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Report Name: Indonesia Updates Regulations on Genetically Engineered Processed Products

Country: Indonesia

Post: Jakarta

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Report Highlights:

On November 18, 2024, the Government of Indonesia (GOI) issued Regulation No. 19/2024 on the Supervision of Genetically Engineered Food which updates the labeling requirements for genetically engineered (GE) products, and regulates microbial biotechnology, genome editing, and the food safety assessment of products with stacked genes. Specifically, the GOI plans to enforce an existing requirement for processed food products containing at least five percent GE material to be labeled accordingly. This may have little impact on U.S. GE product exports to Indonesia, currently valued at over $2.1 billion, since fresh GE products (e.g., soybeans) and those which have been refined and no longer contain GE DNA/proteins are exempt. To date, no processed food products containing five percent GE materials have been registered with the GOI, and so FAS Jakarta is not aware of any products in commerce in Indonesia that are required to be labeled in accordance with this new regulation.

BPOM Regulation No. 19/2024
Signed on November 18, 2024, Indonesian Food and Drug Agency (BPOM) Regulation No. 19/2024 on the Supervision of Genetically Engineered (GE) Food supersedes BPOM Regulation No. 6/2018. The new regulation covers requirements for genome edited products, required labeling procedures for food products containing GE ingredients, as well as guidelines for the food safety approval process for GE food products and GE products with stacked genes. In addition, this regulation covers the guidelines for the food safety approval process for refined GE food products produced using GE microorganisms such as enzymes, monosodium glutamate, amino acid, vitamin B12, and preservatives.

Although the regulation is already in effect, there is a 12-month grace period for processed food products containing at least 5-percent GE material to come into compliance with the labeling requirements if the product was already in commerce in Indonesia prior to the enactment of this regulation. The Government of Indonesia (GOI) has not notified this measure to the WTO; however, BPOM officials reported they are in the process of notifying it to the WTO.

Labeling of GE Food Products
Although there has been no change in the actual procedures for GE food labeling, these guidelines have now become requirements. For example, packaged food containing at least five percent GE Deoxyribo Nucleid Acid (DNA) must be labeled "PRODUK REKAYASA GENETIK" (Genetically Engineered Product). According to BPOM Regulation No. 19/2024, in order to confirm the GE content of a product, "the GE DNA content is evidenced by testing results from government laboratories and/or other accredited laboratories in accordance with the provision of the prevailing regulation." When asked for clarification on the testing requirements for imports, BPOM informed Post that GE DNA content testing for imported products should be conducted in the exporting country at a "laboratory accredited by the competent authority." Local product testing should occur at GOI laboratories or GOI-accredited laboratories. Post is seeking further clarity from BPOM on which competent authority should accredit the testing laboratory and according to which standards.

If the food product contains more than one GE food ingredient, the percentage of GE DNA content must be calculated for each GE food ingredient. Although this regulation does not include guidelines on how to calculate GE DNA percentages, BPOM officials shared their internal guidelines to implement their regulations in certain processed foods, including processed GE food, which is a guideline for interpretating GE food DNA testing results. An excerpt of these guidelines can be seen at this link. BPOM officials reported that they will re-review these guidelines this year and FAS Jakarta will continue to seek clarity.

To obtain an entry permit (SKI) for an imported product, BPOM requires the applicant to provide either a Genetically Modified Organism (GMO) or non-GMO statement for food containing soybeans, corn, tomatoes, and potatoes. A qualitative testing result is sufficient to prove the product is a GE product that must obtain a food safety certificate from BPOM. Then, to obtain a distribution permit, this product should be tested quantitatively to meet labeling requirements. According to this guideline, a quantitative analysis of GE DNA is calculated as follows:

$$\% \text{ DNA GE} = \frac{\text{GE-specific DNA event}}{\text{Endogenous gene DNA}} \times 100\%$$

Notes:
Endogenous DNA is a specific gene that is always expressed in a particular species, which is different for each commodity, such as:

- soybean : lectin
- corn : hmg
- potato : ugp
- sugar cane : p5cs

The rule on when to include "PRODUK REKAYASA GENETIK" labeling is as follows:

1) For GE food products containing a single raw GE ingredient, the name of the food type should be included in the main part of the label, for example: "Tahu PRODUK REKAYASA GENETIK" (Tofu GENETICALLY ENGINEERED PRODUCT).
2) If a GE product is used as a raw material in processed food, the name of the GE product should be put in the list of used ingredients. For example, a tortilla chip should be labelled "Komposisi: Jagung Produk Rekayasa Genetik, Bumbu (mengandung penguat rasa MSG), Pewarna makanan kuning FCF CI 15985" (Composition: Genetically Engineered Corn Product, Seasoning (contains flavor enhancer MSG), yellow food coloring FCF CI 15985).

This labeling requirement does not apply to fresh GE food products, such as GE soybeans or GE corn. In addition, GE food products that have been refined and no longer contain GE DNA/protein, such as oils, fats, sucrose, and starch, do not need to include GE labeling.

To date, no food products containing five percent GE material have reportedly been registered with BPOM. As a result, FAS Jakarta is not aware of any U.S. products in commerce in Indonesia that are required to be labeled in accordance with this new regulation.

Genome Editing
This regulation states that food produced through the genome editing process could result in GE food or non-GE food. Only GE food products are required to obtain food safety approval from BPOM, while non-GE food can be considered conventional food. This regulation does not specify how to differentiate between GE food or non-GE food derived from genome editing but defers to the mechanisms that will be provided by Indonesia's Biosafety Commission on Genetically Engineered Products (BCGEP). Currently, BCGEP is still drafting the scheme for approving genome edited products. Please see GAIN report ID2024-0034 to see the scheme draft.

Microbial Biotechnology
GE products produced using GE microorganisms include food additives, processing aids, and compounds used as ingredients. Unlike the food safety approval process for other GE products (in which the Head of BPOM issues the food safety certificate after receiving the Biosafety Commission's recommendations), refined GE food products derived from GE microorganisms (microbial biotechnology) require written approval from the Head of BPOM through the Director

of Processed Food Standardization. The scope of the assessment of this type of product includes the safety of the GE microorganisms used and the content of GE DNA and/or GE protein in the product. Although this regulation lays out specific requirements for approving the use of refined GE products derived from GE microorganisms, it does not provide a timeline for the approval process, making it difficult to determine how long it will take for a product to be approved after the application is submitted to the Director of Processed Food Standardization.

GE Products with Stacked Genes

The issuance of this regulation supersedes BPOM Regulation No. 10/2021 on Business Activity and Product Standards in the Implementation of Risk-Based Business Licensing in the Drug and Food Sector in regulating products with stacked genes. The regulation outlines the food safety approval guidelines for GE products derived from the conventional crossing of GE lines in more detail. The regulation contains the food safety requirements of products with stacked traits, the application procedures and mechanisms for their food safety assessment, and the assessment materials, such as required data and information.

The high-covers-low policy is applied for approving the food safety of stacked trait products. The highest stack covers its sub-combination, but all single events must have already obtained their own food safety approvals. Moreover, a stacked traits product resulting from the conventional crossbreeding of GE lines, and not from molecular crossing, does not require its own food safety assessment. For example, if event A, event B, event C, and event D have all obtained their food safety approvals, A x B x C x D or A x B x C or A x C will also automatically be approved.

Attachments:

No Attachments.