



国家食品安全风险评估中心
China National Center for Food Safety Risk Assessment

Brief Introduction of the Regulation and Evaluation of Agricultural GM Organisms in China

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**National Center for Food Safety Risk
Assessment (CFSA)**



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Content

- **Regulations for agricultural GMO safety management**
- **Food safety evaluation for GMO**



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Regulations



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中华人民共和国国务院令

第 304 号

《农业转基因生物安全管理条例》已经 2001 年 5 月 9 日国务院第 38 次常务会议通过，现予公布，自公布之日起施行。

总 理

朱 镕 基

二〇〇一年五月二十三日

《Regulations on Administration of Agricultural Genetically Modified Organisms Safety》 was issued in 2001 by the State Council of P.P.China



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Regulation Framework

- **The State Council**
 - **Regulations on Administration of Agricultural Genetically Modified Organisms Safety**
 - **Ministry of Agriculture**
 - **The measures for the administration of safety assessment of agricultural genetically modified organisms**
 - **The measures for the administration of agricultural genetically modified organisms identification**
 - **The measures for the examination and approval of agricultural genetically modified organisms processing**
- **AQSIQ**
 - **The measures for the administration of inspection and Quarantine of entry and exit of transgenic products — import inspection**
 - **Relevant announcement, guideline, standards and rules**



Regulations on MOA Genetically Modified Organisms Safety

- **Article 6. The State institutes a class-based administration and evaluation system for agricultural genetically modified organisms safety.**
- **Article 7. The State established a safety evaluation system for agricultural genetically modified organisms.**
- **Article 9. The competent agricultural administrative department of the State Council shall strengthen the safety evaluation administration of research into and testing of agricultural genetically modified organisms, and set up a biosafety committee on agricultural genetically modified organisms responsible for safety evaluation of agricultural genetically modified organisms.**
- **Article 10. Based on the needs of the safety evaluation of agricultural genetically modified organisms, the competent agricultural administrative ministry of the State Council may entrust the inspection of agricultural genetically modified organisms to technical inspection bodies with necessary inspecting facilities and capability.**



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Referred genetically modified organism

- **Animals, plants, microorganisms and their products whose genomic structures have been modified by genetic engineering technologies for the use in agricultural production or processing, which mainly include:**
 - **GM animals, plants (including plant seeds, breeding livestock and poultry, aquatic fry and seeds) and microorganisms.**
 - **Products of GM animals, plants and microorganisms.**
 - **Products directly processed from GM agricultural products**
 - **Products containing ingredients of GM**



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GM Safety management in China

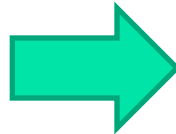
Full chain inspection (Products mainly, Process also concerned)

- **Legislation management**
- **Division management: one competent with multiple participation**
- **Technical review: bio-safety committee**
- **Supervision and management: Approval by MOA, territorial supervision**

Scope

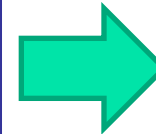
■ territory

China
mainland



■ scope

- research
- experiment
- production
- process
- distribution
- import
- export



■ goals

- Prevention
- Human health
- Animals and plants
- Microorganism
- Ecology environment
- Potential risk.



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Management system

■ **Joint Ministries conference**

- **Responsibilities:** investigations and coordination of significant problems in Agricultural GM organisms safety
- **Composition:** MOA takes the lead, including 11 departments, like MOA, Ministry of Science and Technology, MOH, Ministry of commerce, Ministry of environmental protection, Inspection and Quarantine .

■ **Ministry of Agriculture.**

- **Responsibilities :** Safety evaluation, inspection and management, system construction, standard formulation, import approval and import claim management.
- **Organization:** Ministry of Agriculture administration of agricultural genetically modified organisms safety leading group, The Department of Agriculture GMO Safety Management and intellectual property rights Office



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Management system

- **The competent administrative ministry of agriculture at or above the county level**
 - **Responsibilities: supervision and management of production, processing and claim approval.**
 - **Organization: Provincial MOA GMO Safety Management Office (affiliated to Department of science and education in Department of Agriculture at the province level)**
- **AQSIQ**
 - **Inspection and Quarantine of import and export**



