Report Name: Thailand Updates Its Implementation on GM Foods Regulations

Country: Thailand

Post: Bangkok

Report Category: Biotechnology and Other New Production Technologies

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Report Highlights:

The Ministry of Public Health (MOPH) Notification No.431 B.E. 2565 (2022) RE: Foods Derived from the Genetically Modified Organisms and Ministerial Notification No.432 RE: Labeling of GM Foods went into force on December 4, 2022. The Thai Food and Drug Administration (Thai FDA) has also published updates on the implementation of both these regulations on its website.
Below are key updates on the announcement:

MOPH Ministerial Notifications No. 431 and No. 432 categorize "food derived from genetically modified organisms (GMOs)" into the following three groups:

**Group 1**: Plants, animals, and microorganisms that are edited, trimmed, modified, or altered genetic material or incorporated new genetic material from modern biotechnology and consumed as food.

**Group 2**: Food products that use Group 1 as food ingredients or manufactured from Group 1

**Group 3**: Produced from Group 1 that are used as food ingredient, food additive or nutrient.

<table>
<thead>
<tr>
<th></th>
<th>GM Plants</th>
<th>GM Animals</th>
<th>GM Microorganisms</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1</strong></td>
<td>Parts of corn plants such as young corn</td>
<td>portions of salmon, including fish</td>
<td>microorganisms used in fermentation by</td>
</tr>
<tr>
<td></td>
<td>pods, corn kernels consumed as food, etc.</td>
<td>eggs consumed as food, etc.</td>
<td>consuming living microorganisms together with food (Live starter culture) etc.</td>
</tr>
<tr>
<td><strong>Group 2</strong></td>
<td>canned corn, corn soup, etc.</td>
<td>smoked salmon fillet, seasoned</td>
<td>yeast extract, etc.</td>
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<td></td>
<td></td>
<td>fried salmon skin, etc.</td>
<td></td>
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<tr>
<td><strong>Group 3</strong></td>
<td>corn oil, sorbitol from corn starch,</td>
<td>salmon oil, salmon collagen, salmon</td>
<td>Oligosaccharides, Vitamin B12, Steviol Glycoside, etc.</td>
</tr>
<tr>
<td></td>
<td>modified starch, etc.</td>
<td>cartilage extract.</td>
<td></td>
</tr>
</tbody>
</table>

**Import Documentation**

Genetically Modified (GM) food in Group 2 that were registered with the Thai FDA and imported or sold in Thailand before December 4, 2022, are exempted from providing additional import documents for Thai FDA inspection at the port of entry. However, such food products must comply with GM food regulations. The Thai FDA will conduct random checks to determine whether events contained in the imported food products match the events listed in the positive and temporary approval lists.

GM foods in Group 1 and 3 and GM foods in Group 2 that are registered with the Thai FDA after December 4, 2022, must present one of the following import documents. Both the Positive List (Annex 1) and the Temporary Approval List (Annex 6) are available on page 31 and 60, respectively, in *Agricultural Biotechnology Annual Report 2022*.

- The Thai FDA requires import shipments of Group 1, 2, and 3 to have one of following documents:
  - an analytical report issued by a government laboratory from the country of origin, a government laboratory in Thailand or a private laboratory accredited by the Thai government;
  - a certificate of analysis (COA) for a specific silo/batch issued by a government laboratory from the country of origin, a government laboratory in Thailand or a private laboratory accredited by the Thai government;
• a phytosanitary certification that specifies the events/traits or OECD unique identifier of GM plants;
• a health certification that specifies the events and/or traits or OECD unique identifier or that specifies the absence of any unauthorized GM;
• identify preservation documentation;
• an invoice or packing list that specifies the events or OECD unique identifiers contained if food is derived from GM organisms;
• a self-verified document issued by the manufacturer or exporter stating, “This shipment of (name of plant or animal or microorganism) may contain genetically modified events as following….?” OR other statement with a similar meaning including the contact information of the importing party; or
• a self-verified document of the manufacturer or exporter with a written statement that states the shipment “adheres to MOPH Ministerial Notification No. 431.”
• Import shipments of Group 3 that have undetectable genetically modified organisms and recombinant proteins due to processing may present one of following import documents if a Thai FDA inspector requests for clarification:
  • an analytical report from a recognized laboratory or a government laboratory; or
  • a COA for a specific silo/batch issued by a government agency or from a recognized laboratory.

