

# **Regulations and safety assessment for genetically modified foods and feeds in Taiwan**

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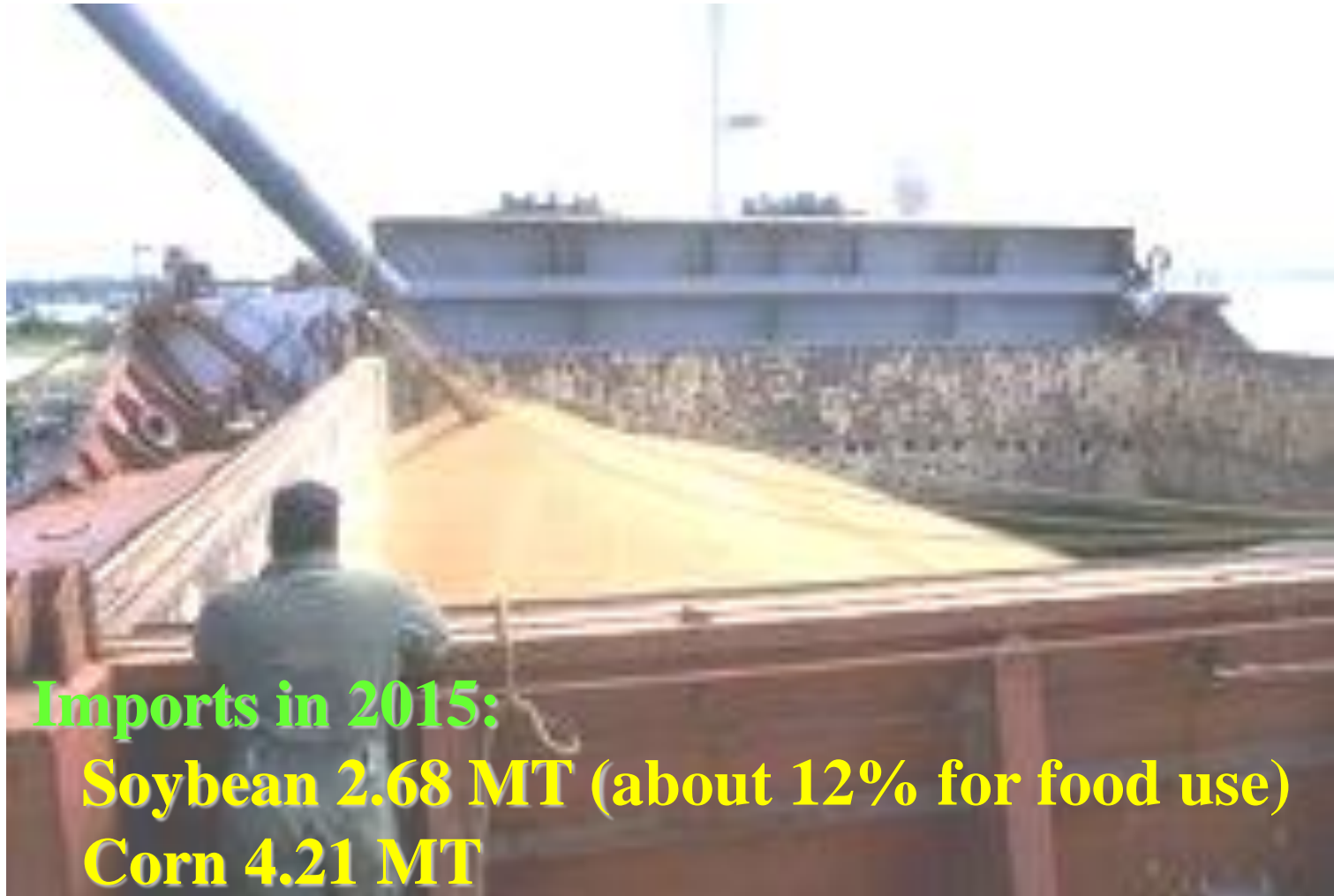
**Food Industry Research and Development Institute**

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# Taiwan is one of the major importing countries of GM crops



**Imports in 2015:**

**Soybean 2.68 MT (about 12% for food use)**

**Corn 4.21 MT**

# **Overview of Taiwan Regulatory Systems for GMOs**

# Regulatory Authorities

## I. Ministry of Science and Technology

- **Laboratory researches**

## II. Council of Agriculture

- **Environment and feed safety**

## III. Ministry of Health and Welfare

- **Food safety**

# Ministry of Science and Technology

- **Basic researches**
- **“The Rules for Conduct in Respect to Genetic Recombination Experiment”**
  - an administrative rule with no legal power
- **Going to set appropriate legal authority in the “Fundamental Science and Technology Act”**
  - a “GM Technology Research and Development Management Regulation” will then be drafted based on the Act

