

REGULATION OF FOODS CONTAINING GMO COMPONENTS IN THAILAND

What are the draft amendments and potential impact to the industry?



Use of genetically modified organisms (GMOs) in food products is not uncommon in various markets. In Thailand, only imported foods are allowed to contain approved plant-derived GMOs. In the latest draft amendment in July 2019, Thai FDA proposed to enforce mandatory safety assessment for all GM foods. In addition, the regulation on labelling of GMOs in foods is currently undergoing internal reviews by the Sub-Committee of Food Labelling under Thailand Food and Drug Administration. Key proposed amendments to the labelling requirements include making labelling of GM microorganism component in food product mandatory, introduction of a yellow triangular symbol with the text "GMO" and requirement to indicate a statement that food is produced from a specific GM plant or animal or microorganism. This report evaluates the draft amendments and its impact to industry and aims to provide clarity for industry to take necessary actions.

THAILAND'S PROPOSED AMENDED REGULATION AT A GLANCE

| Criteria | P | roposed Ame <mark>nde</mark> d Regulation | Current Regulation | |
|----------|---|---|---|--|
| Scope | • | GM plants, GM animals, GM microorganisms Food produced from GM plants, GM animals, GM microorganisms Food produced from GM plants or animals or microorganisms and used as a component of food or as food additives or as nutrients | Only designated <u>GM plants</u> (soybean and soybean products, corn and corn products) are required to be labelled above a certain threshold | |

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| Safety Assessment | • | Mandatory safety assessment for <u>all</u> GM foods in accordance to Appendix 2 (GM plants), Appendix 3 (GM animals) and Appendix 4 (GM microorganisms) | • | Voluntary notification of <u>GM</u> plants through submission of documents on safety for human consumption before import Quarantine for plant commodities imports |
|-------------------------|---|---|---|---|
| Declaration / Labelling | • | Labelling is mandatory when GM food contains 5% or more of the GM-derived plant or animal components in a food product Labelling is mandatory when GM food contains GM components derived from GM microorganisms Introduction of a yellow Triangular mark containing the word "GMO" in black colour font Indication of the statement "[Food/product name] is produced from genetically- modified [plant / animal / microorganism name]" shall be displayed along with the product that is derived from genetically-modified plant or animal or microorganisms | • | Labelling is required when: The GM ingredients contributes to 5% and above of the total combined weight of the top 3 ingredients; and in addition, each ingredient should be at least 5% of the total weight of food product |

EVALUATION OF DRAFT AMENDMENTS

GM Food Safety Assessment

- GMO Regulations to include requirements for food safety assessment for 3 broad categories
 of GM foods namely GM-derived plants, GM-derived animals and GM-derived
 microorganisms
- In case GM-derived plants and its products have not passed the food safety assessment in Thailand according to Article 4, but are still being produced or imported in accordance with the criteria and conditions specified by Thai FDA, manufacturer or importer shall submit documents or evidence not exceeding 5 years from the date that this notification comes into effect. The documents or evidence include:

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- Submission of documents or evidence to show that ingredient is a GM-derived plant that have passed the food biological safety assessment from the exporting countries' government agency responsible or approved agencies designated by the exporting government agency that already have in place guidelines for evaluating food safety from GMOs based on Codex Alimentarius Commission, Joint FAO/WHO Food Standards Program (GM-derived plant must first be proven safe in exporting country)
- Alternatively, submission of the guidelines for safety assessment as specified in the Appendix 2 for minimum 3 other third-party countries which do not develop or manufacture GM-derived plants for commercial purposes
- Next, submission of evidence to prove that the GM-derived plants are in the process
 of undergoing food biological safety assessment in Thailand in accordance with
 requirements in Article 4 (1)(a). Such evidence includes the terms of reference,
 reference material, method of analysis or other information necessary for the analysis
 to the Department of Medical Sciences or other departments or laboratories
 designated by FDA
- Finally, when the above proceedings are completed, submission of the food biological safety assessment's results from the National Center for Genetic Engineering and Biotechnology, National Science and Technology Development Agency or a designated agency by FDA that indicate that the GM-derived plant in use has passed the food biosecurity assessment in Thailand.
- Last but not least, manufacturer or importer must submit these documents and evidence to FDA to confirm that use of GM-derived plant is in accordance with Article 4 (1)

Impact Analysis

The flexibility of allowing GM-derived plants that have passed food biological safety assessment in the country of manufacture but not in Thailand enables industry to import food products containing such GM-derived plants into Thailand amid ongoing food biological safety assessment that is carried out by approved Thai agencies. It also provided an alternative for proof of the safety of GM-derived plants by allowing the submission of guidelines provided by three third-party countries that the Thai FDA recognises.

