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A Collection of MOA Regulations on Ag GMO Approvals

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Report Highlights:

On May 22, 2013, the Ministry of Agriculture released a notice containing seven regulations for review of agricultural GMO-related applications. These regulations clarify steps MOA will take in reviewing of agricultural GMO-related applications for entry of GMO materials, safety certificates, labeling, etc., and set time needed for each step. Together with the Working Rules of the Committee for Safety of Agricultural Genetically Modified Organisms issued a day later, these regulations for the first time put procedure of GMO-related application review work on paper, which is a signal that MOA is trying to standardize its approval work.

This Report provides unofficial translation of the seven regulations in the Notice.

General Information:

BEGIN TRANSLATION

Regulations for Review of Applications for Entry of Agricultural GMO Materials

The Regulations were formulated, in accordance with the “Administrative Licensing Law of the People’s Republic of China,” “Regulations on Administration of Agricultural Genetically Modified Organisms Safety,” “Administrative Measures for Safety Evaluation of Agricultural GMOs” and “Administrative Measures for the Safety of Agricultural GMO Imports,” to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture’s Administrative Review Office accepts dossier

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the application form;
- 2) Examine validity and completeness of the dossier.

2. Procedure

MOA’s Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to applicants that pass examination, which will be sent to MOA’s Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to applicants that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two workdays.

II. Initial examination by MOA's Science and Technology Development Center

1. Content review

- 1) Examine validity of the dossier;
- 2) Examine whether the dossier meets provisions and requirements provided in the "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Regulations on Administration of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports";
- 3) Examine whether the dossier complies with the provisions and requirements in safety evaluation guidelines, such as the "Guidance for Safety Evaluation of Transgenic Plants," and the "Guidance for Safety Evaluation of the Genetically Modified Microorganisms for Animal Use";
- 4) Examine qualification of the applicant pursuant to relevant requirements.

2. Procedure

The Science and Technology Development Center, MOA's Department of Science, Technology and Education, and some members of the Agricultural BioSafety Committee (hereinafter referred to as "the BioSafety Committee") will jointly conduct initial examination of the dossier. The Science and Technology Development Center will submit dossiers that passed the initial examination to the BioSafety Committee for examination. Meanwhile, the Science and Technology Development Center shall prepare for technical examination by the BioSafety Committee.

3. Time limit

One month.

III. Safety review by the BioSafety Committee

1. Content review

- 1) Molecular characteristics of agricultural GMOs;
- 2) Environmental safety of agricultural GMO;
- 3) Food safety of agricultural GMO;
- 4) Relevant studies already carried out abroad (in foreign countries), certifications of approval, and other materials on the agricultural GMOs to be introduced.

2. Procedure

The BioSafety Committee conducts the technical examination on the dossier and drafts examination opinion; the opinion shall be submitted to MOA's Department of Science, Technology and Education.

3. Time limit

Two months.

IV. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine whether the procedure for technical examination is valid and meets standards;
- 3) Examine whether the materials and opinions developed in the technical examination are complete and accurate and meets standards;
- 4) Opinion of the BioSafety Committee's verification review;
- 5) Examine whether information in the official written replies is the same as shown in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education will:

- Produce or submit examination opinion;
- Prepare reports for signature;
- Send the reports to relevant competent departments (bureaus) for signature;
- Submit the reports to MOA for minister signature following procedures;
- (If obtains approval by ministry leaders), develop responses and deliver the responses to MOA's Administrative Review Office.

3. Time limit

Three months plus fifteen workdays.

V. The Administrative Review Office Completes Review Work

1. Content review

- 1) Compare decisions made in review and ministry leader opinions;
- 2) Examine whether the reasons given to denied applications are accurate;
- 3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue official written response or notification of (application) completion to the applicants as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three workdays.

VI. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall publish the examination result on MOA's official website.

VII. Filing of documents

MOA's Department of Science, Technology and Education files MOA internal reports for signature and opinions by the BioSafety Committee; MOA's Science and Technology Development Center files materials (including dossiers) used in the process of examination; the retention period of files shall comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued during the year, and keeps them for reference for one year.

Regulations for Review of Applications for Agricultural GMO Safety Certificate (Imports) Submitted for the First Time by Foreign Developers

The Regulations were formulated, in accordance with the "Administrative Licensing Law of the People's Republic of China," "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports," to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture's Administrative Review Office accepts dossier

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the

application form;

2) Examine validity and completeness of the dossier.

