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Thai FDA's New GMP Requirements for Low Acid and Acidified Foods

Report Categories:

Sanitary/Phytosanitary/Food Safety

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Report Highlights:

TH2114: The Thai Food and Drug Administration (FDA) has notified the WTO of its new GMP requirements for low acid and acidified foods in sealed containers (G/SPS/N/THA/206 and G/TBT/N/THA/406). U.S. exporters of low acid and acidified foods in sealed containers to Thailand must provide a certificate of place of production that meets the standard set by the proposed regulation. U.S. exports of low acid and acidified foods in sealed containers to Thailand are estimated to be more than \$8 million annually.

General Information:**Thailand's New GMP Requirements for Low Acid and Acidified Foods in Sealed Containers.**

On September 18, the Thai Food and Drug Administration (FDA) notified the WTO of its new Good Manufacturing Practice (GMP) requirements for low acid and acidified foods in sealed containers (G/SPS/N/THA/206 and G/TBT/N/THA/406). In its notification, the Thai Government stated that it has a policy to promote the production of foods in sealed containers, especially those products that contain processed and preserved agricultural ingredients in sealed containers. However, there are some concerns in Thailand that if the production does not correctly conform to the principles in relation with the production process, quality control of production, and equipments used in the production, the product can be risky for consumers' health and may cause death from toxic microorganisms like clostridium botulinum. The botulinal toxin can cause botulism, which affects the body's central nervous system and has been continually seen in patients in Thailand. As a result, the Thai FDA has proposed the new GMP regulation for low acid and acidified foods in sealed containers. This specific GMP regulation is aimed to control the tools and equipments used for sterilization in the production process.

Main points of the draft notification are as follow:

- The draft notification stipulates the definitions of “low-acid food in sealed container” and “acidified foods in sealed container.”
- The draft notification defines the criteria, production methods, tools and equipments used in the production and food storage for low-acid and acidified foods in sealed containers. It includes the auditing records for the place of production.
- The draft notification defines the list of tools, machines, and equipments used in the sterilization process.
- The draft notification sets training courses for retort supervisors and the process authorities that control the heat sterilization process for the production of low acid and acidified foods in sealed containers.
- The draft notification requires the importer of low acid and acidified foods in sealed containers to import the products from the place of production that passed the audit performed by the Thai FDA or other organizations authorized by the Thai FDA. The place of production is required to meet the standards defined in the draft notification. In absence of a Thai FDA audit, the importer must provide a certificate of place of production stipulated under the draft notification.

- Law enforcement duration:

Existing food manufacturers and importers who already received the food production/import license or registration number from the Thai FDA for the place of production of low acid and acidified foods prior to the enforcement date of the notification is required to comply with clauses 3, 5, and 6 of the draft notification or provide a certificate as stipulated in clause 4 of the draft notification within a year from the enforcement date of the notification.

New food manufacturers or importers must conform to the notification after 180 days following the date of publication in the Government Gazette.

The proposed regulation is expected to impact the export of U.S. low-acid and acidified foods to Thailand, which is estimated to be more than \$8 million annually. U.S. exporters of low acid and acidified foods in sealed containers to Thailand must provide a certificate of place of production that meets the standards set under the proposed regulation.

Below is the draft notification of the Ministry of Public Health Re: Production methods, tools and equipments used in the production and food storage of low acid and acidified foods in sealed containers.

(Unofficial)

Notification of the Ministry of Public Health

Re: Production methods, tools and equipments used in the production, and food storage for low acid and acidified foods in sealed containers

Whereas it is deemed to improve and elevate the production standard of foods in sealed containers to be suitable and ensure the quality or standard in order to increase the safety of consumers.

By virtue of Section 5(1) and Section 6(7) of the Food Act B.E. 2522 (1979) in which contain provisions in relation to the restriction of Rights and Liberties of the Person, in respect of which Section 29 and in conjunction with Section 33, Section 41, Section 43 and Section 45 of the Constitution of the Kingdom of Thailand so permit by virtue of provisions of law; the Minister of Public Health hereby issues the notification as follows:

No.1 In this Notification,

“Low-acid foods in sealed containers” means foods passed through the heat sterilization process to destroy or restrain the propagation of microorganism before or after containing or being sealed. This also includes other foods in sealed containers made of metal or other materials, which are fixed or unfixed in shapes, of similar production process with pH value of more than 4.6 and water activity value of more than 0.85. The containers must be able to prevent air penetration into the containers and must be stored in the normal temperature.

“Acidified foods in sealed containers” means foods passed through the heat sterilization process to destroy or restrain the propagation of microorganism before or after containing or being sealed. This

also includes other foods in sealed containers made of metal or other materials, which are fixed or unfixed in shapes, of similar production process with low acid, the process adjusting pH value to be not greater than 4.6, and water activity value is greater than 0.85. The containers must be able to prevent air penetration into the containers and must be stored in the normal temperature.

No.2 Low acid and acidified foods in sealed containers are particularly prescribed to production methods, tools and equipments used in the production, and food storage.

No.3 The producers of low acid and acidified foods in sealed containers shall conform to the production methods, tools and equipments used in the production, and food storage not lower than the criteria mentioned in the appendix 1 attached to this Notification.

No.4 The importers of low acid and acidified foods in sealed containers for sale shall import such products from the production places following the production methods, tools and equipments used in the production, and food storage not lower than the criteria mentioned in the appendix 1 attached to this Notification; and passed the audit from the Food and Drug Administration or other organizations defined by the Thai FDA or the importer shall provide the certificate for place of production of low acid and acidified food imports to at least follows the requirements of production methods, tools and equipments used in the production, and food storage in the appendix 1 attached to this Notification.

In the case that there are some reasons or necessity for the verification of food safety system to preventing the consumer safety, Food and Drug Administration shall specify the production places as mentioned in clause 1 to be required to be audited by the Food and Drug Administration, or other organizations, or agencies specified by Food and Drug Administration.

No.5 The producers of low acid and acidified foods in sealed containers shall provide the lists of tools, machines, and equipments used in the production of low acid and acidified foods in sealed containers not lower than the required criteria mentioned in the appendix 1 and 2 attached to this Notification.

No.6 The producers of low acid and acidified foods in sealed containers shall arrange to have the Retort Supervisors and Process Authority who controls the heat sterilization process for the production of low acid and acidified foods in sealed containers that passed the training courses not lower than the requirements mentioned in appendix 3 attached to this notification.

No.7 The audit of production places for low acid and acidified foods in sealed containers shall follow appendix 4 attached to this Notification.

No.8 The consideration of audit results of production places for low acid and acidified foods in sealed containers shall conform to the requirements mentioned in appendix 5 attached to this Notification.

No.9 The persons who received the license for food production, registration number of food production place, or license for the import of low acid and acidified foods in seal containers, whichever case applied prior to the date of enforcement of this Notification must perform the improvement and amendment or provide the certificate follow clause 3, 5, and 6 or clause 4, whichever case applied, within one year from the date of enforcement of this Notification.

No.10 This notification shall come into force after 180 days as from the day following date of its publication in the Government Gazette.