# Council of Agriculture (1/3)

- **GM plant field trials**

- Agriculture and Food Agency (AFA) of COA
- **"The Plant Variety and Plant Seed Act"** and its derived regulations
  - The "Transgenic Plant Field Testing Guidelines",
  - The "Transgenic Plant Hereditary Characteristics Study and Biosafety Assessment Criteria"
  - The "Transgenic Plant Hereditary Characteristics Study and Biosafety Assessment Criteria Implementation Guidelines"

- **GM animal field trials**

- Department of Animal Industry (DAI) of COA
- The **"Animal Industry Act"** and its derived regulations
  - "Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment"

# Council of Agriculture (2/3)

- **GM aquatic animal and plant field trials**
  - **Fisheries Agency (FA) of COA**
  - **"The Fishery Law"** and its derived regulations
    - **The "Rules for the Field Trial of Transgenic Aquatic Animals and Plants"**



# Council of Agriculture (3/3)

- **COA is implementing the regulations on GM feeds**
  - The **“Feed Control Act”** was amended as the legal basis for managing GM feeds

# Ministry of Health and Welfare

- **Food and Drug Administration of the Ministry of Health and Welfare**
- **The “Act Governing Food Sanitation” and its derived regulations**
- **Amendment of the “Act Governing Food Sanitation” on 5 Feb, 2014**

# TFDA regulations for GM foods before the amendment

In accordance with the Act Governing Food Sanitation

*DOH Gazette (22 Feb, 2001)*

- **Registration requirements** for GM soybean and GM corn (Article 14)
- **Labeling requirements** for foods containing and/or derived from GM soybean or GM corn (Article 17)
- **Mandatory:** GM soybean and GM corn

# **Amendment of the “Act Governing Food Sanitation”**

- **Date: 5 Feb, 2014**
- **To enhance the management of GM foods**
- **Title changed: “Act Governing Food Safety and Sanitation”**
  - **7 out of 60 articles regarding GM foods**

# Act Governing Food Safety and Sanitation (1/2)

- Set the **definition of genetic engineering** (Article 3)
- To establish **a council advisory committee** to facilitate regulation of ..... genetically modified foods..... (Article 4)
- **All genetically modified food raw materials (GMFRM) shall file product registration** with and procuring a permit document..... (Article 21)
  - Soybean, corn, **canola, cotton, sugar beet, alfalfa, etc.**
  - **A gracious period of two years for unregistered GMFRM** already on the local market prior to the amendment..... (Article 21)

# Act Governing Food Safety and Sanitation (2/2)

- Importers shall establish **a traceability system** for tracing the source and tracking the flow of the GMFRM with **a gracious period of one year**. (Article 21)
- The competent authority may request food businesses or their representative to provide **relevant records, documents and electronic files or databases of the imported products** which shall be **retained for five years**. (Article 32)
- **Labeling requirements** for foods containing and/or derived from GMFRM (Article 22, 24, and 25)

# **Regulations and Food Safety Assessment for GMFRM**

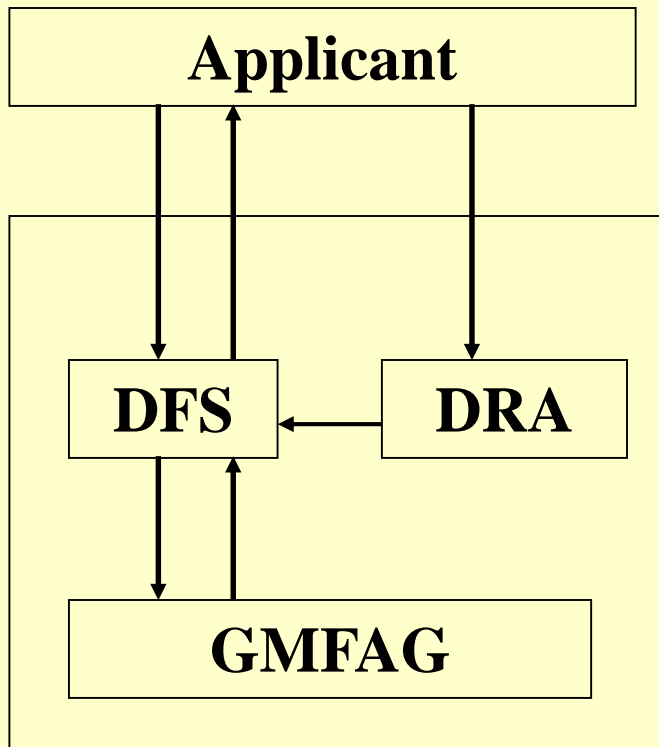
- **TFDA Regulations and Registration Process**
- **Food Safety Assessment for GMFRM**
- **GM Food Labeling**

