2025년 한-아세안 위생협력 ODA 세미나

Food Safety Management and Product Inspection in Indonesia

Dewi Prasetyaningrum I Indonesian FDA Ikeu Siti Khodijah I Indonesian FDA



2025년 한-아세안 위생협력 ODA 세미나

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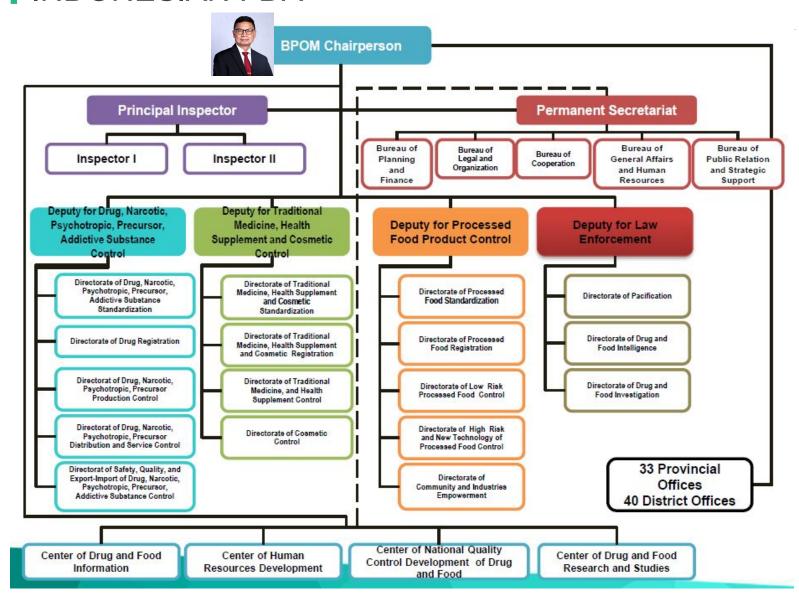


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# 01 Introduction



## I INDONESIAN FDA



Indonesian FDA is a regulatory authority responsible for food and drug control whose Chairperson reports directly to the President of the Republic of Indonesia.

- Legal Basis:
- ☐ Presidential Decree No. 80/2017
- ☐ Presidential Instruction No. 3/2017
- ☐ Presidential Instruction No. 6/2016
- 33 provincial offices
- 40 district city offices
- approx. 6000 human resources

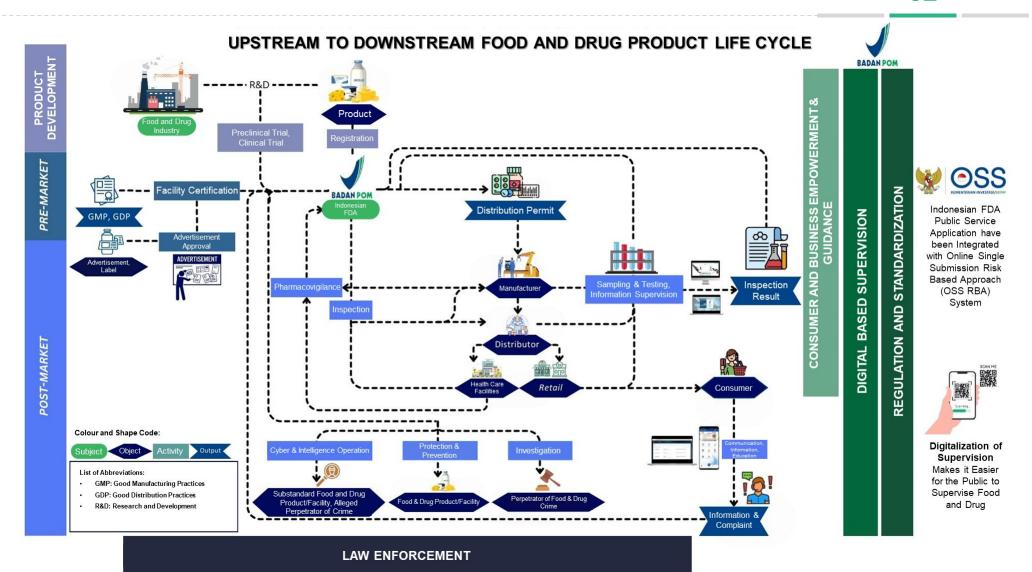
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# 02 Scope of Food and Drug Control