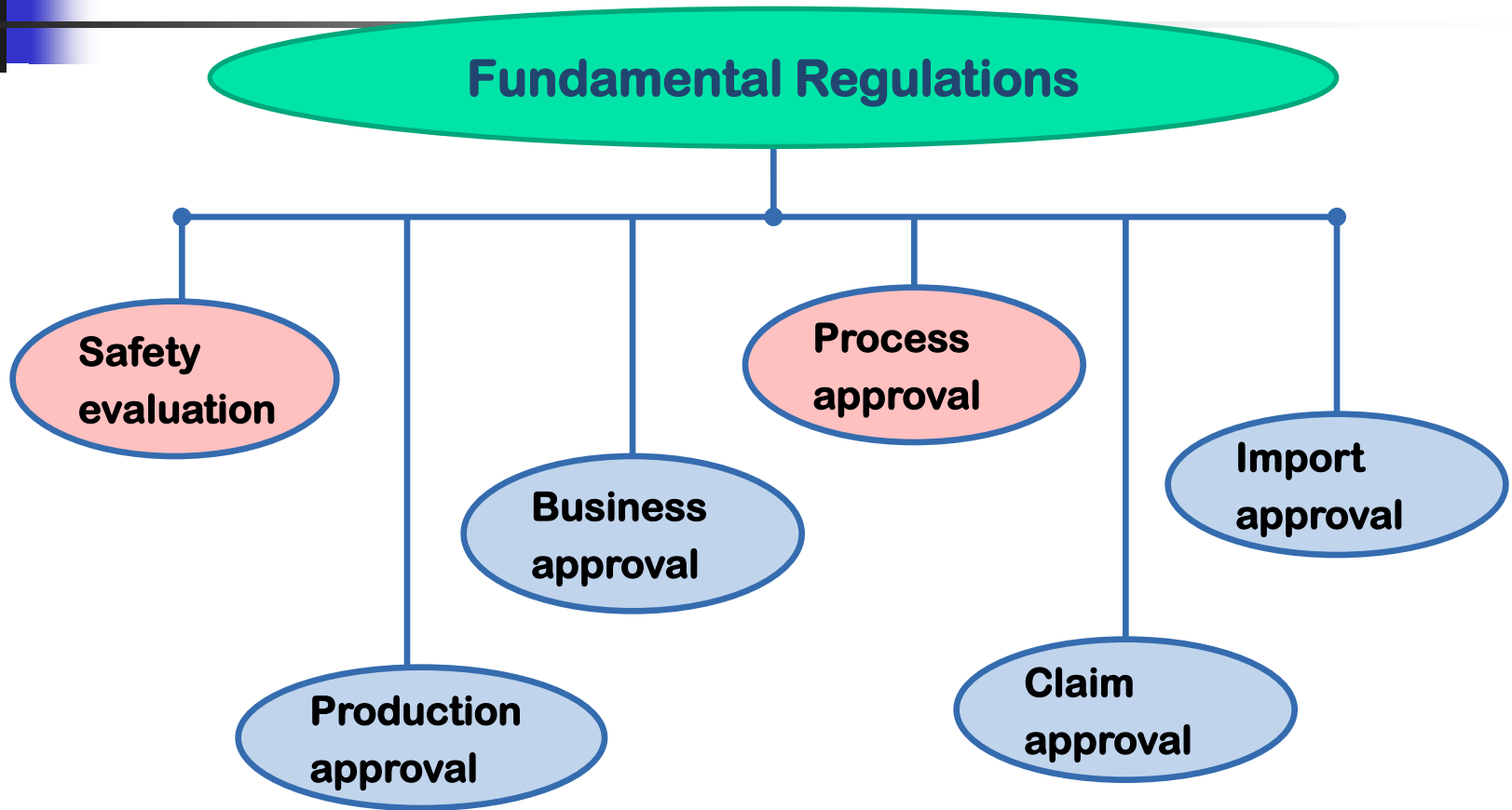
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Technical support system

- **Committee of Agricultural Genetically Modified Organisms Safety.**
 - The 4th Session
- **The national administration of agricultural genetically modified organisms safety standardization technical committee**
 - Hundreds of standards (Mainly measurement standards)
- GM inspection institutes**
 - Environment protection, food safety, and product ingredients.
 - 37 certified by MOA
 - 20 certified by AQSIQ



