中国转基因生物安全管理
Bio-safety Administration in China

2017.6.26

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Bio-safety Administration in China

国家科委 State Commission of Science 1993.12.24

基因工程安全管理办法

Measures for Biosafety Control of Genetic Engineering

农业部MOA 1996.7.1

农业生物基因工程安全管理办法

Measures for Biosafety Control of Agricultural Genetic Engineering

国务院 the State Council 2001.5.23

农业转基因生物安全管理条例

Regulations on Safety of Agricultural GMOs

- 中国转基因生物安全管理经过20多年的实践探索，逐步形成了比较完备的法规体系、管理体系和技术支撑体系。

  After 20 years of practice, the Biosafety Regulation of GMOs in China has gradually formed a relatively complete legal, management and technical supporting system.

法规体系 Regulation System

国务院 the State Council

农业转基因生物安全管理条例

Regulations on Safety of Agricultural GMOs

农业部 MOA

农业转基因生物安全评价办法

Implementation Regulations on Safety Assessment of Agricultural GMOs

农业转基因生物标识管理办法

Implementation Regulations on labeling of Agricultural GMOs

农业转基因生物进口安全管理办法

Implementation Regulations on Safety of Import of Agricultural GMOs

农业转基因生物加工审批办法

Implementation Regulations on Process of Agricultural GMOs

相关公告、技术指南、标准和规范

Related Notices, technical guidelines, standards and norms

法规体系 Regulation System

质检总局 AQSIQ

进出境转基因产品检验检疫管理办法

Implementation Regulations on Inspection and Quarantine of Entry and Exist

管理体系 Administration System

部际联席会议 inter-ministerial joint conference

职责：研究、协商农业转基因生物安全管理的重大问题

Responsibility: discussion and coordination of major issues involved in the administration of agricultural genetically modified organisms safety

组成：中国农业部牵头，农业、科技、食药、卫生、商务、环保、检验检疫等12个部门组成

composed of responsible persons from 12 departments, including departments of agriculture, science and technology, environmental protection, food and drug, public health, commerce, inspection and quarantine.

管理体系 Administration System

中国农业部 MOA

职责：负责安全评价、监督管理、体系建设、标准制定、进口审批和进口标识管理

Responsibility: safety evaluation, supervision and inspection , formulate standards, import approval and import labeling

机构：农业部农业转基因生物安全管理领导小组及农业部农业转基因生物安全管理办公室

Agency: Agricultural GMOs Administration Leading Committee and Bio-safety Office bear the above responibility

管理体系 Administration System

县级以上农业行政主管部门

The agricultural departments of local people's governments at or above the county level

职责：负责本区域监督管理，生产、加工和标识许可

Responsibility: the administration of agricultural GMOs , and approvals for production, processing and labeling within their respective administrative areas

机构：各省农业转基因生物安全管理办公室

Agency: agricultural bio-safety office at provincial level(Science and Education Division of Agricultural Department of the people's government of the province)

管理体系 Administration System

中国质检总局 AQSIQ

负责进出境转基因检验检疫

responsible for inspection and quarantine of entry and exist

中国食药局 FDA

按照职能分段负责转基因食品标识监管

responsible for the supervision and administration of genetically modified food within its administrative area

技术支撑体系 Technical supporting system

国家农业转基因生物安全委员会

Bio-safety committee on agricultural GMOs

负责农业转基因生物的安全评价工作。由从事农业转基因生物研究、生产、加工、检验检疫、卫生、环境保护等方面专家组成。

Responsible for safety evaluation of agricultural GMOs. composed of experts focused on biological research, production, processing, inspection and quarantine, public health and environmental protection.

技术支撑体系 Technical supporting system

国家农业转基因生物安全委员会

Bio-safety committee on agricultural GMOs

2002-2004：第一届　58人　the 1st session　58 members

2005-2008：第二届　74人　the 2nd session　74 members

2009-2012：第三届　60人　the 3rd session　60 members

2013-2015：第四届　64人　the 4th session　64 members

2016-2020：第五届　75人　the 5th session　75 members

技术支撑体系 Technical supporting system

中国农业转基因生物安全管理标准化技术委员会

Bio-standard technical committee on agricultural GMOs

- 委员41名

41 members

- 秘书处设在农业部科技发展中心

Secretariat is in Science and Development Center of MOA

- 发布实施标准160项

Issued 160 standards

技术支撑体系 Technical supporting system

转基因检测机构 Inspection organizations

- **40个机构通过认证**

40 technical inspection organizations have been certified by MOA

- **三个领域：“转基因植物、动物、微生物”**

3 different fields: plant, animal, microorganism

- **三个类别：“产品成分、环境安全、食用安全”**

3 categories: molecular characteristics, food safety, environmental safety .