### 02

# Scope of Food and Drug Control



# Scope of Food and Drug Control







**Medicines and biological products** 

Narcotics, psychotropics, precursors, and addictive substances

Traditional medicines and natural products







**Health supplements** 

**Cosmetics** 

**Processed food** 

# Scope of Food and Drug Control

# Food Safety Supervision Before Distribution



# **Food Certificate**

| Category                   | Product Type                        | Certification/License                            | Responsible Authority                    |
|----------------------------|-------------------------------------|--|--|
| Packaged<br>Processed Food | MD/ML Processed Food                | MD (Domestic) / ML (Imported) Food Registration  | BPOM (National Food and Drug Authority)  |
|                            | Home Industry Processed Food (PIRT) | PIRT (Home Industry Food Production License)     | Local Government                         |
| Ready-to-Eat Food          | Prepared Food Sold Directly         | Hygiene and Sanitation Eligibility Certificate   | Local Government                         |
| Fresh Food                 | Fresh Plant-Based Food              | PSAT Certificate (PD/PL/PDUK)                    | Ministry of Agriculture                  |
|                            | Fresh Animal-Based Food             | PSAH Certificate (PHD/PHI)                       | Ministry of Agriculture                  |
|                            | Fresh Fish-Based Food               | PSAI Certificate                                 | Ministry of Marine Affairs and Fisheries |
| Food Containing<br>Herbal  | Food Containing Herbal Ingredients  | Depends on claim (functional, traditional, etc.) | Relevant Authorities (BPOM or others)    |

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Updates and Revisions to the National Food Safety Regulatory System (Last 3 Years)



Main Reference: Law No. 18 of 2012 on Food

### **Latest Legal Updates:**

- Law No. 11 of 2020 on Job Creation (Omnibus Law)
- Amendment: Law No. 6 of 2023

# Key Innovations in Processed Food Supervision: All processes through OSS (Online Single Submission)

- Registration for production facilities:
  - Good Processed Food Production Practices (CPPOB)
  - Risk Management Program (PMR)
- Risk-Based Processed Food Registration
- Processed Food Safety Management System (SMKPO)
  - for retail facilities

| No                               | Area/Topic                           | Regulation  | Key Points   |  |
|----------------------------------|--------------------------------------|---|--|--|
| 1                                | General Food Law                     | Law No. 18/2012 on Food   | Governs food production, safety, labeling, distribution, and consumer protection               |  |
| 2                                | Licensing Reform                     | Law No. 11/2020 (Job Creation<br>Law) Amended by Law No. 6 of<br>2023 | Introduces Risk-Based Approach to licensing through OSS (Online Single Submission)             |  |
| 3                                | Risk-Based Licensing                 | Government Regulation (PP) No. 5/2021                                 | Classifies business risks (low, medium, high) to determine licensing requirements              |  |
| 4 Food Safety Supervision        |                                      | Government Regulation (PP) No. 86/2019                                | Provides national framework on food safety, traceability, emergency measures                   |  |
| 5                                | Processed Food Supervision           | BPOM Regulation No. 20/2021   | Covers pre-market and post-market supervision, inspections, product recalls                    |  |
| 6 Registration of Processed Food |                                      | BPOM Regulation No. 6/2020  | Basis for food registration through e-Reg; includes document requirements and evaluation scope |  |
| 7                                | Risk-Based Supervision<br>Guidelines | BPOM Regulation No. 27/ 2022  | Risk categories determine inspection intensity and scope                                       |  |