While the GM food safety assessment is proposed to ensure that products are being assessed based on its risk and toxicity to human health, there are areas within the draft regulation that may pose potential challenges to the industry.

In this reg<mark>ulation</mark>, it proposed to take into account various GM-derived sources including GM-derived plants, GM-derived animals and GM-derived microorganisms. With the introduction of two new areas into the scope, industry may face the challenge of feasibility and ability to follow the regulations.

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It is proposed to prioritise GM-derived plants used by the industry because industry is more familiar with the import of GM-derived plants to Thailand. Nonetheless, industry would need time to adjust to the amendments for GM-derived plants which require industry to provide mandatory safety assessment results. One concern around processed food products that contain GM plant ingredients is the availability of data from suppliers.

In light of the differences in safety assessment measures required for different GM-derived food categories and the complexity of addressing the requirements for GM microorganisms such as issue around how to address living microbes, non-living microbes and more, more consideration is needed and therefore it is proposed to postpone the implementation of safety assessment for GM-derived microorganisms.

GM Food Labelling

- Amendments are still at the stage of drafting by the Sub-committee on Food Labelling under Thailand FDA
- GM Food Labelling is applicable to GM-derived plants, GM-derived animals and GM-derived
 microorganisms intended for consumption as food, food products resulting from the use of
 GM-derived plants, animals or microorganisms, and products of GM-derived plants, animals
 or microorganisms which are used as food components or food additives or nutrients to be
 added into food.
- Proposed that food with GM food shall be labelled
- Declaration of the text "Genetically-Modified" when a food product comprises of 5% and above of the GM-derived plants, GM-derived animals in bold and clearly legible font size and colour against the label's background colour
- Declaration of the text "Genetically-Modified" when a food product comprises of GM-derived microorganism components in bold and clearly legible font size and colour against the label's background colour
 - For food product with single component or one main GM-derived component present, the text "Genetically-Modified" shall be displayed along with the food name
 - o For multiple GM-derived components present, the text "Genetically-Modified" shall be displayed at the end or beneath the name of that component (within the ingredient list), as is appropriate to each case
 - The statement "[Food/product name] is produced from genetically-modified [plant / animal / microorganism name]" shall be displayed along with the product that is derived from GM-derived plant or animal or microorganisms
- Display of a yellow **Triangular mark** containing the word "GMO" or text providing additional information in black colour font

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- Exclusion of labelling requirements for GM food which does not contain genetically-modified substances or proteins resulting from genetic modification in its end product
- Prohibited to display text "GMO-free food" or "Not a GMO food" or "No components containing genetically-modified organisms" or "Sorting out or separation of geneticallymodified components has been performed" or any other text or symbols in the same manner in every category of food labelling
- Under Section 6, it mentions that food labelling that has received authorisation for production or import from genetically-modified organisms prior to the enforcement of the new draft amended GMO labelling regulation may still be distributed, for a duration no longer than 2 years from the enforcement of the updated regulation.

Impact Analysis

Labelling of "GM-modified" is mandated since 2002, requiring imported food products that carry 5% and above by weight based on the top 3 ingredients and 5% and above of GM content of the total weight to be labelled. Under the proposed new regulation, GM-derived plant and animal products with 5% and above content and GM-derived microorganism components shall be labelled accordingly.

Furthermore, industry would also need to take note of additional labelling requirements. GM products shall also declare a statement indicating that food product is produced from specific type of genetically-modified plant or animal or microorganism.

In addition, a new label is being introduced – a yellow triangle mark indicating "GMO" on GM products that is similar to the practice in Brazil to identify GMO foods. The inclusion of the yellow triangular mark may mislead consumers to perceive the mark as a warning label and cause unnecessary alarm. It is proposed to omit the inclusion of a yellow triangular mark in the regulations.



REFERENCE OF THE DRAFT REGULATION (SAFETY ASSESSMENT)

| Part of amended regulation | Content | | | |
|----------------------------|---|--|--|--|
| Appendix 1 | List of genetically modified plants that have passed food safety assessments | | | |
| Appendix 2 (Part 1) | Supporting evidence requirements of food safety evaluation from genetically modified plants | | | |
| Appendix 2 (Part 2) | Supporting evidence requirements of food safety evaluation from genetically modified plants (stacked event) | | | |
| Appendix 3 | Classification of Genetically modified microorganisms | | | |
| | Supporting evidence requirements for the food safety assessment from genetically modified microorganisms | | | |
| Appendix 4 | Supporting evidence requirements of food safety assessment from genetically modified animals | | | |
| Appendix 5 | Methods of analysis of food derived from GM sources | | | |

This report is prepared by the FIA Regulatory team. Should you have any questions, please contact:

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