Contamination of Maleic Anhydride Modified Starch in Food

Submitted by: Chinese Taipei
Contamination of Maleic Anhydride Modified Starch in Food

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Taiwan Food and Drug Administration
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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

- 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
<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Maleic acid</th>
<th>Maleic anhydride</th>
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<tbody>
<tr>
<td>acute toxicity</td>
<td>Low (LD$_{50}$ 708 mg/Kg, Rat)</td>
<td>Low (LD50 400 mg/Kg, Rat)</td>
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<tr>
<td>reproductive and developmental toxicity, genotoxicity, carcinogenicity</td>
<td>none</td>
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<td>nephrotoxicity</td>
<td>Kidney damage was observed in dog with a single dose of 9 mg/kg maleic acid.</td>
<td>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.</td>
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<td>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.</td>
<td>Similarly, no kidney damage was observed in a dose of 60 mg/kg maleic anhydride every day for 90 days in dog.</td>
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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
  
  \[ 0.5 \text{ mg/kg} \times 60 \text{ kg} = 30 \text{ mg/day} \]

- **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 nationwide 5/14~
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.
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
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.
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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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
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

<table>
<thead>
<tr>
<th>抽樣日期</th>
<th>檢驗件數</th>
<th>檢出率 (%)</th>
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<tbody>
<tr>
<td>4/16~4/25</td>
<td>29</td>
<td>34.5%</td>
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<td>4/26~5/6</td>
<td>13</td>
<td>53.8%</td>
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<tr>
<td>5/7~5/13</td>
<td>47</td>
<td>31.9%</td>
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<tr>
<td>5/14~5/20</td>
<td>415</td>
<td>13.7%</td>
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<tr>
<td>5/21~5/27</td>
<td>723</td>
<td>8.3%</td>
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<td>5/28~6/3</td>
<td>1364</td>
<td>5.7%</td>
</tr>
<tr>
<td>6/4~6/10</td>
<td>393</td>
<td>5.3%</td>
</tr>
<tr>
<td>6/11~6/17</td>
<td>94</td>
<td>1.1%</td>
</tr>
<tr>
<td>6/18~6/30</td>
<td>16</td>
<td>0.0%</td>
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</table>

製表日期：102年7月22日(一)
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
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

Source has been controlled and the inspection has completed. The DOH ensure food safety and the reputation for foods in Taiwan.
THANK YOU FOR YOUR ATTENTION

歡迎至本署網站查詢更多資訊 http://www.fda.gov.tw/
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