| No | Area/Topic                          | Regulation  | Key Points  |  |
|----|-------------------------------------|---|---|--|
| 8  | Good Distribution Practices (CDOB)  | BPOM Regulation No. 24/2021   | Distribution facilities encouraged to implement SMKPO; mandatory for new importers          |  |
| 9  | Food Labeling                       | BPOM Regulation No. 30/2017   | Regulates mandatory labeling, including name, ingredients, net weight, nutrition info, etc. |  |
| 10 | Food Additives (BTP)                | BPOM Regulation No. 11/2019   | Lists approved food additives, maximum limits, and declaration requirements                 |  |
| 11 | Special Medical Purpose Food        | Minister of Health Regulation No. 14/2021                                     | Regulates FSMP (Food for Special Medical Purposes), nutrient content, and claims            |  |
| 12 | Fishery Product Safety              | Minister of Marine Affairs<br>Regulation No.<br>51/Permen-KP/2015             | Quality, sanitation, and safety assurance for fish and seafood products                     |  |
| 13 | Home Industry Processed Food (PIRT) | Local Government Regulations (Pemda) under Law No. 23/2014 and MOH guidelines | PIRT managed at district level for home-scale producers, integrated with OSS                |  |

#### Izin Penerapan CPPOB

**Good Manufacturing Practices (GMP) Certificate of** Compliance is a valid document certifying that a food processing facility complies with GMP standards. The certificate is location- and/or process-specific.

The CPPOB Implementation Permit is issued according to the location and/or processed food production process.

The GMP Certificate of Compliance is valid for 5 years, subject to no changes and continued compliance with requirements.

Applications are processed through the e-certification portal, integrated with the Online Single Submission (OSS) system of the Investment Coordinating Board.



#### PEMERINTAH REPUBLIK INDONESIA

#### PERIZINAN BERUSAHA UNTUK MENUNJANG KEGIATAN USAHA IZIN PENERAPAN CARA PRODUKSI PANGAN OLAHAN YANG BAIK PB-UMKU: 120800071150900140003

Pemerintah Republik Indonesia menerbitkan Perizinan Berusaha Untuk Menurjang Kegistan Usaha (PS-UMKU), yang merupakan Izin Penerapan Cara Produksi Pangan Olahan yang Baik kapada Pelaku Usaha berikut inti

- 1. Marca Dalaku Usaha
- 2. Norror Induk Berusaha (NIB):
- 3. Alamat Kantor
- 4. Status Persenaman Modal
- Indonesia (KBLI)
- 6. Lokasi Ukaha

- BURN ALAM DAMA : 1208000711509
- : Beltway Office Park, Tower B Level S, Jl. TB. Simelupang No.41
- Kode Pos: 12550 : Pananaman Modal Dalam A
- 5. Kode Klasifikasi Baku Lepangan Usaha : 10212 Industri Pengan an Pemanggangan Ikan

- 1. Penerapan CPPOS pada Sarana Produkai Pangan m rangka pendaftaran, eksportasi atau hipiera
- Stander den Persyansten ich Perenspan
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   Jang balk berdassakan hasti pemerikasan oleh lembaga pemerikah yang menyelenggasak basi pemerintah di bidang pengawasan Olah dan Makanan

Lampinan Perizinan Berusaha Untuk M. Leripti, Kogiatan Usaha ini memuat data teknik yang merupakan bagian tida terpisahkan dari dokumen ini. Pelaku U. M. temebut di atas wajib menjalankan kegiatan usahanya sesuai denga Koglatan Usaha ini memuat data teknis yang merupakan bagian tidal keteréuan perundang-undangan yang berlaku.

Dilerbitken tanggal: 26 Oktober 2021

a.n. Kepata Badan Pengawas Obst dan Makanan Mantari Impostanti epale Badan Koordinasi Penanaman Model



Ditandatangani secara elektronik

Dicetak tenggal: 27 Oktober 2021

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Commercial Sterile Food and Special Purpose Food are required to implement a Risk Management Program (BPOM Regulation No. 10/2023)

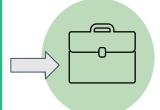


Recognition of industry independence in ensuring product safety.