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Safety evaluation system

3 objects



Animals



Plants



Microorganisms



4 security levels

5 stages

2 methods

Safety evaluation system

3 objects

4 security levels

5 stages

2 methods



I: no risk

II: low risk

III: medium risk

IV: high risk

Safety evaluation system

3 objects

4 security levels

5 stages

2 methods



- 1. Experiments**
- 2. Intermediate test**
- 3. Environmental release**
- 4. Production test**
- 5. Safety certificate**

Safety evaluation system

3 objects

4 security levels

5 stages

2 methods



**Report
Approval**



Management methods

- **MOA could authorize qualified technical institutes to conduct GM organisms measurements and provide basis for safety evaluation and management.**
 - **Inspection institutes for environmental safety assessment for GM plants**
 - **Inspection institutes for GM products**
 - **Inspection institutes for GM food safety evaluation.**



Management organization and professional committee

- **Management organization: MOA established GMO Safety Management Office to take charge of agricultural GM organisms safety evaluation management.**
- **Based on the Regulations, Committee of Agricultural Genetically Modified Organisms Safety take charge of safety evaluation. The committee was composed of experts on GM research, production, process, inspection and quarantine, health and environment protection with a term of 3 years.**



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Safety evaluation---report

Only for national independent research

- (1) security level I , II for experimental stage**
Review by institute biosafety group
- (2) security level I , II for intermediate test**
Directly report to MOA



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Safety evaluation---approval

- (1) Review by institute biosafety group**
- (2) Provincial competent administrative departments**
- (3) Review by the committee of Agricultural Genetically Modified Organisms Safety**
- (4) Reply by approval or not approval documents, certified documents**



Stages for GM plants declare (I)

- 1.Experiments: refers to study gene manipulation and genetically modified organisms in the laboratory in a control system .**
 - **Security level and II GM organisms experiments will be reviewed and approved by institute agricultural GM safety group;**
 - **Security level I I and IV GM organisms experiments will be reported to agricultural GM Safety management office.**
- 2.Intermediate test: refers to small scale tests in control system or under control conditions**



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Stages for GM plants declare (II)

- 3. Environmental release: refers to a medium size test under natural conditions with appropriate safety measurements.**
- 4. Production test: refers to a larger scale experiment before production and application.**
- 5. Security certificate declaration.**

Intermediate test, environment release, production test and security certificate declaration should be reported to agricultural GM safety management office and could not start without approval.



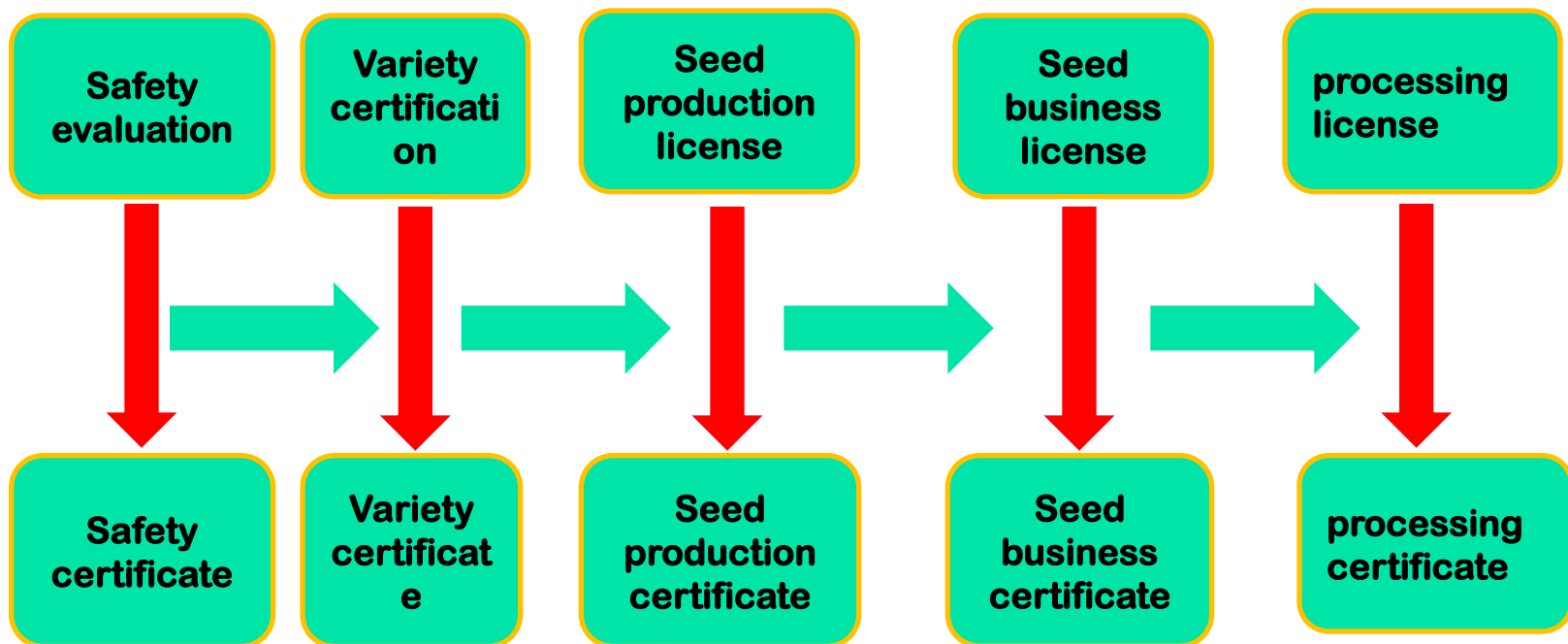
Declaration condition for safety evaluation