2. Procedure

The Ministry of Agriculture's Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to applicants that pass examination, which will be sent to MOA's Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to applicants that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two workdays.

II. Initial examination by MOA's Science and Technology Development Center

1. Content review

1) Examine validity of the dossier;

2) Examine whether the dossier meets provisions and requirements provided in the "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports";

3) Examine whether the dossier complies with the provisions and requirements in safety evaluation guidelines, such as the "Guidance for Safety Evaluation of Transgenic Plants," and the "Guidance for Safety Evaluation of the Genetically Modified Microorganisms for Animal Use";

4) Examine qualification of the applicant pursuant to relevant requirements.

2. Procedure

The Science and Technology Development Center, MOA's Department of Science, Technology and Education, and some members of the Agricultural BioSafety Committee (hereinafter referred to as "the BioSafety Committee") will jointly conduct initial examination of the dossier. The Science and Technology Development Center will submit dossiers that passed the initial examination to the BioSafety Committee for examination. Meanwhile, the Science and Technology Development Center shall prepare for technical examination by the BioSafety Committee.

3. Time limit

One month.

III. Safety review by the BioSafety Committee

1. Content review

- 1) Molecular characteristics of agricultural GMOs;
- 2) Environmental safety of agricultural GMO;
- 3) Food safety of agricultural GMO;
- 4) Relevant studies already carried out abroad (in foreign countries), certifications of approval, and other materials on the agricultural GMOs to be introduced.

2. Procedure

The BioSafety Committee conducts the technical examination on the dossier and drafts examination opinion; the opinion shall be submitted to MOA's Department of Science, Technology and Education.

3. Time limit

Two months.

IV. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine whether the procedure for technical examination is valid and meets standards;
- 3) Examine whether the materials and opinions developed in the technical examination are complete and accurate and meets standards;
- 4) Opinion of the BioSafety Committee's verification review;
- 5) Examine whether information in the official written replies is the same as shown in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education then:

- Produce or submit examination opinion;
- Prepare reports for signature;
- Send the reports to relevant competent departments (bureaus) for signature;
- Submits the report to MOA for ministry leader signature following procedures;
- (If obtains approval by ministry leaders), develop responses and deliver the responses to MOA's Administrative Review Office.

3. Time limit

Three months plus fifteen workdays.

V. The Administrative Review Office Completes Review Work

1. Content review

- 1) Compare decisions made in review and ministry leader opinions;
- 2) Examine whether the reasons given to denied applications are accurate;
- 3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue the official written response or notification of (application) completion to the applicant as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three workdays.

VI. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall publish the examination result on MOA's official website.

VII. Filing of documents

MOA's Department of Science, Technology and Education files MOA internal reports for signature and opinions by the BioSafety Committee; MOA's Science and Technology Development Center files materials (including dossiers) used in the process of examination; the retention period of files shall comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued during the year, and keeps them for reference for one year.

Regulations for Review of Applications for Agricultural GMO Safety Certificate (Imports) Submitted By Foreign Traders

The Regulations were formulated, in accordance with the “Administrative Licensing Law of the People’s Republic of China,” “Regulations on Administration of Agricultural Genetically Modified Organisms Safety,” “Administrative Measures for Safety Evaluation of Agricultural GMOs” and “Administrative Measures for the Safety of Agricultural GMO Imports,” to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture’s Administrative Review Office accepts dossier

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the application form;
- 2) Examine validity and completeness of the dossier.

2. Procedure

The Ministry of Agriculture’s Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to applicants that pass examination, which will be sent to MOA’s Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to applicants that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two workdays.

II. Initial examination by MOA’s Science and Technology Development Center

1. Content review

- 1) Characteristics of the GMO.
- 2) Purpose of use and safety in transportation;

- 3) Destination of GMO (transportation).
- 4) Deregulation of the GMO in the country of production and other relevant information.
- 5) Qualification of the applicant pursuant to relevant requirements

2. Procedure

The Science and Technology Development Center conducts initial examination of the dossier, prepare examination opinion, and submit the opinions to MOA's Department of Science, Technology and Education.

3. Time limit

Seven workdays.

III. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine opinion by the Science and Technology Development Center;
- 3) Examine whether information in the response is the same as that in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education submits its review opinions to director general of the Department for signature (who is authorized by the MOA minister to sign the paper), which will be developed to the response document and delivered to MOA's Administrative Review Office.

3. Time limit

Eight workdays.

IV. The Administrative Review Office Completes Review Work

1. Content review

- 1) Compare decisions made in review and ministry leader opinions;
- 2) Examine whether the reasons given to denied applications are accurate;
- 3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue the official written response or notification of (application) completion to the applicant as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three workdays.

V. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall publish the examination result on MOA's official website.

VI. Filing of documents

MOA's Department of Science, Technology and Education files internal reports (of the Department) for signature; MOA's Science and Technology Development Center keeps materials (including dossiers) used in the process of examination; the retention period of files shall comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued

during the year, and keeps them for reference for one year.

Regulations for Issuing Approval Document to Agricultural GMO Labels after Review and Approval Procedures

The Regulations were formulated, in accordance with the “Administrative Licensing Law of the People’s Republic of China,” “Regulations on Administration of Agricultural Genetically Modified Organisms Safety,” “Regulations on Administration of Agricultural Genetically Modified Organisms ,” “Measures for Agricultural GMO Label Management” and “Administrative Measures for the Safety of Agricultural GMO Imports,” to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture’s Administrative Review Office accepts application

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the application form;
- 2) Examine validity and completeness of the application.

2. Procedure

The Ministry of Agriculture’s Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to dossiers that pass examination, which will be sent to MOA’s Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to dossiers that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two workdays.

II. Initial examination by MOA's Science and Technology Development Center

1. Content review

- 1) Characteristics of the GMO.
- 2) Examine whether the content of the label is complete, accurate and standardized.
- 3) Examine whether the label is placed in the appropriate placed following relevant standards.
- 4) The information of entry of GMOs and other relevant materials.
- 5) Qualification of the applicant pursuant to relevant requirements.

2. Procedure

The Science and Technology Development Center conducts initial examination on the application, prepare examination opinion, and submit the opinions to MOA's Department of Science, Technology and Education.

3. Time limit

Seven workdays.

III. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine opinion by the Science and Technology Development Center;
- 3) Examine whether information in the response is the same as that in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education submits its review opinions to director general of the Department for signature (who is authorized by the MOA minister to sign the paper), which will be developed to the response document and delivered to MOA's Administrative Review Office.

3. Time limit

Eight working days.

IV. The Administrative Review Office Completes Review Work

1. Content review

- 1) Compare decisions made in review and ministry leader opinions;
- 2) Examine whether the reasons given to denied applications are accurate;
- 3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue the official written response or notification of (application) completion to the applicant as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three working days.

V. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall

publish the examination result on MOA's official website.

VI. Filing of documents

MOA's Department of Science, Technology and Education files internal reports (of the Department) for signature; MOA's Science and Technology Development Center keeps materials (including dossiers) used in the process of examination; the retention period of files shall comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued during the year, and keeps them for reference for one year.

Regulations for Examination and Issuing Response Letter to Applications for BioSafety Certificates of Agricultural GMOs

The Regulations were formulated, in accordance with the "Administrative Licensing Law of the People's Republic of China," "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports," to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture's Administrative Review Office accepts dossier

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the application form;
- 2) Examine validity and completeness of the dossier

2. Procedure

The Ministry of Agriculture's Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to dossiers that pass

examination, which will be sent to MOA's Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to dossiers that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two workdays.

II. The initial examination by the Ministry of Agriculture's Science and Technology Development Center

1. Content review

- 1) Examine validity of the dossier;
- 2) Examine whether the dossier meets provisions and requirements provided in the "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports";
- 3) Examine whether the dossier complies with the provisions and requirements in safety evaluation guidelines, such as the "Guidance for Safety Evaluation of Transgenic Plants," and the "Guidance for Safety Evaluation of the Genetically Modified Microorganisms for Animal Use";
- 4) Examine qualification of the applicant pursuant to relevant requirements.

2. Procedure

The Science and Technology Development Center, MOA's Department of Science, Technology and Education, and some members of the Agricultural BioSafety Committee (hereinafter referred to as "the BioSafety Committee") will jointly conduct initial examination of the dossier. The Science and Technology Development Center will submit dossiers that passed the initial examination to the BioSafety Committee for examination. Meanwhile, the Science and Technology Development Center shall prepare for technical examination by the BioSafety Committee.

