



**Asia-Pacific  
Economic Cooperation**

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2014/SCSC/WKSP1/011

## **Contamination of Maleic Anhydride Modified Starch in Food**

Submitted by: Chinese Taipei



**Workshop on Improved Food Inspection  
Capacity Building Based on Risk Analysis  
Seoul, Korea  
21-23 May 2014**

# Contamination of Maleic Anhydride Modified Starch in Food

藥求安全 食在安心

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Taiwan Food and Drug  
Administration  
May 23, 2014



衛生福利部食品藥物管理署

Food and Drug Administration,  
Ministry of Health and Welfare

<http://www.fda.gov.tw/>

# Outline

- Basic Information
- Actions Taken
- Amendment of the Act
- Information Transparent and Consumer Protection
- Conclusions

# Basic Information

# Modified Starch for Food Use

- ❖ **Modified starch is a starch treated with chemicals to modify its physical characteristics, such as viscosity, texture, and stability.**
- ❖ **In Taiwan, modified starch for food use, is classified as food additive-pasting agent to increase the viscosity. 21 modified starches were approved by FDA as food additives.**
- ❖ **Food additive shall be registered and receive a permit from FDA.**

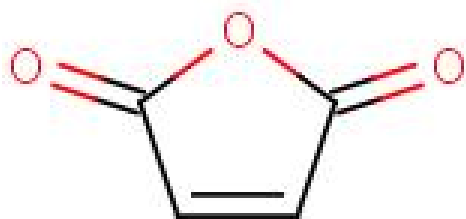


# Maleic Anhydride Modified Starch



**Starch**

+



**Maleic Anhydride**

chemical synthesis



**Maleic Anhydride  
Modified Starch**

**Maleic anhydride modified starch**

**1. not approved as food additive**

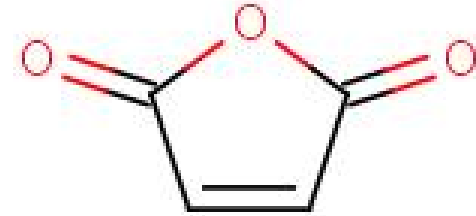
**2. currently its metabolic mechanism in animal and human is not clearly understood**

# Maleic Anhydride

## Background

### Synonyms

*cis*-butenedioic anhydride



### Usages

- ❖ an ingredient to manufacture *trans*-butenedioic acid, tartaric acid, malic acid, and resin
- ❖ used in food packaging materials, and is an indirect food additive approved by the US FDA and EU EFSA; may exist in trace amount in legal food additives such as malic acid and *trans*-butenedioic acid

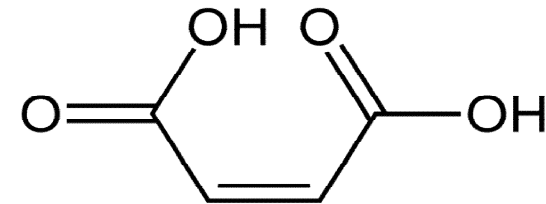


# Maleic Acid

## Background

### Synonyms

*cis*-butenedioic acid



### Possible sources in food

- ❖ transformed from malic acid and *trans*-butenedioic acid in fermentation or produced *via* maillard reaction during high temperature baking
- ❖ migrating into foods from packaging materials with legally adding maleic acid



# Safety of Maleic Acid/Maleic Anhydride

Toxicity	Maleic acid	Maleic anhydride
acute toxicity	<b>Low</b> (LD <sub>50</sub> 708 mg/Kg, Rat)	<b>Low</b> (LD50 400 mg/Kg, Rat)
reproductive and developmental toxicity, genotoxicity, carcinogenicity	<b>none</b>	<b>none</b>
nephrotoxicity	<ul style="list-style-type: none"> <li>❖ Kidney damage was observed in dog with a single dose of 9 mg/kg maleic acid.</li> <li>❖ In the same study, no nephrotoxicity was observed in rat, mice and monkey, at doses of 117, 191, and 29 mg/kg maleic acid, respectively. It indicates animals of different species show different sensitivity.</li> </ul>	<ul style="list-style-type: none"> <li>❖ US EPA reported that no kidney damage was observed in a dose of 100 mg/kg maleic anhydride every day for 2 years in rat.</li> <li>❖ Similarly, no kidney damage was observed in a dose of 60 mg/kg maleic anhydride every day for 90 days in dog.</li> </ul>



Based on EFSA's information, a TDI (tolerable daily intake) of 0.5 mg/kg is set for maleic acid.