- **Applied security levels and justification;**
- **Technical report provided by agricultural GM organisms inspection institutes (character, environmental safety inspection and food safety inspection)**
- **Test report of previous stages;**
- **Corresponding safety management and prevention interventions;**
- **Related regulations issued by the State competent agricultural administrative departments**



- **Application time: twice a year, deadline**
 - **First : March 31st**
 - **Second: September 30th**
- **Reply time: within 6 months after the deadline for application Evaluation, replay within 20 working days after safety evaluation is finished**

The flowchart for GM production management



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Labeling system

- **Label directory**
- **Mandatory label**
- **Qualitative label**

The label directory is formulated, adjusted and published by MOA and relevant departments of the State Council

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The first label directory



**Soybean seed, soybean, soybean meal,
soybean oil, soybean meal**



Corn seed, corn, corn oil, corn flour



Rapeseed, rapeseed, canola oil, rape seed meal



Cotton seed



Tomato seed, fresh tomato, tomato sauce

蛋白质	0	克
胆固醇	0	毫克
天然维生素E	60	毫克

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加工原料中含有转基因油菜籽和转基因大豆

配料：菜籽色拉油、大豆色拉油、玉米色拉油、葵花籽色拉油、浓香花生油、芝麻油、亚麻籽油、红花籽油、抗氧化剂(TBHQ)

生产日期及保质期：瓶面所示

商标持有人
地址：上

胆固醇	0	毫克
天然维生素E	40-100	毫克

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Safety inspection

- **The competent administrative department of agriculture at or above the county level responsible for local agricultural GM organisms safety inspection ;**
- **There are 27 provincial agricultural administrative departments with agricultural GM organisms safety management offices.**



Transgenic cotton (No.989 document of MOA)

- Those transgenic insect-resistant cotton varieties with security certificate (type I) may directly apply for all suitable ecological zone production and application security certificate。
- Those transgenic insect-resistant cotton varieties (type II) which derived from transgenic insect-resistant cotton varieties with security certificate using conventional breeding, can directly apply for all suitable ecological zone production and application security certificate。
- As to type I and II, they have to follow the requirements of the attachment during application。
- For those outside the scope of the notice, still need to follow the requirements of Regulations on Administration of Agricultural Genetically Modified Organisms Safety。
- This notice came into force in 2008-10-10 upon promulgation and No. 410 documents from MOA abolished。



Notice of the MOA of the P.R.China(No.1693)(I)

- **With the simplified application procedure for transgenic insect-resistant cotton varieties security certificate, decided to further standardize the inspection work, and adopt classification management:**
 - **Type 1: Those transgenic insect-resistant cotton varieties with security certificate may directly apply for all suitable ecological zone production and application security certificate**
 -
 - **Type 2: Those transgenic insect-resistant cotton varieties (type II) which derived from transgenic insect-resistant cotton varieties with security certificate using conventional breeding, can directly apply for all suitable ecological zone production and application security certificate .**



Notice of the MOA of the P.R.China(No.1693)(II)