3. Time limit

One month.

III. Safety review by the BioSafety Committee

1. Content review

- 1) Molecular characteristics of agricultural GMOs;
- 2) Environmental safety of agricultural GMO;
- 3) Food safety of agricultural GMO;
- 4) Relevant studies already carried out abroad (in foreign countries), certifications of approval, and other materials on the agricultural GMOs to be introduced.

2. Procedure

The BioSafety Committee conducts the technical examination on the dossier and drafts examination opinion; the opinion shall be submitted to MOA's Department of Science, Technology and Education.

3. Time limit

Two months.

IV. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine whether the procedure for technical examination is valid and meets standards;
- 3) Examine whether the materials and opinions developed in the technical examination are

complete and accurate and meets standards;

4) Opinion of the BioSafety Committee's verification review;

5) Examine whether information in the official written replies is the same as shown in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education then:

- Produce or submit examination opinion;
- Prepare reports for signature;
- Send the reports to relevant competent departments (bureaus) for signature;
- Submits the report to MOA for ministry leader signature following procedures;
- (If obtains approval by ministry leaders), develop responses and deliver the responses to MOA's Administrative Review Office.

3. Time limit

Three months plus fifteen working days.

V. The Administrative Review Office Completes Review Work

1. Content review

1) Compare decisions made in review and ministry leader opinions;

2) Examine whether the reasons given to denied applications are accurate;

3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue the official written response or notification of (application) completion to the applicant as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three working days.

VI. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall publish the result in MOA's official website.

VII. Filing of documents

MOA's Department of Science, Technology and Education files MOA internal reports for signature and opinions by the BioSafety Committee; MOA's Science and Technology Development Center files materials (including dossiers) used in the process of examination; the retention period of files shall comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued during the year, and keeps them for reference for one year.

Regulations for Examination and Issuing Response Letter to Applications for BioSafety Certificates of Agricultural GMOs (for Processing)

The Regulations were formulated, in accordance with the "Administrative Licensing Law of the People's Republic of China," "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports," to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal

of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture's Administrative Review Office accepts dossier

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the application form;
- 2) Examine validity and completeness of the dossier.

2. Procedure

The Ministry of Agriculture's Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to dossiers that pass examination, which will be sent to MOA's Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to dossiers that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two working days.

II. Initial examination by MOA's Science and Technology Development Center

1. Content review

- 1) Examine validity of the dossier;
- 2) Examine whether the dossier meets provisions and requirements provided in the "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports";
- 3) Examine whether the dossier complies with the provisions and requirements in safety evaluation guidelines, such as the "Guidance for Safety Evaluation of Transgenic Plants," and

the “Guidance for Safety Evaluation of the Genetically Modified Microorganisms for Animal Use”;

4) Examine qualification of the applicant pursuant to relevant requirements.

2. Procedure

The Science and Technology Development Center, MOA’s Department of Science, Technology and Education, and some members of the Agricultural BioSafety Committee (hereinafter referred to as “the BioSafety Committee”) will jointly conduct initial examination of the dossier. The Science and Technology Development Center will submit dossiers that passed the initial examination to the BioSafety Committee for examination. Meanwhile, the Science and Technology Development Center shall prepare for technical examination by the BioSafety Committee.

3. Time limit

One month.

III. Safety review by the BioSafety Committee

1. Content review

- 1) Molecular characteristics of agricultural GMOs;
- 2) Environmental safety of agricultural GMO;
- 3) Food safety of agricultural GMO;
- 4) Relevant studies already carried out abroad (in foreign countries), certifications of approval, and other materials on the agricultural GMOs to be introduced.

2. Procedure

The BioSafety Committee conducts the technical examination on the dossier and drafts examination opinion; the opinion shall be submitted to MOA’s Department of Science, Technology and Education.

3. Time limit

Two months.

IV. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine whether the procedure for technical examination is valid and meets standards;
- 3) Examine whether the materials and opinions developed in the technical examination are complete and accurate and meets standards;
- 4) Opinion of the BioSafety Committee's verification review;
- 5) Examine whether information in the official written replies is the same as shown in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education then:

- Produce or submit examination opinion;
- Prepare reports for signature;
- Send the reports to relevant competent departments (bureaus) for signature;
- Submits the report to MOA for ministry leader signature following procedures;
- (If obtains approval by ministry leaders), develop responses and deliver the responses to MOA's Administrative Review Office.