中国转基因安全评价制度
China Biotech Safety Assessment System

安全评价制度
Safety Assessment System

评价原则 Principle
- 科学合理 Scientific and reasonable
- 个案审查 Case-by-case

评价种类 Object
- 植物 动物 微生物 Plant, animal, microbe

评价等级 Classification
- ①尚不存在危险 ① There shouldn't be any danger
- ②具有低度危险 ② Low risk of danger
- ③具有中度危险 ③ Mediate risk of danger
- ④具有高度危险 ④ High risk of danger

评价阶段 Stage
- 实验研究 Research and development
- 中间试验 Intermediate test
- 环境释放 Environment release
- 生产性试验 Production trial
- 申请安全证书 Safety certificate

安全评价内容 Content of safety assessment

一、分子特征 **Molecular characteristics**

二、食用安全 **Edible safety**

三、环境安全 **Environmental safety**

分子特征评价 Molecular Characteristics

❖ 分子特征 Molecular characteristics

1. 表达载体相关资料 Information of expression vector

2. 目的基因在植物基因组中的整合情况 Information of target gene's integration in the plant genome

3. 外源插入序列的表达情况 Expression of inserted fragments

❖ 遗传稳定性 Genetic stability

1. 目的基因整合的稳定性 the stability of target gene's integration

2. 目的基因表达的稳定性 the stability of target gene's expression

3. 目标性状表现的稳定性 the stability of target characters

食用安全评价 Food Safety

- 新表达物质毒理学评价 Toxicological assessment of new substances
- 致敏性评价 Allergenicity assessment
- 关键成分分析 Key components analysis
- 全食品安全性评价 Whole food safety evaluation
- 营养学评价 Nutritional evaluation
- 生产加工对安全性影响的评价 Assessment of production and processing impact on safety
- 按个案分析原则需要进行的其他安全性评价 Other safety assessment according to case-by-case principle

环境安全评价 Environmental Safety

- 生存竞争能力 Competition ability
- 基因漂移的环境影响 Environmental impact of gene flow
- 功能效率评价 Functional efficiency evaluation
- 对非靶标生物的影响 Effects on non-target organism
- 对生态系统群落结构和有害生物地位演化的影响 Impact on ecosystem and pest evolution
- 靶标生物的抗性 Resistance of target organism

农业转基因生物安全证书发放情况
GMO safety certificate issued in China

截止目前，批准发放7种作物生产应用安全证书

Up to now, safety certificate for 7 kinds of plants issued

1997年: 耐储存番茄（过期）

Delayed ripening tomato (expired)

抗虫棉花 （续）

Bt cotton (extended)

1999年: 改变花色矮牵牛 （过期）

Modified flower color petunia(expired)

抗病辣椒 (过期)

VR pepper (expired)

农业转基因生物安全证书发放情况
GMO safety certificate issued in China

2006年：抗病番木瓜（续）

VR papaya (extended)