**Food Safety Assessment**

GM developers must submit a food safety assessment to the Thai FDA and get approval for any GM events that are not listed in the Positive List (Annex 1) or the Temporary Approval List (Annex 6) of Ministerial Notification No.431 B.E. 2565 (2022) RE: Foods Derived from the Genetically Modified Organisms before the GM food can be imported and sold. The developer must submit documentation or evidence as stipulated in Annex II for GM plants, Annex III for GM Microorganisms (GMMs) or Annex IV for GM animals to the National Center for Genetic Engineering and Biotechnology (BIOTEC). BIOTEC will then conduct a food safety assessment and send the final report to the developer. The developer must also submit reference materials or details of the analysis to the Department of Medical Sciences. The last step is for the developer to submit the final food safety report from BIOTEC and the Department of Medical Science’s proof of receipt of the reference material or details of analysis to the Thai FDA. Key details of Ministerial Notification No.431 Re: Food derived from GMOs is available on page 15 in *Agricultural Biotechnology Annual Report 2022*.

Highly refined products produced from GE plants and microorganisms (e.g., rape seeds oil, corn starch, sugar, and syrup) including some food additives and nutrients derived from GMM (e.g., lecithin, sorbitol, propylene glycol esters of fatty acids, mono- and diglycerides, tocopherol, modified starches and maltodextrin riboflavin (vitamin B2) from GM bacillus subtilis, vitamin B12, and amino acid ) are exempted from in-country safety assessments based upon the substantial equivalence principle that examines food safety in the aspects of molecular characteristics, nutrition, toxicology and allergenicity.

Cooking oil, sugar/syrup, corn starch, and nutrients that are highly purified food derived from non-listed GMOs in the Positive List (Annex 1) and Temporary Approval List (Annex 6) of Ministerial Notification No. 431 with undetectable genetically modified organisms and recombinant proteins due to processing are not required to present the import documentation mentioned above but must meet the
same food safety requirements as foods derived from traditional organisms. The following outlines which regulations and guidelines each product must follow:

- **Cooking oil:** MOPH Ministerial Notification No. 421 Re: Oil and Fats
- **Sugar/syrup:** CXS 211-1999: Standard for sugars
- **Corn Starch:** TIS 637-2563 Corn Starch
- **Nutrients:** Pharmacopeia or Food Chemicals Codex

Extracts, substances, and nutrients derived from GMOs must pass in-country food safety assessments by the National Center of Genetic Engineering and Biotechnology (BIOTEC) to determine the appropriate amount used in food.

Food additives derived from GMOs that have passed a safety assessment from the Joint WHO/FAO Committee on Food Additives (JECFA) and adhere to the standard outlined in Ministerial Notification on Food Additive or Codex Combined Compendium of Food Additive Specifications are exempt from in-country food safety assessments. However, the developer must submit the reference material or details on the analysis to the Medical Science Department and inform the Thai FDA so that the approved GMO events can be added to the Positive List (Annex 1).

If any food additive that was previously registered and included in the Positive List (Annex 1) or Temporary Approval List (Annex 6) changes in terms of production or condition of use, BIOTEC will have to conduct an in-country food safety assessment to re-approve its use in Thailand. Developers must submit an in-country assessment from BIOTEC, an analytical report issued by the Department of Medical Science, and the following documents to the Thai FDA to update the registered formula of the food additive:

- an executive summary in Thai and English of the findings of the Food Safety Assessment Report from BIOTEC; and
- documents relating to the submission of information for food analysis from the Department of Medical Sciences, such as books or notifications of the Department of Medical Sciences.

The Thai FDA does not consider self-cloning microorganisms as GMOs and does not require a food safety assessment for them. However, the Thai FDA may classify self-cloning microorganisms as novel food according to Ministerial Notification Re: Novel Food B.E.2559 (2016) and may require a food safety assessment on molecular biology of GM microorganisms and novel food to determine the proportional use as a food ingredient.

**Labeling**

Packaged food products containing any GM ingredients equal to or greater than 5 percent of the total weight with detectable GMOs and recombinant protein resulting from biotechnology must have a label stating the product contains GMOs. In addition, packaged food products that intentionally contain GM plants or animals even less than 5 percent must also be labeled according to Ministerial Notification No. 432 Re: Labeling of GM Foods. If an importer cannot provide the specification of the raw materials in the product, then the Thai FDA requires packaged food products with detectable GMOs and recombinant protein at the level of detection of 0.1 percent to be labeled if the product’s ingredients consists of GMOs over 5 percent of total weight even if it is unintentional. Details of Ministerial
The Thai FDA requires importers or manufacturers to request for a food serial number and display the text “genetically modified” with product name (e.g., “Genetically Modified Soybean” or “Genetically Modified Corn”) for imported GM soybean or corn as raw material for further food processing or manufacturing. Food operators need to display food additives on the label of the final product only if there is genetic material or recombinant proteins detectable in the final product.

Attachments:

No Attachments.