 35. The variety registration standard of rice, wheat, corn, cotton, soybean, rape and potato shall be established by National Crop Variety Registration Committee. The variety registration standard of major crops determined by provincial agricultural administrative department shall be established by provincial Crop Variety Registration Committee and reported to National Crop Variety Registration Committee for the record.

Chapter VI – Variety Withdraw

Article 36. The varieties that have passed registration should exit the market if the following situation occurs during production:

- (1) Serious flaws found in the application;
- (2) Severely degradation of variety characters;
- (3) Agronomic traits such as yield ability, stress resistance and characters cannot be applicable for the needs of agriculture production.

Article 37. For the variety that is proposed to withdraw, the office of Variety Registration Committee shall make the proposal. After preliminary examination by Special Committee, the result shall be published on the official website of the peer agricultural administrative department. The exposure duration should be more than 15 days.

After public exposure, the review comments and exposure results should be submitted by the office of Variety Registration Committee to the Director Committee of Variety Registration Committee for review. The Director Committee should finish the review within 30 days. After getting the permission, the variety shall be announced to exit the market by the peer agricultural administrative department.

For the variety announced to withdraw the production should be stopped from the publish date of announcement, and the operation and marketing should be stopped within one production cycle from the publish date of announcement. Variety Registration Committee may decide to stop operation and marketing from the publish date of announcement if necessary.

The provincial Crop Variety Registration Committee should report to the National Variety Registration Committee for the record within 30 days after publishing the announcement.

Chapter VII – Supervision and Administration

Article 38. The personnel related to variety trial and administrative management may not take the advantage of the position convenience to provide the seeds applying for variety registration or seek illegal interests.

Article 39. The commitment institution practicing fraud should be cancelled the qualification of variety trial, and shall be investigated for the administrative responsibility of the units or individuals who are responsible. The responsible units or individuals shall make corresponding compensations if result losses, or be held criminally responsible if constitute a crime.

Article 40. The personnel of test trial and registration administration who practices fraud, favoritism, abuse of authority, or dereliction of duty shall be given administrative sanctions; or be held criminally responsible if constitute a crime.

Article 41. The units and individuals who make significant achievements in variety trials and variety validation shall be awarded by agricultural administrative department in accordance with the relevant provisions.

Chapter VIII – Supplementary Provisions

Article 42. The major crop variety that passes provincial registration may be introduced to the same appropriate ecological zones of neighboring provinces, autonomous regions, municipalities directly under the Central People's Government after getting the permission of respective agriculture and forestry administrative departments. However, firstly, the introduction test should be carried out in accordance with the “Agricultural Technology Promotion Act - People's Republic of China” to demonstrate that their applicability.

Article 43. The work funding and variety test funding required by crop variety registration shall be included in the special fiscal budget of the peer agricultural administrative department.

Article 44. The variety test of silkworm variety registration is with reference to the implementation of this measure.

Article 45. This measure would be effective from the date XXXX. At the same time the “the Administrative Measure of Major Crop Variety Registration” issued by MOA Decree No. 44 on February 26, 2001 and revised by MOA Decree No. 6

on November 8, 2007 should be abolished.

For those provisions of provincial crop variety registration that are inconsistent with this measure, this measure shall prevail.

END TRANSLATION