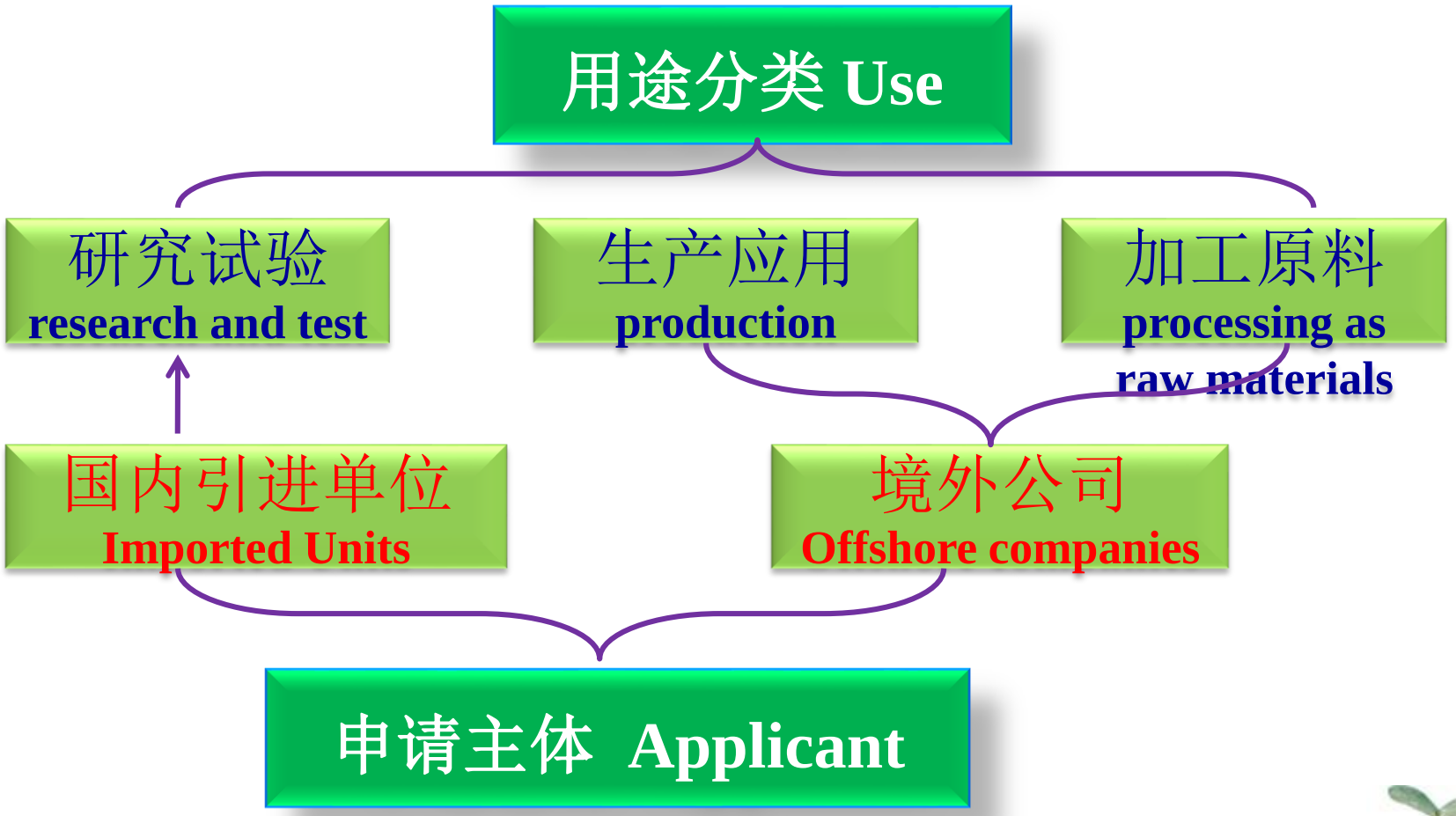
2009年：转植酸酶玉米（续）

Phytase maize (extended)

抗虫水稻（续）

Bt rice (extended)

农业转基因生物进口管理　GMO import



农业转基因生物进口管理　GMO import

分类管理

Imported agricultural GMOs are divided into three groups in accordance with their intended uses:

- **用于研究试验：从实验阶段开始申请**

  For research and test: starting from the stage of research and development

- **用于生产应用：从中间试验开始申报**

  For production: starting from the stage of restricted field-testing, then step-by-step

- **用作加工原料：直接申请安全证书**

  For processing as raw materials: May apply directly for safety certificate

进口用作加工原料审批 Review and Approval of Products for Import FFP Purpose

- 境外研发商进口安全证书

  Import safety certificates for foreign developers

- 境外贸易商进口安全证书

  Import safety certificates for foreign traders

进口用作加工原料审批程序 Approval Process

① 境外研发商提交进口用作加工原料安全证书申请 **Submit Application**

② 农业部受理、初审，提交安委会审查
MOA accepts application, first review and NBC review

③ 如符合要求，发放入境材料批件 **No questions, issue import permit**

④ 试验材料进口 **Import materials for local studies**

⑤ 开展身份验证、环境安全及食用安全检测
Identity verification, environmental and food safety assessment