- **With the simplified application procedure for transgenic insect-resistant cotton varieties security certificate, decided to further standardize the inspection work, and adopt classification management :**
 - **As to type I and II, they have to follow the requirements of the attachment during application .**
 - **The measurements reports for type I and II will be organized by MOA.**
 - **For those outside the scope of the notice, still need to follow the requirements of Regulations on Administration of Agricultural Genetically Modified Organisms Safety.**



《Transgenic cotton seed production and business license regulations》 (No.1643 Notice of MOA)

- According to the requests from Seed Law of the people's Republic of China, Regulations on Administration of Agricultural Genetically Modified Organisms Safety and crop seed production license management regulations, MOA promulgated the transgenic cotton seed production and business license regulations;
- Authorized provincial agricultural administrative departments review and approval the license of transgenic cotton seed production and business. ◦
- Came into force in October 7th, 2011. ◦



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Others.....

- **<<Catalogue for the guidance of Foreign Investment Industries >> is issued by National Development and Reform Commission in January 30th, 2012**
- **Guidelines for safety evaluation of transgenic plants。**



Transgenic crops in southern propagation rules

- For those need southern propagation, declare institute need to fill out the relevant information like plant identification, seed propagation to MOA during application based on this rules.
- For those still in the stage of safety evaluations(intermediate test), declare institute need to specify the south numerous test the starting and ending time, place and scale and technologies.
- For those applied for safety certificate, declare institute could apply more than one time southern propagation test within the valid period of the certificate.



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Food safety assessment of GMO



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Guideline for safety evaluation of genetically modified Microorganism for animals(1)

- A technical guideline, including 4 parts and they are classification and definition, application procedures, general requirements, and requirements for different animals。
- Part I, 8 types animal vaccinations, like genetic engineering subunit vaccine, genetic engineering live vector vaccine, gene deletion vaccine, nucleic acid vaccine
 -
- Part II, Refinement of the transgenic microorganism declaration procedures for various types of animal 。



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Guideline for safety evaluation of genetically modified Microorganism for animals(2)

- Part III, Put forward evaluation indicators and data requirements based on the information of molecular character, genetic stability, biological character of transgenic organisms for animals。
- Part IV. To further clarify the safety assessment of genetically modified microorganisms requirements of different kinds of animal 。

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Guideline for safety evaluation of genetically modified plants(1)

- **According to the principle of case by case analysis, to evaluate the relative safety of genetically modified plants compare to non-transgenic one。**
- **Choices of traditional non-transgenic control**
 - **As to genetically modified plants with asexual reproduction, use non genetically modified parent plant as the ;**
 - **As to genetically modified plants with sexual reproduction , use comparable genetic background non transgenic plant as control。**
 - **Comparable in environment (time and place) 。**



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Guideline for safety evaluation of genetically modified plants(2)

- 1. Toxicological evaluation for new expressed substance**
 - (1) Data for the new protein expression**
 - (2) The toxicology tests for new expressed proteins**
 - (3) Evaluation of a new expressed non protein substances**
 - (4) Intake estimation.**
- 2. Allergy evaluation**
 - (1) Allergic data for new expressed protein.**
 - (2) Homology analysis with a known allergen**
 - (3) Having homology with known allergens, serologic test for allergen antibody**
 - (4) Stability of exogenous protein to heat, machining process and digestion**



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Guideline for safety evaluation of genetically modified plants(3)

3. The key ingredients analysis

- (1) nutrients**
- (2) Natural toxins and harmful substances**
- (3) Anti nutritional factor**
- (4) Other ingredients**
- (5) The unexpected components**

4. The food safety evaluation

- (1) 90 days Rat feeding test**
- (2) Other traditional toxicology test when necessary**



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Guideline for safety evaluation of genetically modified plants(4)

5. Nutritional evaluation

If the genetically modified plants have changes in nutritional, physiological effect

- (1) Data of in vivo nutrients absorption and utilization among animals**
- (2) evaluation of human nutrient intakes and impact on marketing mode**

6. Evaluation the impact of production and processing on the safety

7. Other safety evaluation carried out by case by case analysis principle

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Food safety assessment of Stick genetically modified plants by conventional breeding

- **Scope: use those already had GMO safety certificates as parents, Obtained by conventional breeding。**
- **procedures:**
 - **No difference with new individual transformants;**
 - **Those composited GMO intended for imported raw materials, can directly apply for safety certificates ;**
 - **Those composited GMO intended for production application should apply from the production test stages**
- **Focus: gene interaction?**



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Thank you!