### **Risk Management Program**

A program designed and developed to ensure the safety and quality of food products, as well as compliance with applicable regulations and laws, through risk-based supervision carried out independently by the food industry.



Manifestation of the implementation of Risk-Based Preventive Food Safety Control.



Preventive control is considered more effective in controlling food safety risks.

03

#### HIGH RISK (T)

- New registration for PKGK food.
- Includes: fortified food, GMO food, irradiated food, food using food additives (BTP)/raw materials with maximum usage limits, alcoholic beverages, pasteurized food, commercial sterilization, or other new technologies.
- Registration for major variation of high-risk food.

#### **HIGH RISK (Notification)**

New registration for high-risk food with PMR, voluntary SNI certificate, similar food (same high risk) already registered, and organic food.

#### MEDIUM-HIGH RISK (MT)

- Registration of food required to comply with SNI.
- Major variation registration for medium-high-risk food.

#### MEDIUM-LOW RISK (MR)

- New registration for processed food without claims, specific uses, with or without freezing, including: Use of BTP without ADI or no maximum limit (CPPB), Use of BTP or ingredients with maximum limits
- Re-registration
- Minor variations (MR, MT, T)
- Major variations of medium-low risk food

Output: Certificate of **Approval** verification Output: Certificate of

Commitment

Fulfillment

**Output: Marketing** 

Authorization

**SNI Certificate** 

No Assessment

Label assessment

Product assessment

Notification

Evaluation

### Domestic Product Company Account Requirements

- 1. NPWP
- 2. NIB
- 3. Sertifikat Izin Penerapan CPPOB

Determination of Risk Level for Licensing in Processed Food Registration. Criteria:

- 1. Target consumer
- 2. Claim statements
- 3. Specific manufacturing processes
- 4. Utilization of food additives
- 5. Use of specific raw materials with maximum permitted levels.

| 1 | Aspect               | Low Risk                              | Medium Risk                             | High Risk   |
|---|----------------------|---------------------------------------|---|---|
|   | Licensing            | Simple, often NIB only                | NIB + additional technical requirements | NIB + certification, inspections, HACCP, etc.         |
|   | Risk Management      | Voluntary                             | Encouraged                              | Mandatory (HACCP, GMP,<br>Self-report)                |
|   | Distribution (SMKPO) | Optional                              | Encouraged                              | Mandatory for new importers, encouraged for retailers |
|   | Registration (e-Reg) | Auto-approved (safe declare with BTP) | Reviewed if special ingredients used    | Full evaluation by BPOM                               |

# Required Documents Registration of Processed Food Products:

- 1. Composition
- 2. Production Process
- 3. Production Code Explanation
- 4. Shelf Life Explanation
- 5. Material Specification
- 6. Label Design
- 7. Analysis Results

The following regulations have been issued by the National Agency of Drug and Food Control (BPOM):

- 1. Regulation No. 8/2018 on Maximum Limits for Chemical Contaminants in Processed Foods
- 2. Regulation No. 13/2019 on Maximum Limits for Microbial Contaminants in Processed Foods
- 3. Regulation No. 23/2017 on Maximum Limits for Heavy Metal Contaminants in Processed Foods
- 4. Regulation No. 11/2019 on Food Additives, including types and usage limits
- 5. Regulation No. 29/2021 on Compound Food Additives
- 6. Regulation No. 11/2021 amending Regulation No. 13/2020 on Flavorings as Food Additives
- 7. Regulation No. 22/2023 on Prohibited Ingredients in Processed Foods and Prohibited Food Additives

## Claims on Processed Food Labels and Advertisements

There are no specific rules governing health functional foods in Indonesia. There are only regulations related to claims.