⑥ 境外研发商申报书及综合评价报告提交安委会审查
Application dossier and integrate assessment report delivered to NBC review

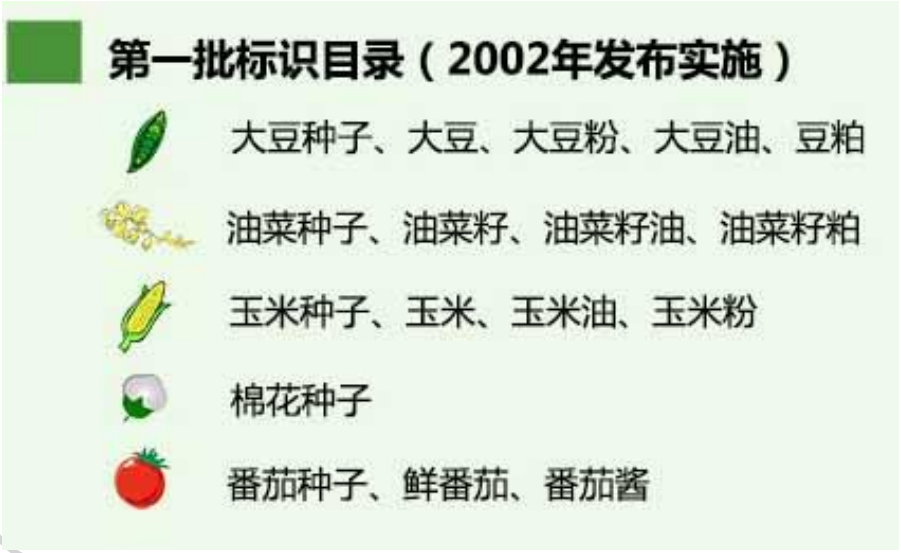
⑦ 如符合要求，发放境外研发商进口用作加工原料安全证书
No questions, safety certificate for import FFP issued to technology developers

⑧ 境外贸易商凭研发商安全证书，办理每批次进口安全证书
With developer's safety certificate, traders apply for import safety certificate for each batch

标识管理 Labelling

- 凡是列入标识目录并用于销售的农业转基因生物，应当进行标识。
  All the commercialized agricultural biotech products listed in the Labeling Category shall be labeled

- 我国标识制度特点：强制标识、按标识目录定性标识
  China biotech labeling: mandatory and qualitative labeling following the Labeling Category



China biotech labeling category (since 2002)

- **Soybean: seed, grain, powder, oil, meal**
- **Canola: seed, grain, oil, meal**
- **Corn: seed, grain, oil, powder**
- **Cotton: seed**
- **Tomato: seed, fresh fruit, sauce**

监督管理 Supervision

- 强化转基因生物安全属地管理制度和研发者“第一责任人”责任

  Enhancing localized management and R&D people as the first responsible person.

- 严格按照法规开展转基因制种及种植试验，防止违规种植扩散

  Carrying out GMO seeds productions and planting experiments in accordance with the regulations strictly, preventing the proliferation of illegal cultivation.

- 加大品种审定环节检测力度，防止未获批准的转基因种子流入市场

  Increasing the intensity of detection during variety approval stage, preventing unauthorized GMO seeds entering the market.

监督管理 Supervision

- 加强农产品及其加工品转基因成分例行监测和重点地区抽检

  Strengthening routine monitoring and key area sampling of GMOs in agricultural and processed products.

- 强化部门协同，实施分段监管，保障公众知情权和选择权，做到有标识、可控制、能溯源

  Strengthening sectoral cooperation, implementing section regulation. Protecting the public's right to know and to choose, achieving GMOs labelled, controllable and traceable.

- 加大案件曝光力度

  Increase the intensity of exposure cases

科普宣传 Popular science propaganda

科普宣传合力
Popular science propaganda efforts

宣传队伍 Team

懂技术、会科普、接地气

- Understand technology
- Good at popularization of science
- Down-to-earth

宣传平台 Platform

宣传主渠道+新兴媒体

Main channel
+
Emerging media

覆盖面 Coverage

学校、社区、公共场所

- Schools
- Communities
- Public places

谢谢！

Thanks for your attention !