# Risk Assessment of Maleic Acid

- ❖ TDI (Tolerable Daily Intake) 0.5 mg/kg for a 60 kg adult

$$0.5 \text{ mg/kg} \times 60 \text{ kg} = \underline{30 \text{ mg/day}}$$

- ❖ Risk Assessment :

- ❖ Assume tapioca balls contain 400 mg/kg maleic acid. More than 75 g tapioca balls (250 tapioca balls) would be consumed every day over a long period of time to exceed the TDI.

- ❖  $30 \text{ mg/day} \div 400 \text{ mg/kg} = 75 \text{ g/day}$

It is postulated that maleic anhydride modified starch may be metabolized and transform to maleic acid and absorbed completely after injection.



# Actions Taken



# Sequential steps

**Step 1: Latent period 2/4~3/15**

**Step 2: Tracing back and pre-investigation 3/18~5/13**

**Step 3: News release 5/10~5/13**

**Step 4: Enforce inspection national wide 5/14~**



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# Latent period 2/4~3/15

- Whistle blower : in Feb, 2013, TFDA was informed that manufacturers use unapproved maleic anhydride to make food chewy (QQ).
- Relevant information was collected and testing method was developed immediately.



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# Tracing back and pre-investigation 3/18~5/13

- **Development of testing method**
- **Sampling starch products in market** : 74 samples including relevant starches and starch based products such as sweet potato balls, tapioca balls, taro balls, etc. were tested and 5 of them were maleic acid positive
- **Tracing back** : tracking and tracing the source and distribution of products and ingredients involved; recalls, and taking products off the shelves



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# News release 5/10~5/13

■ **May 13, 2013** : TFDA released news about this incident and published all relevant information. Calling for starch related producers should self control, avoid using unapproved modified starch.



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# Enforce inspection national wide 5/14

- complete the investigation, recall, seal, and destroy the illegal products
- enforce the overall inspection to starch factories and additives relevant companies
- Start of 0527 Food Safety Project :
  - ✓ relevant food manufacturers shall provide the affidavit or certificate to the sellers to ensure the safety



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# 0527 Food Safety Project

- ❖ **Health authorities complete the investigations, recall and seal the non-compliant products and destroy the product within 1 week**
- ❖ **All manufacturers of starch based products shall provide Affidavit or Certificate to the sellers**
- ❖ **Health authorities start the overall inspection from June 1**
- ❖ **Speed up amendment of the Act Governing Food Sanitation**
- ❖ **Cooperation among governmental Agencies: chemical management, food exporting, and public communications**

# 0527 Food Safety Project Inspection of Affidavit or Certificate Provided starting from June 1



# 0527 Food Safety Project

## Safe Food Logo is Designed and Distributed by Local Health Bureaus

八大類澱粉加工食品

品名：  
編號：  
有效期限： 年 月 日



嘉義縣政府 關心您



NO.00199



DBP-DEHP-DINP-DIDP-BBP-DNOP

本店所販售之5大類食品皆已提出符合衛生署要求之安全證明。  
五大類食品（運動飲料、果汁飲料、茶飲料、果醬果凍或果凍、膠囊錠狀粉狀之型態）  
The five categories of food we sell all meet the safety standards required by the Department of Health.

The category list is as follows:

1. Sports drink.
2. Juice beverage.
3. Tea beverage.
4. Jam, jelly and fruit juice concentrate.
5. Capsule, tablet and Powder form dietary supplements or goods.