BPOM Regulation No. 1 of 2022 concerning Supervision of CLAIMS on Processed Food Labels and Advertisements

# Functional Claims of Nutrients/Non-Nutrients

- Claims describing the PHYSIOLOGICAL ROLE of NUTRIENTS/NONNUTRIENTS for growth, development and normal body function.
- Meets the requirements of the SOURCE CLAIM, EXCEPT for nutrients/non-nutrients DO NOT HAVE THE REQUIREMENTS OF THE SOURCE CLAIM

#### Disease Risk Reduction Claims

- Claims that LINK the consumption of a food or food component in the total diet to a REDUCED RISK OF A SPECIFIC DISEASE or HEALTH CONDITION.
- Can only be used AFTER RECEIVING WRITTEN APPROVAL from the Head of BPOM.
- Didasarkan pada penelitian yang dilakukan dengan subjek manusia dengan memenuhi kaidah UJI KLINIK

#### Glycemic Claims

- Must contain AVAILABLE CARBOHYDRATES at least 25 grams per serving, excluding dietary fiber.
- Glycemic index value must be proven by CLINICAL TESTS using READY TO EAT FOOD.
- Inclusion of glycemic claims:
   a. GLYCEMIC LOAD VALUE and CATEGORY; or
   b. GLYCEMIC LOAD VALUE and CATEGORY, accompanied by GLYCEMIC INDEX VALUE and CATEGORY
   c. Include a warning: "PEOPLE V
  - c. Include a warning: "PEOPLE WITH DIABETES SHOULD CONSULT A PHYSICIAN OR NUTRITION EXPERT", adjacent to theglycemic claim

## Claims on Processed Food Labels and Advertisements

- Products with this logo mean that they have met the criteria of being "healthier" based on their nutritional content when compared to similar products, if consumed in reasonable amounts.
- Must meet the NUTRITION PROFILE CRITERIA (nutrient profile) set for each type of Processed Food (PerBPOM 26/2021).





### 20 Types of Processed Foods that Have Determined Nutritional Profiles

- Cereal drink powder
- Ready-to-drink beverages
- Oatmeal
- Instant pasta and instant noodles
- Ready-to-eat cereal
- Plain powdered milk
- Granola
- Flavored powdered milk
- Crackers and malted biscuits
- Cheese

- Specialty bakery products
- Ice cream
- Chili sauce
- Plain yogurt
- Sweet soy sauce
- Flavored yogurt
- Ready-to-eat snacks
- Chocolate drink powder
- Processed nuts, including coated nuts and nut mixes such as nuts with dried fruits
- Fruit-based desserts including water-based fruit-flavored desserts

Importation of Food into the Territory of Indonesia is regulated in :

- Regulation of The Food and Drug Supervisory Agency Number 26 of 2022
- Regulation of The Food and Drug Supervisory Agency Number 28 of 2023

## 1. Applicant Registration

- The applicant (company/importer) must have a Business Identification Number (NIB) issued via the Online Single Submission (OSS) system.
- Select the Post Border SKI permit code in the OSS system.
- Register for a username and password through:
  - The official SKI Post Border BPOM service portal, or
  - The Indonesia National Single Window (SINSW) system.

### 2. Upload Registration Documents

- Original application letter signed by the director or authorized representative.
- Original statement letter of responsibility (with sufficient stamp duty).
- Notarized power of attorney (if authorized representative).
- List of HS Codes for the commodities to be imported.
- National ID (KTP) of the responsible person.
- Photos of the warehouse and office (front and back).
- Cooperation agreement (if the importer is not the owner of the goods).
- Food Safety Management System Certificate (if required).

## Procedure to Obtain SKI (Import Notification Letter) for Food Products to Indonesia

### 3. SKI Post Border Application Submission

- Certificate of Analysis (COA) or SPPT SNI (for food with mandatory Indonesian National Standard).
- Safety data sheet (SDS) and/or ingredient specification sheet.
- Statement letter of use/distribution purpose (with stamp duty).
- Invoice.
- Health Certificate or Certificate of Free Sale issued by the competent authority in the country of origin.
- Letter of origin from the producer (if different from the exporter).
- Distribution report of previously imported goods.
- Order letter and smallest product package photo (if intended for hotels/restaurants/food outlets).
- Any additional certificates or documents required by regulations.