# TFDA Regulations

- **In accordance with the "Act Governing Food Safety and Sanitation"**
  - **Registration requirements** for all GMFRM (Article 21)
  - **Labeling requirements** for foods containing and/or derived from GMFRM (Article 22, 24, and 25)



# Registration Process for GMFRM



**DFS:** administration and approval

**DRA:** development of detection method

**GMFAG:** scientific evaluation of food  
safety

**DFS:** Division of Food Safety, TFDA

**DRA:** Division of Research and Analysis,  
TFDA

**GMFAG:** GM Food Advisory Group

# GM Food Advisory Group

- **The 8th GMFAG (1/1/2016 – 12/31/2017)**
  - **21 members**
  - **Four subgroups** : basic information, nutrition, allergenicity, and toxicity
- **The “Guideline for Food Safety Assessment of Genetically Modified Foods Derived from Recombinant-DNA Organisms”**
  - **Promulgated: 7 Nov, 2000**
  - **Latest amendment: 9 Sep., 2010 (in alignment with Codex guidelines)**
    - **Foods Derived from Recombinant-DNA Plants and Microorganisms**
    - **Foods Derived from Nutritionally Enhanced Recombinant-DNA Plants**

# Data requirements for food safety assessment dossiers (1/3)

- **Basic Data**
  - Description of the r-DNA plant
  - Description of the host plant and its use as food
  - Description of the donor organism(s)
  - Description of the genetic modification(s)
  - Characterization of the genetic modification(s)
  - Safety assessment
  - Literatures and references

# Data requirements for food safety assessment dossiers (2/3)

- **Basic data**

- **Safety assessment**

- **Compositional analyses of key components**
    - **Initial assessment of possible toxicity and/or allergenicity of newly expressed substances**
    - **Evaluation of metabolites**
    - **Nutritional modification**
    - **Food processing**
    - **Antibiotic resistance marker genes**
    - **Other considerations**

# Data requirements for food safety assessment dossiers (3/3)

- **Further assessment of possible toxicity/allergenicity**
  - **Assessment of basic data indicates the presence of possible toxin(s) and/or allergen(s).**
- **Animal study with whole food (90 days)**
  - **Basic data and assessment of possible toxicity/allergenicity indicate the available data are insufficient.**

# Stack regulation

- **Promulgated on 6 May, 2008**
- **For all GMFRM with stack traits after the amendment of the Act**

# **Food safety assessment for stacks**

- **Guideline for food safety assessment of foods derived from GM plants with stacked traits**

# **Guideline for food safety assessment of foods derived from GM plants with stacked traits**

- **Apply only to foods produced using GM plants with stacked traits obtained through conventional breeding between GM plants that are already approved**



# Classification of GM plants with stacked traits

- **Category I:** plants with two or more traits that are **unrelated**. (eg., HT/IR)
- **Category II:** plants with two or more traits that **are related but with different modes of action**. (eg., HT<sup>a</sup>/HT<sup>b</sup> or IR<sup>a</sup>/IR<sup>b</sup>)
- **Category III:** plants with two or more traits that **function in the same biosynthetic pathway**. (eg., ENZ<sup>a</sup>/ENZ<sup>b</sup> for  $\beta$ -carotene biosynthesis in golden rice)

# Food safety assessment of stacks

- **Category I and II**
  - **Bridging studies needed**
  - **To confirm that the stacked product is derived from the combination by traditional breeding of the single genetically modified events**
- **Category III**
  - **Considered as new genetically modified foods**

# Bridging studies

- **Molecular characterization**
- **Information on the expression of new proteins**
- **Compositional analysis and agronomic variables**
- **Protein safety evaluation and animal feeding studies when necessary**

# Foods derived from category III

- **A full food safety assessment** carried out in accordance with MOHW guideline is required

# Current approvals of genetically modified foods in Taiwan (as of 19 May, 2016)

- **Single trait** – 53 events (16 soybeans, 19 corns, 5 canola, 12 cottons, 1 sugarbeet)
- **Stacked trait** – 63 events (7 soybeans, 45 corns, 5 canola, 12 cottons)