嘉義市政府關心您  
Chiayi City Government Cares for You |  
若有任何疑問請撥 TEL:05-2338066





# Audit in place

## Package



Asking staff in operation line, in particular for recipe, raw material coming in record

## Food Additives



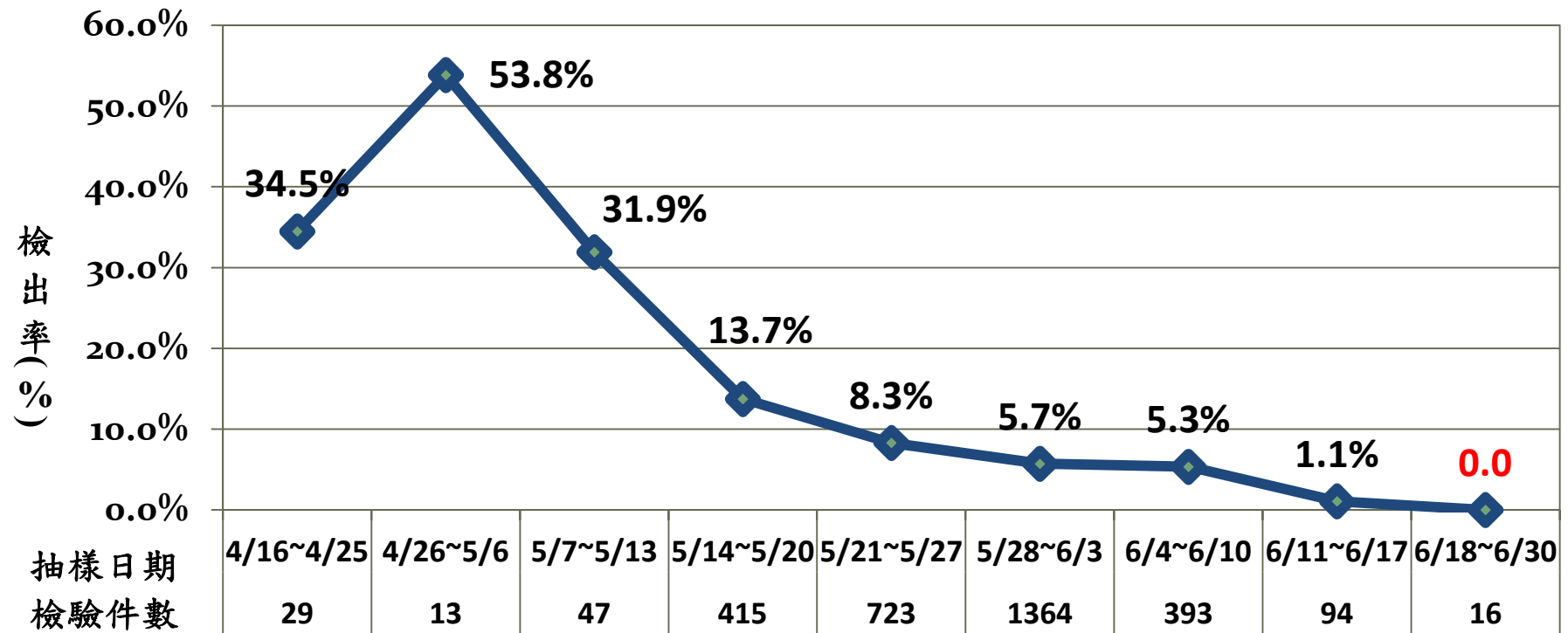
Operation area

# Relevant starch manufacturers involved

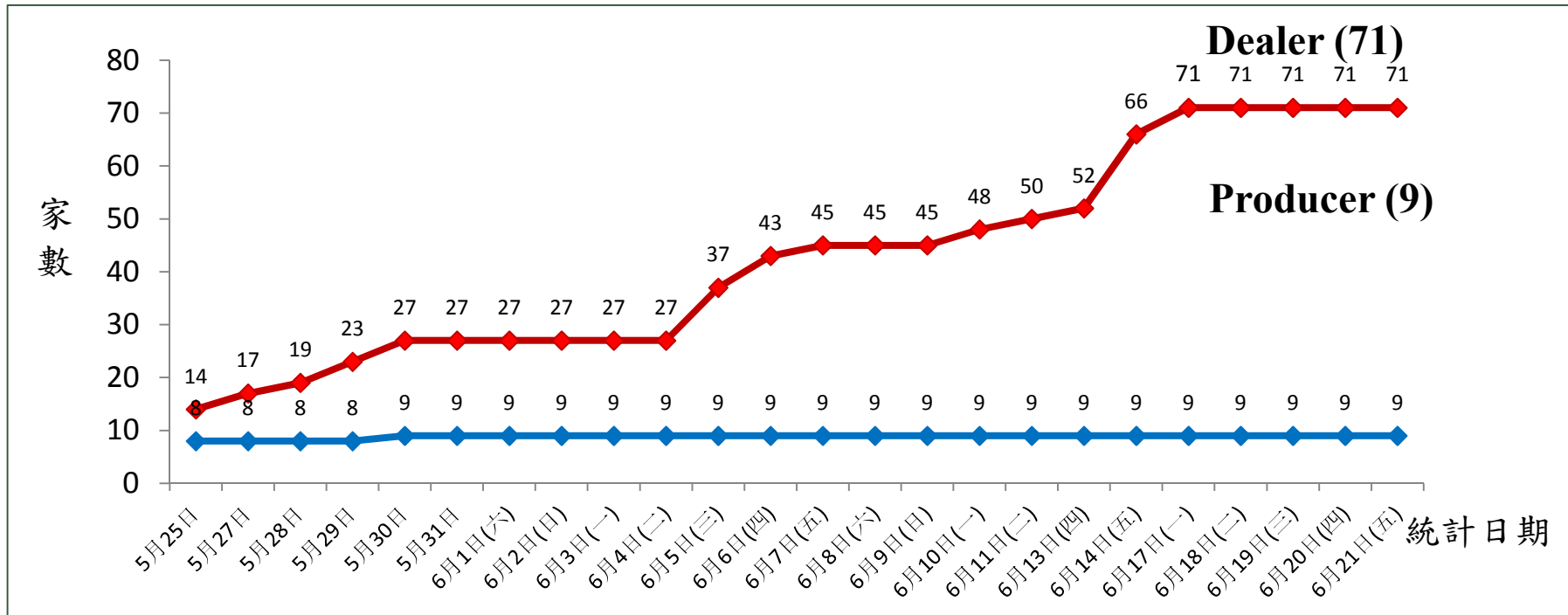
- **Until June 30, 2013, testing 3094 samples.**
- **Test results: 249 positive to MC (79 products, 170 ingredients)**
  - **chemical sellers involved: 4**
  - **starch manufacturers involved: 9**
  - **starch importer involved: 1**
  - **starch dealers involved: 71**
  - **products involved: 11**