3. Time limit

Three months plus fifteen working days.

V. The Administrative Review Office Completes Review Work

1. Content review

- 1) Compare decisions made in review and ministry leader opinions;
- 2) Examine whether the reasons given to denied applications are accurate;
- 3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue the official written response or notification of (application) completion to the applicant as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three working days.

VI. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall publish the examination result on MOA's official website.

VII. Filing of documents

MOA's Department of Science, Technology and Education files MOA internal reports for signature and opinions by the BioSafety Committee; MOA's Science and Technology Development Center files materials (including dossiers) used in the process of examination; the retention period of files shall

comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued during the year, and keeps them for reference for one year.

Review Work Specification concerning the Imported Agricultural Genetically Modified Organisms Used Directly as Consumer Goods

The Regulations were formulated, in accordance with the "Administrative Licensing Law of the People's Republic of China," "Regulations on Administration of Agricultural Genetically Modified Organisms Safety," "Administrative Measures for Safety Evaluation of Agricultural GMOs" and "Administrative Measures for the Safety of Agricultural GMO Imports," to further clarify duties and tasks for every link in the administrative examination and approval of agricultural GMOs, with the goal of regulating and standardizing evaluation and approval work.

I. Ministry of Agriculture's Administrative Review Office accepts dossier

1. Content review

- 1) Verify qualification and profile of the applicant; examine accuracy and completeness of the application form;
- 2) Examine validity and completeness of the dossier.

2. Procedure

The Ministry of Agriculture's Administrative Review Office examines the dossiers, and makes decides whether to accept the dossier. The Office will issue a notification of acceptance to applicants that pass examination, which will be sent to MOA's Science and Technology Development Center along with the dossier for initial examination; the Office will issue a notification of rejection to applicants that fail to pass the examination, which will contain detailed reasons for rejection.

3. Time limit

Two workdays.

II. Initial examination by MOA's Science and Technology Development Center

1. Content review

- 1) Characteristics of the GMO.
- 2) Purpose of use and safety in transportation;
- 3) Destination of GMO (transportation).
- 4) Deregulation of the GMO in the country of production and other relevant information.
- 5) Qualification of the applicant pursuant to relevant requirements

2. Procedure

The Science and Technology Development Center conducts initial examination of the dossier, prepare examination opinion, and submit the opinions to MOA's Department of Science, Technology and Education.

3. Time limit

Seven workdays.

III. Examination by MOA's Department of Science, Technology and Education and its reporting to a higher body for signature

1. Content review

- 1) Examine whether the matters comply with relevant regulations, provisions and policy requirements concerning agricultural GMO safety;
- 2) Examine opinion by the Science and Technology Development Center;
- 3) Examine whether information in the response is the same as that in the dossier.

2. Procedure

MOA's Department of Science, Technology and Education submits its review opinions to director general of the Department for signature (who is authorized by the MOA minister to sign the paper), which will be developed to the response document and delivered to MOA's Administrative Review Office.

3. Time limit

Eight workdays.

IV. The Administrative Review Office Completes Review Work

1. Content review

- 1) Compare decisions made in review and ministry leader opinions;
- 2) Examine whether the reasons given to denied applications are accurate;
- 3) Check whether information in the official written response is the same as in the approval opinion.

2. Procedure

MOA's Administrative Review Office checks the review decisions and the official written response. The Office shall timely complete the application procedure, issue the official written response or notification of (application) completion to the applicant as requested by the latter. The Office will return the failed applications back to MOA's Department of Science, Technology and Education for re-submission.

3. Time limit

Three workdays.

V. Release results of administrative examination

MOA's Administrative Review Office, while completing the administrative licensing application, shall

publish the result in MOA's official website.

VI. Filing of documents

MOA's Department of Science, Technology and Education files internal reports (of the Department) for signature; MOA's Science and Technology Development Center keeps materials (including dossiers) used in the process of examination; the retention period of files shall comply with relevant regulations on archival management. MOA's Administrative Review Office keeps record of notifications issued during the year, and keeps them for reference for one year.

END Translation