(<http://www.fda.gov.tw/TC/siteContent.aspx?sid=2197>)

# Labeling of GMFRM

- **The scope of labeling was expanded and implemented on 31 Dec., 2015**
  - For packaged foods, **food additives**, and **bulk foods**
  - **Zero threshold** for foods containing GMFRM
  - **Highly refined products with undetectable DNA/protein shall also be labeled**

# Threshold for non-GMFRM

- **Adjusted from 5% to 3% and below**
- **Non-GMFRM containing more than 3% GMFRM is treated as GMFRM and needs to be labeled.**
- **May be further adjusted to 0.9% depending on the supply and demand of non-GMFRM and consumer opinions**

# **Regulations and Feed Safety Assessment for GM Feeds**



# Management of GM feeds

- **No regulation for GM feeds before 2015 due to **lack of legal basis**.**
- **The “**Feed Control Act**” was amended in 2015 as the legal basis for managing GM feeds.**

# Amendment of the “Feed Control Act”

- **Genetically modified feed or feed additives developed abroad** by the industry shall file application with the central competent authority for licensing.
- The genetically modified feed or feed additives can be imported for sales or use in Taiwan **only after procuring a license certificate** by completing the safety assessment and inspection.

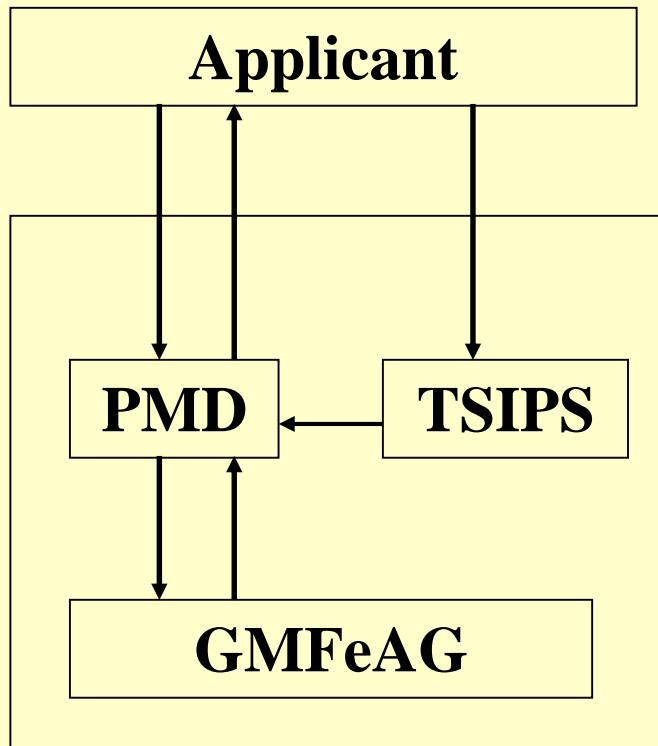
# Amendment of the “Feed Control Act”

- Promulgated on **4 Feb., 2015**
- **A grace period of 2 years for GM feeds already on the local market**
  - **Over 120 events need to be registered before 3 Feb., 2017.**

# Regulations for GM feed or feed additives

- **“Regulations of Permission and Inspection on Genetically Modified Feed or Feed Additives”**
  - **New regulations for GM feeds in accordance with the revised “Feed Control Act”**
  - **Promulgated on 4 Jan., 2016**
- **Events already procured or in the process of procuring a license certificate of GM food before the implementation of the new regulations are exempted from safety assessment.**

# Registration Process for GM Feed/Feed Additives



**PMD:** administration and approval

**TSIPS:** development of detection method

**GMFeAG:** scientific evaluation of feed safety

**PMD:** Pasture Management Division, DAI

**TSIPS:** Taiwan Seed Improvement and Propagation Station, COA

**GMFeAG:** GM Feed/Feed Additives Advisory Group

# GM Feed/Feed Additives Advisory Group

- **The 1st GM Feed/Feed Additives Advisory Group**
  - **From 5/12/2016 to 5/11/2018**
  - **18 members**
  - **Three subgroups**
    - **Biotechnology: microorganism (4), plant (2), and animal (2)**
    - **Nutrition (5)**
    - **Toxicity (5)**

# **Safety Assessment for GM Feeds**

- **Guideline for feed/feed additives safety assessment derived from genetically modified plants**
- **Draft is expected to be available before Oct., 2016.**

**Thank you for your attention!**