# Maleic Acid positive rate

Until June 30, 2013, testing 3094 samples, 249 cases were positive to MC



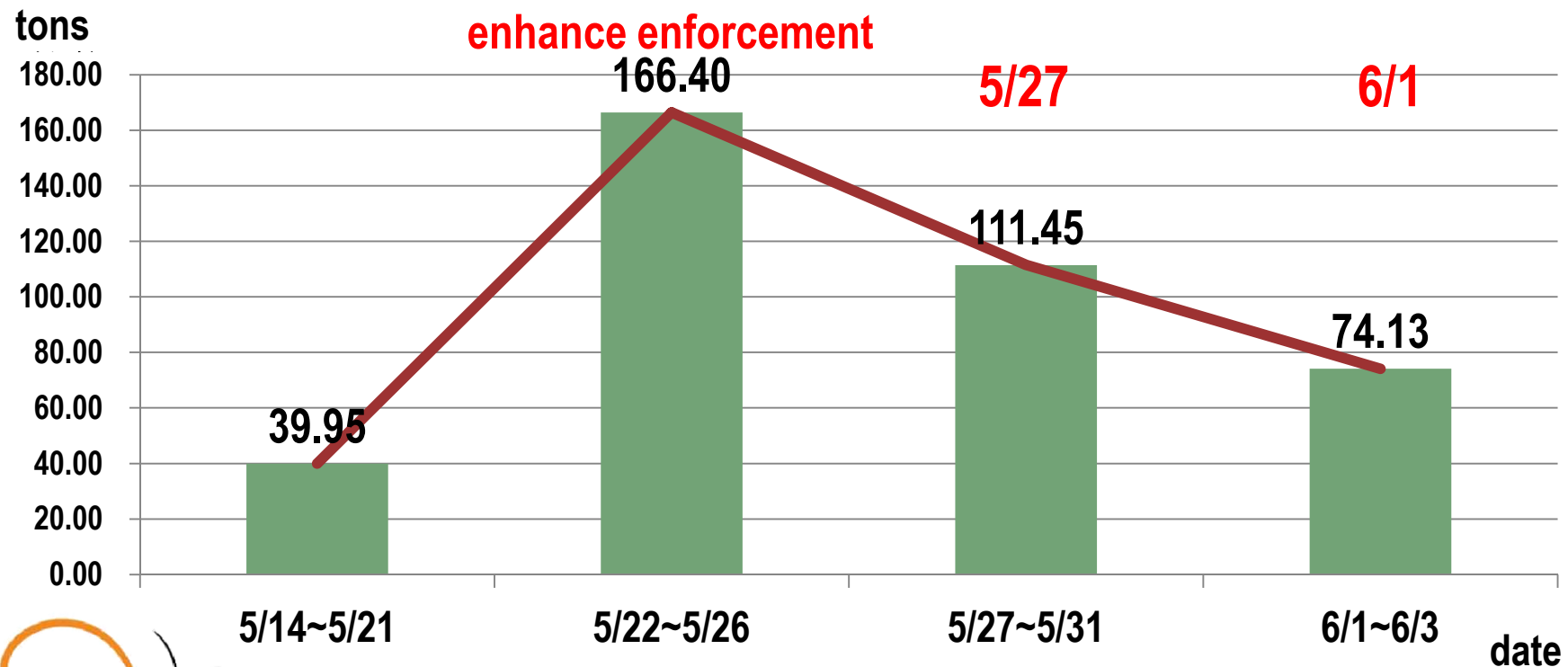
# starch manufacturers involved



統計日期：102年7月22日

# Recalls of Maleic Acid Positive Food Products and Ingredients

By June 3, 2013, 392 tons of products and ingredients were recalled.





# Amendment of Act Governing Food Sanitation



# Amendment of Act Governing Food Sanitation

- ❖ **The statutory bill passed by the legislative Yuan on May 31, 2013**

# Main Points of the Amendment (1/2)

- ❖ **Strengthen domestic food businesses management**
- ❖ **Stipulate food businesses taking responsibilities of self management**
- ❖ **Mandate specific food business to register before doing business**
- ❖ **Establish food tracing and tracking system**
- ❖ **Additional mandatory labeling items**



# Main Points of the Amendment (2/2)

## ❖ **Impose heavier penalties**

- ❖ **Impose heavier fines (up to 15 million NT dollars);**
- ❖ **For adulteration, counterfeiting, using unapproved additives or causing death, the people will be put in jail for 3 years.**

## ❖ **Consumer protection**

- ❖ **Consumer damage compensate, whistleblower protection or penalty reduction to whistleblower**



# Information Transparent and Consumer Protection



# Information Transparent & Consumer Protection

- ❖ **Set up a section of Maleic Anhydride Modified Starch on the websites of TFDA**
- ❖ **TFDA has set up Consumer Hotline at 02-27878200**
- ❖ **26 hospitals of DOH provide related medical consultations; if one consumes food products with modified starches and has any health concern, physicians can help in outpatient referral if needed**



# Conclusions

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**Source has been controlled and the inspection has completed. The DOH ensure food safety and the reputation for foods in Taiwan.**

A stylized graphic featuring two human figures in red and pink, holding hands to form a heart shape. The figures are surrounded by colorful, abstract shapes in orange, green, and blue. The text "THANK YOU FOR YOUR ATTENTION" is overlaid in the center.

**THANK YOU FOR YOUR ATTENTION**

**吃安心 藥安全**



歡迎至本署網站查詢更多資訊 <http://www.fda.gov.tw/>

安全

安門

安定

安通

安產