#### 4. Evaluation Process

- BPOM will evaluate the application within 6 working hours after complete documents and payment of non-tax revenue (PNBP) are received.
- If revisions are required, applicants have up to 3 attempts within 30 calendar days to provide corrections.

### 5. Approval or Rejection

- If approved, the SKI Post Border will be issued electronically (no stamp or wet signature).
- Applicants or authorized institutions can print the SKI via the BPOM or SINSW portal.
- If rejected, the rejection will be notified electronically through the system.

## Procedure to Obtain SKI (Import Notification Letter) for Food Products to Indonesia

### **Additional Notes**

- SKI is valid for one-time import only.
- For Small and Medium Industries (IKM), applications may be submitted by an importer in cooperation with the IKM (a cooperation agreement must be attached).
- The food materials must not be distributed or sold before the SKI is issued.

# Required Documents Registration of Processed Food Products:

- 1. Composition
- 2. Production Process
- 3. Production Code Explanation
- 4. Shelf Life Explanation
- 5. Material Specification
- 6. Label Design
- 7. Analysis Results
- 8. Health Certificate/Free Sale Certificate
- Letter of Appointment (LoA)
- 0. Product Photo
- 1. Label Translation

# Halal Regulation

- The institution authorized for halal certification of food products in Indonesia is the Indonesian Ulama Council (MUI), specifically through
  its Halal Product Assurance Agency (LPPOM MUI) or Badan Penyelenggara Jaminan Produk Halal (BPJPH) under the Ministry of
  Religious Affairs, which is responsible for issuing halal certificates for food products.
- Since 2019, the responsibility for halal certification has been transferred to the Halal Product Assurance Organizing Agency (BPJPH)
  under the Ministry of Religious Affairs of the Republic of Indonesia.
- Since 2024, BPJPH operates as an independent Non-Ministerial Government Agency.



The role of BPOM (National Agency of Drug and Food Control) in ensuring the halalness of food products in Indonesia is related to supervision of food labeling

Effective October 18, 2024, products without halal certification must display a 'Non Halal' label

October 17, 2019 → October 17, 2024

Mandatory halal certification applies to:

- Food and beverages
- Raw materials, food additives, and ingredients for food and beverages
- Slaughtered products and slaughtering services

# Halal Regulation

# The government has implemented a national halal label standard



Existing halal labels issued by MUI remain valid for up to 5 years from the enactment of Government Regulation No. 39/2021

#### Halal Label Usage

- 1 Effective March 1, 2022, products certified halal by BPJPH must display the Halal Label on packaging, accompanied by the halal certificate number
- Por products certified halal by BPJPH prior to March 1, 2022:
  - 1. New packaging: apply the Indonesian Halal Label directly
  - 2. Existing packaging: exhaust stock, then apply the Indonesian Halal Label

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04 Summary



# Food Safety Management and Product Inspection in Indonesia

- The Indonesian Food and Drug Authority (BPOM) is a government agency responsible for regulating and supervising the safety, efficacy, and quality of drugs, food, cosmetics, and health supplements in Indonesia.
- BPOM performs various tasks, including:
  - Evaluating and approving new drugs, traditional medicines, and food products before they are allowed on the market.
  - Monitoring the safety of products through post-market surveillance and product sampling.
  - **Issuing product registration numbers** (like "BPOM RI MD" or "BPOM RI ML") to indicate that a product has been tested and approved.
  - Inspecting manufacturing facilities to ensure they comply with Good Manufacturing Practices (GMP).
  - Educating the public about safe and healthy consumption practices.
- The food oversight activities carried out by the National Agency of Drug and Food Control (BPOM) include Pre-Market Control, Post-Market Surveillance, Enforcement and Sanctions, and Public Communication and Education.
- BPOM ensures that food consumed by the public is safe, nutritious, and compliant with national food safety standars.

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# THANK YOU

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